

BOARD MEETING AGENDA

**Oregon Board of Pharmacy
800 NE Oregon Street
Portland, OR 97232
April 6-7, 2016**

1891- Celebrating 125 Years of Excellence - 2016

The mission of the Oregon State Board of Pharmacy is to promote, preserve and protect the public health, safety and welfare by ensuring high standards in the practice of pharmacy and by regulating the quality, manufacture, sale and distribution of drugs.

**Wednesday, April 6, 2016 @ 8:30 AM, Conference Room 1A
Thursday, April 7, 2016 @ 8:30 AM, Conference Room 1A**

≈ If special accommodations are needed for you to attend or participate in this Board Meeting, please contact Loretta Glenn at: (971) 673-0001. ≈

WEDNESDAY, APRIL 6, 2016

I. 8:30 AM OPEN SESSION, Roberto Linares, R.Ph, Presiding

- A. Roll Call
- B. Introduction & Installation of newly added Pharmacy Technician Board Members:
 - Cyndi Vipperman
 - Dianne Armstrong
- C. Agenda Review and Approval *Action Necessary*
- D. Board Counsel Update and Report (10 min) - *Cowan*

II. Contested Case Deliberation pursuant to ORS 192.690(1) - **Not Open to the Public**

III. EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 676.175, ORS 192.660 (1) (2) (f) (k).

- A. Items for Consideration and Discussion:
 - 1. Deliberation on Disciplinary Cases and Investigations
 - 2. Personal Appearances
 - 3. Warning Notices
 - 4. Case Review
- B. Executive Director Performance Update & Review pursuant to ORS 192.660(2)(i).

IV. OPEN SESSION - PUBLIC MAY ATTEND - At the conclusion of Executive Session, the Board may convene Open Session to begin the scheduled agenda for April 7, 2016. Items that may be covered are marked with an asterisk *.

Adjourn

THURSDAY, APRIL 7, 2016

8:30AM

V. OPEN SESSION, Roberto Linares, R.Ph. Presiding

- A. Roll Call
- B. Introduce New Pharmacy Technician Board Members
 - Cyndi Vipperman
 - Dianne Armstrong

8:45AM

- C. Motions for Contested Cases & Disciplinary Action *Action Necessary*

9:00AM

VI. GENERAL ADMINISTRATION

- A. Rules – (1 hr)
 - 1. Review Rulemaking Hearing Report & Comments **#A**
 - 2. Consider Adoption of Temporary Rules - none
 - 3. Review & consider rules for May 24, 2016 Rulemaking Hearing
Phase I – draft rules second review
 - a) Div 006 – Definitions **#A1**
 - b) Div 019 - PIC in-state rules **#A2**
 - c) Div 025 – CPT Biennial Licensure and Housekeeping **#A3**
 - d) Div 041 – Pharmacy Operations:
 - a. -1010 Resident PIC **#A4**
 - b. -2320 Epi-Pen **#A5**
 - c. -4200 Remote Distribution Facility **#A6**
 - e) Div 043 - Family Planning / County Health Rules **#A7**
 - f) Div 110 – update CPT Biennial and Workforce data collection fee **#A8**
 - 4. Consider Adoption of Rules
 - g) Div 019 - Contraceptive rules **#A9 to A12**
 - 5. Policy Issues for Discussion
 - h) Naloxone **#F4**
- B. Discussion Items
 - 1. Waiver/Exception/Extensions/New Application Requests – none
 - 2. ORS 689 Review for Housekeeping Legislative Concept – *Karbowicz* **#B**
(15 min) *Action Necessary*
 - 3. OBOP Special Records Retention Schedule – *MacLean* **#**
(20 min) *Action Necessary*
 - 4. Staff Authority Grid discussion – Miner **#B2** (20 min)
 - 5. Technician Discussion – *Watt/Cowan/Miner* (30 min)

APPEARANCES

11:00 AM Debbie Mack, RPh, CCEP, CHC, Wal-Mart, Senior Director, Corporate Compliance
Tim Koch, RPh, CHC, Wal-Mart, Senior Director, Corporate Compliance
RE: Technician Certification Requirements (1 hr)

12:00-1:00 Lunch

Resume outstanding Discussion items or move on to Issues and Activities

***VII. ISSUES/ACTIVITIES**

***A. Reports:**

1. Board President/Members
2. Executive Director **#C**
3. Compliance Director
4. Pharmacist Consultant
5. Administrative Director
6. Licensing Department Supervisor

***B. Board Member/Staff Presentations – Linares**

- Pharmacy Coalition – 3/15/16
- Professional Practice Roundtable – 3/15/16, 5/10/16
- Health System Outreach Meeting – 4/19/16

***C. Committees/Meetings**

1. OSPA Lane Co. Mid-Winter Mtg, 2/27-28/2016, Eugene, OR – *Watt/Karbowicz*
2. OSHP Annual Seminar, 4/22-24/2016, Sunriver, OR – *Watt/Karbowicz/Wallace*
3. Linn Benton Pharmacy Association Mtg, 4/26/16, Corvallis, OR *Karbowicz*
4. NABP 112th Annual Meeting – 5/14-17/2016, San Diego, CA – *James/Watt*
#D-D1and D2 – CONFIDENTIAL (15 min) *Action Necessary*
5. NABP 2016 District VI-VIII Meeting 9/11-14/2016, Portland, OR – *Watt/MacLean*

***D. Board Meeting Dates**

- June 8-9, 2016 Portland
- August 10-12, 2016* Portland (3 day meeting planned)
- September 11-14, 2016 Portland NABP District VI-VII annual meeting
- October 5-6, 2016 Portland
- November 2-3, 2016 TBA (Strategic Planning)
- December 7-8, 2016 Portland
- February 8-10, 2017* Portland (3 day meeting planned)
- April 5-6, 2017 Portland
- June 7-8, 2017 Portland
- August 9-11, 2017* Portland (3 day meeting)
- October 11-10, 2017 Portland
- November 8-9, 2017 TBA (Strategic Planning)
- December 13-14, 2017 Portland

*E. Rulemaking Hearing Dates

- May 24, 2016
- November 22, 2016
- May 25, 2017
- November 28, 2017

*F. Financial/Budget Report – *Watt/MacLean* #E (10 min)

G. Legislative 2016 Session update – *Watt* (20 min)

- Charitable Pharmacy, SB 1514 #F
- HPSP concept HB 4016 #F1
- Biosimilar, HB 4105 #F3
- Naloxone, HB 4124 #F4

H. Strategic Planning – *MacLean/Karbowicz*

- Review & status update re: 2014 plan #G
- Review & status update re: 2015 plan #
- 2016 planning update

Action Necessary

I. 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.

1. NAPLEX Scores – May 1, 2015-December 31, 2015

#H-H2 CONFIDENTIAL

2. MPJE Scores – May 1, 2015 – December 31, 2015

#H3-H4 CONFIDENTIAL

3. License/Registration Ratification - February 9, 2016 – April 5, 2016

4. Extension Requests – #H5

5. Approval of Board Meeting Minutes – February 10-13, 2016

VIII. OPEN FORUM At the completion of regular Board Business, any Board licensee or member of the public is invited to meet with the Board to discuss issues of interest (typically the last item of the meeting)

Adjourn



Oregon

Kate Brown, Governor

Oregon Board of Pharmacy
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To: Board Members

From: Karen MacLean, Hearing Officer

Date: March 23, 2016

Subject: Hearing Officer's Report for Proposed Rules in Division 019

General Background:

A public hearing was held at the Portland State Office Building, located at 800 NE Oregon St. Conference Room 1A Portland, OR 97232 on March 23, 2016 at 9:30am. The purpose of the hearing was to receive public comment on the following proposed rules:

- Div 019 Pharmacist Prescriptive Authority

These proposed rules permanently implement administrative rules for 2015 HB 2879 that were previously adopted as Temporary Rules in November 2015.

The Rulemaking Hearing deadline for comments as noticed in the March 2016 Bulletin was 4:30 p.m. on March 23, 2016 in order for comments to be taken into consideration.

The following Board Members were in attendance in person or by phone: Roberto Linares, Kate James, Brad Fujisaki, Heather Anderson, Ken Wells, Penny Reher, Christine Chute and Cyndi Vipperman.

Summary of Oral Testimony:

Four individuals provided oral testimony or comment on proposed rules in Division 019.

Paige Clark, RPh from Oregon State University (OSU), commented that she had just returned from presenting at an APHA conference on this topic and the training. People are impressed with this law and the Oregon Board of Pharmacy (OBOP) rules for implementation in Div 019. She thanked the Board and Staff for all of their work. She provided some additional information to the Board for review at the April Board meeting regarding the OSU training program roll out and feedback.

Joe Schnabel, RPh commented that he thought the rules were very good and that he has taught them to the OSU Law class.

Marcie Sauer RPh commented that she had recently completed the training, but hadn't applied it yet. She thinks there needs to be something in the rules about transferring prescriptions. Executive Director Marc Watt commented that OBOP could address this in the FAQ's, but confirmed that a prescription can be transferred. It was also pointed out that OAR 855-019-0425(3) covers this issue.

James Bui, RPh commented that he sees some ambiguity regarding the appointment issue. At Costco their policy is no appointments, however if they are busy and the individual wants to come back when the pharmacist has more time, they will set an appointment. He wondered if a sign to that effect would be acceptable.

For the interest of the group, I read the two written comments received by e-mail to the group that was present from Valerie Bousquet and Kristin Wagner.

Summary of Written Comments:

The Board received two written comments on proposed rules in Division 019.

Written Comments:

Both written comments questioned the same issue relating to why a pharmacist is not allowed to make appointments for prescribing.

Director Watt spoke to this issue and pointed out that it was actually a part of the legislation, which is why it was included in the rule. The legislative interested parties felt strongly that an appointment could be seen as a barrier to access.

The hearing was attended by 16 individuals. When asked if anyone else had additional comments, there were none. Receiving no other comment, the hearing was closed at approximately 9:55am; copies of written comment are included as part of the permanent rulemaking record.

From: [Kristin Wagner](#)
To: [Karen S MacLean](#)
Subject: Div 019 Pharmacist Prescriptive Authority
Date: Tuesday, March 22, 2016 5:38:49 PM

Good day,

Regarding the rulemaking hearing scheduled for tomorrow, March 23rd, 2016, I have the following comment:

Why is a pharmacist not allowed to make appointments for prescribing of contraceptive tablets or patches?

If the intent of the law is to increase access and not put a higher standard on pharmacists relative to what other prescribers are required to do, NOT allowing appointments seems counter productive. Doctors, nurse practitioners, or physicians assistants ALL would require a first-time patient to have an appointment.

Keeping in mind pharmacy workflow, not allowing appointments could actually decrease access. This one sentence would make me decide not to offer this service.

Thank you for your consideration,

Kristin Dome RPH
(509) 981-9950

From: [Valerie Bousquet](#)
To: [Karen S MacLean](#)
Subject: Notice of Proposed Rule-making Hearing
Date: Saturday, March 19, 2016 2:42:31 PM

I would like to comment on 855-019-0430 97
regarding: A Pharmacist must not require a patient to schedule an appointment....for the dispensing
of....contraceptive...

Pharmacists, being the most accessible health care professionals, are working in environments where business volume is already unpredictable and much of the time chaotic. The Pharmacist should have flexibility to be able to deliver the professional care that will be required for assessing appropriate contraceptive prescribing. We should be able to have control over our work flow in order to provide safe care for all of our patients. If we are denied this control, we will be placed into a situation where the safety of all our patients will be diminished as we are pulled into many directions. We should be able to ask our patients to come back at a reasonable time so we can meet their needs without being rushed.

I suggest that this statement be removed from proposed rules so that individual pharmacies can determine how to best accomplish a work flow so that we provide safe care to our patients.

Respectfully Submitted
Valerie Bousquet Pham D

1 **855-006-0005**2 **Definitions**

3 As used in OAR chapter 855:

4 (1) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required
5 by the context.6 (2) "Certified Pharmacy Technician" means a person licensed by the State Board of
7 Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the
8 Board and has completed the specialized education program pursuant to OAR 855-025-
9 0005. Persons used solely for clerical duties, such as recordkeeping, cashiering,
10 bookkeeping and delivery of medications released by the pharmacist are not considered
11 pharmacy technicians.12 (3) "Clinical Pharmacy Agreement" means an agreement between a pharmacist or
13 pharmacy and a health care organization or a physician that permits the pharmacist to
14 engage in the practice of clinical pharmacy for the benefit of the patients of the health
15 care organization or physician.16 (4) "Collaborative Drug Therapy Management" means the participation by a pharmacist
17 in the management of drug therapy pursuant to a written protocol that includes
18 information specific to the dosage, frequency, duration and route of administration of the
19 drug, authorized by a practitioner and initiated upon a prescription order for an individual
20 patient and:

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

22 (b) Is agreed to by one or more pharmacists at a single pharmacy registered by the board
23 and one or more practitioners in a single organized medical group, such as a hospital
24 medical staff, clinic or group practice, including but not limited to organized medical
25 groups using a pharmacy and therapeutics committee.26 (5) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of
27 a drug or device:28 (a) As the result of a practitioner's prescription drug order, or initiative based on the
29 relationship between the practitioner, the pharmacist and the patient, in the course of
30 professional practice; or31 (b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and
32 not for sale or dispensing; or33 (c) The preparation of drugs or devices in anticipation of prescription drug orders based
34 on routine, regularly observed prescribing patterns; or35 (d) As a component of a Shared Pharmacy Service agreement as defined in section (21)
36 of this rule.37 (6) "Confidential Information" means any patient information obtained by a pharmacist
38 or pharmacy.39 (7) "Consulting Pharmacist" means a pharmacist that provides a consulting service
40 regarding a patient medication, therapy management, drug storage and management,
41 security, education, or any other pharmaceutical service.42 (8) The "Container" is the device that holds the drug and that is or may be in direct
43 contact with the drug.44 (9) "Dispensing or Dispense" means the preparation and delivery of a prescription drug
45 pursuant to a lawful order of a practitioner in a suitable container appropriately labeled

46 for subsequent administration to or use by a patient or other individual entitled to receive
47 the prescription drug.

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

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

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

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

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

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

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

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

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

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

82 (d) Maintaining confidentiality of patient information.

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

88 (18) Participation in Drug Selection and Drug Utilization Review:

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

- 91 (b) "Drug utilization review" means evaluating prescription drug order in light of the
 92 information currently provided to the pharmacist by the patient or the patient's agent and
 93 in light of the information contained in the patient's record for the purpose of promoting
 94 therapeutic appropriateness by identifying potential problems and consulting with the
 95 prescriber, when appropriate. Problems subject to identification during drug utilization
 96 review include, but are not limited to:
- 97 (A) Over-utilization or under-utilization;
 - 98 (B) Therapeutic duplication;
 - 99 (C) Drug-disease contraindications;
 - 100 (D) Drug-drug interactions;
 - 101 (E) Incorrect drug dosage;
 - 102 (F) Incorrect duration of treatment;
 - 103 (G) Drug-allergy interactions; and
 - 104 (H) Clinical drug abuse or misuse.
- 105 (19) "Pharmaceutical Care" means the responsible provision of drug therapy for the
 106 purpose of achieving definite outcomes that improve a patient's quality of life. These
 107 outcomes include:
- 108 (a) Cure of a disease;
 - 109 (b) Elimination or reduction of a patient's symptomatology;
 - 110 (c) Arrest or slowing of a disease process; or
 - 111 (d) Prevention of a disease or symptomatology.
- 112 (20) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy
 113 who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board but
 114 has not completed the specialized education program pursuant to OAR 855-025-0012.
- 115 (21) "Practice of clinical pharmacy" means:
- 116 (a) The health science discipline in which, in conjunction with the patient's other
 117 practitioners, a pharmacist provides patient care to optimize medication therapy and to
 118 promote disease prevention and the patient's health and wellness;
 - 119 (b) The provision of patient care services, including but not limited to post-diagnostic
 120 disease state management services; and
 - 121 (c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.
- 122 (22) "Practice of pharmacy" is as defined in ORS 689.005.
- 123 (23) "Prescription released by the pharmacist" means, a prescription which has been
 124 reviewed by the pharmacist that does not require further pharmacist intervention such as
 125 reconstitution or counseling.
- 126 (24) "Prohibited conduct" means conduct by a licensee that:
- 127 (a) Constitutes a criminal act against a patient or client; or
 - 128 (b) Constitutes a criminal act that creates a risk of harm to a patient or client.
- 129 (25) "Proper and safe storage of drugs and devices and maintenance of proper records
 130 therefore" means housing drugs and devices under conditions and circumstances that:
- 131 (a) Assure retention of their purity and potency;
 - 132 (b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other
 133 reason;
 - 134 (c) Assure security and minimize the risk of their loss through accident or theft;
 - 135 (d) Accurately account for and record their receipt, retention, dispensing, distribution or
 136 destruction;

