

**Oregon Board of Pharmacy**  
**BOARD MEETING AGENDA**  
Meeting Location: Conference Call  
April 7-9, 2021

**Public Attendance by Phone: 877-873-8017 Participant code: 139360#**

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

Wednesday, April 7, 2021 @ 8:00AM

Thursday, April 8, 2021 @ 8:00AM

~~Friday, April 9, 2021 @ 8:00AM~~ **\*Canceled**

Due to the COVID-19 [State of Emergency](#) and Governor Brown's [Executive Order 21-05](#), the Board will meet via teleconference and the public may attend by phone.

- All Board meetings except Executive Session 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 4/8/2021**.

*≈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, April 7, 2021**

**I. OPEN SESSION, Shannon Beaman RPh, Presiding**

- a. Roll Call
- b. Agenda Review and Approval *Action Necessary*
- a. Public Health and Pharmacy Formulary Advisory Committee Update – *Davis*
  - i. Meeting Minutes
- b. Rules Advisory Committee Update – *Davis*
- c. Discussion Items:
  - i. COVID-19 Update - *Schnabel*
  - ii. Strategic Planning Update – *Schnabel*
    1. 2020-2024 Plan Updates
      - Technicians
      - Technology
      - Licensing
      - Regulation
      - Communication

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

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

Agenda – April 7-8, 2021

NOTE: The Board may rearrange its agenda to accommodate the Board or Members of the public.

- III. **Contested Case Deliberation pursuant to ORS 192.690(1) – Not open to the public**
- IV. **EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 192.660(2)(i) for Employee Performance Review.**
- V. **OPEN SESSION – PUBLIC MAY ATTEND** – At the conclusion of Executive Session, the Board may convene Open Session to review scheduled agenda items as time permits.

Adjourn

*Action Necessary*

**THURSDAY, April 8, 2021**

**I. OPEN SESSION, Shannon Beaman RPh, Presiding**

- a. Roll Call

**PUBLIC COMMENT –**

- There will be an opportunity for public comment
- The Board will not deliberate any issues or requests during Public Comment such as formal requests, issues currently under investigation or requests pending before the Board
- To sign-up to provide public comment, email [Karen MacLean](#) by **12:00PM on 4/8/2021**

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

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

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

**IV. GENERAL ADMINISTRATION**

- a. Rules
  - i. Review Rulemaking Hearing Report & Comments – none
  - ii. Consider Adoption of Rules – none
  - iii. Consider Adoption of Temporary Rules – none
  - iv. Rulemaking Policy Discussion Items - *Davis*
    - 1. Div 001/041 – Procedural Rules/Operation of Pharmacies **#A** *Action Necessary*
    - 2. Div 006/050 – Definitions Prescription Drugs/Restriction on Retail Sales **#A1** *Action Necessary*
    - 3. Div 007 - Public Health Emergency **#A2** *Action Necessary*
    - 4. Div 019/021/025/031- Cultural Competency CE **#A3** *Action Necessary*
    - 5. Div 041 – Operation of a Pharmacy (Epinephrine) **#A4** *Action Necessary*
    - 6. Div 041/043/044 LEP (Insert) **#A5** *Action Necessary*
    - 7. Div 041- Drug Take Back **#A6** *Action Necessary*
    - 8. Div 020 – Pharmacist Prescriptive Authority **#A8** *Action Necessary*
      - a. Continuation of Therapy **#A8-a**
      - b. Cough & Cold: Benzonatate **#A8-b**
      - c. Cough & Cold: Intranasal Corticosteroids **#A8-c**

Agenda – April 7-8, 2021

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- d. Cough & Cold: Pseudoephedrine **#A8-d**
- e. Cough & Cold: SABAs **#A8-e**
- f. Conditions: Vulvovaginal Candidiasis (VVC) **#A8-f**
- g. Preventative Care: Condoms **#A8-g**
- h. Preventative Care: Emergency Contraception **#A8-h**
- i. Preventative Care: HIV Post-Exposure Prophylaxis (PEP) **#A8-i**
- j. Preventative Care: HIV Pre-Exposure Prophylaxis (PrEP) **#A8-j**
- k. Preventative Care: Tobacco Cessation - NRT (Nicotine Replacement Therapy) and Non-NRT **#A8-k**
- l. Preventative Care: Travel Medications **#A8-l**
- m. Sample Visit Summary Template **#A8-m**
- n. List of updates to Formulary Compendium **#A8-n**

- 9. Div 080 – Controlled Substances **#A9** *Action Necessary*
- 10. Div 110 – Fees *Melvin* **#A10** *Action Necessary*

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

iii. Reports:

- 1. Board President/Members
- 2. Executive Director
- 3. Compliance Director
- 4. Administrative Director
- 5. Licensing Manager
- 6. Pharmacist Consultant
- 7. Operations Policy Analyst
- 8. Office Manager

iv. Financial/Budget Report – *MacLean* **#B-B1**

- 1. Financial Update

v. Legislative Updates – *Schnabel*

vi. Board Meeting Dates

- June 9-10, 2021 Portland
- August 11-13, 2021\* Portland
- October 13-14, 2021 Portland
- 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

\*Note: 3-day meeting

vii. Rulemaking Hearing Dates

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

- May 26, 2021
- November 23, 2021
- May 24, 2022
- November 22, 2022

viii. Conferences/Meetings - Schnabel

*PAST MEETINGS*

1. OSPA Mid-Winter Seminar (virtual) – February 20-21, 2021

*FUTURE MEETINGS*

1. OHSP Spring Seminar (virtual) – April 29, 2021
2. 117<sup>th</sup> Annual NABP Meeting (virtual) – May 13-14, 2021

**VI.** Motions related to Disciplinary Actions – *Efremoff* *Action Necessary*

**VII. 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.*

- d. NAPLEX Scores – September 1, 2020 – December 31, 2020 **#CONSENT – 1 CONFIDENTIAL**
- e. MPJE Scores – September 1, 2020 – December 31, 2020 **#CONSENT – 2 CONFIDENTIAL**
- f. License/Registration Ratification February 2, 2021-March 22, 2021 **# CONSENT - 3**
- g. Pharmacy Technician Extensions – None
- h. Board Meeting Minutes – February 10-11,2021 **# CONSENT – 4**

**PUBLIC COMMENT –**

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

Adjourn

*Action Necessary*

**Division 001/041– Procedural Rules / Operation of Pharmacies  
(Inspections / Record Storage)**

**Filing Caption (max 15 words):**

Proactive procedural rule review

**Need for Rules:**

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

**Fiscal Impact:**

None anticipated

**Documents Relied Upon:**

None

**Rules Summary:**

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

1 [855-001-0040](#)

2 **Inspections**

3 ~~(1) The Board or its authorized representative~~ **A Compliance Officer is a board authorized**  
 4 **representative** ~~may enter and shall must be allowed permitted entry to any drug outlet where~~  
 5 ~~drugs are stored, and the premises where the records associated with those drugs are stored,~~  
 6 ~~to conduct inspections at all reasonable hours. times in a reasonable manner for the purpose~~  
 7 ~~of:~~

8 ~~(a) Inspecting, copying, and verifying the correctness of records, reports, or other documents~~  
 9 ~~required to be kept under the Uniform Controlled Substances Act, the Oregon Pharmacy Act~~  
 10 ~~and these rules including, but not limited to, shipping records identifying the name of each~~  
 11 ~~carrier used and the date and quantity of each shipment, and storage records identifying the~~  
 12 ~~name of each warehouse used and the date and quantity of each;~~

13  
 14 ~~(b) Inspecting within reasonable limits and a reasonable manner all pertinent equipment,~~  
 15 ~~finished and unfinished drugs and other substances or materials, containers, and labeling found~~  
 16 ~~at the drug outlet;~~

17  
 18 ~~(c) Making a physical inventory of all drugs on hand at the premises;~~

19  
 20 ~~(d) Collecting samples of drugs or ingredients;~~

21

22 ~~(e) Checking of records and information on distribution of drugs by the registrants as they~~  
23 ~~relate to total distribution of the registrant;~~

24

25 ~~(f) All other things appropriate for verification of the records, reports, documents referred to~~  
26 ~~above or otherwise bearing on the provisions of the Uniform Controlled Substances Act, the~~  
27 ~~Oregon Pharmacy Act and these rules.~~

28

29 ~~(2) The inspections hereunder may be conducted in connection with applications for initial or~~  
30 ~~renewal registration or modification or amendment thereof and at such other times where the~~  
31 ~~Board or its authorized representative determines that there is reasonable basis for concluding~~  
32 ~~that inspection is necessitated in order to ensure that there is compliance with the Uniform~~  
33 ~~Controlled Substances Act, the Oregon Pharmacy Act and these rules.~~

34

35 **(2) The Compliance Officer is authorized and must be permitted to perform the following to**  
36 **determine compliance with ORS 475, ORS 689, and OAR 855 and board orders including but**  
37 **not limited to:**

38

39 **(a) Inspecting conditions, structures, equipment, materials, and methods for compliance;**

40

41 **(b) Inspecting all drugs and devices;**

42

43 **(c) Taking photographs, recording video and audio; and**

44

45 **(d) Reviewing, verifying and making copies of records and documents.**

46

47 **(3) All records and documents required by ORS 475, ORS 689, and OAR 855:**

48

49 **(a) Must be stored on-site for 12 months and must be provided to the board immediately**  
50 **upon request at the time of inspection;**

51 **(b) May be stored in a secured off-site location after 12 months of on-site storage and must**  
52 **be provided to the board upon request within three business days; and**

53 **(c) May be in written or electronic format.**

54 **(4) All licensees and employees must fully comply and cooperate with all questions and**  
55 **requests made by the Compliance Officer at the time of inspection.**

56

57 ~~(35) Refusal to allow inspection is grounds for **discipline** denial, suspension, or revocation of a~~  
58 ~~registration.~~

59

60 Statutory/Other Authority: ORS 475.125 & ORS 689.205

61 Statutes/Other Implemented: ORS 689.155

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855-041-1160

~~Prescription Records and Retention~~

(1) Definitions. The following definitions apply to this rule:

(a) An "original prescription" is a prescription maintained in the same physical manner in which a pharmacy first receives the prescription. For example, for a prescription received by the pharmacy in writing on a prescription form, the original prescription consists of the original writing on the prescription form. For a prescription received by the pharmacy orally over the telephone, the original consists of the writing or electronic record that reflects receipt of the oral prescription.

(b) "Filing" and "file" mean the storage of the original prescription in such a manner that the original prescription is safeguarded and readily retrievable.

(2) Every pharmacy and pharmacist-in-charge of a pharmacy must ensure that original prescriptions are properly filed in compliance with this rule.

~~(3) All original prescriptions shall be filed for a minimum of three years from the date of first dispensing and shall at all times be open for inspection by the prescriber, and the Board of Pharmacy or its duly authorized agent.~~

(4) After 120 days, the paper prescription may be destroyed and filed in an electronic form if:

(a) The electronic form shows the exact and legible image of the original prescription;

(b) Notes of clarifications of and changes to the prescription are directly associated with the electronic form of the prescriptions; and

(c) The prescription is not for a controlled substance.

(5) This rule is not intended to alter or supersede the recordkeeping requirements of any other federal or Oregon statute or rule, including but not limited to ORS 689.508, OAR 855-041-1120, and rules related to records for prescriptions for controlled substances.

~~(6) Unless specified otherwise, all records and documentation required by OAR 855 division 041 must be retained for three years and made available to the Board for inspection upon request.~~

**All records and documents required by ORS 475, ORS 689, and OAR 855:**

**(a) Records must be stored on-site for at least one year 12 months and must be provided to the board immediately upon request.**

104 ~~(b) and m~~May be stored in a secured off-site location after 12 months of on-site storage if  
105 retrievable within and must be provided to the board upon request within three business  
106 days; and

107 ~~(c) Records and documentation m~~May be in written, or electronic ~~or a combination of the two~~  
108 format.

109  
110 Statutory/Other Authority: ORS 689.205

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

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113

114 855-041-6220

115 Records

116

117 (1) ~~Unless specified otherwise, all records and documentation required by these rules, OAR~~  
118 ~~855-041-6000 through 855-041-6999 must be retained for three years and made available to~~  
119 ~~the Board for inspection upon request. All R records and documents required by ORS 475, ORS  
120 689, and OAR 855:~~

121 ~~(a) m~~Must be stored on-site for at least one year 12 months and must be provided to the  
122 board immediately upon request.

123 ~~(b) and m~~May be stored in a secured off-site location after 12 months of on-site storage if  
124 retrievable within and must be provided to the board upon request within three business  
125 days; and

126 ~~(c) Records and documentation m~~May be written, or electronic ~~or a combination of the two~~  
127 format.

128

129 (2) The PIC must ensure maintenance of written or electronic records and ~~reports~~ documents  
130 as necessary to ensure patient health, safety and welfare. Records must include:

131

132 (a) Patient profiles and drug administration records;

133

134 (b) Reports of suspected adverse drug reactions;

135

136 (c) Inspections of drug storage areas;

137

138 (d) Annual controlled substance inventories;

139

140 (e) Controlled drug accountability reports;

141

142 (f) Collaborative Drug Therapy agreements;

143

144 (g) Current hospital drug formulary;

145

146 (h) Any other records and reports required by state and federal laws and regulations.

147

148 Statutory/Other Authority: ORS 689.205

149 Statutes/Other Implemented: ORS 689.155 & ORS 689.508

PROPOSED

**Division 006– Definitions (Prescription Drug)**

**Filing Caption** (max 15 words):

Defines prescription drug

**Need for Rules:**

The revision 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.

**Fiscal Impact:**

None

**Documents Relied Upon:**

None

**Rules Summary:**

By repealing Division 050, the definition of “prescription drug” will need to be retained. Division 006- Definitions will now include the definition of “prescription drug.”

1 **855-006-0005**

2 Definitions

3

4 As used in OAR chapter 855:

5

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

7

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

13

14 (3) “Clinical Pharmacy Agreement” means an agreement between a pharmacist or pharmacy and a  
 15 health care organization or a physician that permits the pharmacist to engage in the practice of clinical  
 16 pharmacy for the benefit of the patients of the health care organization or physician.

17

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

22

- 23 (a) Is agreed to by one pharmacist and one practitioner; or  
24
- 25 (b) Is agreed to by one or more pharmacists at a single pharmacy registered by the board and one or  
26 more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group  
27 practice, including but not limited to organized medical groups using a pharmacy and therapeutics  
28 committee.  
29
- 30 (5) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or  
31 device:  
32
- 33 (a) As the result of a practitioner's prescription drug order, or initiative based on the relationship  
34 between the practitioner, the pharmacist and the patient, in the course of professional practice; or  
35
- 36 (b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or  
37 dispensing; or  
38
- 39 (c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine,  
40 regularly observed prescribing patterns.  
41
- 42 (6) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.  
43
- 44 (7) "Consulting Pharmacist" means a pharmacist that provides a consulting service regarding a patient  
45 medication, therapy management, drug storage and management, security, education, or any other  
46 pharmaceutical service.  
47
- 48 (8) The "Container" is the device that holds the drug and that is or may be in direct contact with the  
49 drug.  
50
- 51 (9) "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a  
52 lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration  
53 to or use by a patient or other individual entitled to receive the prescription drug.  
54
- 55 (10) "Interpretation and evaluation of prescription orders" means the review of the order for  
56 therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug  
57 ordered, its applicability and its relationship to the other known medications used by the patient and  
58 determination of whether or not the dose and time interval of administration are within accepted limits  
59 of safety. The legal review for correctness of the prescription order includes a determination that the  
60 order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose,  
61 contains all information required by federal and state law, and is within the practitioner's scope of  
62 practice.  
63
- 64 (11) "Labeling" means the process of preparing and affixing of a label to any drug container exclusive,  
65 however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or  
66 commercially packaged legend drug or device.

67  
68 (12) "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of the  
69 therapeutic or adverse effect of medication upon a patient, including direct consultation with the  
70 patient or his agent and review of patient records, as to result and side effect, and the analysis of  
71 possible interactions with other medications that may be in the medication regimen of the patient. This  
72 section shall not be construed to prohibit monitoring by practitioners or their agents.

73  
74 (13) "Medication Therapy Management (MTM)" means a distinct service or group of services that is  
75 intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management  
76 services are independent of, but can occur in conjunction with, the provision of a medication product.

77  
78 (14) "Nationally Certified Exam" means an exam that is approved by the Board which demonstrates  
79 successful completion of a Specialized Education Program. The exam must be reliable, psychometrically  
80 sound, legally defensible and valid.

81  
82 (15) "Non-legend drug" means a drug which does not require dispensing by prescription and which is  
83 not restricted to use by practitioners only.

84  
85 (16) "Offering or performing of those acts, services, operations or transactions necessary in the conduct,  
86 operation, management and control of pharmacy" means, among other things:

- 87  
88 (a) The creation and retention of accurate and complete patient records;  
89  
90 (b) Assuming authority and responsibility for product selection of drugs and devices;  
91  
92 (c) Developing and maintaining a safe practice setting for the pharmacist, for pharmacy staff and for the  
93 general public;  
94  
95 (d) Maintaining confidentiality of patient information.

96  
97 (17) "Oral Counseling" means an oral communication process between a pharmacist and a patient or a  
98 patient's agent in which the pharmacist obtains information from the patient (or agent) and the  
99 patient's pharmacy records, assesses that information and provides the patient (or agent) with  
100 professional advice regarding the safe and effective use of the prescription drug for the purpose of  
101 assuring therapeutic appropriateness.

102  
103 (18) Participation in Drug Selection and Drug Utilization Review:

104  
105 (a) "Participation in drug selection" means the consultation with the practitioner in the selection of the  
106 best possible drug for a particular patient.

107  
108 (b) "Drug utilization review" means evaluating prescription drug order in light of the information  
109 currently provided to the pharmacist by the patient or the patient's agent and in light of the information  
110 contained in the patient's record for the purpose of promoting therapeutic appropriateness by

111 identifying potential problems and consulting with the prescriber, when appropriate. Problems subject  
112 to identification during drug utilization review include, but are not limited to:

113  
114 (A) Over-utilization or under-utilization;

115  
116 (B) Therapeutic duplication;

117  
118 (C) Drug-disease contraindications;

119  
120 (D) Drug-drug interactions;

121  
122 (E) Incorrect drug dosage;

123  
124 (F) Incorrect duration of treatment;

125  
126 (G) Drug-allergy interactions; and

127  
128 (H) Clinical drug abuse or misuse.

129  
130 (19) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of  
131 achieving definite outcomes that improve a patient's quality of life. These outcomes include:

132  
133 (a) Cure of a disease;

134  
135 (b) Elimination or reduction of a patient's symptomatology;

136  
137 (c) Arrest or slowing of a disease process; or

138  
139 (d) Prevention of a disease or symptomatology.

140  
141 (20) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the  
142 pharmacist in the practice of pharmacy pursuant to rules of the Board but has not completed the  
143 specialized education program pursuant to OAR 855-025-0012.

144  
145 (21) "Practice of clinical pharmacy" means:

146  
147 (a) The health science discipline in which, in conjunction with the patient's other practitioners, a  
148 pharmacist provides patient care to optimize medication therapy and to promote disease prevention  
149 and the patient's health and wellness;

150  
151 (b) The provision of patient care services, including but not limited to post-diagnostic disease state  
152 management services; and

153  
154 (c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.

155  
156 (22) "Practice of pharmacy" is as defined in ORS 689.005.  
157

158 **(23) "Prescription drug" or "legend drug" is as defined in ORS 689.005 and:**

159  
160 **(a) Required by federal law, prior to being dispensed or delivered, to be labeled with "Rx only"; or**

161  
162 **(b) Required by any applicable federal or state law or regulation to be dispensed on prescription only**  
163 **or is restricted to use by practitioners only.**

164  
165 ~~(234)~~ "Prescription released by the pharmacist" means, a prescription which has been reviewed by the  
166 pharmacist that does not require further pharmacist intervention such as reconstitution or counseling.  
167

168 ~~(245)~~ "Prohibited conduct" means conduct by a licensee that:

169  
170 (a) Constitutes a criminal act against a patient or client; or

171  
172 (b) Constitutes a criminal act that creates a risk of harm to a patient or client.  
173

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

176  
177 (a) Assure retention of their purity and potency;

178  
179 (b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;  
180

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

182  
183 (d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;  
184

185 (e) Protect the health, safety and welfare of the pharmacist, pharmacy staff and the general public from  
186 harmful exposure to hazardous substances.  
187

188 ~~(267)~~ "Quality Assurance Plan" is a written set of procedures to ensure that a pharmacy has a planned  
189 and systematic process for the monitoring and evaluation of the quality and appropriateness of  
190 pharmacy services and for identifying and resolving problems.  
191

192 ~~(278)~~ "Responsibility for advising, when necessary or when regulated, of therapeutic values, content,  
193 hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing  
194 as required by these rules or federal regulation, of the possible therapeutic response to the medication,  
195 the names of the chemicals in the medication, the possible side effects of major importance, and the  
196 methods of use or administration of a medication.  
197

198 ~~(289)~~ "Specialized Education Program" means;

199

200 (a) A program providing education for persons desiring licensure as pharmacy technicians that is  
201 approved by the board and offered by an accredited college or university that grants a two-year degree  
202 upon successful completion of the program; or

203

204 (b) A structured program approved by the board and designed to educate pharmacy technicians in one  
205 or more specific issues of patient health and safety that is offered by:

206

207 (A) An organization recognized by the board as representing pharmacists or pharmacy technicians;

208

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

210

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

212

213 ~~(2930)~~ "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy  
214 technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control  
215 and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action.

216 During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic,

217 "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being

218 supervised, coupled with the ability to control and be responsible for the technician or interns actions

219 and for the following remote processing functions only: prescription or order entry, other data entry,

220 and insurance processing of prescriptions and medication orders.

221

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

225

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

229

230 Statutory/Other Authority: ORS 689.205

231 Statutes/Other Implemented: ORS 689.151 & ORS 689.155

## Division 050– Restriction on Retail Sales

**Filing Caption (max 15 words):** Proactive procedural rule review

**Need for Rules:**

The revision 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.

**Fiscal Impact:**

None

**Documents Relied Upon:**

None

**Rules Summary:**

Division 050 is no longer relevant for current pharmacy practice.

- 1 Division 50
- 2 RESTRICTION ON RETAIL SALES
- 3 ~~855-050-0035~~
- 4 ~~Over the Counter Drug Restrictions~~
- 5 (1) The following items shall be sold only by or under the direct supervision of a licensed pharmacist in
- 6 registered pharmacies. They need not bear the store name and address, if in original container, need
- 7 not be registered, but must be properly labeled. They shall not be available by self-service, but stored in
- 8 or immediately adjacent to the prescription department. Items bearing prescription legend are excepted
- 9 and may be sold only on prescription:
- 10 (a) Ammoniated Mercury ointment, five percent;
- 11 (b) Sulfa drugs — Alone or in combination;
- 12 (c) Blue Ointment.
- 13 (2) The following items shall be sold only by a licensed pharmacist(s) in registered pharmacies, must
- 14 bear the store name and address, must be properly labeled with adequate warning, must be registered
- 15 in Official Poison Register, and the purchaser must provide acceptable identification, providing the
- 16 preparations do not bear prescription legend, in which case they may be sold only on prescription:
- 17 (a) Arsenic and its preparations;
- 18 (b) Corrosive sublimate;
- 19 (c) Cyanides and preparations, including hydrocyanic acid;
- 20 (d) Hydrochloric acid and any preparation containing free or chemically unneutralized hydrochloric acid
- 21 (HC1) in a concentration of ten percent or more;

22 (e) Nitric acid or any preparation containing free or chemically unneutralized nitric acid (HNO<sub>3</sub>) in a  
23 concentration of five percent or more;

24 (f) Sulphuric acid and any preparation containing free or chemically unneutralized sulphuric acid (H<sub>2</sub>SO<sub>4</sub>)  
25 in a concentration of ten percent or more;

26 (g) Solution of ammonia, U.S.P. 28 percent;

27 (h) Carbolic acid.

28 ~~Statutory/Other Authority: ORS 689~~

29

30 ~~855-050-0045~~

31 **Organic Silver Salts**

32 (1) May be sold only by licensed pharmacists in registered pharmacies.

33 (2) Solutions must be freshly prepared, unless stabilized.

34 (3) Must be adequately labeled, to include name and address of store, date of preparation, and  
35 percentage content.

36 ~~Statutory/Other Authority: ORS 689~~

37

38 ~~855-050-0070~~

39 **Prescription Drugs**

40 (1) The following are prescription drugs:

41 (a) Drugs required by federal law to be labeled with either of the following statements:

42 (A) "Caution: Federal law prohibits dispensing without prescription"

43 (B) "Caution: Federal law restricts this drug to be used by or on the order of a licensed veterinarian"; or

44 (C) "Rx only"

45 (b) Drugs designated as prescription drugs by the Oregon Board of Pharmacy

46 (2) The Oregon Board of Pharmacy designates the following drugs as prescription drugs:

47 (a) Preparations containing codeine or salts of codeine

48 (b) Preparations containing opium/paregoric

49 (3) No person shall sell, give away, barter, transfer, purchase, receive or possess prescription drugs  
50 except upon the prescription of a practitioner.

51 (4) The following are exempt from the prohibition of section (3) of this rule:

52 (a) Manufacturers

53 (b) Wholesalers;

54 ~~(c) Institutional and retail drug outlets;~~

55 ~~(d) Practitioners.~~

56 ~~(5) Individuals who purchase, receive, or possess a prescription drug for the purpose of administration~~  
57 ~~or delivery to a patient are exempt from the prohibition against purchasing, receiving, or possessing~~  
58 ~~prescription drugs contained in section (3) of this rule and ORS 689.765(6).~~

59 ~~**Statutory/Other Authority:** ORS 689.205~~

60 ~~**Statutes/Other Implemented:** ORS 689.155 & 689.765~~

61

PROPOSED

## Division 007: Public Health Emergency (Intern Ratio in Immunization Clinic)

### Filing Caption (max 15 words):

Will allow immunizing pharmacist supervision of additional interns at immunization clinics

### Need for Rules:

During a declared public health emergency the immunizing pharmacist to intern ratio of 1:2 is amended. High demand for vaccinations may exceed supply of pharmacist and intern vaccinators under the previous ratio. Increasing the immunizing pharmacist to intern ratio may improve the supply of vaccinators and facilitate increased vaccination capacity in the interest of public health.

### Fiscal Impact:

None anticipated

### Documents Relied Upon:

None

### Rules Summary:

During a declared public health emergency, there may be high demand for immunizing pharmacists and interns to provide vaccinations. By allowing pharmacist vaccinators to supervise as many Oregon-licensed immunizing interns as that pharmacist determines, in their own professional judgement, will maintain public health and safety, the number of persons who are vaccinated may be increased.