- 137 (e) Protect the health, safety and welfare of the pharmacist, pharmacy staff and the
 138 general public from harmful exposure to hazardous substances.
- 139 (26) **“Quality assurance plan” is a written set of procedures to ensure that a**
 140 **pharmacy has a planned and systematic process for the monitoring and evaluation**
 141 **of the quality and appropriateness of pharmacy services and for identifying and**
 142 **resolving problems.**
- 143 ~~(26)~~ **(27)** "Responsibility for advising, when necessary or when regulated, of therapeutic
 144 values, content, hazards and use of drugs and devices" means advice directly to the
 145 patient, either verbally or in writing as required by these rules or federal regulation, of the
 146 possible therapeutic response to the medication, the names of the chemicals in the
 147 medication, the possible side effects of major importance, and the methods of use or
 148 administration of a medication.
- 149 ~~(27)~~ **(28)** "Shared Pharmacy Service" means a written agreement, that has been approved
 150 in writing by the board, that exists for the processing by a pharmacy of a request from
 151 another pharmacy or a practitioner licensed to prescribe the drug, to fill or refill a
 152 prescription or a drug order, or to perform processing functions including but not limited
 153 to:
- 154 (a) Dispensing;
 155 (b) Drug utilization review;
 156 (c) Claims adjudication;
 157 (d) Refill authorizations;
 158 (e) Compounding by a pharmacy located in Oregon for a practitioner or dispenser located
 159 in Oregon for Oregon outlets and practitioners located in Oregon only; and
 160 (f) Therapeutic interventions.
- 161 ~~(28)~~ **(29)** "Specialized Education Program" means;
 162 (a) A program providing education for persons desiring licensure as pharmacy
 163 technicians that is approved by the board and offered by an accredited college or
 164 university that grants a two-year degree upon successful completion of the program; or
 165 (b) A structured program approved by the board and designed to educate pharmacy
 166 technicians in one or more specific issues of patient health and safety that is offered by:
 167 (A) An organization recognized by the board as representing pharmacists or pharmacy
 168 technicians;
 169 (B) An employer recognized by the board as representing pharmacists or pharmacy
 170 technicians; or
 171 (C) A trade association recognized by the board as representing pharmacies.
- 172 ~~(29)~~ **(30)** "Supervision by a pharmacist" means being stationed within the same work area
 173 as the pharmacy technician or certified pharmacy technician being supervised, coupled
 174 with the ability to control and be responsible for the pharmacy technician or certified
 175 pharmacy technician's action.
- 176 ~~(30)~~ **(31)** "Therapeutic substitution" means the act of dispensing a drug product with a
 177 different chemical structure for the drug product prescribed under circumstances where
 178 the prescriber has not given clear and conscious direction for substitution of the particular
 179 drug for the one which may later be ordered.
- 180 ~~(31)~~ "Unprofessional conduct" means ~~conduct unbecoming a licensee or detrimental to~~
 181 ~~the best interests of the public, including conduct contrary to recognized standards of~~

182 ethics of pharmacy or conduct that endangers the health, safety or welfare of a patient or
 183 client. Unprofessional conduct includes but is not limited to:
 184 (a) Fraud or misrepresentation in dealings relating to pharmacy practice with:
 185 (A) Customers, patients or the public;
 186 (B) Practitioners authorized to prescribe drugs, medications or devices;
 187 (C) Insurance companies;
 188 (D) Wholesalers, manufactures or distributors of drugs, medications or devices;
 189 (E) Health care facilities;
 190 (F) Government agencies; or
 191 (G) Drug outlets.
 192 (b) Illegal use of drugs, medications or devices without a practitioner's prescription, or
 193 otherwise contrary to federal or state law or regulation;
 194 (c) Any use of intoxicants, drugs or controlled substances that endangers or could
 195 endanger the licensee or others;
 196 (d) Theft of drugs, medications or devices, or theft of any other property or services
 197 under circumstances which bear a demonstrable relationship to the practice of pharmacy;
 198 (e) Dispensing a drug, medication or device where the pharmacist knows or should know
 199 due to the apparent circumstances that the purported prescription is bogus or that the
 200 prescription is issued for other than a legitimate medical purpose, including
 201 circumstances such as:
 202 (A) Type of drug prescribed;
 203 (B) Amount prescribed; or
 204 (C) When prescribed out of context of dose.
 205 (f) Any act or practice relating to the practice of pharmacy that is prohibited by state or
 206 federal law or regulation;
 207 (g) The disclosure of confidential information in violation of Board rule;
 208 (h) Engaging in collaborative drug therapy management in violation of ORS Chapter 689
 209 and the rules of the Board;
 210 (i) Authorizing or permitting any person to practice pharmacy in violation of the Oregon
 211 Pharmacy Act or the rules of the Board;
 212 (j) Any conduct or practice by a licensee or registrant which the Board determines is
 213 contrary to accepted standards of practice; or
 214 (k) Failure to cooperate with the Board pursuant to OAR 855-001-0035.
 215 (32) "Verification" means the confirmation by the pharmacist of the correctness,
 216 exactness, accuracy and completeness of the acts, tasks, or functions performed by an
 217 intern or a pharmacy technician or a certified pharmacy technician.

218
 219 Stat. Auth.: ORS 689.205
 220 Stats. Implemented: ORS 689.005, 689.151, 689.155, 689.305, 689.405 & 689.455,
 221 689.645 & 2015 OL Ch. 362
 222

223 **855-006-0015**

224 **Additional Definitions**

225 (1) Electronically Transmitted Prescription:
 226 (a) Where used in this chapter, Electronically Transmitted Prescription (ETP) means a
 227 prescription for a drug or medical device issued by a practitioner, who is licensed and

- 228 authorized to prescribe pursuant to the laws of this state and is acting within the scope of
 229 his or her practice, which has been transmitted by an electronic means that may include
 230 but is not limited to:
- 231 (A) Transmission by facsimile or hand held digital electronic device to a computer or
 - 232 facsimile;
 - 233 (B) Transmission from a computer to another computer;
 - 234 (C) Transmission by facsimile to computer; or
 - 235 (D) Transmission from a computer to facsimile.
- 236 (b) ETP does not include an oral prescription that has been reduced to writing by a
 237 pharmacist pursuant to OAR 855-041-0085 and does not include prescriptions, or drug or
 238 device orders written for inpatient use in a hospital.
- 239 (c) For an ETP to be valid, it must contain the name and immediate contact information
 240 of the prescriber, and be electronically encrypted or in some manner protected by up-to-
 241 date technology from unauthorized access, alteration or use.
- 242 (2) Tamper-resistant Prescription:
- 243 (a) Where used in this chapter, Tamper-resistant Prescription means a form for the
 - 244 purpose of issuing a hand written or typed prescription, intended to be manually delivered
 - 245 to a pharmacy, which has been developed, produced and formatted to ensure security,
 - 246 integrity and authenticity using currently accepted technologies.
 - 247 (b) Formatted features may include but are not limited to characteristics such as:
 - 248 (A) The word "void" appears when photocopies are attempted;
 - 249 (B) Background ink which reveals attempted alterations;
 - 250 (C) Heat sensitive ink that changes colors;
 - 251 (D) Penetrating ink to prevent chemical alterations;
 - 252 (E) A watermark which cannot be photocopied;
 - 253 (F) Coin reactive ink that reveals word when rubbed with a coin;
 - 254 (G) Sequential numbering.
- 255 **(3) "Unprofessional conduct" means conduct unbecoming a licensee or detrimental**
 256 **to the best interests of the public, including conduct contrary to recognized**
 257 **standards of ethics of pharmacy or conduct that endangers the health, safety or**
 258 **welfare of a patient or client. Unprofessional conduct includes but is not limited to:**
- 259 **(a) Fraud or misrepresentation in dealings relating to pharmacy practice with:**
 - 260 **(A) Customers, patients or the public;**
 - 261 **(B) Practitioners authorized to prescribe drugs, medications or devices;**
 - 262 **(C) Insurance companies;**
 - 263 **(D) Wholesalers, manufactures or distributors of drugs, medications or devices;**
 - 264 **(E) Health care facilities;**
 - 265 **(F) Government agencies; or**
 - 266 **(G) Drug outlets.**
 - 267 **(b) Illegal use of drugs, medications or devices without a practitioner's prescription,**
 268 **or otherwise contrary to federal or state law or regulation;**
 - 269 **(c) Any use of intoxicants, drugs or controlled substances that endangers or could**
 270 **endanger the licensee or others;**
 - 271 **(d) Theft of drugs, medications or devices, or theft of any other property or services**
 272 **under circumstances which bear a demonstrable relationship to the practice of**
 273 **pharmacy;**

- 274 **(e) Dispensing a drug, medication or device where the pharmacist knows or should**
275 **know due to the apparent circumstances that the purported prescription is bogus or**
276 **that the prescription is issued for other than a legitimate medical purpose, including**
277 **circumstances such as:**
278 **(A) Type of drug prescribed;**
279 **(B) Amount prescribed; or**
280 **(C) When prescribed out of context of dose.**
281 **(f) Any act or practice relating to the practice of pharmacy that is prohibited by**
282 **state or federal law or regulation;**
283 **(g) The disclosure of confidential information in violation of Board rule;**
284 **(h) Engaging in collaborative drug therapy management in violation of ORS**
285 **Chapter 689 and the rules of the Board;**
286 **(i) Authorizing or permitting any person to practice pharmacy in violation of the**
287 **Oregon Pharmacy Act or the rules of the Board;**
288 **(j) Any conduct or practice by a licensee or registrant which the Board determines is**
289 **contrary to accepted standards of practice; or**
290 **(k) Failure to cooperate with the Board pursuant to OAR 855-001-0035.**

291
292 Stat. Auth.: 689.205

293 Stats. Implemented: ORS **689.005 and** 689.155

1 **855-019-0300**

2 **Duties of a Pharmacist-in-Charge**

3 (1) In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have
 4 one Pharmacist-in-Charge (PIC) **practicing onsite an average of 20 hours or fifty percent of**
 5 **the pharmacy operating hours if less than 40 hours per week except as authorized by**
 6 **855-041-1010(2)** employed on a regular basis.

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

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

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

12 (3) A pharmacist may not be designated PIC of more than two **Oregon licensed** pharmacies.
 13 ~~without prior written approval by the Board. If such approval is given, the pharmacist must~~
 14 ~~comply with the requirements in sub-section (4)(e) of this rule. **A pharmacist may be**~~
 15 **designated as a PIC of up to two Oregon licensed pharmacies only upon notification of the**
 16 **second site to the Board in writing.**

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

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

20 (b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within
 21 15 days of becoming PIC;

22 (c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the
 23 pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may
 24 be granted as specified in OAR 855-041-0420 **6310**;

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

28 ~~(e) A pharmacist designated as PIC for more than one pharmacy shall personally conduct and~~
 29 ~~document a quarterly compliance audit at each location. This audit shall be on the Quarterly PIC~~
 30 ~~Compliance Audit Form provided by the Board;~~

31 ~~(f)~~**(e)** If a discrepancy is noted on a Board inspection, the PIC must submit a plan of correction
 32 within **15 days for a Non-Compliance Notification and** 30 days of receiving a **Deficiency**
 33 **Notification.** notice.

34 ~~(g)~~**(f)** The records and forms required by this section must be filed in the pharmacy, made
35 available to the Board for inspection upon request, and must be retained for three years.

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

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

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

43 (c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form
44 provided by the Board, by February 1 each year. The completed self-inspection forms must be
45 signed and dated by the PIC and maintained for three years from the date of completion;

46 (d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;

47 ~~(e) Performing a quarterly inventory reconciliation~~ **Maintaining a reconciled (written)**
48 **perpetual inventory** of all Schedule II controlled drugs **and confirm accuracy at least**
49 **monthly. The documentation of the cause of each discrepancy must be signed and dated by**
50 **the PIC and maintained for three years from the date of the audit.**

- 51 • *For discussion*
- 52 • *Do we need “written”?*
- 53 • *Do we need documentation of discrepancies?*

54

55 (f) Ensuring that all pharmacy staff ~~have been~~ **is** trained appropriately for the practice site. Such
56 training should include an annual review of the PIC Self-Inspection Report;

57 ~~(g) Implementing a~~ **Overseeing the** quality assurance plan, **per OAR 855-006,** for the pharmacy
58 **and make available to the Board upon request.**

59 (h) The records and forms required by this section must be filed in the pharmacy, made available
60 to the Board for inspection upon request, and must be retained for three years.

61 (6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in
62 compliance with all state and federal laws and rules governing the practice of pharmacy ~~and that~~
63 ~~all controlled substance records and inventories are maintained in accordance with all state and~~
64 ~~federal laws and rules.~~

65 Stat. Auth.: ORS 689.205

66 Stats. Implemented: ORS 689.151, 689.155

35 (1) The license of a Pharmacy Technician expires the second June 30 from the date of issue and
36 is not to exceed ~~more than~~ two years.

37 (2) The Pharmacy Technician license is not renewable, ~~except by petition to the Board.~~

38 **(3) A time limited extension of a Pharmacy Technician license may be granted once by**
39 **petition to the Board. The written completed petition must be received by the Board prior**
40 **to the expiration of the PT license.**

41 ~~(3)~~ **(4)** An individual may reapply for a Pharmacy Technician license if ~~his or her~~ **the** previous
42 **PT** license is lapsed for a period greater than five years ~~or by petition to the Board.~~

43 Stat. Auth.: ORS 689.205

44 Stats. Implemented: ORS 689.155

45 **855-025-0012**

46 **Licensure as a Certified Oregon Pharmacy Technician**

47 ~~(1) To obtain a Certified Oregon Pharmacy Technician license, the applicant must demonstrate~~
48 ~~that the applicant~~ **qualify for licensure as a Certified Oregon Pharmacy Technician, the**
49 **applicant must demonstrate that he or she** has taken and passed a national pharmacy
50 technician certification examination offered by:

51

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

53

54 (b) The National Healthcareer Association (NHA).

55

56 (2) The license of a Certified Oregon Pharmacy Technician expires ~~September~~ **June 30 in even**
57 **numbered years and must be renewed biennially** ~~annually.~~

58

59 Stat. Auth.: ORS 689.205

60 Stats. Implemented: ORS 689.155

61

62 **855-025-0015**

63 **Renewal of Licensure as a Certified Oregon Pharmacy Technician**

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

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

68 (a) Pay the **biennial** license fee prescribed in OAR 855-110.

69 (b) Satisfactorily complete a minimum of ~~120~~ continuing pharmacy educating hours during the
 70 period from ~~September~~ **July 1** through ~~August 31,~~ **June 30**, of each license renewal cycle. These
 71 hours must include:

72 (A) ~~One~~ **Two** hours of continuing pharmacy education in pharmacy law;

73 (B) ~~One~~ **Two** hours of continuing pharmacy education in patient safety or error prevention; and

74 (C) ~~Eight~~ **Sixteen** other hours of continuing pharmacy education ~~hours~~ or documented onsite
 75 training, approved by the Board.

76 (c) OAR 855-025-0015(2)(b) does not apply to **a** Certified Oregon Pharmacy Technicians
 77 applying for the first renewal of their license, if they have not been licensed by the Board for at
 78 least one year prior to ~~October 1~~ **July 1** of the renewal period.

79 (d) Be subject to an annual criminal background check.

80 (3) The Board may randomly select and audit applications for renewal to verify completion of
 81 ~~the~~ continuing education or documented onsite training reported on the application for renewal.
 82 **A** Certified Oregon Pharmacy Technicians whose applications for renewal ~~are~~ **is** selected for
 83 audit must provide documentation of completion of the continuing pharmacy education reported.

84 (4) Effective January 1, 2015, national certification is not required to renew a license as a
 85 Certified Oregon Pharmacy Technician.

86 (5) A Certified Oregon Pharmacy Technician who fails to renew his or her license by the
 87 expiration date and whose license has been ~~less than 180 days~~ **lapsed for less than one year** may
 88 renew his or her license as follows:

89 **(a) Complete the renewal process;**

90 ~~(a)~~ **(b) Pay the biennial license fee as prescribed in OAR 855-110.;** **and**

91 ~~(b)~~ **(c) Pay a delinquent fee.;** **and**

92 **(d) Complete the required continuing education pursuant to OAR 855-025-0015(2)(b).**

93 ~~(6) A Certified Oregon Pharmacy Technician who fails to renew their license by the deadline and~~
 94 ~~whose license has been lapsed 180 days may reinstate his or her license under OAR 855-025-~~
 95 ~~0060(1).~~

96
 97 Stat. Auth.: ORS 689.205
 98 Stats. Implemented: ORS 689.155
 99

100 **855-025-0060**

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

102 (1) A Certified Oregon Pharmacy Technician who fails to renew their license by the deadline and
 103 whose license has been lapsed ~~180 days or longer~~ **for greater than one year** may reinstate their
 104 license as follows:

105 (a) Complete a new application for licensure and provide the Board with a valid e-mail address;
 106 ~~and~~

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

108 **(c) Submit to a national fingerprint background check;**

109 **(d) Provide certification of completion of 10 continuing education hours. These hours may**
 110 **not be counted toward renewal; and must include:**

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

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

113 **(C) Eight other hours of pharmacy technician-specific continuing education.**

114 (2) A Certified Oregon Pharmacy Technician whose license has been lapsed greater than ~~four~~
 115 **five** years must:

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

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

119 ~~(e a)~~ Re-take and pass a national pharmacy technician certification examination offered by:

120 (A) The Pharmacy Technician Certification Board (PTCB); or

121 (B) National Healthcareer Association (NHA).

122 (b) Satisfy reinstatement requirements pursuant to OAR 855-025-0060(1).