1 **855-007-0080**

2 **Emergency Immunization and Drug Distribution**

3

4

5 When a public health emergency has been declared, the following principles and procedures shall apply to the  
6 distribution, dispensing and administration of vaccines or drugs:

7

8 (1) The distribution of vaccines and drugs is to be in accordance with instructions provided by OSPHD.

9

10 (2) LHDs are authorized to distribute SNS or state stockpile drugs to designated Treatment Centers (TC) or  
11 health-care providers designated by the State Public Health Director or a local health administrator.

12

13 (3) A TC may include but is not limited to:

14

15 (a) A LHD;

16

17 (b) A clinician;

18

19 (c) A community health clinic;

20

21 (d) An independent or chain pharmacy;

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23 (e) A hospital or other health-care facility;

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25 (f) A temporary pharmacy;

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27 (g) A mobile pharmacy; or

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(h) A tribal health-care facility.

(4) A TC may possess, distribute, dispense and administer vaccines and drugs if these rules are in effect.

(5) A health-care provider, designated by the local health administrator, at a TC shall be responsible for administration, distribution and tracking of vaccines and drugs in accordance with procedures established by OSPHD.

(6) A health-care provider may, if permitted under that provider's scope of practice and these rules, distribute, dispense and administer vaccines and drugs.

(7) An Individual Data Collection Form (IDCF) shall be filled out for each person receiving a vaccine or drug at a TC or from a health-care provider, and this IDCF shall be treated as a valid prescription and retained as follows:

(a) An IDCF initiated at a pharmacy or other licensed health-care facility shall be filed and retained for three years;

(b) An IDCF initiated at a facility that is not a licensed health-care facility or at a temporary or mobile pharmacy shall be sent to OSPHD at the end of the state of emergency except that where the temporary or mobile facility has been established under the authority of OAR 855-007-0100 all records shall be filed and retained in accordance with 855-007-0110.

(8) Community Partner: A Community Partner means any entity that is authorized by OSPHD or OBOP to:

(a) Purchase and store vaccines or drugs prior to a pandemic event;

(b) Store vaccines or drugs in a Board registered facility or at a tribal site;

(c) Take possession of the vaccines or drugs and distribute to critical infrastructure and key resources when so directed by OSPHD in accordance with OSPHD protocols and procedures.

(d) A Community Partner shall:

(A) Distribute all drugs within 72 hours of removal from the storage site;

(B) Store all drugs in accordance with manufacture's guidelines;

(C) Record all distributions on a Distribution Log that shall include:

(i) The name and age of the person receiving the drugs;

(ii) The name, strength and quantity of the drugs;

(iii) The date and the time of the distribution.

(e) The Distribution Log shall be treated as a valid prescription and stored or otherwise disposed of as specified in 855-007-0110;

(9) This authority for LHDs, TCs, health-care providers and Community Partners to possess drugs shall extend beyond the declared emergency until procedures issued by OSPHD for the return or destruction of unused drugs have been completed.

(10) A pharmacist may administer a vaccine to a person who is at least three years of age or older.

83 (11) For immunization clinics, an immunizing pharmacist may supervise as many Oregon-licensed immunizing  
84 interns as that pharmacist determines, in their own professional judgment, will maintain public health and  
85 safety.

86

87 **Statutory/Other Authority:** ORS 401.065, ORS 433.441, ORS 689.205

88 **Statutes/Other Implemented:** ORS 689.155, ORS 689.645

PROPOSED

**Division 019– Pharmacists (Cultural Competency CE)**

**Filing Caption** (15 word limit): [2019 HB 2011](#) directs licensees when renewing to obtain cultural competency CE

**Need for Rules:** Revisions to Division 019 are necessary to incorporate continuing education requirement directives set forth in [2019 HB 2011](#), related to cultural competency.

**Fiscal Impact:**

In Oregon, it is estimated that 8,896 pharmacists will be impacted by these new requirements. The cultural competency CE could cost \$0-60 per renewal cycle depending on the CE course(s) completed.

**Documents relied upon include:**

[OHA Cultural Competence Continuing Education \(CCCE\)](#)

[2019 HB 2011](#) and related statutes

[ORS 676.850](#) Authority of regulatory boards to require cultural competency continuing education; documentation of participation; rules

[ORS 413.450](#) Continuing education in cultural competency

**Rules Summary:**

Revisions to Division 019 are necessary to incorporate continuing education requirement directives set forth in [2019 HB 2011](#), related to cultural competency.

The additional revisions to Division 019 are in alignment with the board’s 2020-2024 Strategic Plan to proactively review & update rules to ensure clarity, transparency and promote patient safety.

- 1 Division 19
- 2 LICENSING OF PHARMACISTS
- 3 [855-019-0122](#)
- 4 **Renewal of Licensure as a Pharmacist**
- 5 (1) An application for renewal of a pharmacist license must include documentation of:
- 6 (a) Completion of continuing **pharmacy** education requirements as ~~prescribed~~ **outlined** in
- 7 ~~chapter 855, division 21~~ **OAR 855-021**; and
- 8 (b) Payment of the biennial license fee as ~~prescribed~~ **required** in OAR 855-110.
- 9 (2) A pharmacist will be subject to an annual criminal background check.
- 10 Statutory/Other Authority: ORS 689.205
- 11 Statutes/Other Implemented: ORS 689.151

12

13 [855-019-0170](#)

14 **Reinstatement of License**

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

17 (a) By payment of the license fees and delinquency fees for all years during which the license  
18 was lapsed and for the current year; and

19 (b) By providing certification of completion of the continuing **pharmacy** education requirement  
20 **in OAR 855-021** for all years in which the license was lapsed; and

21 (c) If their license has been lapsed for more than one year, pass the MPJE with a score of not  
22 less than 75; and

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

25 (2) A pharmacist in good standing who retired from the practice of pharmacy after having been  
26 licensed for not less than 20 years need only pay the annual license fees for the year in which  
27 they seek a license, however they must provide certification of completion of continuing  
28 **pharmacy** education **requirement in OAR 855-021** for all years since their retirement and  
29 pass the MPJE with a score of not less than 75.

30 Statutory/Other Authority: ORS 689.205

31 Statutes/Other Implemented: ORS 689.151 & **ORS** 689.275

32

33

34 [855-019-0205](#)

35 **Duty to Report**

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

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

40 (3) A pharmacist must report to the **B**board within 10 days if they:

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

42 (b) If they are arrested for a felony.

43 (4) A pharmacist who has reasonable cause to believe that another licensee (of the **B**board or  
44 any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional  
45 conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the  
46 board responsible for the licensee who is believed to have engaged in the conduct. The  
47 reporting pharmacist shall **must** report the conduct without undue delay, but in no event later

48 than 10 working days after the pharmacist learns of the conduct unless federal laws relating to  
49 confidentiality or the protection of health information prohibit disclosure.

50 (5) A pharmacist who reports to a board in good faith as required by section (4) of this rule is  
51 immune from civil liability for making the report.

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

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

58 Statutory/Other Authority: ORS 689.205

59 Statutes/Other Implemented: **ORS** 689.151, **ORS** 689.155 & **ORS** 689.455

60

61 [855-019-0300](tel:855-019-0300)

## 62 **Duties of a Pharmacist-in-Charge**

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

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

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

67 (b) Completed a **B**board approved PIC training course either before the appointment or within  
68 30 days after the appointment. With the approval of the **B**board, this course may be employer  
69 provided and may qualify for continuing education credit.

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

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

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

76 (b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within  
77 15 days of becoming PIC;

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

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

- 84 (e) A pharmacist designated as PIC for more than one pharmacy ~~shall~~must personally conduct  
85 and document a quarterly compliance audit at each location. This audit ~~shall~~must be on the  
86 Quarterly PIC Compliance Audit Form provided by the Bboard;
- 87 (f) If a discrepancy is noted on a Bboard inspection, the PIC must submit a plan of correction  
88 within 30 days of receiving notice.
- 89 (g) The records and forms required by this section must be filed in the pharmacy, made  
90 available to the Bboard for inspection upon request, and must be retained for three years.
- 91 (5) The PIC is responsible for ensuring that the following activities are correctly completed:
- 92 (a) An inventory of all controlled substances must be taken within 15 days before or after the  
93 effective date of change of PIC, and must be dated and signed by the new PIC. This inventory  
94 must be maintained in the pharmacy for three years and in accordance with all federal laws and  
95 regulations;
- 96 (b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all  
97 pharmacy personnel who are required to be licensed by the Bboard;
- 98 (c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection  
99 Form provided by the Bboard, by February 1 each year. The completed self-inspection forms  
100 must be signed and dated by the PIC and maintained for three years from the date of  
101 completion;
- 102 (d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;
- 103 (e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.
- 104 (f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such  
105 training should include an annual review of the PIC Self-Inspection Report;
- 106 (g) Implementing a quality assurance plan for the pharmacy.
- 107 (h) The records and forms required by this section must be filed in the pharmacy, made  
108 available to the Bboard for inspection upon request, and must be retained for three years.
- 109 (6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in  
110 compliance with all state and federal laws and rules governing the practice of pharmacy and  
111 that all controlled substance records and inventories are maintained in accordance with all state  
112 and federal laws and rules.
- 113 Statutory/Other Authority: ORS 689.205  
114 Statutes/Other Implemented: ORS 689.151 & ORS 689.155

## Division 021– Continuing Pharmacy Education (Cultural Competency CE)

**Filing Caption** (15 word limit):

[2019 HB 2011](#) directs licensees when renewing to obtain cultural competency CE

### Need for Rules:

Revisions to Division 021 are necessary to incorporate continuing education requirement directives set forth in [2019 HB 2011](#), related to cultural competency.

### Fiscal Impact:

In Oregon, it is estimated that 8,896 pharmacists, 6,186 Certified Oregon Pharmacy Technicians, and 794 Interns will be impacted by these new requirements. The cultural competency CE could cost \$0-60 per renewal cycle depending on the CE course(s) completed.

### Documents relied upon include:

[OHA Cultural Competence Continuing Education \(CCCE\)](#)

[2019 HB 2011](#) and related statutes

[ORS 676.850](#) Authority of regulatory boards to require cultural competency continuing education; documentation of participation; rules

[ORS 413.450](#) Continuing education in cultural competency

### Rules Summary:

Revisions to Division 021 are necessary to incorporate continuing education requirement directives set forth in [2019 HB 2011](#), related to cultural competency.

The additional revisions to Division 021 are in alignment with the board’s 2020-2024 Strategic Plan to proactively review & update rules to ensure clarity, transparency and promote patient safety.

1 Division 21

2 CONTINUING PHARMACY EDUCATION

3 **855-021-0001**

4 **Definitions**

5 **(1) “Continuing Pharmacy Education” or “CPE” means classes of post graduate studies,**  
 6 **informal study group participation, institutes, seminars, lectures, conferences,**  
 7 **workshops, extension study, correspondence courses, teaching, planned and**  
 8 **professional meetings, self-study courses, cassette or audio visual tape/slides or**  
 9 **materials, and other self-instruction units applicable to the practice of pharmacy.**

- 10 **(2) “Contact hour” means fifty minutes of continuing pharmacy education.**
- 11 **(3) “Patient safety” means systems, procedures and processes that ensure that the**  
12 **correct patient receives the correct drug in the correct dose and is counseled**  
13 **appropriately.**
- 14 **(4) “Medication error prevention” means systems, procedures and processes to prevent**  
15 **and avoid adverse events and to ensure that the correct patient receives the correct drug**  
16 **in the correct dose.**
- 17 **(5) "Pain management education program" means a specific one-hour web-based**  
18 **program developed by the Oregon Pain Commission, in addition to six accredited hours**  
19 **of continuing education in pain management, end of life care or a combination of both.**
- 20 **(6) “Cultural competence” means the lifelong process of examining the values and**  
21 **beliefs and developing and applying an inclusive approach to health care practice in a**  
22 **manner that recognizes the content and complexities of provider-patient communication**  
23 **and interaction and preserves the dignity of individuals, families, and communities.**
- 24 **(a) Cultural competence applies to all patients.**
- 25 **(b) Culturally competent providers do not make assumptions on the basis of an**  
26 **individual’s actual or perceived abilities, disabilities or traits whether inherent, genetic or**  
27 **developmental including: race, color, spiritual beliefs, creed, age, tribal affiliation,**  
28 **national origin, immigration or refugee status, marital status, socio-economic status,**  
29 **veteran’s status, sexual orientation, gender identity, gender expression, gender**  
30 **transition status, level of formal education, physical or mental disability, medical**  
31 **condition or any consideration recognized under federal, state and local law.**

32 **Statutory/Other Authority: ORS 689.205, ORS 676.850**

33 **Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450, ORS 413.590**

34  
35

36 [855-021-0005](#)

37 **Continuing Pharmacy Education Required for Pharmacist License Renewal**

38 (1) During the period from July 1 through June 30 of each biennial license renewal cycle, each-a  
39 pharmacist must have satisfactorily completed ~~three~~ (3) **30 hours of** continuing pharmacy  
40 education units (CEU's) in an approved continuing pharmacy education program prior to  
41 submission of the license renewal. Ten contact hours equals 1 CEU. Fifty minutes equals 1  
42 contact hour. These hours must include:

- 43 **(a) Two hours of continuing pharmacy education in pharmacy law;**
- 44 **(b) Two hours of continuing pharmacy education in patient safety or medication error**  
45 **prevention;**
- 46 **(c) Two hours of continuing pharmacy education in cultural competency either approved**  
47 **by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and**

- 48 **(d) Twenty-four additional hours of continuing pharmacy education.**
- 49 **(2) Prior to the second license renewal, a pharmacist licensed under these rules must**  
50 **complete seven hours of continuing education in pain management as detailed in the**  
51 **following sub-sections.**
- 52 **(a) A one-hour pain management course, specific to Oregon, provided by the Pain**  
53 **Management Commission of the Oregon Health Authority; and**
- 54 **(b) A minimum of six hours of continuing education in pain management. This**  
55 **requirement may be fulfilled by any combination of continuing education coursework**  
56 **focusing on pain management including but not limited to the treatment of terminally ill**  
57 **and dying patients, and those with chronic, non-malignant pain.**
- 58 **(c) The pain management continuing education required under this rule may count**  
59 **towards the required 30 continuing pharmacy education contact hours.**
- 60 **(3) Section (1) does not apply to pharmacists applying for the first renewal of their**  
61 **license, if they have not been licensed by the board for at least one year prior to July 1 of**  
62 **the renewal period.**
- 63 **(4) A pharmacist must retain documentation of completed continuing pharmacy**  
64 **education for six years and must provide this documentation if requested by the board.**
- 65 **(5) Continuing pharmacy education credit accumulated in excess of the required 30**  
66 **contact hours for biennial license renewal cannot be carried forward.**

67 Statutory/Other Authority: ORS 689.205, **ORS 676.850**  
68 Statutes/Other Implemented: ORS 689.285 **ORS 413.450, ORS 413.590**

70 **855-021-0007**

71 **Continuing Pharmacy Education Required for Intern License Renewal**

72 **(1) During each license renewal cycle, an intern must have satisfactorily completed 2**  
73 **contact hours of \*approved continuing pharmacy education in cultural**  
74 **competency either approved by the Oregon Health Authority under ORS 413.450 or any**  
75 **cultural competency CPE; and**

76 **(2) An intern must retain documentation of completed continuing pharmacy**  
77 **education for six years and must provide this documentation if requested by the board.**

78 Statutory/Other Authority: ORS 689.205  
79 Statutes/Other Implemented: ORS 689.285, ORS 676.850, **ORS 413.450, ORS 689.151**

80

81 **855-021-0009**

82 **Continuing Pharmacy Education Required for Certified Oregon Pharmacy Technician**  
83 **License Renewal**

84 **(1) During the period from July 1 through June 30 of each biennial license renewal cycle,**  
85 **a Certified Oregon Pharmacy Technician must have satisfactorily completed 20 contact**  
86 **hours of continuing pharmacy education. These hours must include:**

87 **(a) Two hours of continuing pharmacy education in pharmacy law;**

88 **(b) Two hours of continuing pharmacy education in patient safety or medication error**  
89 **prevention;**

90 **(c) Two hours of continuing pharmacy education in cultural competency either approved**  
91 **by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and**

92 **(d) Fourteen additional hours of continuing pharmacy education or documented onsite**  
93 **training approved by the board.**

94 **(2) Section (1) does not apply to a Certified Oregon Pharmacy Technician applying for the**  
95 **first renewal of their license, if they have not been licensed by the board for at least one**  
96 **year prior to July 1 of the renewal period.**

97 **(3) A Certified Oregon Pharmacy Technician must retain documentation of completed**  
98 **continuing pharmacy education for six years and must provide this documentation if**  
99 **requested by the board.**

100 **(4) Continuing pharmacy education credit accumulated in excess of the required 20**  
101 **contact hours for biennial license renewal cannot be carried forward.**

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

103 **Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450, ORS 676.850**

104

105 **[855-021-0010](#)**

106 Continuing Pharmacy Education **Programs**

107 (1) In this rule the terms below have the meanings given: As used in OAR 855-021:

108 (a) ~~“Patient Safety” means procedures and processes that ensure that the correct patient~~  
109 ~~receives the correct drug in the correct dose, and is counseled appropriately.~~

110 (b) ~~“Medication error prevention” means procedures and processes to prevent and avoid~~  
111 ~~adverse events and to ensure that the correct patient receives the correct drug in the correct~~  
112 ~~dose.~~

113 (2) ~~A continuing pharmacy education program means classes of post graduate studies, informal~~  
114 ~~study group participation, institutes, seminars, lectures, conferences, workshops, extension~~  
115 ~~study, correspondence courses, teaching, planned and professional meetings, self study~~  
116 ~~courses, cassette or audio visual tape/slides or materials, and other self instruction units:~~

117 (a1) ~~A **continuing pharmacy education** program shall **must** consist of therapeutics, or~~  
118 ~~pharmacy and drug law or other aspects of health care **applicable to the practice of**~~  
119 ~~**pharmacy**. A minimum of at least two hours of continuing education credit must be earned in~~  
120 ~~the area of pharmacy and drug law. A minimum of two hours of continuing education credit must~~  
121 ~~be earned in the area of patient safety or medication error prevention.~~

- 122 (b~~2~~) Programs ~~shall~~**must** provide for examinations or other methods of evaluation to assure  
123 satisfactory completion by participants.
- 124 (e~~3~~) The person or persons who are to instruct or who are responsible for the delivery or content  
125 of the program ~~shall~~**must** be qualified in the subject matter by education and experience.
- 126 (3~~4~~) Continuing pharmacy education programs ~~shall~~**must** be approved by the Board of  
127 Pharmacy. Application for approval ~~shall~~**must** be made on and in accordance with forms  
128 established by the ~~b~~Board. The forms ~~shall~~**must** require information relating to:
- 129 (a) Name of provider or sponsor;
- 130 (b) Type of program offered;
- 131 (c) Description of subject matter;
- 132 (d) Number of contact hours offered;
- 133 (e) Total number of contact hours in therapeutics or pharmacy and drug law or other aspects of  
134 health care **applicable to the practice of pharmacy**;
- 135 (f) Method of determining satisfactory completion of program;
- 136 (g) Dates and location of program;
- 137 (h) Name and qualification of instructors or other persons responsible for the delivery or content  
138 of the program.
- 139 (4~~5~~) CE programs are not required to carry approval of American Council on Pharmaceutical  
140 Education (ACPE). Programs presented by providers approved by the American Council on  
141 Pharmacy Education (ACPE) are ~~generally accepted, however, the Board reserves the right to~~  
142 ~~determine the number of hours allowed or to disapprove such programs.~~
- 143 (5~~6~~) Providers ~~shall~~**must** provide attendees with proof of attendance that shows the date and  
144 number of contact hours provided. Providers must maintain attendance lists for three years.
- 145 (6) ~~Continuing pharmacy education credit accumulated in excess of the required 30 contact~~  
146 ~~hours for biennial license renewal cannot be carried forward.~~
- 147 (7) A maximum of 120 contact hours (~~2.0 CEU~~) may be earned in any licensing cycle by  
148 preparing and presenting CE programs. Pharmacists **and Certified Oregon Pharmacy**  
149 **Technicians** presenting CE programs may earn one contact hour (~~0.1 CEU~~) for preparation  
150 time of one hour or more, plus credit for the actual contact hour time of the presentation. A  
151 pharmacist **or Certified Oregon Pharmacy Technicians** must show content of the course, and  
152 a description of the intended audience (e.g., pharmacists, technicians, physicians, nurses).  
153 Public service programs, such as presentations to school children or service clubs, are not  
154 eligible for continuing education credit.
- 155 (8) Pharmacists **or Certified Oregon Pharmacy Technicians** taking post graduate studies  
156 applicable to graduate or professional degrees may submit the course syllabus and evidence of  
157 satisfactory completion of the course for continuing education credit approval by the ~~b~~Board.
- 158 (9) The ~~b~~Board may approve up to 26 contact hours of CE credit for pharmacists who have  
159 successfully completed nationally certified Disease State Management courses.

160 (10) Board members or staff may attend CE programs for the purpose of evaluating content,  
161 format and appropriateness of material for Continuing Pharmacy Education credit. Subsequent  
162 programs by CE providers whose current programs are deemed deficient by on-site evaluation  
163 may be required to obtain prior approval by the ~~h~~Board. The ~~h~~Board will provide feedback to CE  
164 providers regarding evaluated CE presentations.

165

166 [855-021-0016](#)

167 **Continuing Education in Pain Management**

168 ~~(1) A pharmacist licensed under these rules must complete seven hours of continuing education~~  
169 ~~in pain management as detailed in the following sub-sections. This is a one-time requirement:~~

170 ~~(a) A one-hour pain management course, specific to Oregon, provided by the Pain Management~~  
171 ~~Commission of the Oregon Health Authority; and~~

172 ~~(b) A minimum of six hours of continuing education in pain management. This requirement may~~  
173 ~~be fulfilled by any combination of continuing education coursework focusing on pain~~  
174 ~~management including but not limited to the treatment of terminally ill and dying patients, and~~  
175 ~~those with chronic, non-malignant pain.~~

176 ~~(2) A pharmacist must complete the required continuing education within 24 months of their first~~  
177 ~~license renewal.~~

178 ~~(3) A pharmacist must retain for three years, documentation showing they have met the~~  
179 ~~requirement of this rule, and must provide this documentation if requested by the Board.~~

180 ~~(4) The pain management continuing education required under this rule shall count towards the~~  
181 ~~3.0 continuing pharmacy education units required under OAR 855-021-0005, in the license~~  
182 ~~cycle in which the pain management continuing education is completed.~~

183

184 [855-021-0025](#)

185 **Continuing Pharmacy Education — Reciprocity**

186 ~~A pharmacist reciprocating into Oregon will not be required to submit proof of continuing~~  
187 ~~pharmacy education during the initial license cycle.~~

188

189 [855-021-0030](#)

190 **Continuing Pharmacy Education — Non-Resident — Dual Licensees**

191 ~~(1) Any Oregon licensed pharmacist residing in another state shall, in order to receive Oregon~~  
192 ~~license renewal, meet Oregon requirements for continuing pharmacy education.~~

193 ~~(2) The Board shall accept for CE credit programs for out of state pharmacists that have been~~  
194 ~~approved by that state's Board of Pharmacy.~~

195 ~~(3) Upon request, the Board may certify to another state's licensing authority the status of a~~  
196 ~~licensee's continuing education participation in Oregon.~~

197 (4) The Board may request certification from another state's licensing authority regarding the  
198 status of an applicant's continuing education.

199

200 [855-021-0045](#)

201 **Notification of Annual Biennial License Renewal**

202 (1) The Board will develop an appropriate send a biennial renewal notice to be issued to all  
203 licensed pharmacists, interns, and Certified Oregon Pharmacy Technicians at least 60 days  
204 prior to May 1 of each odd numbered year the license expiration date that states the  
205 biennial license fee, continuing pharmacy education requirements and other information  
206 necessary for renewal.

207 (2) The notice will state the biennial pharmacist license fee and the continuing pharmacy  
208 education fee due for license renewal.

209 (3) The notice will include the continuing pharmacy education time requirement and any other  
210 information considered pertinent for the licensee's understanding of the renewal requirements.

211 Statutory/Other Authority: ORS 689.205

212 Statutes/Other Implemented: ORS 689.275, ORS 689.486

213

214 [855-021-0050](#)

215 **Renewal Application Continuing Pharmacy Education Audits**

216 (1) The biennial renewal application must be submitted to the Board with the appropriate fee  
217 and the pharmacist licensee must attest that he/she they hasve satisfactorily completed the  
218 continuing pharmacy education requirements.

219 (2) The Board may randomly select and audit applications for renewal to verify completion of the  
220 CE programs continuing pharmacy education by pharmacists, interns and Certified  
221 Oregon Pharmacy Technicians or documented onsite training by Certified Oregon  
222 Pharmacy Technicians reported on the application for renewal.

223 (a) Pharmacists whose applications for renewal are selected for audit must provide  
224 documentation of completion of the CE continuing pharmacy education programs reported. A  
225 pharmacist who fails to provide the requested documentation to the Board or who fails to  
226 complete the biennial CE continuing pharmacy education requirement may be disciplined for  
227 unprofessional conduct.

228 (b) Interns whose applications for renewal are selected for audit must provide  
229 documentation of completion of the cultural competency continuing pharmacy  
230 education. An intern who fails to provide the requested documentation to the board or  
231 who fails to complete the biennial continuing education requirement may be disciplined  
232 for unprofessional conduct.

233 (c) Certified Oregon Pharmacy Technicians whose applications for renewal are selected  
234 for audit must provide documentation of completion of the continuing pharmacy  
235 education or documented onsite training reported. A Certified Oregon Pharmacy  
236 Technician who fails to provide the requested documentation to the board or who fails to

237 **complete the biennial continuing education requirement may be disciplined for**  
238 **unprofessional conduct.**

239

240 **(3) The board may utilize the National Association of Boards of Pharmacy CPE**  
241 **Monitor service when auditing licensees.**

242 Statutory/Other Authority: ORS 689.205

243 Statutes/Other Implemented: ORS 689.275

244

245 [855-021-0055](#)

246 **Reinstatement**

247 ~~(1) Any person petitioning for reinstatement of a pharmacist license as provided within ORS~~  
248 ~~689.445 shall produce certification of the continuing education requirements of all years in which~~  
249 ~~the license has been inactive prior to restoration of the license.~~

250 ~~(2) Retired pharmacists who wish to reinstate their license should refer to OAR 855-019-~~  
251 ~~0170(2).~~

252

PROPOSED

## Division 025– Pharmacy Technicians/Certified Oregon Pharmacy Technicians (Cultural Competency CE)

**Filing Caption** (15 word limit): [2019 HB 2011](#) directs licensees when renewing to obtain cultural competency CE

**Need for Rules:** Revisions to Division 025 are necessary to incorporate continuing education requirement directives set forth in [2019 HB 2011](#), related to cultural competency.

### Fiscal Impact:

In Oregon, it is estimated that 6,186 Certified Oregon Pharmacy Technicians will be impacted by these new requirements. The cultural competency CE could cost \$0-60 per renewal cycle depending on the CE course(s) completed.

### Documents relied upon include:

[OHA Cultural Competence Continuing Education \(CCCE\)](#)

[2019 HB 2011](#) and related statutes

[ORS 676.850](#) Authority of regulatory boards to require cultural competency continuing education; documentation of participation; rules

[ORS 413.450](#) Continuing education in cultural competency

### Rules Summary:

Revisions to Division 025 are necessary to incorporate continuing education requirement directives set forth in [2019 HB 2011](#), related to cultural competency.

The additional revisions to Division 025 are in alignment with the board’s 2020-2024 Strategic Plan to proactively review & update rules to ensure clarity, transparency and promote patient safety.

- 1 Division 25
- 2 PHARMACY TECHNICIANS AND CERTIFIED OREGON PHARMACY TECHNICIANS
- 3 [855-025-0015](#)
- 4 **Renewal of Licensure as a Certified Oregon Pharmacy Technician**
- 5 (1) A person who has taken and passed a national pharmacy technician certification
- 6 examination listed in OAR 855-025-0012(1)(a)–(b) may use the following title, and is referred to
- 7 in these rules as, and is licensed as a “Certified Oregon Pharmacy Technician.”
- 8 (2) An applicant for renewal of a Certified Oregon Pharmacy Technician license must:
- 9 (a) Pay the biennial license fee ~~prescribed~~ **required** in OAR 855-110.

10 **(b) Completion of continuing pharmacy education requirements as directed in OAR 855-**  
11 **021**; Satisfactorily complete a minimum of 20 continuing pharmacy educating hours during the  
12 period from July 1 through June 30, of each license renewal cycle. These hours must include:

13 (A) Two hours of continuing pharmacy education in pharmacy law;

14 (B) Two hours of continuing pharmacy education in patient safety or error prevention; and

15 (C) Sixteen other hours of continuing pharmacy education or documented onsite training  
16 approved by the Board.

17 (c) OAR 855-025-0015(2)(b) does not apply to a Certified Oregon Pharmacy Technician  
18 applying for the first renewal of their license, if they have not been licensed by the Board for at  
19 least one year prior to July 1 of the renewal period.

20 (cd) Be subject to an annual criminal background check.

21 (3) The Board may randomly select and audit applications for renewal to verify completion of  
22 continuing education or documented onsite training reported on the application for renewal. A  
23 Certified Oregon Pharmacy Technician whose application for renewal is selected for audit must  
24 provide documentation of completion of the continuing pharmacy education reported.

25 (4) Effective January 1, 2015, ~~n~~**Continued** national certification is not required to renew a  
26 license as a Certified Oregon Pharmacy Technician.

27 (5) A Certified Oregon Pharmacy Technician who fails to renew his or her license by the  
28 expiration date and whose license has been lapsed for less than one year may renew his or her  
29 license as follows:

30 (a) Complete the renewal process;

31 (b) Pay the biennial license fee as prescribed in OAR 855-110;

32 (c) Pay a delinquent fee; and

33 (d) Complete the required continuing **pharmacy** education pursuant to OAR 855-025-  
34 0015(2)(b)-**021**.

35 Statutory/Other Authority: ORS 689.205

36 Statutes/Other Implemented: ORS 689.225 & 689.486

37

38 [855-025-0020](#)

39 ~~Recordkeeping Responsibilities of Pharmacy Technicians and Certified Oregon~~  
40 ~~Pharmacy Technicians~~

41 **Duty to Report**

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

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

46 (3) A Pharmacy Technician or Certified Oregon Pharmacy Technician must report to the **B**board  
47 within 10 days if they:

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

49 (b) If they are arrested for a felony.

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

59 (5) A Pharmacy Technician or Certified Oregon Pharmacy Technician who reports to a **B**board  
60 in good faith as required by section (4) of this rule is immune from civil liability for making the  
61 report.

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

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

70 ~~(8) A Certified Oregon Pharmacy Technician must obtain certificates of completion that show  
71 the date and number of hours earned to document continuing pharmacy education credit earned  
72 and must keep the certificates of completion for three years from the date of the program.~~

73 Statutory/Other Authority: ORS 689.205

74 Statutes/Other Implemented: ORS 689.155 & Ch. 536-OL-2009 **ORS 689.486**

75 **[855-025-0060](#)**

76 **Reinstatement of a Certified Oregon Pharmacy Technician License**

77 (1) A Certified Oregon Pharmacy Technician who fails to renew their license by the deadline  
78 and whose license has been lapsed for greater than one year may reinstate their license as  
79 follows:

80 (a) Complete a new application for licensure and provide the **B**board with a valid e-mail  
81 address;

82 (b) Pay the biennial license fee as prescribed in OAR 855-110;

83 (c) Submit to a national fingerprint background check; and

- 84 (d) Provide certification of completion of 10 continuing education hours. These hours may not be  
85 counted toward renewal; and must include:
- 86 (A) One hour of continuing pharmacy education in pharmacy law;
- 87 (B) One hour of continuing pharmacy education in patient safety or error prevention; and
- 88 **(C) One hour of continuing pharmacy education in cultural competency either approved**  
89 **by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and**
- 90 ~~(D)~~ **Seven** other hours of pharmacy technician-specific continuing education.
- 91 (2) A Certified Oregon Pharmacy Technician whose license has been lapsed greater than five  
92 years must:
- 93 (a) Re-take and pass a national pharmacy technician certification examination offered by:
- 94 (A) The Pharmacy Technician Certification Board (PTCB); or
- 95 (B) National Healthcareer Association (NHA).
- 96 (b) Satisfy reinstatement requirements pursuant to OAR 855-025-0060(1).
- 97 Statutory/Other Authority: ORS 689.205  
98 Statutes/Other Implemented: ORS 689.225, ORS 413.450, & ORS 689.486

**Division 031– Interns (Cultural Competency CE)**

**Filing Caption** (15 word limit): [2019 HB 2011](#) directs licensees when renewing to obtain cultural competency CE

**Need for Rules:** Revisions to Division 031 are necessary to incorporate continuing education requirement directives set forth in [2019 HB 2011](#), related to cultural competency.

**Fiscal Impact:**

In Oregon, it is estimated that 794 Interns will be impacted by these new requirements. The cultural competency CE could cost \$0-60 per renewal cycle depending on the CE course(s) completed.

**Documents relied upon include:**

[OHA Cultural Competence Continuing Education \(CCCE\)](#)

[2019 HB 2011](#) and related statutes

[ORS 676.850](#) Authority of regulatory boards to require cultural competency continuing education; documentation of participation; rules

[ORS 413.450](#) Continuing education in cultural competency

**Rules Summary:**

Revisions to Division 031 are necessary to incorporate continuing education requirement directives set forth in [2019 HB 2011](#), related to cultural competency.

The additional revisions to Division 031 are in alignment with the board's 2020-2024 Strategic Plan to proactively review & update rules to ensure clarity, transparency and promote patient safety.

- 1 Division 31
- 2 INTERNSHIP REGULATIONS
- 3 [855-031-0005](#)
- 4 **Definitions**
- 5 (1) An "intern" means any person who:
  - 6 (a) Is enrolled in a course of study and is in good academic standing at a school or college of
  - 7 pharmacy that is approved by the Oregon Board of Pharmacy (~~Board~~); or
  - 8 (b) Is a graduate of a school or college of pharmacy that is approved by the ~~B~~board; or
  - 9 (c) Is a foreign pharmacy graduate and holds a certificate from the Foreign Pharmacy Graduate
  - 10 Equivalency Committee (FPGEC); and
  - 11 (d) Is licensed with the ~~B~~board as an intern.

- 12 (2) A "preceptor" means a pharmacist or a person licensed by the **B**oard to supervise the  
13 internship training of an intern.
- 14 (3) "Internship" means a professional experiential program or work experience.
- 15 (a) "Traditional Pharmacy-practice Internship (TPI)" means experience toward achieving  
16 competency in the practice of pharmacy for which no academic credit is granted to the intern.
- 17 (b) "School-based Rotational Internship (SRI)" means experience toward achieving competency  
18 in the practice of pharmacy in programs developed and administered by a school of pharmacy.
- 19 (c) "Other Internship" means experience toward achieving competency in the practice of  
20 pharmacy, other than in an internship as defined in (a) or (b), in a program approved by a  
21 school of pharmacy or the **B**oard.
- 22 (4) "School of pharmacy": In this division of rules, "school of pharmacy" means a school or  
23 college of pharmacy that is approved by the **B**oard.

24 Statutory/Other Authority: ORS 689.151 & **ORS** 689.205

25 Statutes/Other Implemented: **ORS** 689.255

26

27 [\*\*855-031-0010\*\*](#)

28 **Intern License Application**

- 29 (1) Applications for licensure as an intern may be obtained from ~~the Board office or from the~~  
30 **B**oard website.
- 31 (a) Failure to completely, accurately and honestly answer all questions on the application form  
32 for licensure or renewal of licensure is grounds for discipline;
- 33 (b) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony  
34 may result in denial of the application.
- 35 (2) The **B**oard may issue a license to a qualified intern after the receipt of:
- 36 (a) A completed application;
- 37 (b) Payment of the fee prescribed in OAR 855-110;
- 38 (c) A current, passport regulation size photograph (full front, head to shoulders);
- 39 (d) Furnish documentation required to conduct a national fingerprint-based background check;  
40 and
- 41 (e) Confirmation from a school of pharmacy that the applicant is enrolled in a course of study,  
42 except for foreign pharmacy graduates who must:
- 43 (A) Provide a copy of a valid visa permitting full-time employment;
- 44 (B) Provide a copy of the original certificate issued by the Foreign Pharmacy Graduate  
45 Equivalency Examination Committee; and
- 46 (C) Provide evidence that they have passed the Test of English as a Foreign Language  
47 (TOEFL) Internet-based Test (IBT).

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

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

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

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

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

62 (4) An intern must surrender their license to the Board within 30 days of one of the above  
63 events.

64 (5) Notwithstanding the requirements of section (3) above, upon written request the Board may  
65 waive any of the requirements of this rule if a waiver will further public health and safety. A  
66 waiver granted under this section ~~shall~~**must** only be effective when it is issued in writing.

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

68 Statutory/Other Authority: ORS 689.151 & ORS 689.205

69 Statutes/Other Implemented: ORS 689.207, ORS 689.255 & ORS 689.455

70

71 **855-031-0016**

72 **Renewal of Licensure as an Intern**

73 **(1) An application for renewal of an intern license must include documentation of:**

74 **(a) Completion of continuing pharmacy education requirements as directed in OAR 855-**  
75 **021; and**

76 **(b) Payment of the license fee required in OAR 855-110.**

77 **(2) An intern will be subject to an annual criminal background check.**

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

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

80

81

82 **855-031-0020**

83 **Intern Requirements and Responsibilities**

- 84 (1) A licensed intern may practice in any one or a combination of the following approved  
85 internship experience areas:
- 86 (a) Traditional Pharmacy-practice Internship (TPI): an intern may not work in a TPI until after  
87 satisfactorily completing the first academic year in a school of pharmacy. An intern working in a  
88 TPI must be supervised by a licensed pharmacist or pharmacist preceptor;
- 89 (b) School-based Rotational Internship (SRI): an intern must be supervised by a licensed  
90 pharmacist or other person approved by a school of pharmacy to obtain credit for SRI hours;
- 91 (c) Other Internship.
- 92 (2) An intern may not work more than 48 hours per week in SRIs and must comply with all  
93 supervision and ratio requirements.
- 94 (3) An intern must verify that their preceptor is currently licensed with the **B**board.
- 95 (4) An intern may not work in the practice of pharmacy unless supervised by a licensed  
96 pharmacist, except when an intern is working in a federal facility, however, to obtain credit for  
97 SRI experience in a federal facility located in Oregon, the intern must be licensed with the  
98 **B**board.
- 99 (5) An intern who is working in a pharmacy or other place of business must conspicuously  
100 display their intern license in the pharmacy or place of business and must be clearly identified  
101 as an intern at all times.
- 102 (6) An intern may perform only the duties listed in Division 025 of this Chapter before completion  
103 of the first academic year in a school of pharmacy.
- 104 (7) An intern may, after successful completion of their first academic year, perform the duties of  
105 an intern listed in Division 019 of this Chapter, but only after successful completion of  
106 coursework corresponding to those duties at their school of pharmacy and only with the  
107 permission of their supervising pharmacist.
- 108 (8) An intern is responsible for his or her own actions and must comply with all **B**board  
109 regulations.
- 110 (9) An intern must notify the **B**board within 15 days of any change in their academic status that  
111 might affect their eligibility to work as an intern.
- 112 (10) An intern must notify the **B**board in writing within 15 days of a change in permanent  
113 residence and TPI site.
- 114 (11) An intern must report to the **B**board within 10 days if they are:
- 115 (a) Convicted of a misdemeanor or a felony; or
- 116 (b) Arrested for a felony.
- 117 (12) An intern who has reasonable cause to believe that another licensee (of the **B**board or any  
118 other Health Professional Regulatory Board) has engaged in prohibited or unprofessional  
119 conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the  
120 board responsible for the licensee who is believed to have engaged in the conduct. The intern  
121 **shall****must** report the conduct without undue delay, but in no event later than 10 working days

122 after the intern learns of the conduct unless federal laws relating to confidentiality or the  
123 protection of health information prohibit disclosure.

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

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

130 Statutory/Other Authority: ORS 689.151 & **ORS** 689.205

131 Statutes/Other Implemented: ORS 689.255 & ~~2009-OL Ch. 536~~ **ORS**

132

### 133 [855-031-0026](#)

#### 134 **Ratio & Supervision**

135 (1) A pharmacist may not supervise more than one intern at a time at a TPI site who performs  
136 the duties of an intern as listed in OAR 855-019-0200(3)(g). A pharmacist may supervise more  
137 than one intern if only one intern performs the duties of an intern as listed in OAR 855-019-  
138 0200(3)(g) and if other interns supervised by the pharmacist perform the duties listed in OAR  
139 855-025-0040.

140 (2) A preceptor may not supervise more than two interns simultaneously during a shift at an SRI  
141 site where patient specific recommendations for care or medications are provided without prior  
142 written authorization of the **B**board. Through the 2020-2021 academic year, a preceptor may  
143 monitor as many interns as they believe in their professional judgement is appropriate to  
144 achieve desired experiential outcomes for non-direct patient care learning opportunities only,  
145 while also preserving and assuring patient safety. The preceptor must retain documentation of  
146 all interns monitored during this timeframe.

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

150 (4) For immunization clinics, an immunizing pharmacist may supervise up to two immunizing  
151 interns.

152 (5) A licensed preceptor may delegate the preceptor responsibilities to another licensed  
153 pharmacist or preceptor.

154 (6) The majority of an intern's overall experience must be with a licensed pharmacist preceptor.

155 Statutory/Other Authority: ORS 689.151 & ORS 689.205

156 Statutes/Other Implemented: ORS 689.255

157

### 158 [855-031-0030](#)

#### 159 **Out-of-State Internship Experience**

- 160 (1) In order for an Oregon intern to obtain credit for SRI experiences outside the State of  
161 Oregon, an intern must:
- 162 (a) Be licensed as required by state laws and rules in the state in which they will practice;  
163 (b) Meet or exceed the minimum SRI requirements of the **B**board;
- 164 (2) In order for an out-of-state intern to practice in the State of Oregon, the intern must meet all  
165 requirements of these rules.

166 Statutory/Other Authority: ORS 689.151 & **ORS** 689.205

167 Statutes/Other Implemented: **ORS** 689.255

168

169 **855-031-0045**

170 **School and Preceptor Registration and Responsibilities**

- 171 (1) A preceptor license may be issued by the **B**board upon receipt of a completed application.
- 172 (2) A pharmacist preceptor must have been an actively practicing pharmacist for at least one  
173 year immediately prior to supervising an intern.
- 174 (3) A preceptor license must be renewed biennially and will expire on June 30 in odd numbered  
175 years.
- 176 (4) The preceptor may report to the **B**board voluntarily, the progress and aptitude of an intern  
177 under the preceptor's supervision, or must do so upon request of the **B**board.
- 178 (5) The preceptor must be responsible for supervision of the majority of the intern's SRI hours  
179 and must provide the intern with internship experiences, which in the preceptor's judgment will  
180 increase the intern's competency in the practice of pharmacy.
- 181 (6) Before supervising an intern in an SRI program, a preceptor must complete any training  
182 program required by the school of pharmacy.
- 183 (7) A preceptor must advise each school of pharmacy when they are supervising students from  
184 more than one school at the same time. This applies to both in-state and out-of-state schools or  
185 colleges of pharmacy.
- 186 (8) A preceptor must verify that their intern is currently licensed with the **B**board.
- 187 (9) A pharmacist acting as a preceptor in a federal facility is not required to be licensed as a  
188 pharmacist in Oregon, but is required to be licensed as a preceptor with the **B**board.
- 189 (10) The school of pharmacy must maintain a record of each intern's SRIs. This record must be  
190 made available to the **B**board upon request.
- 191 (11) A school of pharmacy located in Oregon must submit a report on their experiential  
192 education program to the **B**board at the end of each academic year. This report must include  
193 the names of students who successfully completed the program and graduated from the school.  
194 The school must maintain a list of preceptors and SRI sites, in and out-of-state, approved by the  
195 school and must make this list available to the **B**board upon request.

196 (12) All records related to a student must be available for three years after the student  
197 graduates.

198 Statutory/Other Authority: ORS 689.151 & **ORS** 689.205

199 Statutes/Other Implemented: ORS 689.255

200

201 **855-031-0050**

202 **Eligibility for Exams — Foreign Pharmacy Graduates**

203 In addition to the other requirements of this Division, a foreign pharmacy graduate must  
204 complete 1440 internship hours before applying to take the Multistate Pharmacy Jurisprudence  
205 Examination (MPJE) and before applying for licensure as a pharmacist as specified in OAR  
206 855-019-0150. Evidence of completing this requirement must be provided to the **B**oard by the  
207 applicant and must be authenticated by each preceptor.

208 Statutory/Other Authority: ORS 689.151 & **ORS** 689.205

209 Statutes/Other Implemented: **ORS** 689.255

210

211 **855-031-0055**

212 **Eligibility for Exams and Pharmacist Licensure**

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

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

218 (a) Complete an application for licensure including providing any fingerprint card or other  
219 documentation required by the **B**oard to conduct a criminal background check;

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

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

222 Statutory/Other Authority: ORS 689.205

223 Statutes/Other Implemented: ORS 689.135, **ORS** 689.207, **ORS** 689.225 & **ORS** 689.275

## **Division 041: Operation of Pharmacies (Epinephrine)**

**Filing Caption (max 15 words):**

Removes limitation on epinephrine dispensed to an entity

**Need for Rules:**

Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a vaccine.

**Fiscal Impact:**

None anticipated

**Documents Relied Upon:**

[CDC Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination](#)

**Rules Summary:**

This rule removes the limit of the number of epinephrine devices that may be dispensed to an entity. Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a vaccine.

1 855-041-2320

2 Epinephrine

3

4 (1) A pharmacist may fill an order for epinephrine to be used by trainees to treat an anaphylactic  
5 reaction. Trainees must be 18 years of age or older and must have responsibility for or contact with at  
6 least one (1) other person as a result of the trainee’s occupation or volunteer status, such as, but not  
7 limited to, a camp counselor, scout leader, forest ranger, school employee, tour guide or chaperone.

8

9 (2) Individuals must successfully complete a training program approved by the Oregon Health Authority,  
10 Public Health Division. Upon successful completion, the trainee will receive the following certificates:

11

12 (a) Statement of Completion; and

13

14 (b) Authorization to Obtain Epinephrine.

15

16 (3) Acquisition of epinephrine from a pharmacy to be used for the treatment of allergic emergencies  
17 may occur in the following manners:

18

19 (a) A pharmacist may dispense epinephrine to a trainee upon presentation of the Statement of  
20 Completion and Authorization to Obtain Epinephrine certificate to a pharmacy when:

21

22 (A) A pharmacist may generate a prescription for, and dispense an emergency supply of epinephrine for  
23 not more than one adult and one child dose package, as specified by the supervising professional whose  
24 name, signature, and license number appear on the Authorization to Obtain Epinephrine certificate.

25

26 (B) The pharmacist who generates the hardcopy prescription for epinephrine in this manner shall reduce  
27 the prescription to writing, and file the prescription in a manner appropriate for a non-controlled  
28 substance.

29

30 (C) Once the pharmacist generates the epinephrine prescription, the pharmacist shall write in the  
31 appropriate space provided on the Authorization to Obtain Epinephrine certificate the date and the  
32 number of doses dispensed, and return the certificate to the trainee.

33

34 (D) The Statement of Completion and the Authorization to Obtain Epinephrine certificate may be used  
35 to obtain epinephrine up to four (4) times within three (3) years from the date of the initial training.

36

37 (E) Both the Statement of Completion and the Authorization to Obtain Epinephrine certificate expire  
38 three (3) years from the date of the trainee's last Oregon Health Authority approved allergy response  
39 training.

40

41 (F) Upon completion of the training, the trainee will receive a new Statement of Completion and  
42 Authorization to Obtain Epinephrine certificate, with a valid duration of three (3) years.

43

44 (b) A pharmacist may dispense epinephrine to an entity when:

45

46 (A) The epinephrine is acquired by a valid prescription presented to the pharmacy;

47

48 (B) The prescription identifies the entity as the patient for the purpose of prescribing; **and labeling the**  
49 **prescription.**

50

51 ~~(i) The pharmacist shall use the name of the entity as the patient for the purpose of labeling the~~  
52 ~~prescription.~~

53

54 ~~(ii) The prescription shall be limited to one adult and one child dose package per trained employee per~~  
55 ~~location.~~

56

57 ~~(C) For the purpose of this rule, an entity conducts business at a single physical location.~~

58

59 Statutory/Other Authority: ORS 689.205

60 Statutes/Other Implemented: ORS 689.155 & ORS 433.825

## 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:

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.

### 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

### 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.

#### 1 **855-041-1001**

#### 2 **Definitions**

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

7 (2) "Biosimilar product" means a biological product licensed by the United States Food and Drug  
8 Administration pursuant to 42 U.S.C. 262(k)(3)(A)(i) **(12/26/2020)**.

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

10 **(4) "Informational insert" is an auxiliary document that is provided to the patient when directions for**  
11 **use by the patient required under OAR 855-041-1130 do not fit on the label affixed to the prescription**  
12 **container.**

13 (45) “Interchangeable” means, in reference to a biological product, that the United States Food and  
14 Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42  
15 U.S.C. 262(k)(4) (12/26/2020).

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

17 (57) “Reference biological product” means the biological product licensed pursuant to 42 U.S.C. 262(a)  
18 (12/26/2020) against which a biological product is evaluated in an application submitted to the United  
19 States Food and Drug Administration for licensure of a biological product as a biosimilar product or for  
20 determination that a biosimilar product is interchangeable.

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

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

23

24 **855-041-1132**

25 **Limited English Proficiency and Accessibility**

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

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

33 (a) Spanish;

34 (b) Russian;

35 (c) Somali;

36 (d) Arabic;

37 (e) Chinese (simplified);

38 (f) Vietnamese;

39 (g) Farsi;

40 (h) Korean;

41 (i) Romanian;

42 (j) Swahili;

43 (k) Burmese;

44 (l) Nepali;

45 (m) Amharic; and

46 (n) Pashtu.

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

48 **(4) An informational insert must only be used when the directions for use by the patient required**  
49 **under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container.**

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

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

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

55 **(b) identifying number;**

56 **(c) name of patient;**

57 **(d) name of drug and strength; and**

58 **(e) dispensing date.**

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

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

61

62 **855-043-0002**

63 **Definitions**

64 In this division of rules:

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

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

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

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

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

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

78 **(5) “Informational insert” is an auxiliary document that is provided to the patient when directions for**  
79 **use by the patient required under OAR 855-041-1130 do not fit on the label affixed to the prescription**  
80 **container.**

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

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

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

86 **Statutes/Other Implemented:** ORS 689.155, **& ORS 689.564**

87

88 **855-043-0436**

89 **Supervising Physician Dispensing Outlet - Limited English Proficiency and Accessibility**

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

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

96 (a) Spanish;

97 (b) Russian;

98 (c) Somali;

99 (d) Arabic;

100 (e) Chinese (simplified);

101 (f) Vietnamese;

102 (g) Farsi;

103 (h) Korean;

104 (i) Romanian;

105 (j) Swahili;

106 (k) Burmese;

107 (l) Nepali;

108 (m) Amharic; and

109 (n) Pashtu.

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

111 **(4) An informational insert must only be used when the directions for use by the patient required**  
112 **under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container.**

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

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

117 **(a) directions for use by the patient;**

118 **(b) identifying number;**

119 **(c) name of patient;**

120 **(d) name of drug and strength; and**

121 **(e) dispensing date.**

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

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

124

125 **855-043-0541**

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

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

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

133 (a) Spanish;

134 (b) Russian;

135 (c) Somali;

136 (d) Arabic;

137 (e) Chinese (simplified);

138 (f) Vietnamese;

139 (g) Farsi;

140 (h) Korean;

141 (i) Romanian;

- 142 (j) Swahili;
- 143 (k) Burmese;
- 144 (l) Nepali;
- 145 (m) Amharic; and
- 146 (n) Pashtu.
- 147 (3) The board must reassess and update (2) as necessary and at least every ten years.

148 **Statutory/Other Authority:** ORS 689.564  
149 **Statutes/Other Implemented:** ORS 689.205

150

PROPOSED

151 **855-044-0005**

152 **Definitions**

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

155 **(2) "Informational insert" is an auxiliary document that is provided to the patient when directions for**  
156 **use by the patient required under OAR 855-041-1130 do not fit on the label affixed to the prescription**  
157 **container.**

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

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

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

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

164

165 **855-044-0061**

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

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

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

174 (a) Spanish;

175 (b) Russian;

176 (c) Somali;

177 (d) Arabic;

178 (e) Chinese (simplified);

179 (f) Vietnamese;

180 (g) Farsi;

181 (h) Korean;

182 (i) Romanian;

183 (j) Swahili;

184 (k) Burmese;

185 (l) Nepali;

186 (m) Amharic; and

187 (n) Pashtu.