123 Stat. Auth.: ORS 689.205

124 Stats. Implemented: ORS 689.155

1 **855-041-1010**

2 **Personnel (Both Retail and Institutional Drug Outlets)**

3 (1) Each resident pharmacy must ~~have~~ **employ** one pharmacist-in-charge (**PIC**) ~~employed on a~~
 4 ~~regular basis at that location~~ who shall be responsible for the daily operation of the pharmacy.
 5 **The PIC must be practicing onsite a minimum of 20 hours or fifty percent of the pharmacy**
 6 **operating hours if less than 40 hours per week.** The pharmacist-in-charge shall be indicated on
 7 the application for a new or relocated pharmacy and for pharmacy renewal registration.

8 **(2) Upon written request, a waiver for the minimum time requirement in OAR 855-041-**
 9 **1010(1) may be submitted to the Board, if a waiver will further public health or safety. The**
 10 **request must include the period of time the waiver would be in effect and the reason for the**
 11 **request. A waiver under this section will only be effective when issued by the Board in**
 12 **writing.**

- 13 • *Grid item?*

14 **(3) In the absence of the PIC during an approved waiver period, the outlet will be**
 15 **responsible for completion of all time sensitive requirements, such as the annual inventory**
 16 **and PIC Self-Inspection Report.**

17 **(4) A resident pharmacy that terminates or allows a Board licensee to resign in lieu of**
 18 **termination must report the termination or resignation to the Board within 10 working**
 19 **days.**

20 **(5) A pharmacy must report a pharmacy medication error that results in serious patient**
 21 **harm or death of a patient within 10 working days.**

- 22 • *Define “serious patient harm”? or FAQ to address*
 23 ○ *NCCMERP/ASHP*
 24 ■ *An error that contributed to or resulted in temporary or permanent harm*
 25 ■ *An error that required initial or prolonged hospitalization*
 26 ■ *An error that required intervention necessary to sustain life*

27 **(6) (2) The A pharmacy must ensure that it is in compliance with all state and federal laws and**
 28 **rules governing the practice of pharmacy and that all controlled substance records and**
 29 **inventories are maintained in conformance with the keeping and inventory requirements of**
 30 **federal law and board rules.**

31 **(7) Unless state or federal laws relating to confidentiality or the protection of health**
 32 **information prohibit disclosure, a registrant who has reasonable cause to believe that**
 33 **another licensee has engaged in prohibited or unprofessional conduct shall report the**
 34 **conduct to the Board responsible for the licensee who is believed to have engaged in the**

35 **conduct. The reporting registrant shall report the conduct without undue delay, but in no**
36 **event later than 10 working days after the reporting registrant learns of the conduct.**

37 Stat. Auth.: ORS 689.205

38 Stats. Implemented: ORS 676.150, 689.151, 689.155, 689.305;

DRAFT

1 **855-041-2320**

2 **Epinephrine**

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

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

11 (a) Statement of Completion; and

12 (b) Authorization to Obtain Epinephrine.

13 (3) ~~(a) Distribution~~ **Acquisition** of epinephrine from a pharmacy to be used for the treatment of
14 allergic emergencies may occur in the following manner:

15 ~~(b)~~ **(a)** A trainee may ~~obtain~~ **acquire** epinephrine upon presentation of the Statement of
16 Completion and Authorization to Obtain Epinephrine certificate to a pharmacy which:

17 (A) A pharmacist may generate a prescription for, and dispense an emergency supply of
18 epinephrine for not more than one (1) child and one (1) adult in an automatic injection device, as
19 specified by the supervising professional whose name, signature, and license number appear on
20 the Authorization to Obtain Epinephrine certificate.

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

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

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

30 ~~(a)~~ **(E)** Both the Statement of Completion and the Authorization to Obtain Epinephrine
31 certificate expire three (3) years from the date of the trainee's last Oregon Health Authority
32 approved allergy response training.

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

35 **(b) An entity may acquire epinephrine if:**

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

37 **(B) The prescription identifies the entity as the patient for the purpose of prescribing;**

38 **(C) The pharmacist may dispense the epinephrine to the entity based on documentation**
39 **that the entity employs a person who has completed a completed training program**
40 **approved by the Oregon Health Authority for the treatment of allergic emergencies; and**

41 **(D) The pharmacist may use the name of the entity as the patient for the purpose of**
42 **labeling the prescription.**

43

44 Stat. Auth: ORS 689.205

45 Stats. Implemented: ORS 689.155, 433.825

46

47 **OHA Statute**

48 **ORS 433.825 Availability of doses of epinephrine, glucagon and medication that treats**
49 **adrenal insufficiency to trained persons.** (1)(a) A person who has successfully completed
50 educational training described in ORS 433.815 for severe allergic responses may receive from
51 any health care professional who has appropriate prescriptive privileges and who is licensed
52 under ORS chapter 677 or 678 in this state a prescription for premeasured doses of epinephrine
53 and the necessary paraphernalia for administration.

54 (b) An entity that employs a person described in paragraph (a) of this subsection may acquire
55 premeasured doses of epinephrine and the necessary paraphernalia for administration in
56 accordance with paragraph (c) of this subsection. A health care practitioner who has appropriate
57 prescriptive privileges and is licensed under ORS chapter 677 or 678 may write a prescription for
58 premeasured doses of epinephrine and the necessary paraphernalia in the name of an entity that
59 employs a person described in paragraph (a) of this subsection.

60 (c) A person described in paragraph (a) of this subsection may possess and administer, in an
61 emergency situation when a licensed health care professional is not immediately available,
62 prescribed epinephrine to any person suffering a severe allergic response.

63

Remote Distribution Facilities

855-041-4200

Remote Distribution Facility (RDF)

- (1) A pharmacy physically located in Oregon may make written application to operate an RDF.
- (2) At its discretion, the Board may approve an application for registration as an RDF which includes the following:
 - (a) An operation plan;
 - (b) Policies and Procedures;
 - (c) A training plan;
 - (d) A quality assurance plan for ensuring that there is a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems; and
 - (e) The fee specified in **OAR 855-110** ~~OAR 855-110-0007(14)~~.
- (3) Notwithstanding the definition of “supervision by a pharmacist” in OAR 855-006-0005, supervision in an RDF may be accomplished by a pharmacist via an audio-visual technology from the applying pharmacy.
- (4) Notwithstanding rules in this division and in Division 19 **and 25**, a Certified Pharmacy Technician who works in an RDF may have access to the facility without the physical presence of a pharmacist, but may only perform Board approved functions when under the supervision of a pharmacist.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

1 This proposed rule replaces OAR 855-043-0110 thru 0130 AND OAR 855-043-0300 thru 0310.
2 If adopted, the above will be repealed.

3 4 5 Community Health Clinic Drug Outlet

6 855-043-0700

7 Purpose and Scope

8 (1) The purpose of 855-043-0700 to 855-043-0750 is to provide minimum requirements of
9 operation for a Community Health Clinic (CHC) which utilizes Registered Nurses to
10 dispense medications. A Community Health Clinic drug outlet registration replaces a
11 Family Planning or County Health Drug Outlet registration. A legend or non-prescription
12 drug may be dispensed to a client for the purpose of birth control, caries prevention, the
13 treatment of amenorrhea, the treatment of a communicable disease, hormone deficiencies,
14 urinary tract infections or sexually transmitted diseases by a practitioner who has been
15 given dispensing privileges by their licensing Board, or a Registered Nurse, who is an
16 employee of a clinic or local public health authority (LPHA) that is registered with the
17 Board, and is recognized by the Oregon Health Authority for the purposes of providing
18 public health services.

19 (2) Such dispensing must be pursuant to the order or prescription of a person authorized
20 by their Board to prescribe a drug or established by the Medical Director or clinic
21 practitioner with prescriptive and dispensing authority.

22 Stat. Auth.: ORS 689.205

23 Stats. Implemented: ORS 689.305

24 25 855-043-0705

26 Registration

27 (1) A Community Health Clinic drug outlet must register with the Board on a form
28 prescribed by the Board, and must renew its registration annually on a renewal form
29 prescribed by the Board.

30 (2) An initial application and renewal application must be accompanied by the fee
31 established in Division 110 of this Chapter.

32 (3) A certificate of registration will be issued upon Board approval of the application.

33 (4) A CHC drug outlet registration expires March 31, annually. If the annual renewal fee
34 is not paid by February 28 of the current year, the applicant for renewal must submit the
35 delinquent fee established in Division 110 of this Chapter with the renewal application.

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

37 (6) The registrant must notify the Board, within 15 days, of any substantial change to the
38 information provided on the registration application. A substantial change shall include
39 but not be limited to: a change of ownership; change of business address; change of normal
40 business hours; any disciplinary action taken or pending by any state or federal authority
41 against the registrant, or any of its principals, owners, directors, officers, or medical
42 director.

43 (7) A new registration form is required for a change of ownership or location and must be
44 submitted to the Board with the fees as specified in Division 110 of this Chapter within 15
45 days of the change.

46 (8) A CHC drug outlet may be inspected by the Board.

47 Stat. Auth.: ORS 689.205

48 Stats. Implemented: ORS 689.305

49

50 855-043-0710

51 Personnel

52 (1) A Community Health Clinic drug outlet must employ a Medical Director who is an
53 Oregon practitioner with prescriptive and dispensing authority. The Medical Director shall
54 establish and enforce policies and procedures, drug dispensing formulary, and protocols
55 for the dispensing of drugs by authorized persons in the CHC.

56 (2) A CHC drug outlet must designate a representative employee who will act as the
57 Oregon Board of Pharmacy contact person. The designated representative must be on site
58 the majority of the CHC's normal operating hours.

59 (a) The Medical Director or designated representative must conduct and document an
60 annual review of the outlet on a form provided by the Board. The completed report form
61 must be filed in the outlet, retained on file for three years and be available to the Board for
62 inspection.

63 (b) The Medical Director shall develop policies and procedures for the outlet in
64 collaboration with the designated representative.

65 Stat. Auth.: ORS 689.205

66 Stats. Implemented: ORS 689.305

67

Policies and Procedures

68 855-043-0715

69 **The Community Health Clinic must:**

70 **(1) Maintain written policies and procedures for drug management, including security,**
71 **acquisition, storage, dispensing and drug delivery, disposal, record keeping; and**

72 **(2) Establish procedures to train a Registered Nurse employed by the CHC to ensure**
73 **continued competence in the dispensing of drugs.**

74 **Stat. Auth.: ORS 689.205**

75 **Stats. Implemented: ORS 689.305**

76

77 **855-043-0720**

78 **Security**

79 **(1) All drugs must be kept in a locked drug cabinet or designated drug storage area that is**
80 **sufficiently secure to deny access to unauthorized persons. The drug cabinet or designated**
81 **drug storage area must remain locked and secured when not in use.**

82 **(2) Only a Physician, Clinical Nurse Specialist, Nurse Practitioner, or Registered Nurse**
83 **shall have a key to the drug cabinet or drug room. In their absence, the drug cabinet or**
84 **drug room must remain locked.**

85 **(3) Upon written request, the Board may waive any of the requirements of this rule if a**
86 **waiver will further public health or safety or the health and safety of a patient. A waiver**
87 **granted under this section shall only be effective when it is issued by the Board in writing.**

88 **Stat. Auth.: ORS 689.205**

89 **Stats. Implemented: ORS 689.305**

90

91 **855-043-0725**

92 **Drug Acquisition**

93 **The CHC must verify that all drugs are acquired from a registrant of the Board.**

94 **Stat. Auth.: ORS 689.205**

95 **Stats. Implemented: ORS 689.305**

96

97 **855-043-0730**

98 **Storage of Drugs**

99 **All drugs, including drug samples, must be stored according to manufacturer's published**
100 **guidelines and be stored in appropriate conditions of temperature, light, humidity,**
101 **sanitation, ventilation, and space.**

102 **Stat. Auth.: ORS 689.205**
103 **Stats. Implemented: ORS 689.305**

104

105 **855-043-0735**

106 **Labeling**

107 **(1) A prescription must be labeled with the following information:**

108 **(a) Unique identifier (i.e. prescription number);**

109 **(b) Name of patient;**

110 **(c) Name of prescriber;**

111 **(d) Name, address, and phone number of the clinic;**

112 **(e) Date of dispensing;**

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

115 **(g) Quantity dispensed;**

116 **(h) Directions for use;**

117 **(i) Initials of the practitioner who has been given dispensing privileges by their licensing**
118 **Board or the Registered Nurse;**

119 **(j) Cautionary statements, if any, as required by law; and**

120 **(k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient**
121 **should not use the drug; and**

122 **(2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the**
123 **practice of an Expedited Partner Therapy treatment protocol, the name of the patient may**
124 **be omitted from the label, the patient's name may be omitted from the records and a drug**
125 **may be dispensed to the patient to be given to the patient's partner even if the partner has**
126 **not been examined by a licensed health care provider acting within their scope of practice.**

127 Stat. Auth.: ORS 689.205
128 Stats. Implemented: ORS 689.305. 689.505
129

130 855-043-0740

131 Dispensing and Drug Delivery

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

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

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

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

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

145 (6) All drugs must be dispensed in a new container that complies with the current
146 provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S.
147 2162) and rules or regulations and with the current United States Pharmacopoeia/National
148 Formulary monographs for preservation, packaging, storage and labeling.

149 (7) Drugs must be repackaged by the practitioner, Registered Nurse, a pharmacy; or a
150 manufacturer registered with the Board.

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

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

156 Stat. Auth.: ORS 689.205
157 Stats. Implemented: ORS 689.305

158 855-043-0750

159 **Disposal of Drugs**

160 **Drugs that are outdated, damaged, deteriorated, misbranded, adulterated, or identified as**
161 **suspect or illegitimate must be documented, quarantined and physically separated from**
162 **other drugs until they are destroyed or returned to the supplier.**

163 **Stat. Auth.: ORS 689.205**

164 **Stats. Implemented: ORS 689.305**

165 **855-043-0750**

166 **Record Keeping**

167 **(1) A dispensing record must be maintained separately from the patient chart and kept for**
168 **a minimum of three years. The record must show, at a minimum, the following:**

169 **(a) Name of patient;**

170 **(b) Unique identifier (i.e. prescription number);**

171 **(c) Dose, dosage form, quantity dispensed and either the brand name of drug, or generic**
172 **name and name of manufacturer or distributor;**

173 **(d) Directions for use;**

174 **(e) Date of dispensing; and**

175 **(f) Initials of person dispensing the prescription.**

176 **(2) All records of receipt and disposal of drugs must be kept for a minimum of three years.**

177 **(3) All records required by these rules or by other State and federal law must be readily**
178 **retrievable and available for inspection by the Board.**

179 **Stat. Auth.: ORS 689.205**

180 **Stats. Implemented: ORS 689.305**

1 **855-110-0003**

2 **General**

3 (1) All fees paid under these rules are non-refundable.

4 (2) Fees cannot be prorated.

5 (3) Fees for initial licensure as a Pharmacist or Certified Oregon Pharmacy Technician may
6 be reduced to one half of a biennial rate, if the application is received or the mailing date of the
7 application is postmarked within 180 days of expiration.

8 (4) A delinquent fee must be paid:

9 (a) When an application is postmarked after the date specified in these rules; or

10 (b) When the Board requests additional information from an applicant and this information is not
11 provided within 30 days.

12 (5) A delinquent fee may be assessed when an application is submitted incomplete and the Board
13 requests the missing information.

14 Stat. Auth.: ORS 689.205

15 Stats. Implemented: ORS 689.135

16

17 **855-110-0005**

18 **Licensing Fees**

19 (1) Pharmacist license examination (NAPLEX) and re-examination fee — \$50.

20 (2) Pharmacist jurisprudence (MPJE) re-examination fee — \$25.

21 (3) Pharmacist licensing by reciprocity fee — \$200*. (*Temporary revenue surplus fee reduction
22 pursuant to ORS 291.055(3)). Fee reduction shall be effective retroactive to July 1, 2013.

23 (4) Pharmacist licensing by score transfer fee — \$200*. (*Temporary revenue surplus fee
24 reduction pursuant to ORS 291.055(3)).

25 (5) Intern license fee. Expires November 30 every two years — \$50.

26 (6) Pharmacist:

27 (a) Biennial license fee. Expires June 30 each odd numbered year. The biennial license fee is —
28 \$120. Delinquent renewal fee, (postmarked after May 31) — \$50.

29 (b) Electronic Prescription Monitoring Fund fee. Due by June 30 biennially— \$50. (This is a
30 mandatory fee, required by ORS 431.972 that must be paid with the pharmacist license renewal
31 fee).

32 (c) Workforce Data Collection fee. Due by June 30 biennially — ~~\$54~~. (This is a mandatory fee, ~~it~~
33 ~~may be charged annually at \$2.50 per year~~ as required by OAR 409-026-0130 that must be paid
34 with the Pharmacist license renewal fee.

35 (7) Certification of approved provider of continuing education course fee, none at this time.

36 (8) Pharmacy Technician license fee — \$50.

37 (a) A Pharmacy Technician license initially issued prior to January 1, 2015 to a person under 18
38 years of age expires June 30 in odd numbered years — \$50. Delinquent renewal fee,
39 (postmarked after May 31) — \$20.