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

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

192 **(5) An informational insert must only be used when the directions for use by the patient required**  
193 **under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container.**

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

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

198 **(a) directions for use by the patient;**

199 **(b) identifying number;**

200 **(c) name of patient;**

201 **(d) name of drug and strength; and**

202 **(e) dispensing date.**

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

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

**Division 041- Operation of Pharmacies (Drug Take Back)**

**Filing Caption** (15 word limit):

Clarifies requirements for pharmacies related to Drug Take Back Programs

**Need for Rules:**

To address directives of [2019 HB 3273](#) which directs Department of Environmental Quality (DEQ) to adopt any rules necessary for the effective administration of ORS 459A.200 to 459A.266. DEQ requested OBOP to assist DEQ in adopting rules under ORS 459A.200 to 459A.266.

**Fiscal Impact:**

None anticipated

**Documents relied upon include:**

[2019 HB 3273](#) and related statutes

[ORS 459A.200 to 459A.266](#) Drug Take Back Program

**Rules Summary:**

Amends rules related to returned drugs and devices and secure and responsible drug disposal to align with the directives of [2019 HB 3273](#).

1 **855-041-1045**

2 **Returned Drugs and Devices**

3 (1) Pharmacists, ~~pharmacies,~~ pharmacy technicians, ~~and~~ certified pharmacy technicians **and interns** may  
4 **not only** accept the return of controlled substances ~~upon receiving a waiver from the Board of~~  
5 ~~Pharmacy.~~

6 (2) Pharmacists, pharmacies, pharmacy technicians, ~~and~~ certified pharmacy technicians **and interns** may  
7 accept the return of drugs or devices as defined by ORS 689.005 once the drugs or devices have been  
8 removed from the pharmacy only if;

9 (a) The drugs or devices are accepted for destruction or disposal and;

10 (b) The drugs or devices were dispensed in error, were defective, adulterated, misbranded, dispensed  
11 beyond their expiration date, were unable to be delivered to the patient, or are subject of a drug or  
12 device recall; or

13 (c) After consultation, a pharmacist determines that, in the pharmacist’s professional judgment, harm  
14 could result to the public or a patient if the drugs or devices were not accepted for return.

15 (3) Notwithstanding ~~section~~ **(2)** of this rule, drugs or devices previously dispensed or distributed may be  
16 returned and redispensed or redistributed provided all the following conditions are met:

- 17 (a) The drug is in an unopened, tamper-evident unit;
- 18 (b) The drugs or devices have remained at all times in control of a person trained and knowledgeable in  
19 the storage and administration of drugs in long term care facilities or supervised living groups using the  
20 services of a consultant pharmacist;
- 21 (c) The drug or device has not been adulterated or misbranded and has been stored ~~under~~according to  
22 ~~conditions meeting United States Pharmacopeia standards~~ the manufacturer recommendations.
- 23 ~~(4) Upon written request, the Board may waive any of the requirements of this rule if a waiver will~~  
24 ~~further public health or safety or the health and safety of a patient. A waiver granted under this section~~  
25 ~~shall only be effective when it is issued by the Board in writing.~~

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

28  
29  
30

#### 31 **855-041-1046**

#### 32 **Secure and Responsible Drug Disposal**

- 33 (1) A pharmacy that operates a drug take back collection program or that participates in a drug take-  
34 back program under ORS 459A.200 to ORS 459A.266 as an authorized collector must be registered  
35 with the DEA as an authorized collector ~~may~~ to collect controlled and non-controlled drugs for  
36 destruction in accordance with all applicable federal laws.
- 37 (2) A pharmacy that operates ~~as a drug take back collection program~~ Drug Enforcement Agency (DEA)  
38 authorized collector shall ~~must~~ notify the ~~Board in writing prior to~~ within 30 days of initiating or  
39 terminating the program and shall ~~must~~ establish and enforce policies and procedures, including but  
40 not limited to:
- 41 (a) Provision of a secure location of the collection receptacle inside the retail drug outlet, which ~~must~~  
42 ~~be is~~ accessible to the public, within view of the pharmacy counter and ~~cannot be~~ must not placed be  
43 located behind the pharmacy counter; and
- 44 (b) Provision of adequate security measures, including proper installation and maintenance of the  
45 collection receptacle, tracking of liners, documentation and key accountability; and
- 46 (c) Personnel training and accountability.
- 47 (3) A pharmacy must inform consumers to directly deposit drugs into the collection receptacle.  
48 Pharmacy personnel shall ~~must~~ not count, sort, inventory, or otherwise handle drugs collected.
- 49 (4) A pharmacy shall ~~must~~ not dispose of ~~quarantined, recalled or outdated~~ drugs from pharmacy stock  
50 in a collection receptacle.
- 51 (5) The liner must be inserted and removed from a locked collection receptacle only by or under the  
52 supervision of two employees of the pharmacy. Upon removal, the liner must be immediately sealed,

53 and the pharmacy employees must document their participation in the insertion and removal of each  
54 liner from a collection receptacle on a log. Sealed liners must not be opened, analyzed or penetrated  
55 at any time by the pharmacy or pharmacy personnel.

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

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

63 ~~(58)~~ A pharmacy shall must maintain all drug disposal records for a minimum of 3 years.

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

65 (a) ORS 459A.200, ORS 459A.203, ORS 459A.206, ORS 459A.209, ORS 459A.212, ORS 459A.215, ORS  
66 459A.218, ORS 459A.221, ORS 459A.224, ORS 459A.227, ORS 459A.230, ORS 459A.233, ORS 459A.236,  
67 ORS 459A.239, ORS 459A.242, ORS 459A.245, ORS 459A.248, ORS 459A.251, ORS 459A.254, ORS  
68 459A.257, ORS 459A.260, ORS 459A.263, and ORS 459A.266;

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

71 (c) 21 CFR 1317.30 (04/01/2020), 21 CFR 1317.35 (04/01/2020), 21 CFR 1317.40 (04/01/2020), 21 CFR  
72 1317.55 (04/01/2020), 21 CFR 1317.60 (04/01/2020), 21 CFR 1317.65 (04/01/2020), 21 CFR 1317.70  
73 (04/01/2020), 21 CFR 1317.75 (04/01/2020), 21 CFR 1317.80 (04/01/2020), and 21 CFR 1317.85  
74 (04/01/2020); and

75 (d) 21 USC 822 (04/01/2021), 21 USC 822a (04/01/2021).

76 Statutory/Other Authority: ORS 689.205 & ORS 459A.266

77 Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215, & ORS 495A.218

**Division 020– Pharmacist Prescriptive Authority**

**Filing Caption** (max 15 words):

Compendia updated to incorporate recent Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) recommendations.

**Need for Rules:**

Appropriately references and reflects current standards incorporated in statewide drug therapy management protocols by reference, amends and repeals outdated regulations. Additional revisions to the proposed rules are a result of input from the Public Health and Pharmacy Formulary Advisory Committee.

**Documents relied upon include:**

Statewide drug therapy management protocols

ORS 689.645 and ORS 689.649

**Fiscal Impact:**

None anticipated

**Rules Summary:**

Updates all protocols in the protocol compendia. Adds one new item to the formulary compendia

- 1 Division 20
- 2 PHARMACIST PRESCRIPTIVE AUTHORITY
- 3
- 4 855-020-0105
- 5 Public Health and Pharmacy Formulary Advisory Committee
- 6
- 7 (1) The Public Health and Pharmacy Formulary Advisory Committee shall consist of:
- 8
- 9 (a) Two physicians licensed to practice medicine under ORS 677.100 to 677.228;
- 10
- 11 (b) Two advanced practice registered nurses who have prescriptive authority and who are licensed by
- 12 the Oregon State Board of Nursing; and
- 13
- 14 (c) Three pharmacists licensed by the State Board of Pharmacy, at least one of whom is employed as a
- 15 community pharmacist and one of whom is employed as a health system pharmacist.
- 16
- 17 (2) A pharmacist may submit a concept, on a form prescribed by the Board to the committee for
- 18 consideration, for the development of a protocol or the addition of a drug or device to the formulary.
- 19

20 (3) The committee shall recommend to the Board, for adoption by rule, a protocol or formulary of drugs  
21 and devices from which a pharmacist may prescribe and dispense to a patient pursuant to a diagnosis by  
22 a qualified healthcare practitioner.

23

24 (4) The committee shall periodically review the formulary and protocol compendium and recommend  
25 the revisions to the Board for adoption by rule.

26

27 Statutory/Other Authority: ORS 689.205

28 Statutes/Other Implemented: ORS 689.645, ORS 689.649 & ORS 689.155

29

30 855-020-0110

31 Prescribing Practices

32

33 (1) A pharmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and  
34 devices included on either the Formulary or Protocol Compendia, set forth in this Division. A pharmacist  
35 shall only prescribe a drug or device consistent with the parameters of the Formulary and Protocol  
36 Compendia, and in accordance with federal and state regulations.

37

38 (2) A pharmacist must create, approve, and maintain policies and procedures for prescribing post-  
39 diagnostic drugs and devices or providing patient care services ~~via implementation of~~ pursuant to  
40 statewide drug therapy management protocols. The policies and procedures shall describe current and  
41 referenced clinical guidelines, and include but not be limited to:

42

43 (a) Patient inclusion and exclusion criteria;

44

45 (b) Explicit medical referral criteria;

46

47 (c) Care plan preparation, implementation, and follow-up;

48

49 ~~(d) Prescribing drugs and devices pursuant to the formulary and protocol compendia;~~

50

51 ~~(ed)~~ Patient education; and

52

53 ~~(fe)~~ Provider notification; and-

54

55 (f) Maintaining confidentiality.

56

57 (3) The pharmacist is responsible for recognizing limits of knowledge and experience and for resolving  
58 situations beyond ~~their~~ his or her pharmacist expertise by consulting with or referring patients to  
59 another health care provider.

60

61 (4) For each drug or device the pharmacist prescribes, the pharmacist must:

62

63 (a) Assess patient and collect subjective and objective information, including the diagnosis for Formulary  
64 Compendia items, about the patient's health history and clinical status. The pharmacist's patient  
65 assessment shall be performed in a face-to-face, in-person interaction and not through electronic  
66 means; and

67  
68 (b) Utilize information obtained in the assessment to evaluate and develop an individualized patient-  
69 centered care plan, pursuant to the statewide drug therapy management protocol and policies and  
70 procedures; and

71  
72 (c) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-  
73 up; and

74  
75 (d) Provide notification, ~~preferably via an interoperable information technology system,~~ to the patient's  
76 identified primary care provider or other care providers when applicable, within five business days  
77 following the prescribing of a Compendia drug or device.

78  
79 (5) The pharmacist shall maintain all records associated with prescribing and other related activities  
80 performed for a minimum of 10 years, and a copy must be made available to the patient and provider  
81 upon request. Pharmacy records must be retained and made available to the Board for inspection upon  
82 request. Records must be stored onsite for at least one year and then may be stored in a secure off-site  
83 location if retrievable within three business days. Records and documentation may be written,  
84 electronic or a combination of the two.

85  
86 Statutory/Other Authority: ORS 689.205

87 Statutes/Other Implemented: ORS 689.645 & ORS 689.649

88  
89 855-020-0120

90 Prescribing Prohibited Practices

91  
92 ~~The responsibility and authority to prescribe pursuant to the Formulary and Protocol Compendia is upon~~  
93 ~~the pharmacist.~~

94  
95 **(1) A pharmacist shall ~~may~~ not prescribe a drug or device to self or immediate family members ~~a spouse,~~**  
96 **domestic partner, parent, guardian, sibling, child, aunt, uncle, grandchild and grandparent, including**  
97 **foster, in-law, and step relationships or other individual for whom a pharmacist's personal or**  
98 **emotional involvement may render the pharmacist unable to exercise detached professional**  
99 **judgment in prescribing pursuant to the Formulary and Protocol Compendia.**

100  
101 **POLICY DISCUSSION:** Defining immediate family

102  
103 **(2) An intern may not prescribe a drug or device.**

104  
105 Statutory/Other Authority: ORS 689.205

106 Statutes/Other Implemented: ORS 689.645 & ORS 689.649

107  
108 855-020-0200  
109 Formulary Compendium

110  
111 A pharmacist may prescribe, according to ~~rules regulations outlined~~ rules outlined in this Division, an FDA-approved  
112 drug and device listed in the following compendium, pursuant to a diagnosis by a health care  
113 practitioner who has prescriptive authority and who is qualified to make the diagnosis. The diagnosis  
114 must be documented.

115  
116 Devices and supplies:  
117 (1) Diabetic blood sugar testing supplies;  
118 (2) Injection supplies;  
119 (3) Nebulizers and associated supplies;  
120 (4) Inhalation spacers;  
121 (5) Peak flow meters;  
122 (6) International Normalized Ratio (INR) testing supplies;  
123 (7) Enteral nutrition supplies; ~~and~~  
124 (8) Ostomy products and supplies; and  
125 **(9) Non-invasive blood pressure monitors**

126  
127 Statutory/Other Authority: ORS 689.205  
128 Statutes/Other Implemented: ORS 689.645 & ORS 689.649

129  
130 855-020-0300  
131 Protocol Compendium

132  
133 A pharmacist may prescribe, via statewide drug therapy management protocol and according to  
134 ~~regulations~~ rules outlined in this Division, an FDA-approved drug and device listed in the following  
135 compendium:

136  
137 (1) Continuation of therapy **(v. 06/2021)**  
138  
139 ~~(a) A pharmacist may prescribe any non-controlled medication to extend a patient's prescription therapy~~  
140 ~~to avoid interruption of treatment; and~~  
141  
142 ~~(b) In such cases, a pharmacist shall only prescribe a drug quantity sufficient for the circumstances, not~~  
143 ~~to exceed a 60-day supply, and no more than two extensions in a 12-month period per medication.~~

144  
145 (2) Conditions  
146  
147 (a) Cough and cold symptom management

148  
149 (A) Pseudoephedrine **(v. 06/2021)** ~~products for patients 18 years of age and older, verified by positive~~  
150 ~~identification, not to exceed 3.6 grams or a 60 count quantity per prescription, whichever is less, or a~~

151 total of three prescriptions in a 12-month period. Pharmacist must review PDMP prior to issuing  
152 prescription and retain documentation of PDMP review;

153  
154 (B) Benzonatate (v. 06/2021), for the treatment of cough, not to exceed a 7-day supply;

155  
156 (C) Short-acting beta agonists (v. 06/2021), not to exceed 1 inhaler with or without a spacer, or 1 box of  
157 nebulizer ampules, per year; and

158  
159 (D) Intranasal corticosteroids (v. 06/2021).

160  
161 (b) Vulvovaginal candidiasis (VVC) Protocol (v. 06/2021 ~~August 2020~~)

162  
163 (3) Preventative care

164  
165 (a) Emergency Contraception (v. 06/2021), not including abortifacients;

166  
167 (b) Male and female condoms (v. 06/2021);

168  
169 (c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT Protocol (v. ~~August 2020~~  
170 06/2021); A pharmacist is permitted to provide patient care services pursuant to this protocol only  
171 upon documented completion of a minimum of 2 hours of tobacco cessation continuing education.

172  
173 (d) Travel Medications Protocol (v. ~~August 2020~~ 06/2021); A pharmacist who meets criteria to  
174 immunize pursuant to OAR 855-019-0270 is permitted to provide patient care services pursuant to this  
175 protocol only upon documented completion of: minimum of 4 hour certificate for pharmacy-based  
176 travel medicine services intended for the pharmacist (one-time requirement), and minimum of 1 hour of  
177 travel medication continuing education every 24 months.

178  
179 (e) HIV Post-exposure Prophylaxis (PEP) Protocol (v. ~~August 2020~~ 06/2021); and A pharmacist is  
180 permitted provide patient care services pursuant to this protocol only upon documented completion of  
181 a comprehensive training program for the prescribing and dispensing of HIV prevention medications, to  
182 include related trauma-informed care.

183  
184 (f) HIV Pre-exposure Prophylaxis (PrEP) Protocol (v. ~~December 2020~~ 06/2021). A pharmacist is permitted  
185 provide patient care services pursuant to this protocol only upon documented completion of a  
186 comprehensive training program for the prescribing and dispensing of HIV prevention medications, to  
187 include related trauma-informed care.

188  
189 [Publications referenced are available from the agency for inspection in the office of the Board of  
190 Pharmacy per OAR 855-010-0021.]

191  
192 Statutory/Other Authority: ORS 689.205

193 Statutes/Other Implemented: ORS 689.645 & ORS 689.649

## **CONTINUATION OF THERAPY**

### **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 any non-controlled medication to extend a patient's prescription therapy to avoid interruption of treatment.

#### **PRESCRIBING PARAMETERS:**

- Quantity sufficient for the circumstances
- Maximum quantity: May not exceed a 60-day supply
- Maximum frequency: No more than two extensions in a **rolling** 12-month period per medication

## **COUGH AND COLD SYMPTOM MANAGEMENT – BENZONATATE**

### **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 benzonatate.

**PRESCRIBING PARAMETERS:**

- Maximum: Not to exceed a 7-day supply

PROPOSED

**COUGH AND COLD SYMPTOM MANAGEMENT – INTRANASAL CORTICOSTEROIDS**

**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 prescription and OTC intranasal corticosteroids.

PROPOSED

## **COUGH AND COLD SYMPTOM MANAGEMENT - PSEUDOEPHEDRINE**

### **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 pseudoephedrine.

#### **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**

- INCLUSION CRITERIA: Age 18 and older, verified by positive ID
- EXCLUSION/REFERRAL CRITERIA: Age < 18

#### **PRESCRIBING PARAMETERS:**

- Pharmacist must review PDMP prior to issuing prescription, and retain documentation of review
- Maximum quantity: 3.6g or a 60 count quantity per prescription, whichever is less
- Maximum frequency: 3 prescriptions in a **rolling** 12-month period

## **COUGH AND COLD SYMPTOM MANAGEMENT – SHORT ACTING B-AGONISTS**

### **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 prescription and OTC short acting beta agonists, with or without a spacer, to treat cough symptoms.

#### **PRESCRIBING PARAMETERS:**

- Maximum: Not to exceed 1 inhaler with or without a spacer or 1 box of nebulizer ampules, per rolling 12-month period

**CONDITIONS**

**VULVOVAGINAL CANDIDIASIS (VVC)**

**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 a single course of treatment for non-complicated vulvovaginal candidiasis (VVC).

**STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**

- Utilize the standardized Vulvovaginal Candidiasis / Yeast Infection Intake Form (pg. 2)
- Utilize the standardized Vulvovaginal Candidiasis Assessment and Treatment Care Pathway (pg. 3-6)

# Vulvovaginal Candidiasis (Yeast Infection) Self-Screening 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 \_\_\_\_\_

1.	Has a provider ever diagnosed you with a yeast infection? If so, how recently? _____ How many have you experienced within the last year? _____ How many have you experienced within your lifetime? _____ Have you ever experienced a difficult to treat yeast infection or had treatment not work? What treatments (if any) have you tried for past and/or current yeast infections? Please list them here: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure  <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
2.	Symptom review: - Soreness, burning, or itchy vaginal area - Abnormal discharge (color, smell, consistency, etc.) - Pain with urination - Fever - Pain in the lower abdomen and/or back - Other symptoms: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
3.	Have you ever been sexually active? If so, how recently? _____	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.	Have you ever been tested for OR diagnosed with a sexually transmitted infection? If yes, when? _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
5.	When was the first day of your last menstrual period?	Date: _____
6.	Are you currently pregnant?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
7.	Are you using any of the following contraceptive devices? 1. Vaginal sponge 2. Diaphragm 3. Intrauterine device (IUD)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
8.	Have you used antibiotics in the last month?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
9.	Has a provider ever diagnosed you with an autoimmune disease? If yes, list them here: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
10.	Do you have diabetes?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
11.	Have you ever been diagnosed with a heart rhythm condition (or QT prolongation)? If yes, list them here: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
12.	Do you have any other medical problems? If yes, list them here: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
13.	Are you currently taking any medications, supplements, and/or vitamins? If yes, list them here: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure

Signature \_\_\_\_\_ Date \_\_\_\_\_

# Standardized Assessment and Treatment Care Pathway

## Vulvovaginal Candidiasis (VVC)

### 1) Vulvovaginal Candidiasis (VVC) and Sexually Transmitted Infection (STI) Screen (Form Qs: #1-5)

- a. Recurrence: If 4 or more episodes within 12 months or recurrent symptoms within 2 months → **Refer**
- b. Symptoms inconsistent with VVC: Pain with urination, fever, pain in the lower abdomen and/or back, symptoms consistent with STI, or any other inconsistencies.  
If YES to any of these symptoms → **Refer**

### 2) Pregnancy Screen (Form Qs: #5-6)

- a. Did you have a baby less than 6 months ago, are you fully or nearly-fully breast feeding, AND have you had no menstrual period since the delivery?
- b. Have you had a baby in the last 4 weeks?
- c. Did you have a miscarriage or abortion in the last 7 days?
- d. Did your last menstrual period start within the past 7 days?
- e. Have you abstained from sexual intercourse since your last menstrual period or delivery?
- f. Have you been using a reliable contraceptive method consistently and correctly?

*If YES to AT LEAST ONE of these questions and is free of pregnancy symptoms, proceed to next step.*

*If NO to ALL of these questions, pregnancy cannot be ruled out → **Refer***

### 3) Medication and Disease State Screen (Form Qs: #7-13)

- a. Are you using the following contraceptive devices: vaginal sponge, diaphragm, IUD → **Refer**
- b. Do you have diabetes or other immunosuppressed conditions? → **Refer**
- c. Are you taking corticosteroids or immunosuppressive medications, including antineoplastics? → **Refer**

### 4) Assess and Initiate Antifungal Therapy:

All therapies are equally effective in treating uncomplicated VVC. Choice of therapy should be based on patient safety, preference, availability, and cost.

All therapy is limited to one course of treatment.

- a. *Oral therapy.* If indicated, the pharmacist shall issue a prescription for fluconazole and counsel on side effects and follow-up.
  - Fluconazole 150mg tablet, #1
- b. *Topical therapy.* If indicated, the pharmacist shall discuss the most appropriate option with the patient, issue a prescription, and counsel on side effects and follow-up of any one of the following treatments:
  - Clotrimazole (various strengths/formulations)
  - Miconazole (various strengths/formulations)
  - Tioconazole (various strengths/formulations)

### 5) Complete Patient Encounter

*Advise:* Patient should seek medical advice from a care provider if symptoms do not resolve in 7-14 days.

*Encourage:* Routine health screenings, STI prevention, etc.

*Document:* All required elements

# Standardized Assessment and Treatment Care Pathway

## Vulvovaginal Candidiasis (VVC)

### Medication options/considerations:

#### - **Fluconazole<sup>1</sup>:**

- *Dose and directions:* 150mg Tablet, quantity #1; Take one tablet by mouth one time. If symptoms do not resolve after 1 week, contact your primary care provider.
- *Warnings/Precautions:* Potential patient harm is associated with known side effects of taking fluconazole. It is well tolerated, but may cause symptoms such as nausea, vomiting, dizziness, and headache. More rare side effects may include:
  - Prolonged QT interval which could lead to Torsades de Pointes. This is rarely a concern unless a patient is taking multiple QT prolonging drugs, has a preexisting heart condition, or known prolonged QT interval.
  - Hepatic toxicity (i.e. hepatitis, cholestasis, fulminant hepatic failure, etc.). Monitor liver function tests of patients with known impaired hepatic function
  - Hypersensitivity reactions: Use with caution in patients with hypersensitivity to other azoles
  - Skin reactions: Monitor for rash development
- *Metabolism:* **Inhibits** CYP2C19 (strong), CYP2C9 (moderate), CYP3A4 (moderate)
- *Contraindications for fluconazole use: (consider other therapy)*
  - Prolonged QT interval
  - Multiple QT prolonging drugs
  - Impaired hepatic function
  - Hypersensitivity reactions: Use with caution in patients with hypersensitivity to other azoles
  - Other interacting medications

#### - **Clotrimazole<sup>2</sup>:**

- *Dose and directions:*
  - Cream: If symptoms do not resolve after 1 week, contact your primary care provider.
    - 1%: One applicatorful inserted intravaginally at night daily for 7 days.
    - 2%: One applicatorful inserted intravaginally at night daily for 3 days.
    - 10%: One applicatorful to be inserted intravaginally at night as a single dose.
- *Warnings/Precautions:* It is well tolerated, but may cause symptoms such as irritation and burning.
- *Drug Interactions:*
  - Progesterone: may diminish the therapeutic effect of Progesterone (*Risk X: Avoid combination*)
  - Sirolimus: may increase the serum concentration of Sirolimus (*Risk C: Monitor therapy*)
  - Tacrolimus (systemic): may increase the serum concentration of Tacrolimus (Systemic) (*Risk C: Monitor therapy*)
- *Contraindications for clotrimazole use: (consider other therapy)*
  - Progesterone
  - Sirolimus
  - Tacrolimus (systemic)
  - Other interacting medications

# Standardized Assessment and Treatment Care Pathway

## Vulvovaginal Candidiasis (VVC)

- **Miconazole<sup>3</sup>:**
  - **Dose and directions:**
    - Suppository Capsule: If symptoms do not resolve after 1 week, contact your primary care provider.
      - 100mg: one capsule inserted intravaginally at night daily for 7 days.
      - 200mg: one capsule inserted intravaginally at night daily for 3 days.
      - 1,200mg: one capsule to be inserted intravaginally at night as a single dose.
    - Cream: If symptoms do not resolve after 1 week, contact your primary care provider.
      - 2%: One applicatorful inserted intravaginally at night daily for 7 days.
      - 4%: One applicatorful inserted intravaginally at night daily for 3 days.
  - **Warnings/Precautions:** It is well tolerated, but may cause symptoms such as irritation and burning.
  - **Drug Interactions:**
    - Progesterone: may diminish the therapeutic effect of Progesterone (*Risk X: Avoid combination*)
    - Vitamin K Antagonists (i.e. warfarin): may increase the serum concentration of Vitamin K Antagonists (*Risk D: Consider therapy modification*)
    - Sulfonylureas: may inhibit the metabolism of oral sulfonylureas
  - **Contraindications for miconazole use: (consider other therapy)**
    - Progesterone
    - Vitamin K Antagonists (i.e. warfarin)
    - Sulfonylureas
    - Other interacting medications
- **Tioconazole<sup>4</sup>:**
  - **Dose and directions:**
    - Ointment: If symptoms do not resolve after 1 week, contact your primary care provider.
      - 6.5%: One applicatorful to be inserted intravaginally at night as a single dose.
  - **Warnings/Precautions:** It is well tolerated, but may cause symptoms such as irritation and burning.
  - **Drug Interactions:**
    - Progesterone: may diminish the therapeutic effect of Progesterone (*Risk X: Avoid combination*)
  - **Contraindications for tioconazole use: (consider other therapy)**
    - Progesterone
    - Other interacting medications

### References:

1. Fluconazole. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Updated February 12, 2020. Accessed February 14, 2020.
2. Clotrimazole. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Updated February 14, 2020. Accessed February 15, 2020.
3. Miconazole. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Updated February 17, 2020. Accessed February 17, 2020.
4. Tioconazole. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: <http://online.lexi.com>. Updated November 22, 2019. Accessed February 15, 2020.
5. Peter G. Pappas, Carol A. Kauffman, David R. Andes, Cornelius J. Clancy, Kieren A. Marr, Luis Ostrosky-Zeichner, Annette C. Reboli, Mindy G. Schuster, Jose A. Vazquez, Thomas J. Walsh, Theoklis E. Zaoutis, Jack D. Sobel, Clinical Practice Guideline for the Management of Candidiasis: 2016 Update by the Infectious Diseases Society of America, *Clinical Infectious Diseases*, Volume 62, Issue 4, 15 February 2016, Pages e1–e50, <https://doi.org/10.1093/cid/civ933>

# Vulvovaginal Candidiasis (VVC) 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:

Sig:

Quantity:

Refills: 0

DAW: \_\_\_\_

Written Date: \_\_\_\_\_

Prescriber Name: \_\_\_\_\_ Prescriber Signature: \_\_\_\_\_

Pharmacy Address: \_\_\_\_\_ Pharmacy Phone: \_\_\_\_\_

**-or-**

Patient Referred

Notes: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## **PREVENTATIVE CARE - CONDOMS**

### **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 male and female condoms.

PROPOSED

**PREVENTATIVE CARE - EMERGENCY CONTRACEPTION**

**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 prescription and OTC emergency contraception, not including abortifacients.

PROPOSED

**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 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: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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.4-8)
  - Utilize the standardized PrEP Provider Fax (pg.10)

**PHARMACIST TRAINING/EDUCATION:**

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

# 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.

<u>Test Name</u>	<u>Date of Test</u>	<u>Result</u>	<u>Needs referral</u>
• HIV ag/ab (4th gen) test: _____/_____/_____ <i>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.</i>		<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative	<input type="checkbox"/> Yes
• Syphilis/Treponemal antibody: _____/_____/_____ <i>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.</i>		<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative	<input type="checkbox"/> Yes
• Hepatitis B surface antigen: _____/_____/_____ <i>Positive surface antigen indicates either acute or chronic Hepatitis B and PrEP should be referred to county health or a specialist physician.</i>		<input type="checkbox"/> positive <input type="checkbox"/> negative	<input type="checkbox"/> Yes
• Gonorrhea/Chlamydia: _____/_____/_____ Urinalysis result: _____ <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative Pharyngeal test result: _____ <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative Rectal test result: _____ <input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative <i>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.</i>			<input type="checkbox"/> Yes
• Renal function (CrCl): _____/_____/_____ mL/min SCr _____mg/dL		<input type="checkbox"/> CrCl > 60 mL/min <input type="checkbox"/> CrCl 30-60 mL/min <input type="checkbox"/> CrCl < 30 mL/min	<input type="checkbox"/> Yes
<i>CrCl &gt; 60mL/min: Kidney function adequate for PrEP; CrCl 30-60mL/min: Only Descovy indicated; CrCl &lt;30 mL/min: referral for evaluation/follow-up. NOTE: Concurrent NSAID use would favor Descovy.</i>			
• 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.

**3. Are all required labs are complete?**  yes  no

• If yes, RPH may prescribe PrEP and next labs due in 90 days. 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.

→ See next page for sample language for reactive (indeterminate) STI tests.

# Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway

## (CONFIDENTIAL- Protected Health Information)

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>

**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
<b>REFERRAL CONDITIONS</b>	
1. Positive HIV test <i>Needs Referral:</i> <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 <i>Needs Referral:</i> <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. Impaired kidney function (<30mL/min) <i>Needs Referral:</i> <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>
4. Other medications <i>Needs Referral:</i> <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>
<b>CONSIDERATIONS</b>	
5. NSAID use Precaution- Counseled on limiting use: <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>
6. Hepatitis B vaccinated If not, would the patient like to be vaccinated? <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>
7. 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:**

<b>Considerations*</b>	<b>Preferred regimen</b>
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:	

# PrEP Prescription

DRAFT

**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:**

- Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets
  - Take one tablet by mouth daily for 90 days
- Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets
  - Take one tablet by mouth daily for 90 days

**Your patient has been tested for and/or indicated the following:**

<u>Test Name</u>	<u>Date of Test</u>	<u>Result</u>	<u>Needs referral</u>
• HIV ag/ab (4th gen):	____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative	<input type="checkbox"/> Yes
• Syphilis/Treponemal antibody:	____/____/____	<input type="checkbox"/> reactive <input type="checkbox"/> indeterminate <input type="checkbox"/> negative	<input type="checkbox"/> Yes
• Hepatitis B surface antigen:	____/____/____	<input type="checkbox"/> positive <input type="checkbox"/> negative	<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"/> negative	<input type="checkbox"/> negative	<input type="checkbox"/> negative	
• 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](#).

**PREVENTIVE CARE**

**TOBACCO CESSATION – NRT (Nicotine Replacement Therapy) and Non-NRT**

**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 individual or multiple Nicotine Replacement Therapy (NRT) OTC and Rx for tobacco cessation.
- Following all elements outlined in [OAR 855-020-0110](#), a pharmacist licensed and located in Oregon may prescribe non-NRT medications for tobacco cessation.

**STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**

- Utilize the standardized Tobacco Cessation Patient Intake Form (pg. 2-4)
- Utilize the standardized Tobacco Cessation Assessment and Treatment Care Pathway (pg. 5-6)

**PHARMACIST TRAINING/EDUCATION:**

- Minimum 2 hours of documented ACPE CE related to pharmacist prescribing of tobacco cessation products

# Tobacco Cessation 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 \_\_\_\_\_

Any allergies to foods (ex. menthol/soy)? Yes / No

If yes, please list \_\_\_\_\_

List of medicine(s) you take: \_\_\_\_\_

Do you have a preferred tobacco cessation product you would like to use? \_\_\_\_\_

Have you tried quitting smoking in the past? If so, please describe \_\_\_\_\_

What best describes how you have tried to stop smoking in the past?

- "Cold turkey"
- Tapering or slowly reducing the number of cigarettes you smoke a day
- Medicine
  - Nicotine replacement (like patches, gum, inhalers, lozenges, etc.)
  - Prescription medications (ex. bupropion [Zyban<sup>®</sup>, Wellbutrin<sup>®</sup>], varenicline [Chantix<sup>®</sup>])
- Other \_\_\_\_\_

### Health and History Screen – Background Information:

1.	Are you under 18 years old?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	Are you pregnant, nursing, or planning on getting pregnant or nursing in the next 6 months?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
3.	Are you currently using and trying to quit non-cigarette products (ex. Chewing tobacco, vaping, e-cigarettes, Juul)?	<input type="checkbox"/> Yes <input type="checkbox"/> No

### Medical History:

4.	Have you ever had a heart attack, irregular heartbeat or angina, or chest pains in the past two weeks?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
5.	Do you have stomach ulcers?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
6.	Do you wear dentures or have TMJ (temporomandibular joint disease)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
7.	Do you have a chronic nasal disorder (ex. nasal polyps, sinusitis, rhinitis)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
8.	Do you have asthma or another chronic lung disorder (ex. COPD, emphysema, chronic bronchitis)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure

### Tobacco History:

9.	Do you smoke fewer than 10 cigarettes a day?	<input type="checkbox"/> Yes <input type="checkbox"/> No
----	--	--

Blood Pressure Reading \_\_\_\_/\_\_\_\_ mmHg (\*Note: Must be taken by a pharmacist)



Stop here if patient and pharmacist are considering nicotine replacement therapy or blood pressure is  $\geq 160/100$  mmHg.



If patient and pharmacist are considering non-nicotine replacement therapy (ex. varenicline or bupropion) and blood pressure is  $< 160/100$  mmHg continue to answer the questions below.

# Tobacco Cessation Self-Screening Patient Intake Form

(CONFIDENTIAL-Protected Health Information)

**Medical History Continued:**

10.	Have you ever had an eating disorder such as anorexia or bulimia?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
11.	Have you ever had a seizure, convulsion, significant head trauma, brain surgery, history of stroke, or a diagnosis of epilepsy?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
12.	Have you ever been diagnosed with chronic kidney disease?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
13.	Have you ever been diagnosed with liver disease?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
14.	Have you been diagnosed with or treated for a mental health illness in the past 2 years? (ex. depression, anxiety, bipolar disorder, schizophrenia)?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure

**Medication History:**

15.	Do you take a monoamine oxidase inhibitor (MAOI) antidepressant? (ex. selegiline [Emsam <sup>®</sup> , Zelapar <sup>®</sup> ], Phenelzine [Nardil <sup>®</sup> ], Isocarboxazid [Marplan <sup>®</sup> ], Tranylcypromine [Parnate <sup>®</sup> ], Rasagiline [Azilect <sup>®</sup> ])	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
16.	Do you take linezolid?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
17.	Do you use alcohol or have you recently stopped taking sedatives? (ex. Benzodiazepines)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure

**The Patient Health Questionnaire 2 (PHQ 2):**

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not At All	Several Days	More Than Half the Days	Nearly Every Day
Little interest or pleasure in doing things	0	1	2	3
Feeling down, depressed or hopeless	0	1	2	3

**Suicide Screening:**

Over the last 2 weeks, how often have you had thoughts that you would be better off dead, or have you hurt yourself or had thoughts of hurting yourself in some way?	0	1	2	3
--	---	---	---	---

Patient Signature \_\_\_\_\_ Date \_\_\_\_\_

# Tobacco Cessation Assessment & Treatment Care Pathway

<b>STEP 1: Health and History Screen Part 1</b> Review Tobacco Cessation Patient Questionnaire (Questions 1-2)	No = No Contraindicating Conditions. Continue to step 2	Yes/Not sure = Contraindicating Conditions. <b>Refer</b>	Refer to PCP and/or Oregon Quit Line 1-800-QUIT-NOW
<b>STEP 2: Health and History Screen Part 2</b> Review Tobacco Cessation Patient Questionnaire (Question 3)	Smoking Cigarettes. Continue to step 3	Yes to question 3 <b>Refer</b>	Refer to Oregon Quit Line 1-800-QUIT-NOW to receive counseling and NRT
<b>STEP 3: Blood Pressure Screen</b> Take and document patient's current blood pressure. (Note: RPh may choose to take a second reading if initial is high)	BP < 160/100. Continue to step 4	BP ≥ 160/100 <b>Refer</b>	Refer to PCP <b>AND</b> Oregon Quit Line 1-800-QUIT-NOW
<b>STEP 4: Medical History</b> Nicotine Replacement Therapy Questions (Questions 4-5)	No, to question 4 and 5. Continue to step 5	Yes, to question 4 and/or 5 <b>Refer</b>	Refer to PCP <b>AND</b> Oregon Quit Line 1-800-QUIT-NOW
<b>STEP 5: Medical History</b> Nicotine Replacement Therapy Questions (Questions 6-8) Question 6 = if Yes, avoid using nicotine gum Question 7 = if Yes, avoid using nicotine nasal spray Question 8 = if Yes, avoid using nicotine inhaler	If patient wants NRT, prescribe NRT*	If patient wants bupropion or varenicline, continue to step 6.	
Prescribing NRT*(pg.6): <ul style="list-style-type: none"> <li>Combination NRT is preferred (Nicotine patch + Acute NRT)</li> <li>Acute NRT = Nicotine gum, Nicotine lozenge, Nicotine nasal spray, Nicotine inhaler</li> </ul>	<b>Tobacco History (Question 9 on questionnaire)</b> If Yes to smoking ≤10 cigs/day, start with nicotine patch 14mg/day If No to smoking > 10 cigs/day start with nicotine patch 21mg/day		
<b>STEP 6: Medical History</b> Bupropion and varenicline screening Questions 10-14	Consider NRT* if yes to any question from 10-14 a) If yes to any question → avoid bupropion. If patient still wants bupropion, refer. <b>Refer</b> b) If yes to any questions from 12-14 → avoid varenicline. If patient still wants varenicline, refer. <b>Refer</b>		Refer to PCP <b>AND</b> Oregon Quit Line 1-800-QUIT-NOW
<b>STEP 7: Medication History</b> Questions 15-17 on questionnaire.	If patient answered no to questions 15-17, review depression screening step 8.	If patient answered yes to any question from 15-17 → Avoid bupropion. - Refer if patient still wants bupropion. - If patient wants varenicline, continue to depression screening step 8. <b>Refer</b>	Refer to PCP if patient wants bupropion; NRT* can be considered
<b>STEP 8: The Patient Health Questionnaire 2 (PHQ 2): Depression Screening</b>	Score < 3 on PHQ2. Review Suicide Screening in step 9.	Score ≥ 3 on PHQ. Avoid bupropion and varenicline, refer to PCP for treatment. NRT* can be offered. <b>Refer</b>	Refer to PCP; NRT* can be considered
<b>STEP 9: Suicide Screening</b>	Score of 0 on suicide screening. May prescribe bupropion or varenicline.	Score ≥ 1 on suicide screening. <b>Immediate</b> referral to PCP. <b>Refer</b>	Call PCP office to notify them of positive suicide screening and determine next steps. After hours, refer to suicide hotline 1-800-273-8255
<b>Prescribing Bupropion:</b> 150mg SR daily for 3 days then 150mg SR twice daily for 8 weeks or longer. Quit day after day 7. Consider combining with Nicotine patch or Nicotine lozenge or Nicotine gum for increased efficacy.* For patients who do not tolerate titration to the full dose, consider continuing 150mg once daily as the lower dose has shown efficacy.		<b>Prescribing Varenicline:</b> 0.5mg daily for 3 days then 0.5mg twice daily <b>for 4 days</b> then 1mg twice daily for 12 to 24 weeks. Quit day after day 7 or alternatively quit date up to 35 days after initiation of varenicline. Generally <b>not used</b> in combination with other smoking cessation medications <b>as first line therapy</b> .	

# Tobacco Cessation Assessment & Treatment Care Pathway

## \*Nicotine Replacement Dosing:

	Dose
<b>Long Acting NRT</b>	
Nicotine Patches	<ul style="list-style-type: none"> <li>• Patients smoking &gt;10 cigarettes/day: begin with 21mg/day for 6 weeks, followed by 14mg/day for 2 weeks, finish with 7mg/day for 2 weeks</li> <li>• Patients smoking ≤ 10 cigarettes/day: begin with 14mg/day for 6 weeks, followed by 7mg/day for 2 weeks</li> <li>• <b>Note:</b> Adjustment may be required during initial treatment (move to higher dose if experiencing withdrawal symptoms; lower dose if side effects are experienced).</li> </ul>
<b>Acute NRT</b>	
Nicotine Gum	<ul style="list-style-type: none"> <li>• Chew 1 piece of gum when urge to smoke occurs. If strong or frequent cravings are present after 1 piece of gum, may use a second piece within the hour (do not continuously use one piece after the other).</li> <li>• Patients who smoke their first cigarette within 30 minutes of waking should use the 4 mg strength; otherwise the 2 mg strength is recommended.</li> <li>• Use according to the following 12-week dosing schedule:               <ul style="list-style-type: none"> <li>○ Weeks 1 to 6: Chew 1 piece of gum every 1 to 2 hours (maximum: 24 pieces/day); if using nicotine gum alone without nicotine patches, to increase chances of quitting, chew at least 9 pieces/day during the first 6 weeks</li> <li>○ Weeks 7 to 9: Chew 1 piece of gum every 2 to 4 hours (maximum: 24 pieces/day)</li> <li>○ Weeks 10 to 12: Chew 1 piece of gum every 4 to 8 hours (maximum: 24 pieces/day)</li> </ul> </li> </ul>
Nicotine Lozenges	<ul style="list-style-type: none"> <li>• 1 lozenge when urge to smoke occurs; do not use more than 1 lozenge at a time</li> <li>• Patients who smoke their first cigarette within 30 minutes of waking should use the 4 mg strength; otherwise the 2 mg strength is recommended.</li> <li>• Use according to the following 12-week dosing schedule:               <ul style="list-style-type: none"> <li>○ Weeks 1 to 6: 1 lozenge every 1 to 2 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day); if using nicotine lozenges alone without nicotine patches, to increase chances of quitting, use at least 9 lozenges/day during the first 6 weeks</li> <li>○ Weeks 7 to 9: 1 lozenge every 2 to 4 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day)</li> <li>○ Weeks 10 to 12: 1 lozenge every 4 to 8 hours (maximum: 5 lozenges every 6 hours; 20 lozenges/day)</li> </ul> </li> </ul>
Nicotine Inhaler	<ul style="list-style-type: none"> <li>• <i>Initial treatment:</i> 6 to 16 cartridges/day for up to 12 weeks; maximum: 16 cartridges/day</li> <li>• Use beyond 6 months is not recommended (has not been studied). If patient is unable to stop smoking by the fourth week of therapy, consider discontinuation.</li> <li>• <i>Discontinuation of therapy:</i> After initial treatment, gradually reduce daily dose over 6 to 12 weeks. Some patients may not require gradual reduction of dosage and may stop treatment abruptly.</li> </ul>
Nicotine Nasal Spray	<ul style="list-style-type: none"> <li>• Initial: 1 to 2 doses/hour (each dose [2 sprays, one in each nostril] contains 1 mg of nicotine)</li> <li>• Adjust dose as needed based on patient response; do not exceed more than 5 doses (10 sprays) per hour [maximum: 40 mg/day (80 sprays)] or 3 months of treatment</li> <li>• If using nicotine nasal spray alone without nicotine patches, for best results, use at least the recommended minimum of 8 doses per day (less is likely to be effective).</li> <li>• Use beyond 6 months is not recommended (has not been studied). If patient is unable to stop smoking by the fourth week of therapy, consider discontinuation.</li> <li>• <i>Discontinuation of therapy:</i> Discontinue over 4 to 6 weeks. Some patients may not require gradual reduction of dosage and may stop treatment abruptly.</li> </ul>

Oregon licensed pharmacist must adhere to Prescribing Parameters, when issuing any prescription for tobacco cessation.

### PRESCRIBING PARAMETERS:

- 1st prescription up to 30 days
- Maximum duration = 12 weeks
- Maximum frequency = 2x in a rolling 12-month period

### TREATMENT CARE PLAN:

- Documented follow-up: within 7-21 days, phone consultation permitted

# Tobacco Cessation 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
- Referred patient to Oregon Quit Line (1-800-QUIT-NOW or [www.quitnow.net/oregon](http://www.quitnow.net/oregon))
- BP Reading: \_\_\_\_/\_\_\_\_ mmHg \*must be taken by a RPh

*Note: RPh must refer patient if blood pressure  $\geq$  160/100*

## Rx

Written Date: \_\_\_\_\_

Prescriber Name: \_\_\_\_\_ Prescriber Signature: \_\_\_\_\_

Pharmacy Address: \_\_\_\_\_ Pharmacy Phone: \_\_\_\_\_

*-or-*

Patient Referred

Notes: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**PREVENTIVE CARE  
TRAVEL MEDICATIONS**

**STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST**

**AUTHORITY and PURPOSE:** Per [ORS 689.645](#), a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in [OAR 855-020-0110](#), a pharmacist licensed and located in Oregon may prescribe pre-travel medications.
  - Malaria prophylaxis
  - Traveler’s diarrhea
  - Acute mountain sickness
  - Motion sickness
  
- **STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:**
  - Utilize the standardized Travel Medications Patient Intake Form (pg. 2-3)
  - Utilize the standardized Travel Medications Assessment and Treatment Care Pathway (pg. 4-10)

**PHARMACIST TRAINING/EDUCATION:**

- APhA Pharmacy-Based Immunization Delivery certificate (or equivalent); and
- Minimum of 4 hour comprehensive training program related to pharmacy-based travel medicine services intended for the pharmacist (**one-time requirement**); and
- A minimum of 1 hour of travel medication continuing education (CE), every **24 months**.

# Travel Medication Self-Screening Patient Intake Form

## (CONFIDENTIAL-Protected Health Information)

### PATIENT 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 \_\_\_\_\_

### TRAVEL SPECIFICS

Purpose of Trip: \_\_\_\_\_

Activities: \_\_\_\_\_

Departure Date: \_\_\_\_\_ Return Date: \_\_\_\_\_

Countries <u>AND</u> Cities to be Visited (In Order of Visits)	Arrival Date	Departure Date

Have you traveled outside the United States before?  Yes  No

If yes, where and when?

\_\_\_\_\_

1.	Will you be ONLY using airplane as your mode of transportation If no, explain: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
2.	Will you be ONLY visiting major cities? If no, explain: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
3.	Will you be ONLY staying in hotels? If no, explain: _____	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
4.	Will you be visiting friends and family?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
5.	Will you be ascending to high altitudes? (> 7,000 ft or 2,300 meters) in the mountains	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
6.	Will you be working in the medical or dental field with exposure to blood or bodily fluids?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure

# Travel Medication Self-Screening Patient Intake Form

## (CONFIDENTIAL-Protected Health Information)

### ALLERGIES

No known drug allergies     No known food allergies

Drug Allergies: \_\_\_\_\_

Food Allergies: \_\_\_\_\_

### VACCINE MEDICAL INFORMATION

Please complete the table below *(please bring your vaccination record to the pre-travel consult)*

Vaccinations	Yes – (Enter vaccination date below)	No	Not Sure
<b>COVID</b> (Manufacturer):	Dose 1:                      2:		
Hepatitis A	Dose 1:                      2:		
Hepatitis B	Dose 1:                      2:                      3:		
Influenza			
Japanese Encephalitis			
Meningococcal Meningitis	Dose 1:                      2:		
MMR (Measles, Mumps, Rubella)	Dose 1:                      2:		
Pneumonia	PPSV23:                      PCV13:		
Polio (Adult Booster)			
Rabies			
Shingles			
Tetanus (Tdap/Td/DTaP/DT)			
Typhoid (Oral / Shot)			
Varicella			
Yellow Fever			
Other:			
Other:			

### MEDICAL HISTORY

List your current prescription medications and medical conditions treated (include birth control pills and anti-depressants):

Current Medical Conditions: \_\_\_\_\_

Current Prescription Medications: \_\_\_\_\_

Regularly used Non-Prescription Medications (over the counter, herbal, homeopathic, vitamins, and supplements including those purchased at health-food stores): \_\_\_\_\_

7.	Are you currently using steroids?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
8.	Are you currently receiving radiation therapy?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
9.	Are you currently receiving immunosuppressive therapy?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
10.	Are you pregnant or are you planning to become pregnant within the next year?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure
11.	Are you currently breast-feeding?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure

### QUESTIONS/CONCERNS

Please list additional questions or concerns that you might have regarding your travel:

\_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

# Travel Medications - Assessment and Treatment Care Pathway

**STEP 1:** Assess routine and travel vaccinations

**STEP 2:** Choose and issue prescription for appropriate prophylaxis medication, in adherence to the CDC's 2020 Yellow Book: Health Information for International Travel (06/11/2019) and this protocol, to include documented screening for contraindications (see pgs. 6-7).