40 (9) Certified Oregon Pharmacy Technician:

41 (a) ~~Biennial~~ License fee. Expires ~~September~~ June 30 each even numbered year annually —
42 \$50. Delinquent renewal fee, (postmarked after August 31) — \$20.

43 (b) Workforce Data Collection fee. Due by June 30 biennially — ~~\$54~~. (This is a mandatory fee,
44 ~~it may be charged annually at \$2.50 per year~~ as required by OAR 409-026-0130 that must be
45 paid with the Certified Oregon Pharmacy Technician license renewal fee.

46 Stat. Auth.: ORS 689.205 & 291.055 & 183.705

47 Stats. Implemented: ORS 689.135, 431.972 & 676.410

48

49 **855-110-0010**

50 **Fees for Registration for Controlled Substances under ORS 475.095**

51 (1) Animal Euthanasia controlled substance registration fee — \$50 annually.

52 (2) Drug Distribution Agent controlled substance registration fee — \$50* annually. (*Temporary
53 revenue surplus fee reduction pursuant to ORS 291.055(3)).

54 (3) Drug Room (including correctional facility) controlled substance registration fee — \$50*
55 annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)).

56 (4) Manufacturer controlled substance registration fee — \$50* annually. (*Temporary revenue
57 surplus fee reduction pursuant to ORS 291.055(3)).

58 (5) Retail or Institutional Drug Outlet controlled substance registration fee — \$50* annually.
59 (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)).

60 (6) Schedule II Precursor registration fee — \$50* annually. (*Temporary revenue surplus fee
61 reduction pursuant to ORS 291.055(3)).

62 (7) Wholesaler controlled substance registration fee — \$50* annually. (*Temporary revenue
63 surplus fee reduction pursuant to ORS 291.055(3)).

64 (8) Remote ~~Dispensing~~ **Distribution** Facility controlled substance registration fee — \$50*
65 annually. (*Temporary revenue surplus fee reduction pursuant to ORS 291.055(3)).

66 Stat. Auth.: ORS 689.205 & 291.055

67 Stats. Implemented: ORS 689.135 & 2013 OL Ch. 503

DRAFT

1 Prescriptive Authority

2 855-019-0400

3 Purpose

4 The purpose of rules OAR 855-019-0400 through 855-019-0435, operative January 1, 2016,
5 is to develop standard procedures for the prescribing of hormonal contraceptive patches
6 and oral contraceptives by an Oregon licensed pharmacist, providing timely access to care.
7 To ensure public safety and provide a consistent level of care, a pharmacist may participate
8 upon completion of a Board approved training program. Under the rules of this section, a
9 qualified pharmacist may prescribe hormonal contraceptives to a patient pursuant to a
10 self-screening risk assessment questionnaire and standard procedural algorithm.

11 Stat. Auth.: ORS 689.205

12 Stats. Implemented: ORS 689.005 & 689.683

13 855-019-0405

14 Definitions

15 In OAR 855-019-0400 through 855-019-0435:

16 (1) “Clinical visit” means a consultation with a healthcare provider, other than a
17 pharmacist, for women’s health, which should address contraception and age-appropriate
18 screening.

19 (2) “Hormonal contraceptive patch” means a transdermal patch applied to the skin of a
20 patient, by the patient or by a practitioner, that releases a drug composed of a combination
21 of hormones that is approved by the United States Food and Drug Administration to
22 prevent pregnancy.

23 (3) “Oral hormonal contraceptive” means a drug composed of a combination of hormones
24 that is approved by the United States Food and Drug Administration to prevent pregnancy
25 and that the patient to whom the drug is prescribed may take orally.

26 Stat. Auth.: ORS 689.205

27 Stats. Implemented: ORS 689.005 & 689.683

28 855-019-0410

29 Prescriptive Practice Consultation

30 In an effort to clarify, improve, and support appropriate pharmacist prescribing, the
31 Board shall periodically review prescribing standards, practices, and scope in consultation
32 with designated representatives from the Oregon Medical Board, Oregon State Board of

33 Nursing, and Oregon Health Authority. The Board will seek recommendations from these
34 representatives to be considered in conjunction with American Congress of Obstetricians
35 and Gynecologists (ACOG) guidelines and other evidence-based standards, as it seeks to
36 evaluate and improve prescribing practices within pharmacy. To the extent that developed
37 standards are incorporated into practice, the forms, screening tools, or requisite training
38 materials shall be prepared by the Board in consultation with these designated
39 representatives.

40 Stat. Auth.: ORS 689.205
41 Stats. Implemented: ORS 689.005 & 689.683

42 855-019-0415

43 Training Program

44 (1) Only a pharmacist, who has completed a Board approved Accreditation Council for
45 Pharmacy Education (ACPE) accredited educational training program related to the
46 prescribing of contraceptives by a pharmacist, may prescribe hormonal contraceptive
47 patches and self-administered oral hormonal contraceptives for a patient.

48 (2) A pharmacist must submit a copy of the certificate of completion of training to the
49 Board within 15 days of completion.

50 (3) A pharmacist must maintain the certificate of completion and make available upon
51 request.

52 Stat. Auth.: ORS 689.205
53 Stats. Implemented: ORS 689.005 & 689.683

54 Delivery of Care

55 855-019-0420

56 Age Requirements

57 (1) A pharmacist may prescribe hormonal contraceptive patches and self-administered oral
58 hormonal contraceptives to a person who is:

59 (a) At least 18 years of age; or

60 (b) Under 18 years of age, only if the person has evidence of a previous prescription from a
61 primary care practitioner or women's health care practitioner for a hormonal
62 contraceptive patch or self-administered oral hormonal contraceptive.

63 Stat. Auth.: ORS 689.205
64 Stats. Implemented: ORS 689.005 & 689.683

65 855-019-0425

66 Procedural Mandates

67 (1) For each new patient requesting contraceptive services and, at a minimum of every
68 twelve months for each returning patient, a participating pharmacist must:

69 (a) Obtain a completed Oregon Self-Screening Risk Assessment Questionnaire; and

70 (b) Utilize and follow the Oregon Standard Procedures Algorithm to perform the patient
71 assessment; and

72 (c) Prescribe, if clinically appropriate, the hormonal contraceptive patch or self-
73 administered oral hormonal contraceptive, or refer to a healthcare practitioner; and

74 (d) Provide the patient with a Visit Summary; and

75 (e) Advise the patient to consult with a primary care practitioner or women's health care
76 practitioner; and

77 (f) Document the encounter and maintain records pursuant to OAR 855-019-0435.

78 (2) If the hormonal contraceptive patch or self-administered oral hormonal contraceptive is
79 dispensed, it must be done as soon as practicable after the pharmacist issues the
80 prescription and shall include any relevant educational materials.

81 (3) Nothing in this rule shall prohibit the partial filling or transferring of a drug prescribed
82 pursuant to this process, per the request of the patient.

83 (4) A pharmacy must:

84 (a) Keep records of the encounter, including but not limited to, the Oregon Self-Screening
85 Risk Assessment Questionnaire for a minimum of five years; and

86 (b) Keep records of the medication dispensed for a minimum of three years; and

87 (c) Establish, maintain and enforce written procedures for the provision of care under this
88 section, including, but not limited to:

89 (A) Providing a workflow process and physical location that maintains confidentiality and
90 is not susceptible to distraction; and

91 (B) Documentation and recordkeeping.

92 Stat. Auth.: ORS 689.205

93 Stats. Implemented: ORS 689.005 & 689.683

94 **855-019-0430**

95 **Prohibited practices**

96 **A pharmacist must not:**

97 **(1) Require a patient to schedule an appointment with the pharmacist for the prescribing**
98 **or dispensing of a hormonal contraceptive patch or self-administered oral hormonal**
99 **contraceptive;**

100 **(2) Continue to prescribe and dispense a hormonal contraceptive to a patient beyond three**
101 **years from the initial prescription without evidence of a clinical visit;**

102 **(3) Prescribe in instances that the Oregon Standard Procedures Algorithm requires**
103 **referral to a provider; and**

104 **(4) Prescribe to self or immediate family members.**

105 **Stat. Auth.: ORS 689.205**

106 **Stats. Implemented: ORS 689.005 & 689.683**

107 **855-019-0435**

108 **Records**

109 **(1) A pharmacist must document the encounter and the prescription, and maintain records**
110 **of drug dispensing.**

111 **(2) A pharmacy must maintain records of the encounter, including but not limited to, the**
112 **Oregon Self-Screening Risk Assessment Questionnaire for a minimum of five years and**
113 **maintain records of the medication dispensed for a minimum of three years.**

114 **(3) Prescriptions are valid for one year pursuant to OAR 855-041-1125.**

115 **Stat. Auth.: ORS 689.205**

116 **Stats. Implemented: ORS 689.005 & 689.683**

Hormonal Contraceptive Self-Screening Questionnaire

Name _____ Health Care Provider's Name _____ Date _____
 Date of Birth _____ Age* _____ Weight _____ Do you have health insurance? Yes / No
 What was the date of your last women's health clinical visit? _____
 Any Allergies to Medications? Yes / No If yes, list them here: _____

Background Information:

1	Do you think you might be pregnant now?	Yes <input type="checkbox"/> No <input type="checkbox"/>
2	What was the first day of your last menstrual period?	____/____/____
3	Have you ever taken birth control pills, or used a birth control patch, ring, or injection? Have you previously had contraceptives prescribed to you by a pharmacist?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
	Did you ever experience a bad reaction to using hormonal birth control? - If yes, what kind of reaction occurred?	Yes <input type="checkbox"/> No <input type="checkbox"/> _____
	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection? - If yes, which one do you use?	Yes <input type="checkbox"/> No <input type="checkbox"/> _____
4	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/> No <input type="checkbox"/>
5	Do you smoke cigarettes?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Medical History:

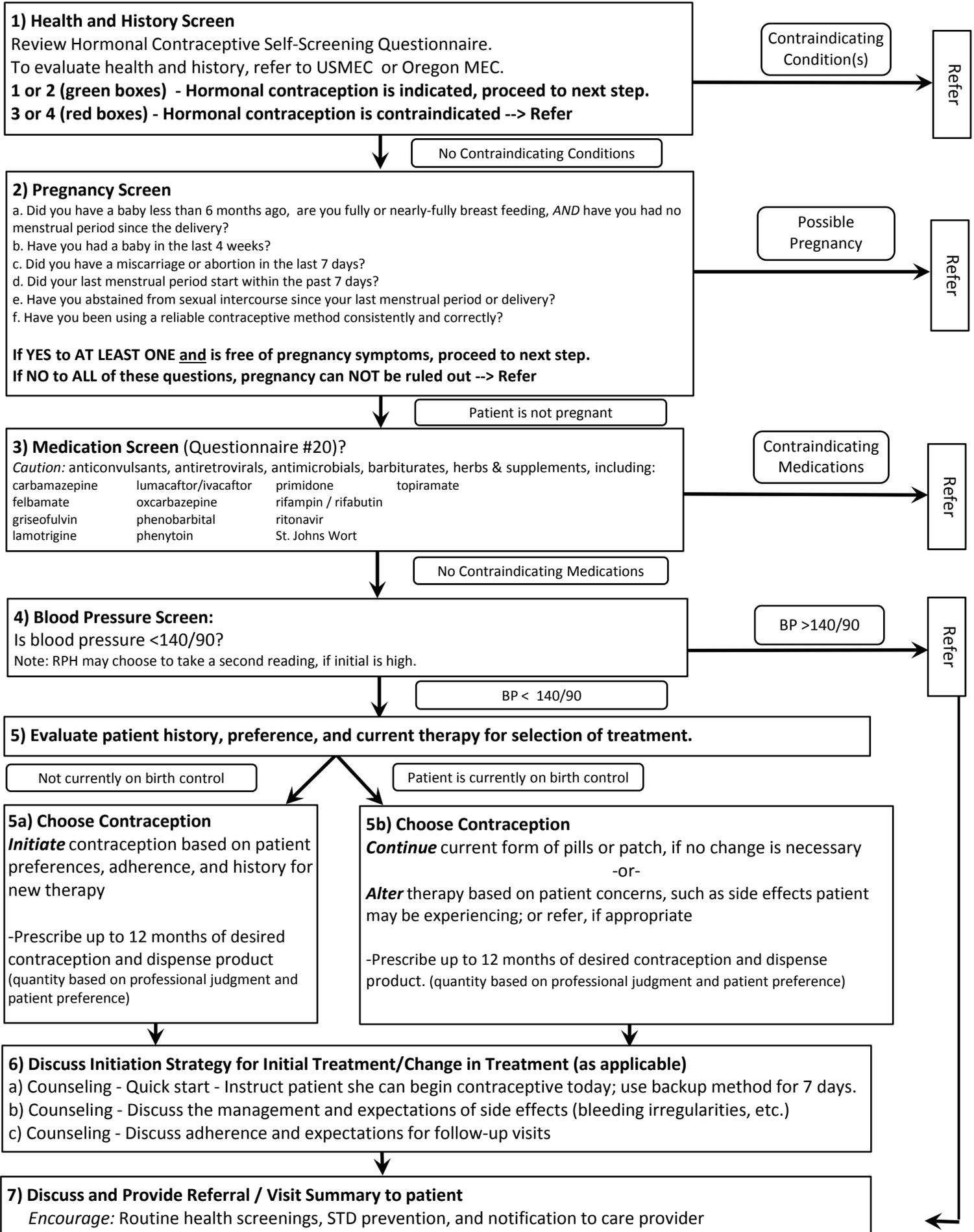
6	Have you given birth within the past 6 weeks?	Yes <input type="checkbox"/> No <input type="checkbox"/>
7	Are you currently breastfeeding?	Yes <input type="checkbox"/> No <input type="checkbox"/>
8	Do you have diabetes?	Yes <input type="checkbox"/> No <input type="checkbox"/>
9	Do you get migraine headaches? If so, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes <input type="checkbox"/> No <input type="checkbox"/>
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes <input type="checkbox"/> No <input type="checkbox"/>
12	Have you ever had a blood clot?	Yes <input type="checkbox"/> No <input type="checkbox"/>
13	Have you ever been told by a medical professional that you are at risk of developing a blood clot?	Yes <input type="checkbox"/> No <input type="checkbox"/>
14	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes <input type="checkbox"/> No <input type="checkbox"/>
15	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
16	Do you have or have you ever had breast cancer?	Yes <input type="checkbox"/> No <input type="checkbox"/>
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/> No <input type="checkbox"/>
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)? - If yes, list them here:	Yes <input type="checkbox"/> No <input type="checkbox"/> _____
20	Do you have any other medical problems or take any medications, including herbs or supplements? - If yes, list them here:	Yes <input type="checkbox"/> No <input type="checkbox"/> _____

Do you have a preferred method of birth control that you would like to use?

A pill you take each day **A patch that you change weekly** **Other (ring, injectable, implant, or IUD)**

<i>Internal use only</i> <input type="checkbox"/> verified DOB* with valid photo ID <input type="checkbox"/> BP Reading _____/_____ Pharmacist Name _____ Pharmacist Signature _____ <input type="checkbox"/> Drug Prescribed _____ Rx# _____ -or- <input type="checkbox"/> Patient Referred-circle reason(s) Sig: _____ (Pharmacy Phone _____ Address _____) Notes: _____
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STANDARD PROCEDURES ALGORITHM FOR OREGON RPH PRESCRIBING OF CONTRACEPTIVES



March 23, 2016

Oregon Board of Pharmacy

BC Prescribing (Certification) Education Course--- Review of Statewide Educational Results

Submitted by: Melanie Mitchell, Interim Director, PACE, Division of Outreach and Engagement, OSU

Paige Clark, Director of Alumni Relations and Professional Development, OSU

Oregon Board of Pharmacy Members;

In response to the state's direction to create an online educational tool to certify pharmacists to prescribe hormonal birth control therapies in Oregon, the PACE (Professional and Continuing Education) division has assisted OSU College of Pharmacy faculty and legislatively mandated content experts in the creation, launch and ongoing maintenance of the educational platform to provide this training. We appreciate the gravity of assuring that all Oregon citizens receive consistent and competent birth control prescriptive services from their Oregon pharmacists. The safety of Oregon citizens in the provision of this, the nation's first expansion in a pharmacist's scope of practice, into the art of prescribing, has been a smooth progressive roll-out thus far. Besides providing consistency in pharmacist education and patient experience, the program also provides certification which leads to credentialing, a necessary component for insurance and other third parties involved in payment provision to the professionals providing this service. As the profession (and nation's) first foray into the element of prescribing, it has been a fortunate outcome that our program has resulted in certification, as well as the first priority; provision of excellent education. While this is not the purview of the OBOP to consider such business matters, the program has not only ensured the patient safety goals of the state, it has met the business needs of pharmacists and organizations as well.

The educational program contains a registration platform that accommodates individual pharmacist registration and group registrations and it includes a monitoring system for pharmacy managers to view the progress of their pharmacists as they take the certification program. A printable certificate is made available to pharmacists upon successful completion of the certification exam. The course contains a pre-test, 5 modules that range from a broad overview of women's reproductive health issues, to a thorough pharmacology overview, to education surrounding the use of the state's patient assessment tools presented with videos, learning exercises and references as well as a final certification exam.

The college provides the ACPE documentation via uploading of the credit to the NABP/ACPE--CPE Monitor system and they provide batched lists of pharmacists completing the program to the OBOP for their records. A password protected searchable database for payers has also been constructed and is used by payers in Oregon to determine certification, which leads to credentialing (required by payers).

It may be useful to note that this certification program provides for 2 continuous years of re-access to the program. Every pharmacist course registrant can *re-access* the entire course as a resource, guide and reference as they encounter patient care questions. The college and PACE have just completed an additional short module in preparation for potential additional pharmaceutical modalities should those become available for pharmacists prescribing in Oregon.

We will push updates out to registered participants electronically as laws change in the coming two years. This system also allows for timely communication with certified pharmacists should there be a need.

The university has provided a volume discount tiered registration fee schedule for organizations who train multiple pharmacists. This discounted system allows for efficiencies and cost savings which helps with our cost recovery and reduces their cost burden significantly. Our platform also allows for creation of customized “landing pages” for organizations to provide customized introduction to their pharmacists on the topic of Birth Control prescribing.

The program has a cost of \$250 per seat, which is discounted to \$150 per seat for group discounts. The average *cash* reimbursement for pharmacist prescribing session is \$45. An individual pharmacist registrant therefore pays for their training in less than six patient encounters and a chain pharmacist in less than four. The state of Oregon has determined that they will pay for pharmacist encounters, regardless of whether a prescription is generated by the encounter. Commercial insurance plans are teaming with chain pharmacies to build billing pathways on the medical side of reimbursement structures. As of 72 days into implementation, 300 Oregon pharmacists are certified to prescribe.

The attached document provides an overview of comments and input from course participants. The components that we hear from pharmacists and organizations are appreciation of the thorough and complete educational package, the assurance (through the certification exam) that every pharmacist is *equally prepared* to prescribe, the re-accessibility of the course material, and the assurance that updates will be provided on an ongoing basis and the “back-end” monitoring program that allows pharmacy management a level of confidence that each course registrant is attending to the learning process in an appropriate manner.

In providing the certification program for the nation’s first pharmacist *scope of practice* expansion, we take seriously the state’s desire to assure educational consistency to assure a baseline for patient experiences with pharmacist’s birth control prescribing in Oregon, for the 2016 launch.

Please see attached document that overviews participant comments.

Best regards,

Paige Clark, RPh.

Director, Professional Development

OSU College of Pharmacy

Melanie Mitchell

Interim Director, PACE

Oregon State University

Comprehensive Contraceptive Education and Training for the Prescribing Pharmacist

Survey Results
March 23, 2016

NOTE: 90 pharmacists responded to the survey

What was your primary reason for taking this course?

Professional Development = 88

Personal Development = 2



How would you rate the overall quality of this course?

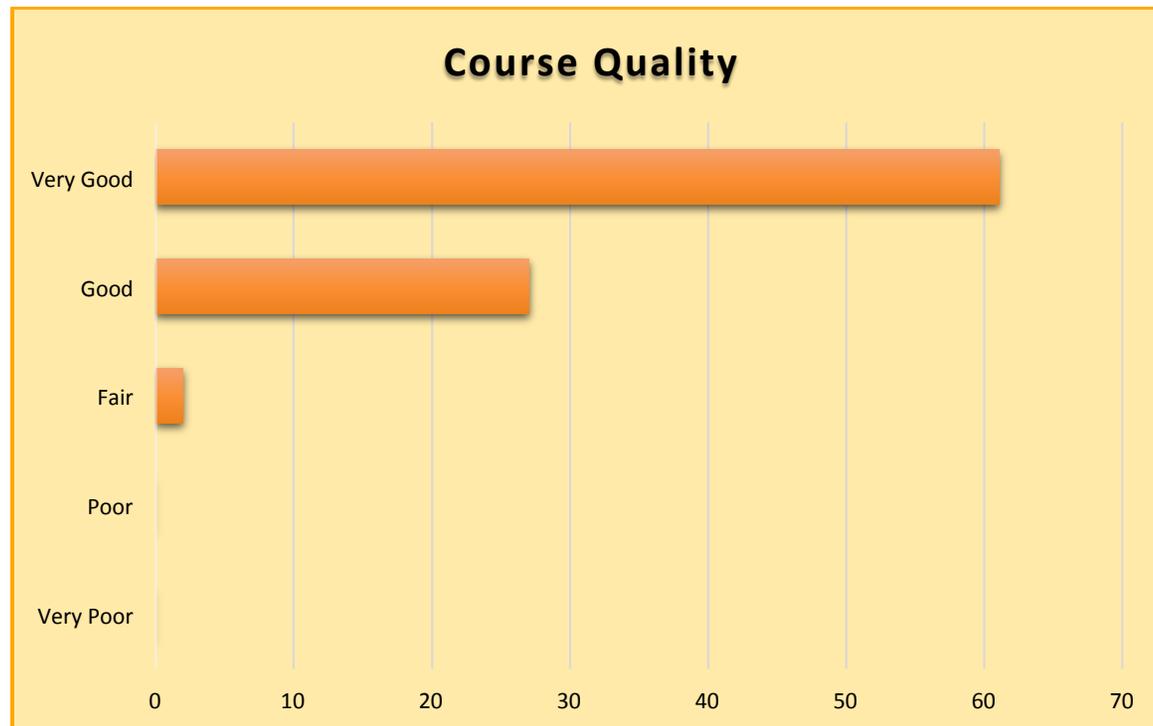
Very Good = 61

Good = 27

Fair = 2

Poor = 0

Very Poor = 0



How relevant was the course content to your job or personal development?

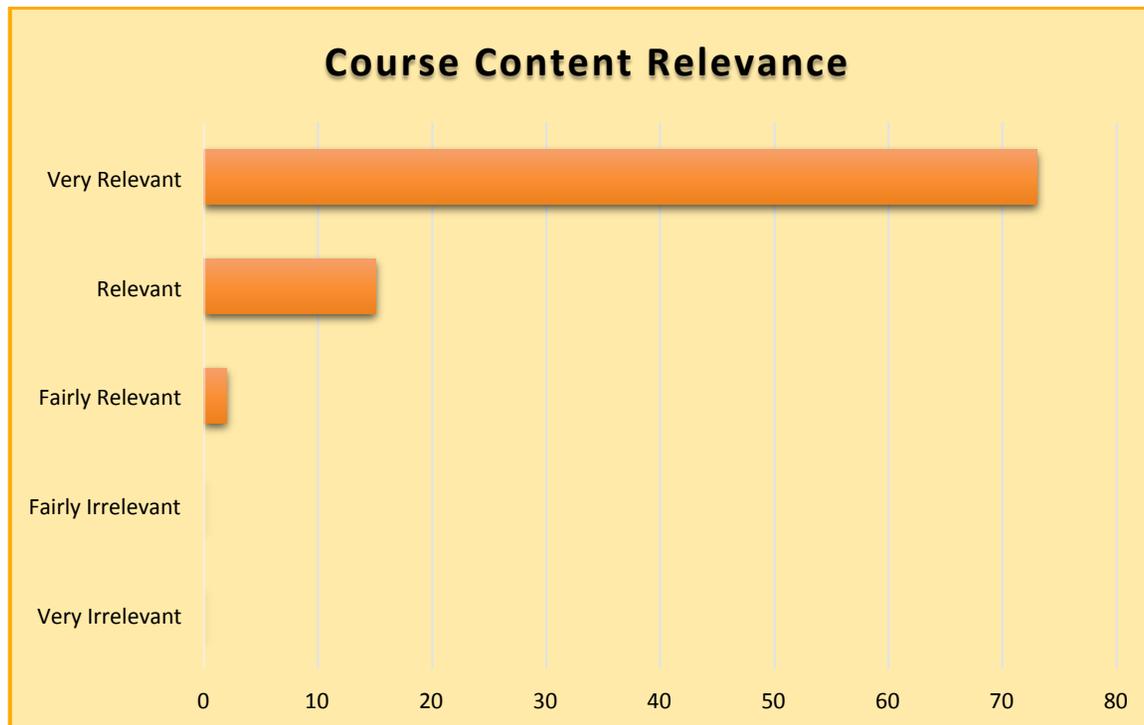
Very relevant = 73

Relevant = 15

Fairly Relevant = 2

Irrelevant = 0

Very Irrelevant = 0



How easy was it to use the course's online resources, e.g. hyperlinks, glossary, videos, and other multimedia?

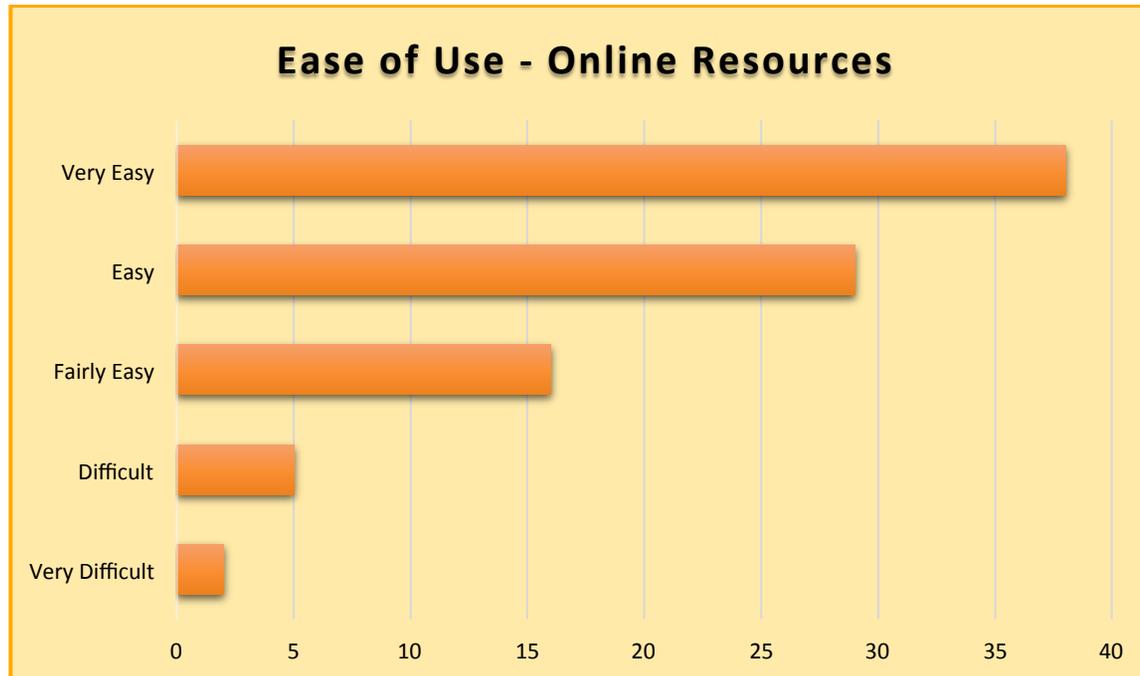
Very difficult = 2

Difficult = 5

Fairly easy = 16

Easy = 29

Very easy = 38



How would you rate the text used in this course?

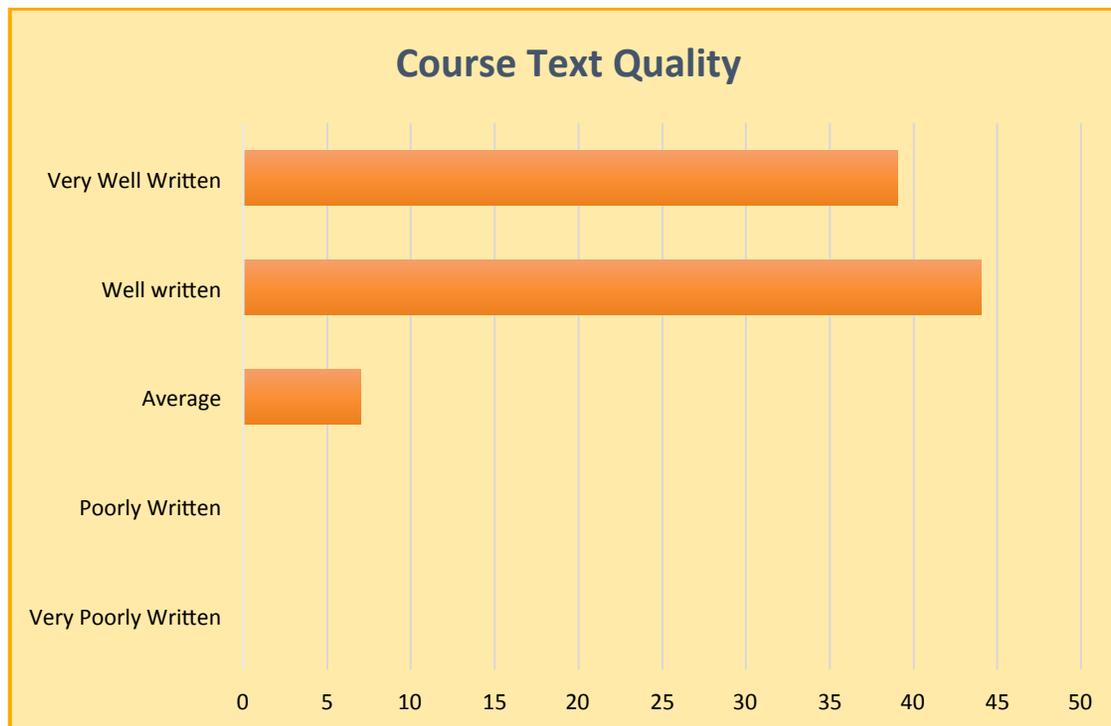
Very well written = 39

Well written = 44

Average = 7

Poorly written = 0

Very poorly written = 0

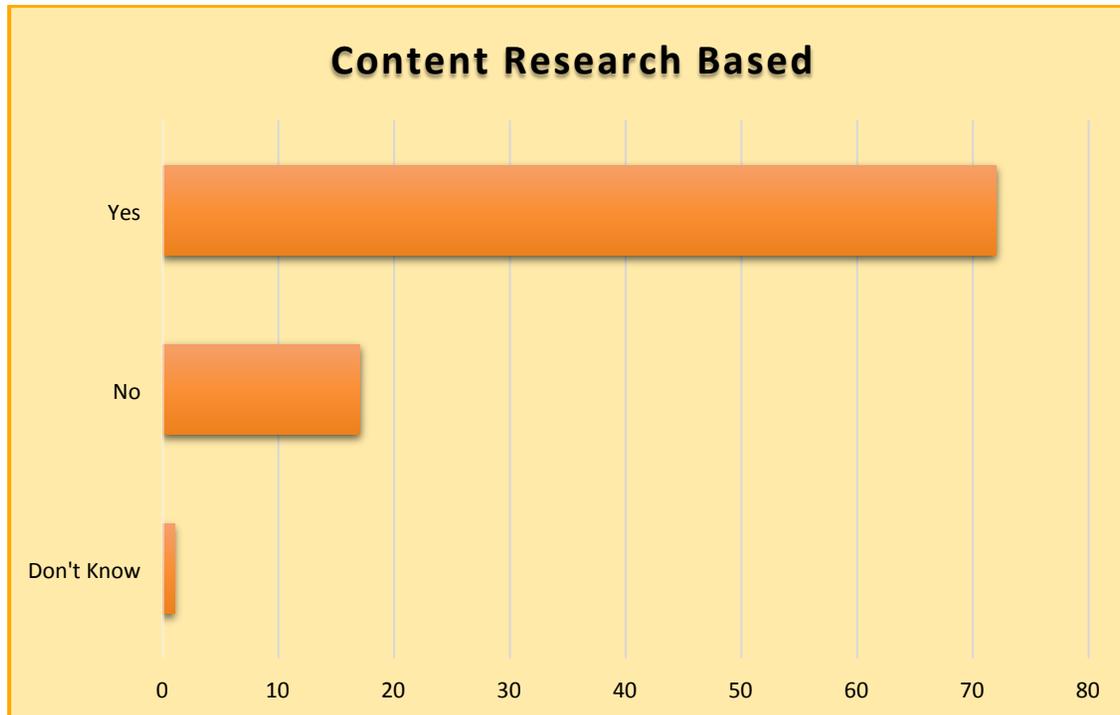


Did you feel that the content of this course was research based?

Yes = 72

No = 17

Don't know = 1



Course Evaluation Results - March 2016

Course Title: Comprehensive Contraceptive Education and Training for the Prescribing Pharmacist

Questions	Average	Variance	Median
Course Content Questions			
How would you rate the overall quality of this course?	4.82	0.23	5.00
How relevant was the course content to your job or personal development?	5.00	0.44	5.00
Did you feel that the content in this course was research based?	4.96	0.44	5.00
How easy was it to use the course's online resources, e.g. hyperlinks, glossary, videos, and other multimedia?	4.14	0.23	5.00
How would you rate the text used in this course?	4.39	0.23	5.00

Noteable Comments
What were the most useful parts of this class:
The material was easy to follow and was to the point and easy to remember. Overall, I feel pretty confident with screening patients and knowing when to refer and when to treat
Great refresher with a great information as we begin a new era in pharmaceutical practice
This course was comprehensive and put together very well. I appreciated that it focused on actual pharmacy practice
I thought the use of a pre-exam prior to the course material was a great tool to help focus on key points.
I was impressed with the input from various health professionals. I feel very prepared for my new scope of practice.
I love that I am able to access the course for 2 more years. The course was informational and concise.
What could be improved in this class?
Could use some more information on Progestin Specific Side Effects
This was a great course, My only suggestion would be to include more patient scenarios and trouble shooting with patient follow-up.
The only thing that should be added would be direct references to the Board of pharmacy laws and procedures, and possibly showing the self-screening questionnaire that we will be using.