**STEP 3:** Prescribe medications and administer vaccinations.

**STEP 4:** Provide a written individualized care plan to each patient.

## 1. Malaria Prophylaxis

### a. Patient assessment

- i. Review detailed itinerary
- ii. Identify zones of resistance
- iii. Review recommendations by the CDC
- iv. Discuss planned activities
- v. Assess risk of acquiring malaria and body weight (kg)

### b. Prophylaxis

- i. Discuss insect precautions and review signs/symptoms of malaria with patient
- ii. Screen for contraindications
- iii. Assess travel areas for resistance:

#### 1. Non-chloroquine resistant zone

##### a. Chloroquine (Aralen®)

Adult dosing: Chloroquine 500 mg

- Begin 1-2 weeks prior to travel-1 tablet weekly
- Taken once weekly during trip and for 4 weeks after leaving

Pediatric dosing:

8.3 mg/kg (maximum is adult dose)

- Begin 1-2 weeks prior to travel-1 tablet weekly
- Taken once weekly during trip and for 4 weeks after leaving

**OR**

##### b. Hydroxychloroquine (Plaquenil®)

Adult Dosing: Hydroxychloroquine 400 mg

- Begin 1-2 weeks prior to travel-1 tablet weekly
- Taken once weekly during trip and for 4 weeks after leaving

Pediatric Dosing:

6.5 mg/kg (maximum is adult dose)

- Begin 1-2 weeks prior to travel-1 tablet weekly
- Taken once weekly during trip and for 4 weeks after leaving

#### 2. Chloroquine-resistant zone

##### a. Atovaquone/Proguanil (Malarone®)

Adult Dosing: Atovaquone/Proguanil 250mg/100mg

- Begin 1 tablet daily 1-2 days prior to travel
- Taken daily during trip and 7 days after leaving

Pediatric Dosing: Atovaquone/Proguanil 62.5mg/25mg

5–8 kg: 1/2 pediatric tablet daily

9–10 kg: 3/4 pediatric tablet daily

11–20 kg: 1 pediatric tablet daily

21–30 kg: 2 pediatric tablets daily

31–40 kg: 3 pediatric tablets daily

## Travel Medications - Assessment and Treatment Care Pathway

> 40 kg: 1 adult tablet daily

- Begin 1 tablet daily 1-2 days prior to travel
- Taken daily during trip and 7 days after leaving

OR

b. *Doxycycline (Vibramycin®)* ( $\geq 8$  years)

Adult Dosing:

- Begin 1 tablet daily 1-2 days prior to travel
- Taken daily during trip and 4 weeks after leaving

Pediatric Dosing:

$\geq 8$  years old: 2.2 mg/kg (maximum is adult dose) daily

- Begin 1 tablet daily 1-2 days prior to travel
- Taken daily during trip and 4 weeks after leaving

OR

c. *Mefloquine (Lariam®)*

Adult Dosing: Mefloquine 250mg

- Begin 1-2 weeks prior to travel-1 tablet weekly
- Taken once weekly during and for 4 weeks after leaving

Pediatric Dosing:

$\leq 9$  kg: 5 mg/kg

10-19 kg:  $\frac{1}{4}$  tablet weekly

20-30 kg:  $\frac{1}{2}$  tablet weekly

31-45 kg:  $\frac{3}{4}$  tablet weekly

> 45 kg: 1 tablet weekly

- Begin 1-2 weeks prior to travel-1 tablet weekly
- Taken once weekly during and for 4 weeks after leaving

### 3. Mefloquine-Resistant zone

a. *Doxycycline (Vibramycin®)* ( $\geq 8$  years)

Adult dosing: Doxycycline 100 mg

- Begin 1 tablet daily 1-2 days prior to travel
- Taken daily during trip and 4 weeks after leaving

Pediatric dosing:

$\geq 8$  years old: 2.2 mg/kg (maximum is adult dose) daily

- Begin 1 tablet daily 1-2 days prior to travel
- Taken daily during trip and 4 weeks after leaving

OR

b. *Atovaquone/Proguanil (Malarone®)*

Adult dosing: Atovaquone/Proguanil 250mg/100mg

Pediatric Dosing: Atovaquone/Proguanil 62.5mg/25mg

5-8 kg:  $\frac{1}{2}$  pediatric tablet daily

9-10 kg:  $\frac{3}{4}$  pediatric tablet daily

11-20 kg: 1 pediatric tablet daily

21-30 kg: 2 pediatric tablets daily

31-40 kg: 3 pediatric tablets daily

> 40 kg: 1 adult tablet daily

- Begin 1 tablet daily 1-2 days prior to travel

## Travel Medications - Assessment and Treatment Care Pathway

- Taken daily during trip and 7 days after leaving

### 2. Traveler's diarrhea (TD)

- a. Patient assessment
  - i. Review detailed itinerary and identify travel areas of increased risk
  - ii. Assess patient's risk of acquiring traveler's diarrhea and body weight (kg)
  - iii. Screen for contraindications
  - iv. Consult CDC guidelines for list of high-risk factors for TD
- b. Prophylaxis education
  - i. Discuss dietary counseling, avoidance of high-risk foods, food and beverage selection and sanitary practices, oral rehydration
  - ii. Educate patient on how to recognize symptoms and severity of traveler's diarrhea
    1. **Mild:** diarrhea that is tolerable, not distressing, and does not interfere with planned activities
    2. **Moderate:** diarrhea that is distressing or interferes with planned activities
    3. **Severe:** dysentery (bloody stools) and diarrhea that is incapacitating or completely prevents planned activities
  - iii. Pharmacotherapy prophylaxis

*Pepto-Bismol*®: Two 262-mg tablets or 2 fluid oz (60 mL) QID for up to 3 weeks  
**Note:** Avoid in patients <12 years old, patients taking doxycycline for malaria prophylaxis, anticoagulants, allergic to aspirin, probenecid, methotrexate
- c. Treatment (*Note: while Yellow Book includes ciprofloxacin, this protocol only permits azithromycin*)
  - i. First line for mild TD and adjunctive treatment for moderate TD
    1. *Loperamide (OTC- Imodium® AD)*

Adult Dosing: Loperamide 2 mg

      - Take 4 mg at onset of diarrhea, followed by additional 2 mg after each loose stool (Max of 16 mg per day)

Pediatric Dosing:

      - 22 to 26 kg: Take 2 mg after first loose stool, followed by 1 mg after each subsequent stool (Max of 4 mg per day)
      - 27 to 43 kg: Take 2 mg after first loose stool, followed by 1 mg after each subsequent stool (Max of 6 mg per day)
    - ii. Antibiotic treatment (for moderate or severe TD)
      1. Consult CDC guidelines for resistance rates to antibiotics
      2. Empiric treatment for moderate TD and severe TD (age <18 requires a prescription form PCP)
        - a. *Azithromycin 500mg*
          - 1 tablet daily for 1-3 days
          - 1 course/14 days, Max 2 courses for trips >14 days

OR

- b. *Azithromycin 1000mg:* Single dose of one tablet (if symptoms are not resolved after 24 hours, continue daily dosing for up to 3 days)

# Travel Medications - Assessment and Treatment Care Pathway

## 3. Acute Mountain Sickness

- a. Patient assessment/Education
  - i. Review detailed itinerary and identify travel areas of increased risk
  - ii. Assess patients' risk of acquiring Acute Mountain Sickness (AMS) and body weight (kg)
  - iii. Review signs/symptoms of AMS, discuss safe ascent rates and tips for acclimating to higher altitudes (alcohol abstinence, limited activity)
  - iv. Screen for contraindications
    1. AcetaZOLAMIDE
      - a. Hypersensitivity to acetazolamide or sulfonamides
- b. Prophylaxis
  - i. Consult CDC guidelines for list of risk factors for AMS. If risk factors are present and warrant prophylaxis:
    1. *AcetaZOLAMIDE (Diamox®)*

Adult Dosing: Acetazolamide 125 mg

      - Take 1 tablet twice daily starting 24 hours before ascent, continuing during ascent, and 2-3 days after highest altitude achieved or upon return

Pediatric Dosing:  
2.5 mg/kg/dose every 12 hours before ascent, continuing during ascent, and 2-3 days after highest altitude achieved or upon return. (Maximum of 125 mg/dose)

# Travel Medications - Assessment and Treatment Care Pathway

## 4. Motion Sickness

- a. Patient assessment
  - i. Review detailed itinerary and identify travel areas of increased risk
  - ii. Assess patients' risk of acquiring motion sickness and body weight (kg)
  - iii. Review signs/symptoms of motion sickness, discuss tips for reducing motion sickness: being aware of triggers, reducing sensory input
  - iv. Screen for contraindications
- b. Prophylaxis
  - i. Consult CDC guidelines for list of risk factors for Motion sickness. If risk factors present and warrant pharmacologic prevention:
  - ii. Adults
    1. **First-line:** *Scopolamine transdermal patches* (Age <18 Requires prescription from PCP)
      - Apply 1 patch (1.5 mg) to hairless area behind ear at least 4 hours prior to exposure; replace every 3 days as needed

AND/OR

### 2. **Second-line:**

- a. *Promethazine 25mg Tablets*: Take one tablet by mouth 30 – 60 minutes prior to exposure and then every 12 hours as needed
- b. *Promethazine 25mg Suppositories*: Unwrap and insert one suppository into the rectum 30-60 minutes prior to exposure and then every 12 hours as needed
- c. *Meclizine 12.5-25mg* (OTC/Rx):  
Take 25 to 50 mg 1 hour before travel, repeat dose every 24 hours if needed

### iii. Pediatrics

#### 1. **First-line:**

- a. 7-12 years old
  - *Dimenhydrinate* (OTC *Dramamine*®) 1-1.5mg/kg/dose: Take one dose 1 hour before travel and every 6 hours during the trip. (Maximum 25 per dose)
  - *Diphenhydramine* (OTC *Benadryl*®) 0.5-1mg/kg/dose: Take one dose 1 hour before travel and every 6 hours during the trip. (Maximum 25 mg per dose)
- b. ≥ 12 years old
  - *Meclizine 12.5-25mg* (OTC/Rx): Take 25 to 50 mg 1 hour before travel, repeat dose every 24 hours if needed

# Travel Medications - Assessment and Treatment Care Pathway

## Screen for Contraindications:

### Malaria Prophylaxis

1. Chloroquine
  - c. Age < 7 years old
  - d. Hypersensitivity to chloroquine, 4-aminoquinolone compounds, or any component of the formulation
  - e. Presence of retinal or visual field changes of any etiology
2. Hydroxychloroquine
  - a. Age < 7 years old
  - b. Hypersensitivity to hydroxychloroquine, 4 aminoquinoline derivatives, or any component of the formulation
3. Atovaquone/proguanil
  - a. Age < 7 years old
  - b. Weight < 5 kg
  - c. Hypersensitivity to atovaquone, proguanil or any component of the formulation
  - d. Prophylactic use in severe renal impairment (CrCl < 30 mL/min)
4. Doxycycline
  - a. Age < 8 years old
  - b. Hypersensitivity to doxycycline, other tetracyclines
  - c. Use in infants and children < 8 years old
  - d. During second or third trimester of pregnancy
  - e. Breast-feeding
5. Mefloquine
  - a. Age < 7 years old
  - b. Hypersensitivity to mefloquine, related compounds (i.e. quinine and quinidine)
  - c. Prophylactic use in patients with history of seizures or psychiatric disorder (including active or recent history of depression, generalized anxiety disorder, psychosis, schizophrenia, or other major psychiatric disorders)

### Traveler's Diarrhea

1. Loperamide
  - a. Age < 7 years old
  - b. Hypersensitivity to loperamide or any component of the formulation
  - c. Abdominal pain without diarrhea
  - d. Acute dysentery
  - e. Acute ulcerative colitis
  - f. Bacterial enterocolitis (caused by *Salmonella*, *Shigella*, *Campylobacter*)
  - g. Pseudomembranous colitis associated with broad-spectrum antibiotic use
  - h. OTC—do not use if stool is bloody or black
2. Azithromycin
  - a. Age < 18 years old will require a prescription from a PCP
  - b. Hypersensitivity to azithromycin, erythromycin or other macrolide antibiotics
  - c. History of cholestatic jaundice/hepatic dysfunction associated with prior azithromycin use

### Acute Mountain Sickness

1. AcetaZOLAMIDE
  - a. Age < 7 years old
  - b. Marked hepatic disease or insufficiency
  - c. Decreased sodium and/or potassium levels
  - d. Adrenocortical insufficiency
  - e. Cirrhosis
  - f. Hyperchloremic acidosis
  - g. Severe renal dysfunction or disease

# Travel Medications - Assessment and Treatment Care Pathway

h. Long term use in congestive angle-closure glaucoma

## Motion Sickness

1. Scopolamine
  - a. Age < 18 years old will require a prescription from a PCP
  - b. Hypersensitivity to scopolamine
  - c. Glaucoma or predisposition to narrow-angle glaucoma
  - d. Paralytic ileus
  - e. Prostatic hypertrophy
  - f. Pyloric obstruction
  - g. Tachycardia secondary to cardiac insufficiency or thyrotoxicosis
2. Promethazine
  - a. Age < 7 years old
  - b. Hypersensitivity to promethazine or other phenothiazines (i.e. prochlorperazine, chlorproMAZINE, fluPHENAZine, perphenazine, etc)
  - c. Treatment of lower respiratory tract symptoms
  - d. Asthma
3. Meclizine
  - a. Age < 12 years old
  - b. Hypersensitivity to meclizine
4. DimenhyDRINATE
  - a. Age < 7 years old
  - b. Hypersensitivity to dimenhyDRINATE or any component of the formulation
  - c. Neonates
5. DiphenhydrAMINE
  - a. Age < 7 years old
  - b. Hypersensitivity to diphenhydrAMINE or other structurally related antihistamines or any component of the formulation
  - c. Neonates or premature infants
  - d. Breast feeding

# SAMPLE Visit Summary

**APRIL 2021/A8-m**

**Collect** Patient Name: \_\_\_\_\_ DOB: \_\_\_\_\_

Chief Complaint	Subjective Data <input type="checkbox"/> On Back	Objective Data <input type="checkbox"/> On Back	History of Present Illness <input type="checkbox"/> On Back
	<input type="checkbox"/> Allergies <input type="checkbox"/> Past Medical History <input type="checkbox"/> Social History		
	<b>Medications</b> <u>Adherence</u> <input type="checkbox"/> Past 90 day use  <u>Safety</u> <input type="checkbox"/> Relevant Medications	<b>Post-diagnostic?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No  <b>Diagnosis:</b> _____ <input type="checkbox"/> Therapy Initiation <input type="checkbox"/> Extension of Therapy <input type="checkbox"/> Device <input type="checkbox"/> Other	

## Assess and Evaluate

<p><b><u>Per Drug Therapy Management Protocol</u></b>  <input type="checkbox"/> Attached</p> <p><input type="checkbox"/> Inclusion Criteria Met</p> <p><input type="checkbox"/> Exclusion Criteria Met</p> <p><input type="checkbox"/> Referral Criteria Met</p>	
--	--

**Resource(s) Used**  
 (e.g. Protocol, Guideline(s), Other Evidence Based Source, etc.) (Note: This information shall be referenced in the established Drug Therapy Management Protocol) \_\_\_\_\_

## Treatment Care Plan

<input type="checkbox"/> Treatment Goals <input type="checkbox"/> Monitoring Parameters  <input type="checkbox"/> Referral Reason	<p>Name _____</p> <p>Address _____ Date _____</p> <p>Phone # _____</p> <p style="text-align: right;">Refills _____</p> <p style="text-align: center;">_____ RPh Signature</p> <p style="text-align: right;">_____ NPI/DEA #</p> <p style="text-align: center;">_____ Address</p>
--	--

## Follow-up:

Office/Pharmacy Visit **OR**  Phone Call With: \_\_\_\_\_ Date: \_\_\_\_\_

Provider Referral: \_\_\_\_\_

Notification Sent

\_\_\_\_\_  
Prescribing RPh Printed Name

\_\_\_\_\_  
RPh Signature

\_\_\_\_\_  
Date

Sample Template: Please feel free to customize this document, however you must retain all elements **required per OAR 855-020-0110**.

**Subjective Data**

**Objective Data**

**History of Present Illness**

**Assessment**

**Care Plan**

Sample Template: Please feel free to customize this document, however you must retain all elements [required per OAR 855-020-0110](#).

## **DEVICES AND SUPPLIES**

### **PRESCRIPTIVE AUTHORITY - OREGON PHARMACIST**

**AUTHORITY and PURPOSE:** Per [ORS 689.645](#), a pharmacist may prescribe and dispense an FDA-approved drug or device, pursuant to a diagnosis by a health care practitioner who has prescriptive authority and who is qualified to make the diagnosis

➤ Following all elements outlined in [OAR 855-020-0110](#), a pharmacist licensed and located in Oregon may prescribe the following devices and supplies:

- Diabetic blood sugar testing supplies;
- Injection supplies;
- Nebulizers and associated supplies;
- Inhalation spacers;
- Peak flow meters;
- International Normalized Ratio (INR) testing supplies;
- Enteral nutrition supplies;
- Ostomy products and supplies; and
- **Non-invasive blood pressure monitors**

## Division 080– Controlled Substances

### Filing Caption (max 15 words):

Proactive rule review incorporating standards by reference

### 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) and to amend and repeal outdated regulations. The revision 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.

### Fiscal Impact:

None

### Documents relied upon include:

#### RELATED FEDERAL STATUTES/RULES:

- [21 CFR \(04/01/2020\)](#)
- [21 USC \(04/01/2021\)](#)

#### RELATED OREGON STATUTES:

- [ORS 475.035](#) Authority to control schedule; rules
- [ORS 475.055](#) Publishing of schedules
- [ORS 183.337](#) Procedure for agency adoption of federal rules.

### Rules Summary:

Rules revisions to ensure clarity, transparency and promote patient safety

1 Division 80

2 SCHEDULE OF CONTROLLED SUBSTANCES

3 [855-080-0015](#)

4 **Definitions**

5 As used in these rules:

6 (1) "Act" means the Uniform Controlled Substances Act, ORS Chapter 475, and rules  
7 thereunder;

8 (2) "CFR" means Code of Federal Regulations;

9 ~~(3) The term "registration" or variants thereof means the annual registration required of~~  
10 ~~manufacturers, distributors and dispensers of controlled substances under ORS 475.125, and~~  
11 ~~the term "registrants" or variants thereof refers to persons so registered; provided that where~~

12 references of this nature are used in CFR sections referred to in these rules, the reference is to  
13 the registration requirements and registrants under the Federal Controlled Substances Act, and  
14 Title 21, CFR.

15 ~~(3)~~(4) "USC" means United States Code;

16 **(4) "Emergency Situations" means those situations in which the prescribing practitioner**  
17 **who authorizes an oral prescription of a controlled substance listed in schedule II of the**  
18 **Federal Controlled Substances Act determines that:**

19 **(a) Immediate administration of the controlled substance is necessary, for proper**  
20 **treatment of the intended ultimate user; and**

21 **(b) No appropriate alternative treatment is available, including administration of a drug**  
22 **which is not a controlled substance under schedule II of the Act, and**

23 **(c) It is not reasonably possible for the prescribing practitioner to provide a written**  
24 **prescription to be presented to the person dispensing the substance, prior to the**  
25 **dispensing.**

26 (5) Terms not defined in this rule have the definitions set forth in ORS 475.005.

27 Statutory/Other Authority: ORS 689.205

28 Statutes/Other Implemented: ORS 475.035 & ORS 475.940, ORS 475.185

29

### 30 855-080-0020

#### 31 Schedules

32 Pursuant to ORS 475.005(6) those drugs and their immediate precursors classified in  
33 Schedules I through V under the Federal Controlled Substances Act, 21 U.S.C. ~~Sections 811 to~~  
34 **(04/01/2021), 21 USC 812 (04/01/2021)** and as amended by the Board pursuant to ORS  
35 475.035 are the controlled substances for purposes of regulation and control under the Act.  
36 Those schedules are set out in OAR 855-080-0021 through 855-080-0026.

37 Statutory/Other Authority: ORS 689.205

38 Statutes/Other Implemented: ORS 475.035

39

### 40 855-080-0021

#### 41 Schedule I

42 (1) Schedule I consists of the drugs and other substances, by whatever official, common, usual,  
43 chemical, or brand name designated, listed in 21\_CFR part 1308.11; **(04/01/2020)**, and unless  
44 specifically ~~excepted~~ **exempt** or unless listed in another schedule, any quantity of the following  
45 substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and  
46 ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the  
47 specific chemical designation:

48 (a) 1,4-butanediol;

49 (b) Gamma-butyrolactone

- 50 (c) Methamphetamine, except as listed in OAR 855-080-0022;
- 51 (d) Dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide (U-47700)
- 52 (e) 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]piperidin-2-ylidene]benzenesulfonamide (W-18) and  
53 positional isomers thereof, and any substituted derivative of W-18 and its positional isomers,  
54 and their salts, by any substitution on the piperidine ring (including replacement of all or part of  
55 the nitrophenylethyl group), any substitution on or replacement of the sulfonamide, or any  
56 combination of the above that are not FDA approved drugs, unless specifically excepted or  
57 when in the possession of an FDA registered manufacturer or a registered research facility, or a  
58 person for the purpose of sale to an FDA registered manufacturer or a registered research  
59 facility.
- 60 (f) Substituted derivatives of cathinone and methcathinone that are not listed in OARs 855-080-  
61 0022 through 0026 (Schedules II through V) or are not FDA approved drugs, including but not  
62 limited to,
- 63 (A) Methylnmethcathinone (Mephedrone);
- 64 (B) Methylenedioxypropylvalerone (MDPV);
- 65 (C) Methylenedioxymethylcathinone (Methylone);
- 66 (D) 2-Methylamino-3',4'-(methylenedioxy)-butyrophenone (Butylone);
- 67 (E) Fluoromethcathinone (Flephedrone);
- 68 (F) 4-Methoxymethcathinone (Methedrone).
- 69 (2) Schedule I also includes any compounds in the following structural classes (2a–2k) and their  
70 salts, that are not FDA approved drugs, unless specifically excepted or when in the possession  
71 of an FDA registered manufacturer or a registered research facility, or a person for the purpose  
72 of sale to an FDA registered manufacturer or a registered research facility:
- 73 (a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with  
74 substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole  
75 ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of  
76 this structural class include but are not limited to: JWH-015, JWH-018, JWH-019, JWH-073,  
77 JWH-081, JWH-122, JWH-200, JWH-210, AM-1220, MAM-2201 and AM-2201;
- 78 (b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with  
79 substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole  
80 ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of this  
81 structural class include but are not limited to: JWH-167, JWH -201, JWH-203, JWH-250, JWH-  
82 251, JWH-302 and RCS-8;
- 83 (c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at  
84 the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any  
85 extent and whether or not substituted in the phenyl ring to any extent. Examples of this  
86 structural class include but are not limited to: RCS-4, AM-694, AM-1241, and AM-2233;
- 87 (d) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure  
88 with substitution at the 5-position of the phenolic ring whether or not substituted in the

89 cyclohexyl ring to any extent. Examples of this structural class include but are not limited to: CP  
90 47,497 and its C8 homologue (cannabicyclohexanol);

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

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

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

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

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

110 (j) Adamantylindolecarboxamides: Any compound containing an N-adamantyl-1-indole-3-  
111 carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further  
112 substituted in the indole ring to any extent and whether or not substituted in the adamantyl ring  
113 to any extent. Examples of this structural class include but are not limited to: STS-135 and  
114 2NE1; and

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

119 (3) Schedule I also includes any other cannabinoid receptor agonist that is not listed in OARs  
120 855-080-0022 through 0026 (Schedules II through V) or is not an FDA approved drug.

121 (4) Schedule I also includes any substituted derivatives of fentanyl that are not listed in OARs  
122 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, and are  
123 derived from fentanyl by any substitution on or replacement of the phenethyl group, any  
124 substitution on the piperidine ring, any substitution on or replacement of the propanamide group,  
125 any substitution on the phenyl group, or any combination of the above.

126 (5) Schedule I also includes any compounds in the following structural classes (a – b), and their  
127 salts, that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or FDA  
128 approved drugs, unless specifically excepted or when in the possession of an FDA registered

129 manufacturer or a registered research facility, or a person for the purpose of sale to an FDA  
130 registered manufacturer or a registered research facility:

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

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

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

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

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

145 (c) Marijuana and delta-9-tetrahydrocannabinol (THC).

146 Statutory/Other Authority: ORS 689.205

147 Statutes/Other Implemented: ORS 475.035, ORS 475.0595 & ORS 475.065, 2017 OL Ch. 021

148

#### 149 [855-080-0022](#)

#### 150 **Schedule II**

151 Schedule II consists of the drugs and other substances by whatever official, common, usual,  
152 chemical, or brand name designated, listed in 21 CFR part 1308.12 (04/01/2020) and any  
153 quantity of methamphetamine, when in the form of a FDA approved product containing  
154 methamphetamine, its salts, isomers and salts of its isomers as an active ingredient for the  
155 purposes of currently accepted medical use.

156 Statutory/Other Authority: ORS 689.205

157 Statutes/Other Implemented: ORS 475.035, ORS 475.0595, ORS 475.065 & 2017 OL Ch.

158 021 ORS

159

#### 160 [855-080-0023](#)

#### 161 **Schedule III**

162 Schedule III consists of the drugs and other substances by whatever official, common, usual,  
163 chemical, or brand name designated, listed in 21 CFR part 1308.13 (04/01/2020); and

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

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

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

169 Statutory/Other Authority: ORS 689.205 & ORS 475.973

170 Statutes/Other Implemented: ORS 475.035

171

172 [855-080-0024](#)

173 **Schedule IV**

174 Schedule IV consists of:

175 (1) The drugs and other substances, by whatever official, common, usual, chemical, or brand  
176 name designated, listed in 21 CFR part 1308.14 (04/01/2020), unless specifically excepted or  
177 listed in another schedule. ~~and~~

178 ~~(2) Products containing carisoprodol or the salts of carisoprodol as an active ingredient.~~

179 Statutory/Other Authority: ORS 689.205

180 Statutes/Other Implemented: ORS 475.035

181

182 [855-080-0026](#)

183 **Schedule V**

184 Schedule V consists of the drugs and other substances, by whatever official, common, usual,  
185 chemical, or brand name designated, listed in 21 CFR part 1308.15 (04/01/2020).

186 Statutory/Other Authority: ORS 689.205

187 Statutes/Other Implemented: ORS 475.035

188

189 [855-080-0028](#)

190 **Excluded Substances**

191 The following ~~d~~Drugs and their generic equivalents listed in 21 CFR 1308.22 (04/01/2020) are  
192 ~~excepted~~ **excluded** from the schedules in OAR 855-080-0021 through 855-080-0026.

193 ~~(1) Benzedrex inhaler (Propylhexedrine).~~

194 ~~(2) Vicks — Vapor inhaler (Levmetamfetamine).~~

195 Statutory/Other Authority: ORS 689.205 & ORS 689.155

196 Statutes/Other Implemented: ~~ORS 689.155~~ ORS 475.035

197

198 [855-080-0031](#)

199 **Registration Requirements**

200 ~~Manufacturers, distributors, and pharmacies or other drug outlets are required to register with~~  
201 ~~the Board under the Uniform Controlled Substances Act.~~

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

206 Statutory/Other Authority: ORS 689.155 & **ORS** 689.205

207 Statutes/Other Implemented: ORS 475.125

208

209

210

211 **855-080-0041**

212 **Exemption to Registration**

213 **(1) The following persons are not required to register to manufacture, dispense or deliver**  
214 **controlled substances and may lawfully possess controlled substances under ORS**  
215 **475.005 to ORS 475.285 and ORS 475.752 to ORS 475.980:**

216 **(a) An agent or employee of any registered manufacturer, distributor or dispenser of any**  
217 **controlled substance if the agent or employee is acting in the usual course of business**  
218 **or employment.**

219 **(b) A common or contract carrier or warehouseman, or an employee thereof, whose**  
220 **possession of any controlled substance is in the usual course of business or**  
221 **employment.**

222 **(c) An ultimate user or a person in possession of any controlled substance pursuant to a**  
223 **lawful order of a practitioner or in lawful possession of a Schedule V substance, unless**  
224 **otherwise prohibited.**

225 **(d) A practitioner otherwise licensed under the laws of this state and authorized to**  
226 **dispense or administer a controlled substance by the licensing authority.**

227 **(e) A person providing proof of a valid DEA registration certificate pursuant to ORS**  
228 **475.135(3) conducting research with controlled substances in Sections I through V within**  
229 **this state.**

230 **Statutory/Other Authority: ORS 689.155 & ORS 689.205**

231 **Statutes/Other Implemented: ORS 475.125 & ORS 475.135**

232

233 **855-080-0050**

234 **Separate Registration for Places of Business**

235 ~~A separate registration is required for each principal place of business where controlled~~  
236 ~~substances are manufactured or from which controlled substances are distributed or dispensed.~~

237 **855-080-0055**

238 **Separate Registration for Independent Activities**

239 The manufacturing and distributing of controlled substances are deemed activities independent  
240 of each other. A separate registration is required for each activity; however, a person registered  
241 to manufacture may distribute or dispense any controlled substance which they are registered to  
242 manufacture, provided that, unless specifically exempted, they comply with all requirements and  
243 duties prescribed by statute and rules for persons registered to distribute or dispense as  
244 applicable.