It would have been helpful to have more information about the business side of prescribing birth control - forms for the patient (self evaluation, general info handout, etc), info about billing insurance. We are hearing a lot of antidotal stories from others and are not too sure what is true
--

I would like to hear more information about when to change a patient from mono to bi-,tri- and four phase OC.

Resource links difficult to pull information in quick reference fashion. Disappointed to NOT be able to print off any information from the modules. Please consider changing to PDF format to allow print or download options

Additional Overall Course Comments:

- I really enjoyed the content of the course. The material was easy to follow and was to the point and easy to remember. I thought that the lecture from Dr Leid was a little intense towards the end and I was a little lost. Overall, I feel pretty confident with screening patients and knowing when to refer and when to treat.
- Great course. I am feeling prepared for my new role in prescribing birth control as a pharmacist.
- Course was relevant and concise. Not sure that 5 hours is enough study to feel totally confident with prescribing birth control.
- Mark Leid's lecture was very well done.
- Great refresher with a great information as we begin a new era in pharmaceutical practice.
- I feel like the information was very well presented and much more organized than when I was taught this information in pharmacy school.
- Excellent course. It was very well written and organized.
- This course was comprehensive and put together very well. I appreciated that it focused on actual pharmacy practice.
- Good course, well done!
- Could use some more information on Progestin Specific Side Effects
- Very well written course
- The course was well put together and had a nice flow. I would have liked to have been able to print slides for notes.
- Excellent job! Easy to get through and very comprehensive.
- This was a great course; my only suggestion would be to include more patient scenarios and trouble shooting with patient follow-up.
- Good Course, Very helpful information to prepare us for this new responsibility
- Good course and wasn't long and drawn out, I learned many new things to apply to my practice
- Well written and presented.
- would like to see more interactive information ie patients and situational videos
- I was impressed with the input from various health professionals. I feel very prepared for my new scope of practice.

- Lecture from osu professor was hard to follow, would have liked print screen function. The documentation for the live lecture was available to print, but not until you finished or someone told you to go to the end first, print and then watch the lecture.
- Seemed to be written from the perspective that oral birth control is a very good idea for most people
- I thought the course went a little deeper into the hormone receptor information than needed for the needed purposes. Otherwise did a good job of patient selection for birth control. I appreciate OSU offering this course, and I feel refreshed on the topics addressed. Thank you.
- I thought this was an excellent course. I thought the use of a pre-exam prior to the course material was a great tool to help focus on key points.
- Enjoyed the course. It was interesting and I liked the videos and video lecture by Dr. Leid.
- Great course! Nicely done. Good applicable information
- Mark Leids lecture was excellent.
- I would have liked more scenario videos
- Great course. It would have been helpful to have more information about the business side of prescribing birth control - forms for the patient (self evaluation, general info handout, etc), info about billing insurance. We are hearing a lot of antidotal stories from others and are not too sure what is true.
- Very well done course! I felt like it answered a lot of the questions I had and the information made certification not so daunting. Thank you!
- enjoyed this course very much. it was informative and easy to learn. The section on the history of contraception was interesting.
- Thank you for the informational birth control course! I felt the information would help me tremendously with my clinical practice.
- I would like to hear more information about when to change a patient from mono to bi-, tri- and four phase OC.
- As interesting as it was, I thought that we didn't need to have a 52-minute pharmacology lecture to be able to successfully serve our patients contraceptive needs.
- I felt that the program was well researched and very informative. Very understandable and well-written course.
- The course was excellent. It answered all of my questions.
- Very well done. Especially enjoyed the video segments and found them helpful.
- Course was excellent, however I could not display video during audio/video portions: Pharmacology Lecture (extremely difficult to follow without visual material), and Pharmacist/patient encounters (not so important in these portions).
- The lecture was easy to understand. The cases were well presented. Would be nice to be able to print out some of the content to be able to refer to at a later time.
- I would have appreciated a section on the legal requirements. The course provided a practical foundation for BC prescribing, but did not mention the law much.
- I'm now feeling more confident with prescribing birth control. Informative, well-organized, substantive.
- It is up to date and meets my need for professional development.
- Great pharmacology refresher course.

Course Access and Student Experience Comments:

- I had a little trouble continuing with the course after viewing a video segment of pharmacist & patient, no other issues.
- Pharmacists need more than just 5 hours CE to qualify writing Rx.
- Glossary did not work, otherwise, outstanding program. Thank you!
- The only thing I would change is to have the access for the slides for Dr. Leids portion before the video.
- How do I get my certificate? Also, it would be helpful if there was better instruction as to how to add the certification to our NPI
- Course could use some discussion of multi-phasic birth control.
- Unable to correct questions I missed on final test
- Good course but have had a lot of difficulty logging in.
- There were a few spelling and grammar errors, which affected the content's reading, but overall, it was well done and easy to follow. I enjoyed watching the video examples.
- The course felt like it was put together quickly and could use some fine-tuning and better organization.
- Resource links difficult to pull information in quick reference fashion. Disappointed to NOT be able to print off any information from the modules. Please consider changing to PDF format to allow print or download options.
- Presentation format a bit awkward, instructions not always clear and complete
- It is unfortunate that the course materials were not available to be printed out, as I learn better in that manner.
- Log in process is complicated
- Excellent course. Need written content for download? Would love a PDF.
- The presentation could use a more detailed table of contents so when I need to go back to look at information it will be faster to retrieve versus going through slide after slide to find the one I am looking for.
- This is a step toward achieving greater professional independence and recognition as a health care provider. I hope to see update to this with follow-up from pharmacists and others as to the implementation and success of the program.
- I love that I am able to access the course for 2 more years. The course was informational and concise.
- Very complete, it took more than 5 hours for me to complete the course
- I had a little trouble with skipping sections of the course because of the way the pages scrolled down to complete a page



Office of the Chairman

National Transportation Safety Board

Washington, DC 20594

March 29, 2016

The Honorable Kate Brown
Governor of Oregon
State Capitol Building
900 Court Street NE, Ste. 160
Salem, OR 97301

Dear Governor Brown:

Thank you for the January 29, 2016, letter from Ms. Kathleen Haley, Executive Director, Oregon Medical Board, and the February 2, 2016, e-mail from Mr. Marcus Watt, Executive Director, Oregon Board of Pharmacy, regarding Safety Recommendations I-14-1 and -2. We issued these recommendations to all 50 states on September 23, 2014, as a result of our safety study *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment*, SS 14/01.

I-14-1

Include in all state guidelines regarding prescribing controlled substances for pain a recommendation that health care providers discuss with patients the effect their medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation.

We are aware that, on November 19, 2015, the Oregon State Board of Nursing voted to add the recommended guidance to its revised "Prescriptive and Dispensing Authority in Oregon," thus satisfying the recommendation for the Oregon Board of Nursing. Pending similar action by the Oregon Medical Board, Safety Recommendation I-14-1 was classified "Open—Acceptable Response." We note that the Oregon Medical Board will vote on a proposed amendment to its Statement of Philosophy on Pain Management on April 8, 2016, which, if adopted, will satisfy the recommendation for the Oregon Medical Board as well. Pending adoption of that amendment, Safety Recommendation I-14-1 remains classified "Open—Acceptable Response."

I-14-2

Use existing newsletters or other routine forms of communication with licensed health care providers and pharmacists to highlight the importance of routinely discussing with patients the effect their diagnosed medical conditions or

recommended drugs may have on their ability to safely operate a vehicle in any mode of transportation.

We note that the Oregon Board of Pharmacy and the Oregon Board of Nursing each published an article in the February editions of their respective newsletters satisfying their part of this recommendation. We further note that the Oregon Medical Board has prepared a similar article for its newsletter that will be published in the next edition. Pending publication of the recommended article by the Oregon Medical Board, Safety Recommendation I-14-2 remains classified “Open—Acceptable Response.”

Please submit updates electronically at correspondence@ntsb.gov regarding these recommendations. Please do not submit both an electronic copy and a hard copy of the same response.

Thank you for your state’s efforts thus far to implement these important safety recommendations across all modes of transportation.

Sincerely,



Christopher A. Hart

Chairman

*Approved for Electronic Transmittal
No Hard Copy Will Follow*

cc: Ms. Stacey O’Neil
Executive Assistant to
Karmen Fore, Senior Director for
Federal/Regional Affairs and
Transportation
Office of Governor Kate Brown
stacey.oneil@oregon.gov

Kathleen Haley, JD, CMBE
Executive Director
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Ms. Nicole Krishnaswami
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Ruby R. Jason, MSN, RN, NEA-BC
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Marcus Watt, RPh
Executive Director
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Evidence That Pilots Are Increasingly Using Over-the-Counter, Prescription, and Illicit Drugs

The National Transportation Safety Board (NTSB) recently analyzed toxicology tests from 6,677 pilots who died in a total of 6,597 aviation accidents between 1990 and 2012. The results demonstrate a significant increase in the use of a variety of potentially impairing drugs.

The study found significantly increasing trends in pilots' use of all drugs, potentially impairing drugs (those with a US Food and Drug Administration warning about sedation or behavior changes in routine use), controlled substances, and illicit drugs (those defined as Schedule I by the US Drug Enforcement Administration). The final report, *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment*, is available on the NTSB's [Safety Studies](#) web page under report number SS-14/01.

In this study, the pilot was considered to be positive for a drug if it could be qualitatively or quantitatively identified in blood or tissue; drugs identified only in urine or used as part of resuscitative efforts were excluded.

Overall, 98% of the study pilots were male and 96% were flying privately rather than for commercial purposes. The average age of study pilots increased from 46 to 57 years over the study period.

Over the course of the study, for fatally injured pilots, the following was found:

The proportion of pilots testing positive for at least one drug increased from 10% to 40%.

More than 20% of all pilots from 2008-2012 were positive for a potentially impairing drug, and 6% of all pilots were positive for more than one potentially impairing drug.

Overall, the most common potentially impairing drug pilots had used was diphenhydramine, a sedating antihistamine (the active ingredient in many Benadryl and Unisom products).

During the most recent 5 years studied, 8% of all pilots tested positive for controlled substances; hydrocodone and diazepam each accounted for 20% of the positive findings.

The percentage of pilots testing positive for marijuana use increased to about 3% during the study period, mostly in the last 10 years.

The large increase in the proportion of fatally injured pilots with evidence of potentially impairing drugs suggests an increasing risk of impairment in general aviation. Aviation is the only transportation mode in which a fatally injured operator (pilot) routinely undergoes extensive toxicology testing; no similar testing is routinely performed for fatally injured operators of boats, trains, trucks, or cars. Given the general increase in drug use in the population, it is likely that there has been a similar trend in drug use among operators across all modes of transportation.

These results highlight the importance of routine discussions between health care providers and pharmacists and their patients about the potential risks that drugs and medical conditions can create when patients are operating a vehicle in any mode of transportation.

APRIL 2016 / D
RECEIVED

MAR 14 2016

OREGON BOARD OF PHARMACY

STUART T. WILLIAMS
1661 Westwood Hills Dr
St. Louis Park, MN 55426

March 11, 2016

Mr. Marc Watt
Executive Director
800 NE Oregon St
Ste 150
Portland, OR 97232

Re: Election to NABP Executive Committee from District V

Dear Mr. Watt,

As one of two nominees from the 2015 NABP/ACCP District 5 meeting, I am seeking your Board's support for election to the NABP Executive Committee representing District 5 at our upcoming meeting this May in San Diego. I am a public member on the Minnesota Board of Pharmacy and serving my third term as President.

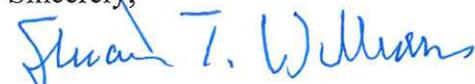
During my tenure on the Minnesota Board, I am proud to have had a role in a number of Board initiatives, including sponsoring and helping enact legislation allowing pharmacists to provide immunization to children, expanding the Board's authority to address the synthetic drug crisis, expanding the scope of the state's Prescription Monitoring Program, and implementing at the state level provisions of Title I of DQSA.

As detailed in my enclosed resume, during my time on the Minnesota Board, I have been active in NABP affairs, including serving on three NABP Task Forces. I have extensive experience serving on other professional boards, including Minnesota's Nursing, Psychology and Lawyer's Boards. I am a United States Army veteran.

It has been eleven years since a public member was last elected to NABP's Executive Committee. Given the Supreme Court's concern in the recent North Carolina Dental Board case regarding the role of active market participants in the affairs of health licensing boards and the increasingly complex legal environment in which pharmacy boards must function, I believe my position as a public member and lawyer will provide a valuable and unique perspective on the Executive Committee as NABP faces the challenges and opportunities of assisting state boards of pharmacy in their mission of protecting public health.

Please share this letter with your Board, in particular with your Board's voting delegate at our meeting in San Diego. If you or your Board have any questions about my candidacy, please call me at 612 867 6869 or contact me at swilliams@hensonefron.com. Thank you.

Sincerely,



Stuart T. Williams

STW/gha
Enclosure

STUART T. WILLIAMS

Attorney with the Minneapolis Law Firm of Henson & Efron, P.A.

Legal Background and Experience

Stuart T. Williams is an attorney with the Minneapolis law firm of Henson & Efron, P.A. He represents a broad cross section of individuals and businesses involved in commercial and business disputes in federal and state courts. His representation includes both plaintiffs and defendants in business, environmental and toxic tort matters, as well as in professional disciplinary proceedings.

Professional/Academic Honors

- *AV® Preeminent peer review rated by Martindale-Hubbell
- University of North Carolina Law Review
- Selected as a Minnesota Super Lawyer eleven times (top 5% of Minnesota lawyers as voted by peers), including 2011, 2012, 2013, 2014 and 2015

Bar Admissions

- Minnesota
- United States District Court for the District of Minnesota
- United States Court of Appeals for the Seventh Circuit
- United States Court of Appeals for the Eighth Circuit
- United States Supreme Court

Education

- J.D. with honors, University of North Carolina at Chapel Hill
- B.A., University of North Carolina at Chapel Hill

Board Service

- Minnesota Board of Pharmacy, 2011-present
 - President, 2014, 2015, 2016
 - Vice-President, 2013

- Board representative to Minnesota's Health Professional Services Program which provides monitoring services for all licensed health professionals with substance use disorders, 2013-present

National Association of Boards of Pharmacy 2011-present

- Attended and participated in NABP's annual meetings and District V meetings for the last five years. Participated in NABP's 2014 Interactive Member Forum; and served on NABP's 2015 Task Force on Sponsorship of NABP District and Annual Meetings, NABP's 2014 Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts, and on NABP's 2013 Task Force on the Regulation of Pharmacy Benefit Managers.
- Minnesota Board of Nursing, 2010-2014
 - Vice President, 2012, 2013, 2014
- Minnesota Board of Psychology, 2014
- Minnesota Drug Formulary Committee, 2014-present
- Minnesota Supreme Court Client Security Board, 2014-present
- Minnesota Lawyers Professional Responsibility Board, 2007-2012
 - Chair, Opinion Committee, 2008-2012
- Fourth Judicial District Ethics Committee, 1999-2006
 - Vice-Chair, 2005-2006
- Fire Civil Service Commission, St Louis Park, Minnesota, 2015-present
 - President 2015

Professional Memberships

- American Society for Pharmacy Law
- American Bar Association, Center for Professional Responsibility
- Association of Professional Responsibility Lawyers

- American Bar Association, Sections on Environment, Energy, Resources and Litigation, and Health Law
- Minnesota State Bar Association, Section on Environmental, Natural Resources, Energy Law, and Health Law
- Hennepin County Bar Association, Section on Environmental Law

Military Service

- United States Army, Combat Engineer

4828-6419-8446, v. 1



March 6, 2016

Dear Colleagues:

At the 2015 NABP/AACP Districts 1 and 2 meeting, I was unanimously elected as the nominee to run for the Open Member Position on the NABP Executive Committee (EC) representing District 2. There are an increasing number of critical issues facing NABP and I believe I have the background and experience to help us confront these challenges. I would very much appreciate your state's vote at the 2016 NABP Annual Meeting.

I have had the pleasure of serving District 2 as its Secretary/Treasurer since 2013. Additionally, I have served on numerous NABP committees since 2012. Most recently I participated on behalf of NABP in the 2015 ACPE CE Stakeholders Conference Invitational and was appointed to the 2015-2016 Implementation of VPP Task Force. I have ten years of leadership experience at the Virginia Board of Pharmacy; we were pleased to be the recipient of the 2014-2015 NABP Fred T. Mahaffey award. I have a strong understanding of the laws and regulations affecting the practice of pharmacy and would be very comfortable engaging in discussions on behalf of District 2.

Having worked directly with the board to improve state oversight of compounding, I see value in states having access to a more uniform inspection process across the states and I have enjoyed working closely with NABP during the development of the VPP process. I have also worked closely on the issue of prescription drug abuse, serving most recently as co-chairman of the Storage and Disposal Workgroup within the Virginia Governor's Task Force on Prescription Drug and Heroin Abuse, as a direct participant in the legislative process to increase access to naloxone in Virginia, and as a panelist during the Appalachian Opioid Summit convened by the Virginia Secretary of Health and Human Resources.

If elected I will do my best to represent all states within District 2, working collaboratively with other district representatives and the executive committee officers, to assist NABP in continuing to ensure patient safety through the provision of quality programs and invaluable support to the state boards of pharmacy. Please feel free to contact me at (804) 367-4578 or caroline.juran@dhp.virginia.gov should you have any questions. I look forward to seeing you in San Diego!

Respectfully,

Caroline D. Juran

Caroline D. Juran, RPh
Executive Director
Virginia Board of Pharmacy

BOARD OF PHARMACY
AY17 CASH FLOW
OF Appn 30235

Budget Objects	LAB ORBITS BUDGET	Rstars Financial Plan	EBoard or Adj Budget or Salary Pot	Adjusted Financial Plan	ACTUALS To Date	Unobligated Balance	% Expended To Date
REVENUE							
0205 Other Business Licenses	4,924,832	5,012,583		5,012,583	1,789,336	3,223,248	36%
0210 Other NonBusiness Licenses and Fees	65,855	127,584		127,584	88,980	38,604	70%
0505 Fines and Forfeits	270,000	360,573		360,573	187,798	172,775	52%
0605 Interest and Investments	35,000	43,095		43,095	21,157	21,938	49%
0975 Other Revenue	29,700	37,811		37,811	19,677	18,135	52%
SubTotal Revenue	5,325,387	5,581,646	0	5,581,646	2,106,946	3,474,700	38%
TRANSFERS							
2443 Transfer out to OHA--Workforce Data	65,855	65,855		65,855		65,855	0%
2443 Transfer out to OHA--PDMP program	283,590	283,590	0	283,590		283,590	0%
SubTotal Transfers	349,445	349,445	0	349,445	0	349,445	0%
TOTAL REVENUE & TRANSFERS	5,674,832	5,931,091	0	5,931,091	2,106,946	3,824,145	36%
PERSONAL SERVICES							
3110 Regular Employees	2,872,872	2,767,324	142,105	2,909,429	881,401	2,057,187.96	30%
Board Member Stipends		29,160		29,160			
3160 Temporary Appointments	24,322	-		0	-	-	0%
3170 Overtime Payments				0	71	(71)	0%
3190 All Other Differential O/Class Lead Work	176,911	174,819		174,819	58,254	116,565	33%
3210 Employment Relations Board Assessments	880	900		900	288	612	32%
3220 Public Employees Retirement Contrib	478,038	435,055	22,438	457,493	136,087	321,407	30%
3221 Pension Bond Contribution	176,574	175,422	2,878	178,300	57,134	121,166	32%
3230 Social Security Taxes	235,168	223,242	10,871	234,113	67,819	166,294	29%
3240 Unemployment Assessment				0	3,171	(3,171)	0%
3250 Workers' Compensation Assessments	1,380	1,345		1,345	387	958	29%
3260 Mass Transit Tax	18,445	17,653	853	18,506	5,634	12,872	30%
3270 Flexible Benefits	610,560	565,483	21,680	587,163	175,711	411,452	30%
3455 Vacancy Savings-ORBITS only				0			0%
3465 Reconciliation Adjustment-ORBITS only				0			0%
3470 Undistributed Personal Services-ORBITS		204,746		204,746		204,746	0%
3991 PERS Policy Adjustment-ORBITS				0			0%
SubTotal Personal Services	4,595,150	4,595,150	200,825	4,795,975	1,385,957	3,410,018	29%
SERVICES AND SUPPLIES							
4100 InState Travel	106,639	106,639		106,639	28,259	78,380	26%
4125 Out of State Travel	19,985	19,985		19,985	4,559	15,426	23%
4150 Employee Training	48,559	48,559		48,559	4,256	44,304	9%
4175 Office Expenses	119,463	119,463		119,463	29,025	90,438	24%
4200 Telecommunications	36,349	36,349		36,349	10,288	26,061	28%
4225 State Govt. Service Chgs.	72,769	72,769		72,769	35,598	37,171	49%
4250 Data Processing	56,060	56,060		56,060	21,595	34,465	39%
4275 Publicity & Publications	37,593	37,593		37,593	7,941	29,652	21%
4300 Professional Services	116,711	116,711		116,711	46,305	70,406	40%
4315 IT Professional Services	78,096	78,096		78,096	18,900	59,196	24%
4325 Attorney General	314,038	314,038		314,038	113,518	200,520	36%
4375 Employee Recruitment & Develop	200	200		200	-	200	0%
4400 Dues & Subscriptions	4,419	4,419		4,419	1,336	3,083	30%
4425 Facilities Rent & Taxes	217,606	217,606		217,606	55,769	161,837	26%
4475 Facilities Maintenance	49	49		49	-	49	0%
4525 Medical Supplies and Services	1,070	1,070		1,070	231	839	22%
4575 Agency Program Related S&S	221,248	221,248		221,248	54,228	167,020	25%
4650 Other Services & Supplies	292,293	292,293		292,293	108,047	184,246	37%
4700 Expendable Property	10,124	10,124		10,124	-	10,124	0%
4715 IT Expendable Property	40,285	40,285		40,285	6,958	33,327	17%
5550 Data Processing Software	271,077	271,077		271,077	-	271,077	0%
5600 Data Processing Hardware	8,000	8,000		8,000	-	8,000	0%
SubTotal Services and Supplies	2,072,633	2,072,633	-	2,072,633	546,814	1,525,819	26%
SPECIAL PAYMENTS							
6085 Other Special Payments	11,563	11,563		11,563	-	11,563	0%
6443 Special Payments to OHA-HPSP	176,899	176,899		176,899	67,190	109,709	38%
SubTotal Transfers	188,462	188,462	0	188,462	67,190	121,272	38%
Total Expenditures Budget	6,856,245	6,856,245	200,825	7,057,070	1,999,962	5,057,109	28%
LAB % PS	67%			7,057,070			
LAB % S&S	30%						68%
LAB % SP	3%						29%
							3%
						Target	100%

AY15 Ending Cash Balance		Cash	5,096,332
Revenue less Expenditures			
Total Revenue & Transfers	2,106,946	Actuals	2,106,946
Total Expenditures	(1,999,962)		(1,999,962)
Total Revenues & Transfers less Expenditures	106,984		106,984
AY17 Cash Balance after the Fiscal Month Closed			5,203,316
Budgeted Revenues not yet received less Estimated Transfers to OHA-PMP & Workforce Data program to be made			3,824,145
Budgeted Expenditures not yet spent			(5,057,109)
AY17 Estimated Cash Balance			3,970,352

Enrolled
Senate Bill 1514

Printed pursuant to Senate Interim Rule 213.28 by order of the President of the Senate in conformance with pre-session filing rules, indicating neither advocacy nor opposition on the part of the President (at the request of Senate Interim Committee on Human Services and Early Childhood)

CHAPTER

AN ACT

Relating to prescription drugs; amending ORS 689.772 and 689.774; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 689.772 is amended to read:

689.772. (1) There is created in the State Board of Pharmacy the Charitable Prescription Drug Program. The purpose of the program is to distribute donated prescription drugs to needy or uninsured individuals. Participation in the program is voluntary.

(2) The program may accept and distribute **within this state:**

(a) Prescription drugs received **as donations** in original, sealed, tamper-evident packaging that displays the lot number and expiration date of the drug; *[and]*

(b) Sealed single unit dose packages received in opened packages containing multiple single unit doses[.]; **and**

(c) Prescription drugs received as donations and repackaged by another charitable prescription drug program.

(3)(a) Except as provided in paragraph (b) of this subsection, the **Charitable Prescription Drug Program** may not distribute donated prescription drugs that:

(A) Fail to meet the requirements of this section;

(B) Bear an expiration date that is less than nine months from the date the *[drug is]* **drugs are** donated;

(C) Are adulterated or misbranded; or

(D) Belong to a category of controlled substances that may not be distributed under the program as adopted by the board by rule pursuant to ORS 689.774.

(b) The board may waive a requirement of this subsection if the board determines that the waiver is in the interest of public health and safety. A waiver under this subsection must be issued in writing in accordance with rules adopted by the board.

(4) The program shall:

(a) Require a donor of **a** prescription *[drugs]* **drug** to complete and sign a donor form, adopted by rule by the board, releasing the prescription drug to the program for distribution under the program and certifying that the donated **prescription** drug has been properly stored and has never been opened, used, adulterated or misbranded;

(b) Require that the pharmacist will use professional judgment, based on a visual inspection, to verify compliance with this section and rules adopted by the board under ORS 689.774;

(c) Properly dispose of all prescription drugs **received as donations** that do not meet the requirements of this section and rules adopted by the board under ORS 689.774;

(d) Maintain separate confidential files for individuals receiving donated prescription drugs through the program;

(e) Eliminate personal information from the labels of donated prescription drugs;

(f) Maintain *[an]* **a separate** inventory of donated prescription drugs *[separate from any other inventory]* **received by the program and transferred to another charitable prescription drug program;**

(g) Store donated prescription drugs in a secure location to be used exclusively for the program;

(h) Report to the board on the activities of the program in the form and manner required by the board; and

(i) Require a recipient of a donated prescription drug to sign a form, as adopted by the board by rule, attesting that the recipient has been notified by the program that:

(A) The prescription drug distributed to the recipient was donated to the program;

(B) A visual inspection was conducted by a pharmacist to ensure that the **donated prescription** drug has not expired, been adulterated or misbranded, and is in its original, sealed packaging **or has been repackaged by another charitable prescription drug program;**

(C) A pharmacist has determined that the **donated prescription** drug is safe to distribute based on the accuracy of the donor's form and the visual inspection by the pharmacist; and

(D) Participants in the program are immune from liability as provided in ORS 689.780.

(5) The program may not charge a fee for accepting a donation but may charge a fee established by the board by rule for distributing a **donated** prescription drug.

(6) The program may not sell any prescription drugs received as a donation through the program.

(7) The program may distribute donated prescription drugs that it received from another charitable prescription drug program only to an individual with a new prescription for prescription drugs who meets the requirements of ORS 689.778.

[(7)] **(8)** The program may refuse to accept **from a donor** a prescription drug that, upon visual inspection, appears not to qualify for distribution under this section or rules adopted by the board under ORS 689.774.

[(8)] **(9)** The program may distribute donated prescription drugs to:

(a) Another charitable prescription drug program, **subject to subsection (7) of this section;**
or

(b) An individual with a new prescription for prescription drugs who meets the requirements of ORS 689.778.

SECTION 2. ORS 689.774 is amended to read:

689.774. The State Board of Pharmacy shall adopt rules to carry out ORS 689.770 to 689.780, including but not limited to:

(1) Specifying categories of prescription drugs that the **Charitable Prescription Drug** Program may not distribute under the program;

(2) Prescribing the forms described in ORS 689.772;

(3) Establishing the criteria for licensure and regulation under the program;

(4) Establishing standards and procedures for accepting, storing, **repackaging**, distributing, shipping and disposing of donated prescription drugs under the program;

(5) Establishing standards and procedures for inspecting donated prescription drugs to ensure that the drugs comply with the requirements of this section and ORS 689.772; and

(6) Establishing record keeping and reporting requirements for the program.

SECTION 3. This 2016 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2016 Act takes effect on its passage.

Passed by Senate February 9, 2016

.....
Lori L. Brocker, Secretary of Senate

.....
Peter Courtney, President of Senate

Passed by House February 23, 2016

.....
Tina Kotek, Speaker of House

Received by Governor:

.....M,....., 2016

Approved:

.....M,....., 2016

.....
Kate Brown, Governor

Filed in Office of Secretary of State:

.....M,....., 2016

.....
Jeanne P. Atkins, Secretary of State

Enrolled
House Bill 4016

Introduced and printed pursuant to House Rule 12.00. Pre-session filed (at the request of House Interim Committee on Health Care)

CHAPTER

AN ACT

Relating to impaired health professional programs; creating new provisions; amending ORS 676.190; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 676.190 is amended to read:

676.190. (1) The [Oregon Health Authority shall] health profession licensing boards may establish or contract to establish an impaired health professional program.

(2) A program established or contracted for under this section [The program] must:

(a) Enroll licensees of participating health profession licensing boards who have been diagnosed with alcohol or substance abuse or a mental health disorder;

(b) Require that a licensee sign a written consent prior to enrollment in the program allowing disclosure and exchange of information between the program, the licensee's board, the licensee's employer, evaluators and treatment entities in compliance with ORS 179.505 and 42 C.F.R. part 2;

(c) Enter into diversion agreements with enrolled licensees;

(d) If the enrolled licensee has a direct supervisor, assess the ability of the direct supervisor to supervise the licensee, including an assessment of any documentation of the direct supervisor's completion of specialized training;

(e) Report substantial noncompliance with a diversion agreement to a noncompliant licensee's board within one business day after the program learns of the substantial noncompliance; and

(f) At least weekly, submit to licensees' boards:

(A) A list of licensees who were referred to the program by a health profession licensing board and who are enrolled in the program; and

(B) A list of licensees who were referred to the program by a health profession licensing board and who successfully complete the program.

[(2)] (3) The lists submitted under subsection [(1)(f)] (2)(f) of this section are exempt from disclosure as a public record under ORS 192.410 to 192.505.

[(3)] (4) When the program reports substantial noncompliance under subsection [(1)(e)] (2)(e) of this section to a licensee's board, the report must include:

(a) A description of the substantial noncompliance;

(b) A copy of a report from the independent third party who diagnosed the licensee under ORS 676.200 (2)(a) or subsection [(6)(a)] (7)(a) of this section stating the licensee's diagnosis;

(c) A copy of the licensee's diversion agreement; and

(d) The licensee's employment status.

[(4)] (5) The program may not diagnose or treat licensees enrolled in the program.

[(5)] (6) The diversion agreement required by subsection [(1)] (2) of this section must:

(a) Require the licensee to consent to disclosure and exchange of information between the program, the licensee's board, the licensee's employer, evaluators and treatment programs or providers, in compliance with ORS 179.505 and 42 C.F.R. part 2;

(b) Require that the licensee comply continuously with the agreement for at least two years to successfully complete the program;

(c) Require that the licensee abstain from mind-altering or intoxicating substances or potentially addictive drugs, unless the drug is:

(A) Prescribed for a documented medical condition by a person authorized by law to prescribe the drug to the licensee; and

(B) Approved by the program if the licensee's board has granted the program that authority;

(d) Require the licensee to report use of mind-altering or intoxicating substances or potentially addictive drugs within 24 hours;

(e) Require the licensee to agree to participate in a recommended treatment plan;

(f) Contain limits on the licensee's practice of the licensee's health profession;

(g) Require the licensee to submit to random drug or alcohol testing in accordance with federal regulations, unless the licensee is diagnosed with solely a mental health disorder and the licensee's board does not otherwise require the licensee to submit to random drug or alcohol testing;

(h) Require the licensee to report to the program regarding the licensee's compliance with the agreement;

(i) Require the licensee to report any arrest for or conviction of a misdemeanor or felony crime to the program within three business days after the licensee is arrested or convicted;

(j) Require the licensee to report applications for licensure in other states, changes in employment and changes in practice setting; and

(k) Provide that the licensee is responsible for the cost of evaluations, toxicology testing and treatment.

[(6)(a)] (7)(a) *[If a health profession licensing board participating in the program establishes by rule an option for self-referral to the program, a licensee of the health profession licensing board may self-refer to the program.]* **A health profession licensing board may establish by rule an option to permit licensees of the health profession licensing board to self-refer to the program.**

(b) The program shall require a licensee who self-refers to the program to attest that the licensee is not, to the best of the licensee's knowledge, under investigation by the licensee's board. The program shall enroll the licensee on the date on which the licensee attests that the licensee, to the best of the licensee's knowledge, is not under investigation by the licensee's board.

(c) When a licensee self-refers to the program, the program shall:

(A) Require that an independent third party approved by the licensee's board to evaluate alcohol or substance abuse or mental health disorders evaluate the licensee for alcohol or substance abuse or mental health disorders; and

(B) Investigate to determine whether the licensee's practice while impaired has presented or presents a danger to the public.

(d) When a licensee self-refers to the program, the program may not report the licensee's enrollment in or successful completion of the program to the licensee's board.

[(7) *The authority shall adopt rules establishing a fee to be paid by the health profession licensing boards participating in the program for administration of the program.*]

[(8) *The authority shall arrange for an independent third party to audit the program every four years to ensure compliance with program guidelines. The authority shall report the results of the audit to the Legislative Assembly, the Governor and the health profession licensing boards. The report may not contain individually identifiable information about licensees.*]

(8) The health profession licensing boards shall arrange for an independent third party to conduct an audit every four years of an impaired health professional program for the licensees of those health profession licensing boards to ensure compliance with program guidelines. The health profession licensing boards shall report the results of the audit to the

Legislative Assembly in the manner provided by ORS 192.245 and to the Governor. The report may not contain individually identifiable information about licensees.

(9) The [authority] health profession licensing boards, in consultation with one another, may adopt rules to carry out this section.

SECTION 2. Section 3 of this 2016 Act is added to and made a part of ORS 676.185 to 676.200.

SECTION 3. (1) The Impaired Health Professional Program Work Group is established.