245

246

247

248 [855-080-0065](#)

249 **Security**

250 (1) **All applicants and registrants registered persons as applicable to the registration**  
251 **classification, for registration and registrants must comply with the security requirements of 21**  
252 **CFR 1301.01 (04/01/2020), 21 CFR 1301.02 (04/01/2020), 21 CFR 1301.71 (04/01/2020), 21**  
253 **CFR 1301.72 (04/01/2020), 21 CFR 1301.73 (04/01/2020), 21 CFR 1301.74 (04/01/2020), 21**  
254 **CFR 1301.75 (04/01/2020), 21 CFR 1301.76 (04/01/2020), 21 CFR through 1301.767**  
255 **(04/01/2020), and 21 CFR 1301.90 through 1301.93 (04/01/2020), 21 CFR 1301.91 (04/01/2020),**  
256 **21 CFR 1301.92 (04/01/2020), through and 21 CFR 1301.93, (04/01/2020),** which apply to their  
257 registration classification. The requirements of 21 CFR 1301.75 and 1301.76 relating to  
258 "practitioners" are applicable to applicants and registrants who are drug dispensers.

259 (2) The security requirements of subsection one (1) of this rule apply to all "controlled  
260 substances," as defined in these rules, except **including** ephedrine, pseudoephedrine and  
261 phenylpropanolamine.

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

264 Statutory/Other Authority: ORS 689.205

265 Statutes/Other Implemented: ORS 475.135 & **ORS 475.125**

266

267 [855-080-0070](#)

268 **Records and Inventory**

269 (1) **All registrants registered persons must** shall, as applicable to the registration classification,  
270 keep records and maintain inventories in **compliance** conformance with 21 U.S.C Section 827;  
271 **21 CFR (04/01/2021); 21 CFR 1304.01 (04/01/2020), 21 CFR 1304.02 (04/01/2020), through**  
272 **1304.11; 21 CFR 1304.21 through 1304.23 (04/01/2020), 21 CFR 1304.04 (04/01/2020), 21 CFR**  
273 **1304.05 (04/01/2020), 21 CFR 1304.06 (04/01/2020); 21 CFR 1304.11 (04/01/2020); 21 CFR**  
274 **1304.21 (04/01/2020), 21 CFR 1304.22 (04/01/2020), 21 CFR 1304.23 (04/01/2020), 21 CFR**  
275 **1304.24 (04/01/2020), 21 CFR 1304.25 (04/01/2020), 21 CFR 1304.26; (04/01/2020); 21 CFR**  
276 **1304.31 through (04/01/2020), through 21 CFR 1304.32 (04/01/2020), 21 CFR 1304.33;**  
277 **(04/01/2020).**

278 ~~(2) except that a~~ written inventory of all controlled substances shall **must** be taken by  
279 registrants annually within 365~~7~~ days of the last written inventory.

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

281 Statutory/Other Authority: ORS 475.035 & **ORS** 689.205

282 Statutes/Other Implemented: ORS 475.165

283

#### 284 **855-080-0075**

#### 285 **Orders for Schedule I and II Controlled Substances** Forms

286 Controlled substances in Schedules I and II shall **must** be distributed by a registrant to another  
287 registrant only pursuant to an order form **or electronic order** in conformance **compliance** with  
288 21 U.S.C. Section 828 **(04/01/2021)** and 21 CFR 1305.01 **(04/01/2020)**, through **21 CFR**  
289 **1305.29.02 (04/01/2020), 21 CFR 1305.03 (04/01/2020), 21 CFR 1305.04 (04/01/2020), 21**  
290 **CFR 1305.05 (04/01/2020), 21 CFR 1305.06 (04/01/2020), 21 CFR 1305.07 (04/01/2020); 21**  
291 **CFR 1305.11 (04/01/2020), 21 CFR 1305.12 (04/01/2020), 21 CFR 1305.13 (04/01/2020), 21**  
292 **CFR 1305.14 (04/01/2020), 21 CFR 1305.15 (04/01/2020), 21 CFR 1305.16 (04/01/2020), 21**  
293 **CFR 1305.17 (04/01/2020), 21 CFR 1305.18 (04/01/2020), 21 CFR 1305.19 (04/01/2020), 21**  
294 **CFR 1305.20 (04/01/2020); 21 CFR 1305.21 (04/01/2020), 21 CFR 1305.22 (04/01/2020), 21**  
295 **CFR 1305.23 (04/01/2020), 21 CFR 1305.24 (04/01/2020), 21 CFR 1305.25 (04/01/2020), 21**  
296 **CFR 1305.26 (04/01/2020), 21 CFR 1305.27 (04/01/2020), 21 CFR 1305.28 (04/01/2020), and**  
297 **21 CFR 1305.29 (04/01/2020).**

298 Statutory/Other Authority: ~~ORS 475 &~~ **ORS** 689.**205**

299 **Statutes/Other Implemented: ORS 475.175**

300

#### 301 **855-080-0080**

#### 302 **Special Exceptions**

303 The provisions of 21 CFR 1307.11 through 1307.13 are applicable under the Act. **The board**  
304 **adopts the exceptions to registration found in 21 CFR 1307.11 (04/01/2020) and 21 CFR**  
305 **1307.13 (04/01/2020).**

306 Statutory/Other Authority: ORS 689.205

307 Statutes/Other Implemented: ORS 475.035

308

#### 309 **855-080-0085**

#### 310 **Prescription Requirements**

311 (1) Except as provided in sections (2) and (3) of this rule, **Registrants, practitioners and**  
312 **pharmacists as specified therein in the issuance, preparation, labeling dispensing,**  
313 **recordkeeping and filing of prescriptions for controlled substances must comply with** the  
314 provisions of 21 CFR 1306.01 **(04/01/2020)**, through **21 CFR 1306.02 (04/01/2020), 21 CFR**  
315 **1306.03 (04/01/2020), 21 CFR 1306.04 (04/01/2020), 21 CFR 1306.05 (04/01/2020), 21 CFR**  
316 **1306.06 (04/01/2020), 21 CFR 1306.07 (04/01/2020), 21 CFR 1306.08 (04/01/2020), 21 CFR**  
317 **1306.09 (04/01/2020); 21 CFR 1306.11 (04/01/2020), 21 CFR 1306.12 (04/01/2020), 21 CFR**  
318 **1306.13 (04/01/2020), 21 CFR 1306.14 (04/01/2020), 21 CFR 1306.15 (04/01/2020); 21 CFR**

319 1306.21 (04/01/2020), 21 CFR 1306.22 (04/01/2020); 21 CFR 1306.23 (04/01/2020), 21 CFR  
320 1306.24 (04/01/2020), 21 CFR 1306.25 (04/01/2020), 21 CFR 1306.26 (04/01/2020), 21 CFR  
321 1306.27 (04/01/2020); and 21 CFR 1304.03(d) (04/01/2020). shall be complied with by the  
322 registrants, practitioners and pharmacists as specified therein in the issuance, preparation,  
323 labeling dispensing, recordkeeping and filing of prescriptions for controlled substances. An  
324 electronic prescription is permitted for any substance listed in OAR 855-080-0022 through 855-  
325 080-0026 when so permitted by federal regulations.

326 (2) The provisions of 21 CFR 1306.11(a) under section (1) of this rule are amended by deleting  
327 "which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act."

328 (3) The provisions of 21 CFR 1306.21 through 1306.27 under section (1) of this rule shall be  
329 deemed to apply also to controlled substances listed in Schedule V.

330 (4) Controlled substances in Schedules III, IV, and V which are prescription drugs determined  
331 by the Board pursuant to ORS 475.185(3) are those prescription drugs as determined under the  
332 Federal Food, Drug, and Cosmetic Act. Such drugs are "Legend Drugs" and bear the legend  
333 "Caution: Federal law prohibits dispensing without a prescription", or an equivalent legend. In  
334 addition, any preparation containing any amount of codeine or its salts, opium, or paregoric in  
335 Schedules III, IV, or V is a prescription drug as determined by the Board pursuant to ORS  
336 475.185(3).

337 (5) "Emergency Situations" as referred to in ORS 475.185(2) mean the same as specified in 21  
338 CFR 290.10.

339 Statutory/Other Authority: ORS 689.205

340 Statutes/Other Implemented: ORS 475.185 & ORS 475.188

341

#### 342 [855-080-0095](#)

#### 343 **Verification of Research Registration**

344 Persons conducting research with controlled substances in Sections I through V within this state  
345 who are not otherwise exempt from registration pursuant to ORS 475.125(3), may, upon  
346 furnishing the Board a copy of a current federal registration certificate issued for such a  
347 purpose, pursuant to ORS 475.135, receive written verification of such submission from the  
348 Board's Executive Director.

#### 349 [855-080-0100](#)

#### 350 **Animal Euthanasia**

351 (1) The following requirements shall be met in order for a humane society or animal control  
352 agency to be registered or registration renewed to allow the purchase, possession and  
353 administration of sodium pentobarbital and sedative and analgesic medications for euthanizing  
354 injured, sick, homeless or unwanted domestic pets and other animals:  
355

356 (a) Registration. Registration as an animal euthanasia drug outlet is limited to animal control  
357 agencies and humane societies for the purpose of purchasing, possessing, or administering  
358 sodium pentobarbital and sedative and analgesic medications to euthanize animals. The outlet  
359 must identify and provide to the Oregon Board of Pharmacy via application, a designated

360 representative who will serve as the primary contact person responsible for managing the outlet  
361 operations. The outlet shall notify the Board within 15 days of any change in designated  
362 representative. Registration requires submission of an application, and a certificate of  
363 registration will be issued upon approval. All registrations and renewals shall be accompanied  
364 by an annual fee defined in Division 110 of this Chapter.  
365

366 (b) Drug Storage. All supplies of sodium pentobarbital and sedative and analgesic medications  
367 shall be acquired from an Oregon registered distributor, and kept in a locked cabinet. An  
368 assigned person designated in writing shall be responsible for the security of the sodium  
369 pentobarbital and sedative and analgesic medications. Such designated person shall allow  
370 access to and withdrawal of the drug only to a person certified by the Oregon State Veterinary  
371 Medical Examining Board to administer sodium pentobarbital and sedative and analgesic  
372 medications;  
373

374 (c) Records. The following records shall be made at the time of the occurrence and shall be  
375 maintained for a minimum of three years, available for inspection by the Board of Pharmacy and  
376 its agents:  
377

378 (A) A record of the withdrawal of sodium pentobarbital and sedative and analgesic medications,  
379 signed by the person who takes possession of the sodium pentobarbital and sedative and  
380 analgesic medications for administration;  
381

382 (B) A record of the weight, species of animal and dosage of each drug administered for  
383 euthanasia signed by the person who administers the drug and by the designated person  
384 responsible for security;  
385

386 (C) A record of all wastage of each drug signed by the person administering the each drug and  
387 the designated person responsible for security; and  
388

389 (D) A weekly record of verification of the amount of each drug on hand, minus the amounts  
390 withdrawn for administration, signed by the designated person responsible for security;  
391

392 (E) A record of disposal of any expired or unwanted sodium pentobarbital and sedative and  
393 analgesic medications. Disposal shall be in conformance with federal regulations.  
394

395 (F) Complete the annual Self-Inspection form by February 1 each year, and retain for Board  
396 inspection.  
397

398 (d) Audits. The registrant shall submit to random audits of records and analysis of prepared  
399 solutions by the Drug Enforcement Administration (DEA), and Board of Pharmacy or its agents.  
400

401 (2) The outlet shall notify the Board of Pharmacy in the event of a significant drug loss or  
402 violation related to drug theft within one (1) business day.

403

404 (3) At the time a Report of Theft or Loss of Controlled Substances (DEA Form 106) is sent to  
405 the DEA, a copy shall be sent to the Board of Pharmacy.

406

407 (4) The Board of Pharmacy will suspend or revoke the registration of an animal euthanasia drug  
408 outlet which allows a person to administer sodium pentobarbital or sedative and analgesic  
409 medications who is not certified by the Oregon State Veterinary Medical Examining Board to  
410 administer such drug.

411 Statutory/Other Authority: ORS 475.095, ORS 475.190 & ORS 689.205

412 Statutes/Other Implemented: ORS 689.151 & ORS 689.155

413

414 [855-080-0105](tel:855-080-0105)

415 **Disposal of Drugs**

416 ~~(1) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be~~  
417 ~~quarantined and physically separated from other drugs until they are destroyed or returned to~~  
418 ~~their supplier.~~

419 ~~(2) Controlled substances which are expired, deteriorated or unwanted shall be disposed of in~~  
420 ~~conformance with 21 CFR 1317.~~

421 ~~(3) Expired, deteriorated, discontinued, or unwanted controlled substances in a long-term care~~  
422 ~~facility shall be destroyed and the destruction jointly witnessed on the premises by any two of~~  
423 ~~the following:~~

424 ~~(a) The consultant pharmacist or registered nurse designee.~~

425 ~~(b) The Director of Nursing Services or supervising nurse designee~~

426 ~~(c) The administrator of the facility or an administrative designee~~

427 ~~(d) A Registered Nurse employed by the facility~~

428 ~~(4) The destruction shall be documented and signed by the witnesses and the document~~  
429 ~~retained at the facility for a period of at least three years. Copies of the document shall be sent~~  
430 ~~to the consultant pharmacist. Any destruction of controlled substances deviating from this~~  
431 ~~procedure must be approved by the Board prior to implementation.~~

432 ~~(5) Upon written request, the Board may waive any of the requirements of this rule if a waiver~~  
433 ~~will further public health or safety or the health and safety of a patient. A waiver granted under~~  
434 ~~this section shall only be effective when it is issued by the Board in writing.~~

**Division 110– Fees**

**Filing Caption** (max 15 words):

Implement amended late fee expiration dates for licensees and registrants

**Need for Rules:**

To align late fees for specific Oregon licensees and registrants to match the expiration date.

**Fiscal Impact:**

This rule amendment has a fiscal impact for specific Oregon licensees and registrants as well as the agency. This rule amendment could potentially result in a savings to licensees and registrants. The agency anticipates a potential revenue reduction of approximately \$90,000-\$95,000 biennially due to a decrease in late fees paid by licensees and registrants.

**Documents Relied Upon:**

None

**Rules Summary:**

Upgrading the agency licensing software eliminated the need for manual processing of license/registration renewals. The late fees for specific license/registration types can be amended to match the expiration date.

**DIVISION 110 FEES**

1 **855-110-0005**  
2 **Licensing Fees**

3 (1) Pharmacist license examination (NAPLEX) and re-examination fee - \$50.  
4

5 (2) Pharmacist jurisprudence (MPJE) re-examination fee - \$25.  
6

7 (3) Pharmacist licensing by reciprocity fee - \$250.  
8

9 (4) Pharmacist licensing by score transfer fee - \$250.  
10

11 (5) Intern license fee. Expires November 30 every two years - \$100.  
12

13 (6) Pharmacist:  
14

15 (a) Biennial license fee. Expires June 30 each odd numbered year. The biennial license fee is -  
16 \$250. Delinquent Late renewal fee (postmarked received after ~~May 31~~ June 30) - \$50.  
17

18 (b) Electronic Prescription Monitoring Fund fee. Due by June 30 biennially - \$50. (This is a  
19 mandatory fee, required by ORS 431.972 that must be paid with the pharmacist license renewal  
20 fee).  
21

22 (c) Workforce Data Collection fee. Due by June 30 biennially - \$4. (This is a mandatory fee as  
23 required by OAR 409-026-0130 that must be paid with the Pharmacist license renewal fee.)  
24

25 (7) Certification of approved provider of continuing education course fee, none at this time.  
26

27 (8) Pharmacy Technician license fee - \$100.  
28

29 (9) Certified Oregon Pharmacy Technician:  
30

31 (a) Biennial license fee. Expires June 30 each even numbered year - \$100. ~~Delinquent~~ **Late**  
32 renewal fee (~~postmarked~~ **received** after ~~May 31~~ **June 30**) \$20.  
33

34 (b) Workforce Data Collection fee. Due by June 30 biennially — \$4. (This is a mandatory fee as  
35 required by OAR 409-026-0130 that must be paid with the Certified Oregon Pharmacy  
36 Technician license renewal fee.)  
37

38 Statutory/Other Authority: ORS 689.205, **ORS** 291.055 & **ORS** 183.705

39 Statutes/Other Implemented: ORS 689.135, **ORS** 431.972, **ORS** 880 & **ORS** 676.410

#### 40 **855-110-0007**

#### 41 **Fees for Registration, Renewal, and Reinspection of Drug Outlets**

42 (1) Community Health Clinic. Expires March 31 annually - \$100. ~~Delinquent~~ **Late** renewal fee  
43 (~~postmarked~~ **received** after ~~February 28~~ **March 31**) - \$25.  
44

45 (2) Drug Distribution Agent. Expires September 30 annually - \$400. ~~Delinquent~~ **Late** renewal fee  
46 (~~postmarked~~ **received** after ~~August 31~~ **September 30**) - \$100.  
47

48 (3) Drug Room (including correctional facility). Expires March 31 annually - \$100. ~~Delinquent~~  
49 **Late** renewal fee (~~postmarked~~ **received** after ~~February 28~~ **March 31**) - \$75.  
50

51 (4) Manufacturers (including Manufacturer Class I, Manufacturer Class II and Manufacturer  
52 Class III). Expires September 30 annually - \$525. ~~Delinquent~~ **Late** renewal fee (~~postmarked~~  
53 **received** after ~~August 31~~ **September 30**) - \$100.  
54

55 (5) Medical Device, Equipment & Gas Class C. Expires January 31 annually - \$75. ~~Delinquent~~  
56 **Late** renewal fee (~~postmarked~~ **received** after ~~December~~ **January** 31) - \$25.  
57

58 (6) Nonprescription Class A. Expires January 31 annually - \$75. ~~Delinquent~~ **Late** renewal fee  
59 (~~postmarked~~ **received** after ~~December~~ **January** 31) - \$25.  
60

61 (7) Nonprescription Class B. Expires January 31 annually - \$75. ~~Delinquent~~ **Late** renewal fee  
62 (~~postmarked~~ **after** ~~December~~ **January** 31) - \$25.  
63

64 (8) Nonprescription Class D. Expires January 31 annually - \$100. ~~Delinquent~~ **Late** renewal fee  
65 (~~postmarked~~ **after** ~~December~~ **January** 31) - \$25.  
66

67 (9) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer - \$50. Expires December  
68 31 annually.  
69

- 70 (10) Re-inspection fee - \$100. Applies to any re-inspection of a drug outlet occasioned to verify  
71 corrections of violations found in an initial inspection.  
72
- 73 (11) Retail, Institutional, or Consulting/"Drugless" Pharmacy Drug Outlet. Expires March 31  
74 annually - \$225. ~~Delinquent~~ Late renewal fee (~~postmarked~~ received after February 28 March  
75 31) - \$75.  
76
- 77 (12) Wholesalers (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III).  
78 Expires September 30 annually - \$525. ~~Delinquent~~ Late renewal fee (~~postmarked~~ received  
79 after August 31 September 30) - \$100.  
80
- 81 (13) Remote Dispensing Machine or Remote Distribution Facility. Expires March 31 annually -  
82 \$120. Due by February 28 March 31 annually.  
83
- 84 (14) Charitable Pharmacy. Expires March 31 annually - \$75. ~~Delinquent~~ Late renewal fee  
85 (~~postmarked~~ received after February 28 March 31) - \$25.  
86
- 87 (15) Home Dialysis. Expires March 31 annually - \$225. ~~Delinquent~~ Late renewal fee  
88 (~~postmarked~~ received after February 28 March 31) - \$75.  
89
- 90 (16) Supervising Physician Dispensing Outlet. Expires March 31 annually - \$175. ~~Delinquent~~  
91 Late renewal fee (~~postmarked~~ received after February 28 March 31) - \$75.  
92
- 93 (17) Dispensing Practitioner Drug Outlet. Expires March 31 annually - \$100. ~~Delinquent~~ Late  
94 renewal fee (~~postmarked~~ received after February 28 March 31) — \$25.  
95
- 96 Stat. Auth.: ORS 689.205 & ORS 291.055  
97 Stats. Implemented: ORS 689.135, ORS 689.774 & ORS 289.305  
98  
99

**Oregon Board of Pharmacy**  
**Budget Report: December 2020 (Month 18)**

**Revenue:**

Through December, revenue is \$187,616 (3.4%) **over** budget

**Expenditures:**

Through December, **total expenditures** are \$729,528 (10.8%) **under** budget

**Personal services** are \$466,235 (10.2%) **under** budget

**Services and Supplies** are \$253,958 (13.1%) **under** budget

**Special Payments** are \$9,335 (100%) **under** budget

**Revenues less Expenditures:**    \$(314,327)

**Cash Balance:**

**Cash balance through December** is \$3,443,322 which represents (9.16 months of operating expense)

Note: This the above is a snap-shot of the biennium to date through December 2020. It does not include projections for the remainder of the biennium.

---

**End of biennium estimated cash balance** is \$3,962,624, which represents (11.44 months of operating expense)

**Cash balance target** is \$2,078,988, (6.0 months of operating expense)

Note: The end of biennium estimated cash balance is calculated based on the biennium to date plus the remaining months projections for 2019-21.

<b>Oregon Board of Pharmacy</b>				
<b>Total All Funds - LAB 2019-2021</b>				
Actuals through December 2020 month-end-close				
	LAB	ACTUAL+PROJ	VARIANCE	
<b>BEGINNING CASH BALANCE</b>	<b>0</b>	<b>3,757,650</b>	<b>0.00</b>	
<b>REVENUE</b>				
50 GENERAL FUND				
205 OTHER BUSINESS LICENSES	7,146,250.00	8,079,065.75	(932,815.75)	
210 OTHER NONBUSINESS LICENSES AND FEES	139,296.00	216,196.00	(76,900.00)	
505 FINES AND FORFEITS	405,000.00	426,762.36	(21,762.35)	
605 INTEREST AND INVESTMENTS	45,000.00	121,186.56	(76,186.56)	
975 OTHER REVENUE	57,090.00	65,262.71	(8,172.71)	
<b>TOTAL REVENUE</b>	<b>7,792,636.00</b>	<b>8,908,473.38</b>	<b>(1,115,837.38)</b>	
<b>TRANSFERS</b>				
1107 TRANSFER IN FROM DAS	-	35,494.97	(35,494.97)	
<b>TOTAL TRANSFER IN</b>	<b>0.00</b>	<b>35,494.97</b>	<b>(35,494.97)</b>	
2010 TRANSFER OUT TO OTHER FUNDS	-	-	-	
2443 TRANSFER OUT TO OREGON HEALTH AUTHORITY	416,146.00	423,040.00	(6,894.00)	
<b>TOTAL TRANSFER OUT</b>	<b>416,146.00</b>	<b>423,040.00</b>	<b>(6,894.00)</b>	
<b>PERSONAL SERVICES</b>				
3110 CLASS/UNCLASS SALARY & PER DIEM	3,890,199.00	3,582,315.43	307,883.57	
3160 TEMPORARY APPOINTMENTS	26,180.00	5,148.66	21,031.34	
3170 OVERTIME PAYMENTS	-	1,088.84	(1,088.84)	
3180 SHIFT DIFFERENTIAL	-	-	-	
3190 ALL OTHER DIFFERENTIAL	190,428.00	234,006.98	(43,578.98)	
3210 ERB ASSESSMENT	1,281.00	1,148.94	132.06	
3220 PUBLIC EMPLOYEES' RETIREMENT SYSTEM	684,570.00	585,842.09	98,727.91	
3221 PENSION BOND CONTRIBUTION	200,306.00	205,536.08	(5,230.08)	
3230 SOCIAL SECURITY TAX	313,870.00	279,473.25	34,396.75	
3240 UNEMPLOYMENT ASSESSMENT	-	-	-	
3250 WORKERS' COMPENSATION ASSESSMENT	1,276.00	959.19	316.81	
3260 MASS TRANSIT	24,607.00	22,827.13	1,779.87	
3270 FLEXIBLE BENEFITS	774,048.00	716,263.12	57,784.88	
3435 Personal Services Budget Adj.	(20,653.00)	-	(20,653.00)	
<b>TOTAL PERSONAL SERVICES</b>	<b>6,086,112.00</b>	<b>5,634,609.71</b>	<b>451,502.29</b>	
<b>SERVICES AND SUPPLIES</b>				
4100 INSTATE TRAVEL	113,572.00	67,214.86	46,357.14	
4125 OUT-OF-STATE TRAVEL	16,322.00	10,916.69	5,405.31	
4150 EMPLOYEE TRAINING	21,400.00	18,639.62	2,760.38	
4175 OFFICE EXPENSES	129,018.00	88,389.53	40,628.47	
4200 TELECOMM/TECH SVC AND SUPPLIES	48,830.00	45,559.90	3,270.10	
4225 STATE GOVERNMENT SERVICE CHARGES	163,176.00	163,550.56	(374.56)	
4250 DATA PROCESSING	80,540.00	307,484.09	(226,944.09)	
4275 PUBLICITY & PUBLICATIONS	39,583.00	19,839.98	19,743.02	
4300 PROFESSIONAL SERVICES	321,394.00	353,190.36	(31,796.36)	
4315 IT PROFESSIONAL SERVICES	652,149.00	328,160.00	323,989.00	
4325 ATTORNEY GENERAL LEGAL FEES	525,607.00	525,156.11	450.89	
4375 EMPLOYEE RECRUITMENT AND DEVELOPMENT	653.00	-	653.00	
4400 DUES AND SUBSCRIPTIONS	5,195.00	7,773.00	(2,578.00)	
4425 FACILITIES RENT & TAXES	210,941.00	203,074.80	7,866.20	
4475 FACILITIES MAINTENANCE	53.00	-	53.00	
4525 MEDICAL SUPPLIES AND SERVICES	1,152.00	1,251.36	(99.36)	
4575 AGENCY PROGRAM RELATED SVCS & SUPP	240,152.00	230,067.69	10,084.31	
4650 OTHER SERVICES AND SUPPLIES	284,656.00	275,491.01	9,164.99	
4700 EXPENDABLE PROPERTY \$250-\$5000	13,526.00	5,352.93	8,173.07	
4715 IT EXPENDABLE PROPERTY	43,363.00	30,231.44	13,131.56	
<b>TOTAL SERVICES &amp; SUPPLIES</b>	<b>2,911,282.00</b>	<b>2,681,343.93</b>	<b>229,938.07</b>	
<b>Capital Outlay</b>				
5600 DATA PROCESSING HARDWARE	8,611.00	-	8,611.00	
5900 OTHER CAPITAL OUTLAY	-	-	-	
<b>Total Capital Outlay</b>	<b>8,611.00</b>	<b>0.00</b>	<b>8,611.00</b>	
<b>Special Payments</b>				
6085 OTHER SPECIAL PAYMENTS	12,447.00	-	12,447.00	
<b>Total Special Payments</b>	<b>12,447.00</b>	<b>0.00</b>	<b>12,447.00</b>	
<b>TOTAL EXPENDITURES</b>	<b>9,018,452.00</b>	<b>8,315,953.64</b>	<b>702,498.36</b>	
<b>PROJECTED BIENNIAL ENDING CASH BALANCE</b>		<b>3,962,624</b>		
End of biennium projected cash balance in months		11.44		
Cash balance target of 6.0 months (working capital)		2,078,988		

**Oregon Board of Pharmacy**  
**Budget Report: January 2021 (Month 19)**

**Revenue:**

Through January, revenue is \$160,520 (2.7%) **over** budget

**Expenditures:**

Through January, **total expenditures** are \$775,310 (10.9%) **under** budget

**Personal services** are \$486,307 (10.1%) **under** budget

**Services and Supplies** are \$279,149 (13.7%) **under** budget

**Special Payments** are \$9,854 (100%) **under** budget

**Revenues less Expenditures:**    \$(364,057)

**Cash Balance:**

**Cash balance through January** is \$3,393,593 which represents (9.03 months of operating expense)

Note: This the above is a snap-shot of the biennium to date through January 2021. It does not include projections for the remainder of the biennium.

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**End of biennium estimated cash balance** is \$3,956,274, which represents (11.44 months of operating expense)

**Cash balance target** is \$2,075,135, (6.0 months of operating expense)

Note: The end of biennium estimated cash balance is calculated based on the biennium to date plus the remaining months projections for 2019-21.

<b>Oregon Board of Pharmacy</b>				
<b>Total All Funds - LAB 2019-2021</b>				
Actuals through January 2021 month-end-close				
		LAB	ACTUAL+PROJ	VARIANCE
	<b>BEGINNING CASH BALANCE</b>	<b>0</b>	<b>3,757,650</b>	<b>0.00</b>
<b>REVENUE</b>				
50	GENERAL FUND			
205	OTHER BUSINESS LICENSES	7,146,250.00	8,079,065.75	(932,815.75)
210	OTHER NONBUSINESS LICENSES AND FEES	139,296.00	216,196.00	(76,900.00)
505	FINES AND FORFEITS	405,000.00	405,000.00	-
605	INTEREST AND INVESTMENTS	45,000.00	121,186.56	(76,186.56)
975	OTHER REVENUE	57,090.00	65,262.71	(8,172.71)
	<b>TOTAL REVENUE</b>	<b>7,792,636.00</b>	<b>8,886,711.02</b>	<b>(1,094,075.02)</b>
<b>TRANSFERS</b>				
1107	TRANSFER IN FROM DAS	-	35,494.97	(35,494.97)
	<b>TOTAL TRANSFER IN</b>	<b>0.00</b>	<b>35,494.97</b>	<b>(35,494.97)</b>
2010	TRANSFER OUT TO OTHER FUNDS	-	-	-
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	416,146.00	423,040.00	(6,894.00)
	<b>TOTAL TRANSFER OUT</b>	<b>416,146.00</b>	<b>423,040.00</b>	<b>(6,894.00)</b>
<b>PERSONAL SERVICES</b>				
3110	CLASS/UNCLASS SALARY & PER DIEM	3,890,199.00	3,580,516.76	309,682.24
3160	TEMPORARY APPOINTMENTS	26,180.00	5,148.66	21,031.34
3170	OVERTIME PAYMENTS	-	1,088.84	(1,088.84)
3180	SHIFT DIFFERENTIAL	-	-	-
3190	ALL OTHER DIFFERENTIAL	190,428.00	234,006.99	(43,578.99)
3210	ERB ASSESSMENT	1,281.00	1,148.94	132.06
3220	PUBLIC EMPLOYEES' RETIREMENT SYSTEM	684,570.00	585,576.79	98,993.21
3221	PENSION BOND CONTRIBUTION	200,306.00	205,409.40	(5,103.40)
3230	SOCIAL SECURITY TAX	313,870.00	278,996.79	34,873.21
3240	UNEMPLOYMENT ASSESSMENT	-	-	-
3250	WORKERS' COMPENSATION ASSESSMENT	1,276.00	937.48	338.52
3260	MASS TRANSIT	24,607.00	22,815.08	1,791.92
3270	FLEXIBLE BENEFITS	774,048.00	716,260.17	57,787.83
3435	Personal Services Budget Adj.	(20,653.00)	-	(20,653.00)
	<b>TOTAL PERSONAL SERVICES</b>	<b>6,086,112.00</b>	<b>5,631,905.91</b>	<b>454,206.09</b>
<b>SERVICES AND SUPPLIES</b>				
4100	INSTATE TRAVEL	113,572.00	65,302.86	48,269.14
4125	OUT-OF-STATE TRAVEL	16,322.00	10,916.69	5,405.31
4150	EMPLOYEE TRAINING	21,400.00	18,164.62	3,235.38
4175	OFFICE EXPENSES	129,018.00	87,293.36	41,724.64
4200	TELECOMM/TECH SVC AND SUPPLIES	48,830.00	45,480.05	3,349.95
4225	STATE GOVERNMENT SERVICE CHARGES	163,176.00	163,545.26	(369.26)
4250	DATA PROCESSING	80,540.00	307,421.17	(226,881.17)
4275	PUBLICITY & PUBLICATIONS	39,583.00	19,653.54	19,929.46
4300	PROFESSIONAL SERVICES	321,394.00	349,120.32	(27,726.32)
4315	IT PROFESSIONAL SERVICES	652,149.00	326,160.00	325,989.00
4325	ATTORNEY GENERAL LEGAL FEES	525,607.00	525,156.11	450.89
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	653.00	-	653.00
4400	DUES AND SUBSCRIPTIONS	5,195.00	7,733.00	(2,538.00)
4425	FACILITIES RENT & TAXES	210,941.00	203,074.80	7,866.20
4475	FACILITIES MAINTENANCE	53.00	-	53.00
4525	MEDICAL SUPPLIES AND SERVICES	1,152.00	1,151.36	0.64
4575	AGENCY PROGRAM RELATED SVCS & SUPP	240,152.00	229,640.44	10,511.56
4650	OTHER SERVICES AND SUPPLIES	284,656.00	273,737.36	10,918.64
4700	EXPENDABLE PROPERTY \$250-\$5000	13,526.00	4,852.93	8,673.07
4715	IT EXPENDABLE PROPERTY	43,363.00	30,231.44	13,131.56
	<b>TOTAL SERVICES &amp; SUPPLIES</b>	<b>2,911,282.00</b>	<b>2,668,635.31</b>	<b>242,646.69</b>
<b>Capital Outlay</b>				
5600	DATA PROCESSING HARDWARE	8,611.00	-	8,611.00
5900	OTHER CAPITAL OUTLAY	-	-	-
	<b>Total Capital Outlay</b>	<b>8,611.00</b>	<b>0.00</b>	<b>8,611.00</b>
<b>Special Payments</b>				
6085	OTHER SPECIAL PAYMENTS	12,447.00	-	12,447.00
	<b>Total Special Payments</b>	<b>12,447.00</b>	<b>0.00</b>	<b>12,447.00</b>
	<b>TOTAL EXPENDITURES</b>	<b>9,018,452.00</b>	<b>8,300,541.22</b>	<b>717,910.78</b>
	<b>PROJECTED BIENNIAL ENDING CASH BALANCE</b>		<b>3,956,274</b>	
	End of biennium projected cash balance in months		11.44	
	Cash balance target of 6.0 months (working capital)		2,075,135	

<p><b>Agenda Open Session Public Meeting*</b></p>	<p style="text-align: right;"><b>Public Health and Pharmacy Formulary Advisory Committee Meeting March 12, 2021 8:00am</b></p> <p style="text-align: center;">Due to the COVID-19 <a href="#">State of Emergency</a> and Governor Brown’s Executive Order <a href="#">21-05</a>, the committee will meet via teleconference and the public may attend by phone.  <b>Public Attendance by Phone: 877-873-8017 Participant code: 139360#</b></p> <p style="text-align: center;"><i>A request for hearing impaired assistance and accommodations for persons with disabilities should be made to <a href="mailto:Pharmacy.board@oregon.gov">Pharmacy.board@oregon.gov</a> or 971-673-0001 at least 72 hours prior to the meeting.</i></p>
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- Committee Members**
- |   |   |
|---|---|
| <input type="checkbox"/> Evon Anukam, RPH | <input type="checkbox"/> Amy Burns, RPH     |
| <input type="checkbox"/> Kat Chinn, APRN  | <input type="checkbox"/> Mark Helm, MD      |
| <input type="checkbox"/> Sean Jones, MD   | <input type="checkbox"/> Helen Turner, APRN |
| <input type="checkbox"/> Amy Valdez, RPH  |   |
- OBOP Staff to Committee**
- |   |   |
|---|---|
| <input type="checkbox"/> Joe Schnabel, Executive Director         | <input type="checkbox"/> Brianne Efremoff, Compliance Director  |
| <input type="checkbox"/> Jennifer Davis, Pharmacist Consultant    | <input type="checkbox"/> Elizabeth Hughes, Compliance Secretary |
| <input type="checkbox"/> Rachel Melvin, Operations Policy Analyst |   |

Agenda Item	Desired Outcome																																									
Welcome	<p>❖ Roll call</p> <table border="1" style="width: 100%; border-collapse: collapse; margin: 5px 0;"> <thead> <tr> <th style="width: 70%;">Committee Members</th> <th style="width: 15%;">Here</th> <th style="width: 15%;">Absent</th> </tr> </thead> <tbody> <tr><td>Committee Member Valdez</td><td style="text-align: center;">X</td><td></td></tr> <tr><td>Committee Member Anukam</td><td style="text-align: center;">X</td><td></td></tr> <tr><td>Committee Member Burns</td><td style="text-align: center;">X</td><td></td></tr> <tr><td>Committee Member Chinn</td><td style="text-align: center;">X</td><td></td></tr> <tr><td>Committee Member Helm</td><td style="text-align: center;">X</td><td></td></tr> <tr><td>Committee Member Jones</td><td style="text-align: center;">X</td><td></td></tr> <tr><td>Committee Member Turner</td><td style="text-align: center;">X</td><td></td></tr> <tr><td>Staff Member Schnabel</td><td style="text-align: center;">X</td><td></td></tr> <tr><td>Staff Member Efremoff</td><td style="text-align: center;">X</td><td></td></tr> <tr><td>Staff Member Davis</td><td style="text-align: center;">X</td><td></td></tr> <tr><td>Staff Member Melvin</td><td style="text-align: center;">X</td><td></td></tr> <tr><td>Staff Member Hughes</td><td style="text-align: center;">X</td><td></td></tr> </tbody> </table> <p>Committee Member Turner joined meeting at 8:08am.</p> <p>❖ Review Housekeeping Items &amp; Meeting Etiquette</p> <p>❖ Agenda review and approval</p> <p><b>Motion to approve agenda was made and unanimously carried (Motion by Valdez, seconded Chinn).</b></p> <p>❖ 10.7.2020 Minutes review and approval</p>			Committee Members	Here	Absent	Committee Member Valdez	X		Committee Member Anukam	X		Committee Member Burns	X		Committee Member Chinn	X		Committee Member Helm	X		Committee Member Jones	X		Committee Member Turner	X		Staff Member Schnabel	X		Staff Member Efremoff	X		Staff Member Davis	X		Staff Member Melvin	X		Staff Member Hughes	X	
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	<p><b>Motion to approve 10/7/2020 Minutes was made and unanimously carried (Motion by Valdez, seconded by Chinn).</b></p> <p><b>Motion to post draft minutes to website and to dispense with evening meetings to approve was made and unanimously carried (Motion by Helm, seconded by Valdez).</b></p>
Committee Business	<ul style="list-style-type: none"> <li>❖ High Priority and Housekeeping Items           <ul style="list-style-type: none"> <li>○ Staff member Schnabel introduced new staff members Jennifer Davis, Pharmacist Consultant and Elizabeth Hughes, Compliance Secretary</li> <li>○ Staff member Schnabel reported information on the reappointment of Amy Burns, RPH and Helen Turner, APRN for terms 12/1/20-11/30/22. Committee member Helm acknowledged that he has not been reappointed but will continue to serve.</li> <li>○ Staff member Davis lead a Policy Discussion concerning officer selection               <ul style="list-style-type: none"> <li>▪ The committee spoke in favor of switching to a 2-year term for Chairperson.</li> <li>▪ The committee discussed that the officer position of Vice Chairperson will no longer be filled as it is not included in statute and that if the Chairperson is unavailable for a meeting, they would work with Board staff to designate a stand in.</li> </ul> </li> <li>○ Election of Chairperson</li> </ul> </li> </ul> <p><b>Motion to select Committee Member Valdez as Chairperson for a 2-year term was made and unanimously carried (Motion by Valdez, seconded by Chinn).</b></p> <ul style="list-style-type: none"> <li>❖ Rules Development/Implementation Update           <ul style="list-style-type: none"> <li>○ Staff member Melvin provided an update from the 11/24/2020 Rulemaking hearing and reported that the Board adopted the HIV Pre-Exposure Prophylaxis – PrEP protocol on 12/17/2020.</li> </ul> </li> <li>❖ Periodic Formulary/Protocol Review           <ul style="list-style-type: none"> <li>○ Staff member Davis introduced the process for a periodic formulary/protocol review as required by statute.               <ul style="list-style-type: none"> <li>▪ Suggest this periodic review be completed every other year in odd years during the March meeting.</li> <li>▪ Protocols with the most feedback or anticipated discussion are scheduled first today.</li> <li>▪ Feedback forms are received ongoing. For today they were made available to committee for review and will be discussed as part of the periodic review.</li> <li>▪ Effort made to standardize forms across all protocols- ie. same demographic information, etc.</li> <li>▪ Effort made to remove any “loose references” and incorporating standards by reference as outlined in the Oregon Attorney General’s Administrative Law Manual and Uniform and Model Rules of</li> </ul> </li> </ul> </li> </ul>

Procedure under the Administrative Procedures Act which states that Administrative agencies may adopt by reference only a specific version of a manual, code, or standard. If the provisions of the manual, code or standard are subsequently modified and the agency wishes to use the new provisions, the agency must formally amend its rule to incorporate the new version.

- The committee discussed the challenge of this with travel medicine protocols and the delay with adopting updated references for standards. Staff will work with AAG to establish language to help resolve this concern.
- [OAR 855-020](#): Pharmacist Prescriptive Authority
  - PHPFAC Feedback Forms: Feedback #4, #5, #6
  - The committee provided feedback on allowing for tele-health for prescriptive authority.
    - They discussed the value of in person consultations and whether access to visiting a pharmacy is an obstacle to care.
    - They discussed the value of allowing the option of tele-health for some treatments that do not require equipment or physical evaluation.
    - The committee voiced mixed support for removing the face-to-face requirement and recommended caution with allowing tele-health without restrictions.
    - The committee voiced support for removing the face-to-face requirement for processes within protocols that do not require equipment or physical examination
    - The committee did not voice support for removing the face-to-face requirement for processes that require equipment or physical examination.
    - Board staff requested feedback on possible minimum requirements such as a required continuous video/audio connection.
  - The committee discussed allowing intake forms and assessment/treatment documents to be provided, completed and stored electronically rather than printed, filled out by hand, and kept physically.
    - They voiced support for electronically generating and filling out forms but for the pharmacist to still be required to collect and enter the information.
  - The committee discussed changing the language of “year” to “rolling 12-month period” for increased clarity. They voiced support for this edit.

**Motion to recommend proposed revisions of OAR 855-020 for the Board to consider to allow tele-health and virtual measurements as determined by the pharmacist, unless face to face is required by the protocol was made and unanimously carried (Motion by Valdez, seconded by Chinn).**

- Protocol Compendium
  - [Preventative Care: Tobacco Cessation - NRT \(Nicotine Replacement Therapy\) and Non-NRT](#)
    - PHPFAC Feedback Forms: Feedback #1, #2, #3
    - SMEs: Kiyomi Lehman, Julie Himstreet, and Sharon Rask
    - The committee discussed how best to record preferred pronouns and preferred name on intake forms in order to be as inclusive as possible.
    - The committee discussed removing exclusion for patients who have been treated for mental illness within the past 2 years versus extending exclusion further than 2 years.
      - They voiced support for leaving the 2-year exclusion as is based on feedback provided from SMEs.
    - The committee discussed maximum dosage recommendations for nicotine gum and lozenges.
    - The committee discussed guidelines for combining other cessation treatments with Varenicline.
      - They discussed removing or clarifying a statement from the assessment pathway that states that Varenicline is generally not used in combination with other cessation medications.
      - They discussed including information about prescribing Varenicline to patients who are already taking Bupropion for depression.
    - The committee discussed tele-health option for smoking cessation prescribing
      - They spoke in favor of allowing the entire smoking cessation prescribing process to be virtual aside from checking patient blood pressure. Concerns were raised on accuracy of blood pressure results taken by patient and recommendations were made to require the blood pressure to be taken face to face by the pharmacist.

Committee Member Chinn left the meeting at 1:34pm.

- [Preventative Care: HIV Pre-Exposure Prophylaxis \(PrEP\)](#)
  - PHPFAC Feedback Forms: Feedback #1

	<ul style="list-style-type: none"><li>• SMEs: Dr. Timothy Menza, Thad Mick, and Sharon Rask</li><li>• The committee discussed including rapid HIV testing as part of initial appointment.</li><li>• The committee discussed the Oregon legislature’s HB 2958 which would allow a pharmacist to prescribe and dispense pre-exposure prophylactic antiretroviral drug to patient after completion of patient assessment. The committee discussed overlap of this bill with the current PrEP protocol.</li><li>• The committee discussed allowing self-screening to be conducted virtually and voiced support for this option.</li><li>• The committee discussed allowing the pharmacist to conduct patient assessment and prescribing virtually and voiced support for this option.</li><li>• Board staff asked for guidance on if PrEP prescription template is optional or required and the committee voiced support for allowing it to be optional to create consistency with other protocols.</li><li>• The committee discussed timeline of completing and sending provider notification fax form after prescribing PrEP.<ul style="list-style-type: none"><li>○ They recommended adding “Pending” option for lab work results.</li><li>○ They recommended adding time limit of 5 business days for how soon after prescribing the pharmacist must send the provider fax form is in alignment with OAR 855-020-0110(4)(d).</li><li>○ They recommended extending prescribing length from 30 days to 90 days pending lab work results.</li></ul></li><li>▪ <a href="#">Preventative Care: HIV Post-Exposure Prophylaxis (PEP)</a><ul style="list-style-type: none"><li>• <a href="#">Provider Notification Template</a></li><li>• The committee discussed the time sensitive nature of prescribing PEP and how to expedite care.</li><li>• The committee discussed the importance of reviewing the patient informational form with the patient and requiring this form within the protocol.</li><li>• The committee discussed concerns on discontinuation of treatment intake by the patient due to questions concerning sexual assault.</li><li>• The committee discussed if the provider notification form should be required to be filled out and sent within 5 days of prescribing and voiced support for this.</li></ul></li></ul>
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	<ul style="list-style-type: none"><li>▪ <a href="#">Preventative Care: Travel Medications</a><ul style="list-style-type: none"><li>• Staff edits were reviewed with no additional edits from the committee.</li><li>• The committee voiced support for allowing travel medications to be prescribed virtually.</li></ul></li><li>▪ <a href="#">Continuation of Therapy</a><ul style="list-style-type: none"><li>• PHPFAC Feedback Forms: Feedback #1</li><li>• The committee discussed the limit of allowing only a 60-day supply to be prescribed.</li><li>• The committee discussed allowing tele-health for continuation of therapy fills.<ul style="list-style-type: none"><li>○ Committee member Valdez asked the committee if they had any concerns or comments, there were no additional comments or concerns.</li></ul></li></ul></li><li>▪ <a href="#">Cough &amp; Cold: Benzonatate</a><ul style="list-style-type: none"><li>• Staff edits were reviewed with no additional edits from the committee.</li></ul></li><li>▪ <a href="#">Cough &amp; Cold: Intranasal Corticosteroids</a><ul style="list-style-type: none"><li>• Staff edits were reviewed with no additional edits from the committee.</li></ul></li><li>▪ <a href="#">Cough &amp; Cold: Pseudoephedrine</a><ul style="list-style-type: none"><li>• The committee discussed the PDMP reporting requirement for pseudoephedrine in order to prevent more than 3 fills within a rolling 12-month period.</li></ul></li><li>▪ <a href="#">Cough &amp; Cold: SABAs</a><ul style="list-style-type: none"><li>• PHPFAC Feedback Forms: Feedback #1</li><li>• Staff edits were reviewed with no additional edits from the committee.</li><li>• The committee discussed allowing tele-health for all cough &amp; cold protocols.<ul style="list-style-type: none"><li>○ Committee member Valdez asked the committee if they had any concerns or comments, there were no additional comments or concerns.</li></ul></li></ul></li><li>▪ <a href="#">Conditions: Vulvovaginal Candidiasis (VVC)</a><ul style="list-style-type: none"><li>• Staff edits were reviewed with no additional edits from the committee.</li></ul></li></ul>
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- The committee discussed allowing tele-health for VVC protocol.
  - Committee member Valdez asked the committee if they had any concerns or comments, there were no additional comments or concerns.
- [Preventative Care: Condoms](#)
  - Staff edits were reviewed with no additional edits from the committee.
    - Committee member Valdez asked the committee if they had any concerns or comments, there were no additional comments or concerns.
- [Preventative Care: Emergency Contraception](#)
  - Staff edits were reviewed with no additional edits from the committee.
  - The committee discussed the importance of requiring a face-to-face interaction for prescribing emergency contraception and considered how this could create a barrier to care for a time sensitive matter.
    - A committee member expressed concerns on bypassing face to face consultation.
    - Other committee members felt that not making it available virtually could be a barrier to timely access to care

**Motion to recommend all reviewed Protocol “packages” except emergency contraception as proposed to the Board for adoption by rule was made and carried with Valdez, Anukam, Burns, Helm, Jones, and Turner in favor and Chinn absent. (Motion by Valdez, seconded by Jones).**

**Motion to recommend the protocol for emergency contraception as proposed to the Board for adoption by rule was made and carried with Valdez, Anukam, Burns, Jones, and Turner in favor, Helm opposed, and Chinn absent. (Motion by Valdez, seconded by Jones).**

- Role of: [Sample Visit Summary Template](#)
  - PHPFAC Feedback Forms: Feedback #7
  - Staff edits were reviewed with no additional edits from the committee.

**Motion to recommend the reviewed Sample Visit Summary Template as proposed to the Board was made and carried with Valdez, Anukam, Burns, Helm, Jones, and Turner in favor and Chinn absent. (Motion by Valdez, seconded by Helm).**

- Formulary Compendium
  - [Formulary: Devices & Supplies](#)

	<ul style="list-style-type: none"><li>❖ Items to explore<ul style="list-style-type: none"><li>○ Idea #1: Formulary- Blood Pressure Monitors<ul style="list-style-type: none"><li>▪ The committee discussed adding blood pressure monitors to the Devices &amp; Supplies list and voiced support for doing so.<ul style="list-style-type: none"><li>• The committee discussed concerns about what monitors will be covered by insurance and the quality of said monitors.</li><li>• The committee discussed creating a preferred product list but considered that this may not be a practical option.</li></ul></li></ul></li></ul><p><b>Motion to recommend the addition of Non-Invasive Blood Pressure Measurement Systems to the list of Formulary of Drugs and Devices for adoption by the Board by rule was made and carried with Valdez, Anukam, Burns, Helm, Jones, and Turner in favor and Chinn absent. (Motion by Valdez, seconded by Anukam).</b></p><ul style="list-style-type: none"><li>○ Idea #2: Protocol- Uncomplicated Infections<ul style="list-style-type: none"><li>▪ The committee discussed how creating/following a protocol for prescribing treatment for conjunctivitis and otitis would be challenging, and committee members raised serious concerns about this concept.</li><li>▪ The committee discussed that creating a protocol for uncomplicated UTI (acute dysuria) could be an option, but recommended proceeding with caution if they chose to proceed, especially in treatment for children.</li><li>▪ Board staff reminded the committee that pharmacists are not permitted to make a diagnosis.</li><li>▪ The committee discussed focusing on symptom management for infections and created a list of infections to recommend creating protocols for:<ul style="list-style-type: none"><li>• Topical Steroids- itchy rash</li><li>• Topical Acne Agents</li><li>• Poison Oak</li><li>• Swimmers Ear</li><li>• Herpes- oral – blistering rashes</li><li>• Acute Dysuria</li><li>• Headache</li><li>• Burns</li><li>• Lice</li><li>• Pinworms</li></ul></li></ul></li></ul></li></ul>
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	<p><b>Motion to bring idea of Symptom Management of use to pharmacists to include, but not limited to itchy rash, acne, herpes simplex/zoster, dysuria, headaches, sprains/strains, swimmers ear, burns and parasites as a Protocol concept to a future PHPFAC meeting was made and carried with Valdez, Anukam, Burns, Helm, Jones, and Turner in favor and Chinn absent. (Motion by Valdez, seconded by Anukam).</b></p> <ul style="list-style-type: none"> <li>❖ Committee Protocol Development             <ul style="list-style-type: none"> <li>○ Concept #1: All FDA/ACIP Recommended Immunizations                 <ul style="list-style-type: none"> <li>▪ The committee reviewed current laws and processes.</li> <li>▪ The committee discussed that pharmacist immunization authority currently resides with the OHA but that this authority could be transferred to the Formulary Committee.                     <ul style="list-style-type: none"> <li>• Concerns were raised about the clinical considerations that are in place related to their intent.</li> <li>• The committee gave direction for Board staff to have discussions with the OHA about the possibility of transferring authority to the Formulary Committee or having shared responsibility</li> </ul> </li> </ul> </li> </ul> </li> </ul> <p><b>Motion to bring Concept 2020-021 Immunizations to a future PHPFAC meeting was made and carried with Valdez, Burns, Jones, and Turner in favor, Anukam and Helm opposed, and Chinn absent (Motion by Valdez, seconded by Turner).</b></p> <p>ADJOURN</p> <p><b>Motion to adjourn at 4:13PM was made and carried with Anukam, Burns, Helm, Jones, and Turner in favor (Motion by Valdez, seconded by Turner).</b></p>
<p>Upcoming Meeting Schedule – subject to change</p>	<ul style="list-style-type: none"> <li>❖ Meetings Scheduled             <ul style="list-style-type: none"> <li>➤ 9/24/2021</li> </ul> </li> <li>❖ <i>TENTATIVE 2022 Meeting Dates:</i> <ul style="list-style-type: none"> <li>➤ 3/11/2022 and 9/23/2022</li> </ul> </li> </ul>

*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.*