(2) The work group consists of the designees of any health profession licensing boards that elect to establish or contract for an impaired health professional program as described in ORS 676.190.

(3) The work group shall facilitate the establishment and continuation of the impaired health professional program described in ORS 676.190.

(4) A majority of the members of the work group constitutes a quorum for the transaction of business.

(5) Official action by the work group requires the approval of a majority of the members of the work group.

(6) The work group shall elect one of its members to serve as chairperson.

(7) The work group shall meet at times and places specified by the call of the chairperson or of a majority of the members of the work group.

(8) The work group may adopt rules necessary for the operation of the work group.

(9) The Oregon Medical Board shall provide staff support to the work group.

(10) Members of the work group are not entitled to compensation, but may be reimbursed for actual and necessary travel and other expenses incurred by them in the performance of their official duties in the manner and amounts provided for in ORS 292.495. Claims for expenses shall be paid out of funds appropriated to the health professional licensing board that the member represents for purposes of the work group.

(11) All agencies of state government, as defined in ORS 174.111, are directed to assist the work group in the performance of duties of the work group and, to the extent permitted by laws relating to confidentiality, to furnish information and advice the members of the work group consider necessary to perform their duties.

SECTION 4. The amendments to ORS 676.190 by section 1 of this 2016 Act become operative on July 1, 2017.

SECTION 5. This 2016 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2016 Act takes effect on its passage.

Passed by House February 9, 2016

.....
Timothy G. Sekerak, Chief Clerk of House

.....
Tina Kotek, Speaker of House

Passed by Senate February 19, 2016

.....
Peter Courtney, President of Senate

Received by Governor:

.....M,....., 2016

Approved:

.....M,....., 2016

.....
Kate Brown, Governor

Filed in Office of Secretary of State:

.....M,....., 2016

.....
Jeanne P. Atkins, Secretary of State

Enrolled
House Bill 4105

Sponsored by Representative NOSSE (Pre-session filed.)

CHAPTER

AN ACT

Relating to biological products; creating new provisions; amending ORS 689.522; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 689.522 is amended to read:

689.522. [(1) As used in this section:]

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

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

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

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

[(2)] (1) A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a [biosimilar] biological product for the prescribed biological product unless:

(a) The [biosimilar] substitute biological product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;

(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;

(c) The patient for whom the biological product is prescribed is informed of the substitution [prior to dispensing the biosimilar product] in a manner reasonable under the circumstances; and

(d) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three years.

(2) Not later than five business days after the dispensing of a biological product, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, by making an entry into an electronic system that the prescribing practitioner can access electronically and that is:

(a) An interoperable electronic medical records system;

- (b) An electronic prescribing technology;
- (c) A pharmacy benefit management system; or
- (d) A pharmacy record.

(3) If the pharmacy or pharmacist, or the pharmacist's designee, does not have access to an electronic system described in subsection (2) of this section, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate not later than five business days to the prescribing practitioner the specific biological product dispensed to the patient, including the name and manufacturer of the biological product. The communication may be by facsimile, electronic mail, telephone or another method.

(4) If the biological product is dispensed to a patient in a clinic, community-based care facility, hospital or long term care facility, an entry made to the patient's medical record of the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, satisfies the communication requirements of subsections (2) and (3) of this section.

(5) Notwithstanding subsections (2) and (3) of this section, the pharmacy or pharmacist, or the pharmacist's designee, is not required to communicate to the prescribing practitioner the specific biological product dispensed to the patient if:

- (a) The United States Food and Drug Administration has not approved an interchangeable biological product for the prescribed biological product;
- (b) The pharmacy or pharmacist is refilling a prescription and the pharmacy or pharmacist is dispensing the same biological product that was dispensed the last time the pharmacy or pharmacist filled or refilled the patient's prescription; or
- (c) The pharmacy or pharmacist is filling a prescription for a vaccine.

(6) The entries described in subsections (2) and (4) of this section or the communication described in subsection (3) of this section provides notice to the prescribing provider of the dispensation of a biological product to a patient.

[3] (7) The State Board of Pharmacy shall, *[post and regularly update]* on a website maintained by the board, **maintain a link to the current list, if available, of biological** *[a list of biosimilar]* products determined by the United States Food and Drug Administration to be interchangeable.

(8)(a) For purposes of this section, the board shall adopt by rule definitions for the terms "biological product" and "interchangeable."

(b) The rule defining the term "biological product" must be consistent with 42 U.S.C. 262(i)(1).

(c) The rule defining the term "interchangeable" must:

(A) For biological products licensed under the Public Health Service Act, define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as meeting the standards in 42 U.S.C. 262(k)(4); and

(B) For biological products approved by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as therapeutically equivalent as set forth in the latest edition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

SECTION 2. ORS 689.522, as amended by section 1 of this 2016 Act, is amended to read:

689.522. (1) A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biological product for the prescribed biological product unless:

- (a) The substitute biological product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;
- (b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;

(c) The patient for whom the biological product is prescribed is informed of the substitution in a manner reasonable under the circumstances; and

(d) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three years.

[(2) Not later than five business days after the dispensing of a biological product, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, by making an entry into an electronic system that the prescribing practitioner can access electronically and that is:]

[(a) An interoperable electronic medical records system;]

[(b) An electronic prescribing technology;]

[(c) A pharmacy benefit management system; or]

[(d) A pharmacy record.]

[(3) If the pharmacy or pharmacist, or the pharmacist's designee, does not have access to an electronic system described in subsection (2) of this section, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate not later than five business days to the prescribing practitioner the specific biological product dispensed to the patient, including the name and manufacturer of the biological product. The communication may be by facsimile, electronic mail, telephone or another method.]

[(4) If the biological product is dispensed to a patient in a clinic, community-based care facility, hospital or long term care facility, an entry made to the patient's medical record of the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, satisfies the communication requirements of subsections (2) and (3) of this section.]

[(5) Notwithstanding subsections (2) and (3) of this section, the pharmacy or pharmacist, or the pharmacist's designee, is not required to communicate to the prescribing practitioner the specific biological product dispensed to the patient if:]

[(a) The United States Food and Drug Administration has not approved an interchangeable biological product for the prescribed biological product;]

[(b) The pharmacy or pharmacist is refilling a prescription and the pharmacy or pharmacist is dispensing the same biological product that was dispensed the last time the pharmacy or pharmacist filled or refilled the patient's prescription; or]

[(c) The pharmacy or pharmacist is filling a prescription for a vaccine.]

[(6) The entries described in subsections (2) and (4) of this section or the communication described in subsection (3) of this section provides notice to the prescribing provider of the dispensation of a biological product to a patient.]

[(7)] (2) The State Board of Pharmacy shall, on a website maintained by the board, maintain a link to the current list, if available, of biological products determined by the United States Food and Drug Administration to be interchangeable.

[(8)(a)] (3)(a) For purposes of this section, the board shall adopt by rule definitions for the terms "biological product" and "interchangeable."

(b) The rule defining the term "biological product" must be consistent with 42 U.S.C. 262(i)(1).

(c) The rule defining the term "interchangeable" must:

(A) For biological products licensed under the Public Health Service Act, define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as meeting the standards in 42 U.S.C. 262(k)(4); and

(B) For biological products approved by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as therapeutically equivalent as set forth in the latest edition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

SECTION 3. The amendments to ORS 689.522 by section 2 of this 2016 Act become operative on January 2, 2022.

SECTION 4. ORS 689.522 does not prohibit an insurer or other health care payer from requiring prior authorization or imposing other appropriate utilization controls in approving coverage for any biological product.

SECTION 5. This 2016 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2016 Act takes effect on its passage.

Passed by House February 11, 2016

Received by Governor:

Repassed by House February 29, 2016

.....M.,....., 2016

Approved:

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Timothy G. Sekerak, Chief Clerk of House

.....M.,....., 2016

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Tina Kotek, Speaker of House

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Kate Brown, Governor

Passed by Senate February 26, 2016

Filed in Office of Secretary of State:

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Peter Courtney, President of Senate

.....M.,....., 2016

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Jeanne P. Atkins, Secretary of State

Enrolled
House Bill 4124

Sponsored by Representative BUEHLER, Senator STEINER HAYWARD, Representatives WILLIAMSON, PARRISH; Representatives DAVIS, FAGAN, GREENLICK, KENY-GUYER (Pre-session filed.)

CHAPTER

AN ACT

Relating to prescription drugs; creating new provisions; amending ORS 431A.865 and 689.681; and declaring an emergency.

Be It Enacted by the People of the State of Oregon:

SECTION 1. ORS 431A.865 is amended to read:

431A.865. (1)(a) Except as provided under subsection (2) of this section, prescription monitoring information submitted under ORS 431A.860 to the prescription monitoring program established in ORS 431A.855:

- (A) Is protected health information under ORS 192.553 to 192.581.
(B) Is not subject to disclosure pursuant to ORS 192.410 to 192.505.

(b) Except as provided under subsection [(2)(a)(E)] (2)(a)(G) of this section, prescription monitoring information submitted under ORS 431A.860 to the prescription monitoring program may not be used to evaluate a practitioner's professional practice.

(2)(a) To the extent that the law or regulation is applicable to the prescription monitoring program, if a disclosure of prescription monitoring information, other than the sex of a patient for whom a drug was prescribed, complies with the federal Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) and regulations adopted under it, including 45 C.F.R. parts 160 and 164, federal alcohol and drug treatment confidentiality laws and regulations [adopted under those laws], including 42 C.F.R. part 2, and state health and mental health confidentiality laws, including ORS 179.505, 192.517 and 192.553 to 192.581, the Oregon Health Authority shall disclose the information:

(A) To a practitioner or pharmacist, or, if a practitioner or pharmacist authorizes the authority to disclose the information to a member of the practitioner's or pharmacist's staff, to a member of the practitioner's or pharmacist's staff. If a practitioner or pharmacist authorizes disclosing the information to a member of the practitioner's or pharmacist's staff under this subparagraph, the practitioner or pharmacist remains responsible for the use or misuse of the information by the staff member. To receive information under this subparagraph, or to authorize the receipt of information by a staff member under this subparagraph, a practitioner or pharmacist must certify that the requested information is for the purpose of evaluating the need for or providing medical or pharmaceutical treatment for a patient to whom the practitioner or pharmacist anticipates providing, is providing or has provided care.

(B) In accordance with subparagraph (A) of this paragraph, to a practitioner or pharmacist or to a member of the practitioner's or pharmacist's staff through a health in-

formation technology system that is used by the practitioner or pharmacist or a member of the practitioner's or pharmacist's staff to access information about patients if:

(i) The practitioner or pharmacist or a member of the practitioner's or pharmacist's staff is authorized to access the information in the health information technology system;

(ii) The information is not permanently retained in the health information technology system, except for purposes of conducting audits and maintaining patient records; and

(iii) The health information technology system meets any privacy and security requirements and other criteria, including criteria required by the federal Health Insurance Portability and Accountability Act, established by the authority by rule.

[(B)] (C) To a practitioner in a form that catalogs all prescription drugs prescribed by the practitioner according to the number assigned to the practitioner by the Drug Enforcement Administration of the United States Department of Justice.

(D) To the State Medical Examiner or designee of the State Medical Examiner, for the purpose of conducting a medicolegal investigation or autopsy.

[(C)] (E) To designated representatives of the authority or any vendor or contractor with whom the authority has contracted to establish or maintain the electronic system of the prescription monitoring program.

[(D)] (F) Pursuant to a valid court order based on probable cause and issued at the request of a federal, state or local law enforcement agency engaged in an authorized drug-related investigation involving a person to whom the requested information pertains.

[(E)] (G) To a health professional regulatory board that certifies in writing that the requested information is necessary for an investigation related to licensure, **license** renewal or disciplinary action involving the applicant, licensee or registrant to whom the requested information pertains.

[(F)] (H) To a prescription monitoring program of another state if the confidentiality, security and privacy standards of the requesting state are determined by the authority to be equivalent to those of the authority.

[(G) *To the State Medical Examiner or designee of the State Medical Examiner, for the purpose of conducting a medicolegal investigation or autopsy.*]

(b) The authority may disclose information from the prescription monitoring program that does not identify a patient, practitioner or drug outlet:

(A) For educational, research or public health purposes;

(B) To a local public health authority, as defined in ORS 431.003; or

(C) To officials of the authority who are conducting special epidemiologic morbidity and mortality studies in accordance with ORS 413.196 and rules adopted under ORS 431.001 to 431.550 and 431.990.

(c) The Oregon Health Authority shall disclose information relating to a patient maintained in the electronic system operated pursuant to the prescription monitoring program [*established under ORS 431A.855*] to that patient at no cost to the patient within 10 business days after the authority receives a request from the patient for the information.

(d)(A) A patient may request the authority to correct any information about the patient that is erroneous. The authority shall grant or deny a request to correct information within 10 business days after the authority receives the request.

(B) If the authority denies a patient's request to correct information under this paragraph, or fails to grant a patient's request to correct information under this paragraph within 10 business days after the authority receives the request, the patient may appeal the denial or failure to grant the request. Upon [*receipt*] **receiving notice** of an appeal under this subparagraph, the authority shall conduct a contested case hearing as provided in ORS chapter 183. Notwithstanding ORS 183.450, [*in the contested case hearing,*] the authority has the burden **in the contested case hearing** of establishing that the information included in the prescription monitoring program is correct.

(e) The information in the prescription monitoring program may not be used for any commercial purpose.

(f) In accordance with ORS 192.553 to 192.581 and federal privacy regulations, any person authorized to prescribe or dispense a prescription drug and who is entitled to access a patient's prescription monitoring information may discuss or release the information to other health care providers involved with the patient's care[, *in order to provide*] **for the purposes of providing safe and appropriate care coordination.**

(3)(a) The authority shall maintain records of the information disclosed through the prescription monitoring program including, but not limited to:

(A) The identity of each person who requests or receives information from the program and [*the organization, if any,*] **any organization** the person represents;

(B) The information released to each person or organization; and

(C) The date and time the information was requested and the date and time the information was provided.

(b) Records maintained as required by this subsection may be reviewed by the Prescription Monitoring Program Advisory Commission.

(4) Information in the prescription monitoring program that identifies an individual patient must be removed no later than three years from the date the information is entered into the program.

(5) The authority shall notify the Attorney General and each affected individual of an improper disclosure of information from the prescription monitoring program.

(6)(a) If the authority or a person or entity required to report or authorized to receive or release controlled substance prescription information under this section violates this section or ORS 431A.860 or 431A.870, a person injured by the violation may bring a civil action against the authority, person or entity and may recover damages in the amount of \$1,000 or actual damages, whichever is greater.

(b) Notwithstanding paragraph (a) of this subsection, the authority and a person or entity required to report or authorized to receive or release controlled substance prescription information under this section are immune from civil liability for violations of this section or ORS 431A.860 or 431A.870 unless the authority, person or entity acts with malice, criminal intent, gross negligence, recklessness or willful intent.

(7) Nothing in ORS 431A.855 to 431A.900 requires a practitioner or pharmacist who prescribes or dispenses a prescription drug to obtain information about a patient from the prescription monitoring program. A practitioner or pharmacist who prescribes or dispenses a prescription drug may not be held liable for damages in any civil action on the basis that the practitioner or pharmacist did or did not request or obtain information from the prescription monitoring program.

(8) The authority shall, at regular intervals, ensure compliance of a health information technology system described in subsection (2) of this section with the privacy and security requirements and other criteria established by the authority by rule under subsection (2) of this section.

SECTION 2. ORS 689.681 is amended to read:

689.681. (1) As used in this section:

(a) "Opiate" means a narcotic drug that contains:

(A) Opium;

(B) Any chemical derivative of opium; or

(C) Any synthetic or semisynthetic drug with opium-like effects.

(b) "Opiate overdose" means a medical condition that causes depressed consciousness and mental functioning, decreased movement, depressed respiratory function and the impairment of the vital functions as a result of ingesting opiates in an amount larger than can be physically tolerated.

(2) The Oregon Health Authority shall establish by rule protocols and criteria for training on lifesaving treatments for opiate overdose. The criteria must specify:

(a) The frequency of required retraining or refresher training; and

(b) The curriculum for the training, including:

(A) The recognition of symptoms and signs of opiate overdose;

(B) Nonpharmaceutical treatments for opiate overdose, including rescue breathing and proper positioning of the victim;

(C) Obtaining emergency medical services;

(D) The proper administration of naloxone to reverse opiate overdose; and

(E) The observation and follow-up that is necessary to avoid the recurrence of overdose symptoms.

(3) Training that meets the protocols and criteria established by the authority under subsection (2) of this section must be subject to oversight by a licensed physician or certified nurse practitioner and may be conducted by public health authorities, organizations or other appropriate entities that provide services to individuals who take opiates.

(4) Notwithstanding any other provision of law, a pharmacy, a health care professional **or a pharmacist** with prescription and dispensing privileges or any other person designated by the State Board of Pharmacy by rule may distribute unit-of-use packages of naloxone, and the necessary medical supplies to administer the naloxone, to a person who:

(a) Conducts training that meets the protocols and criteria established by the authority under subsection (2) of this section, so that the person may possess and distribute naloxone and necessary medical supplies to persons who successfully complete the training; or

(b) Has successfully completed training that meets the protocols and criteria established by the authority under subsection (2) of this section, so that the person may possess and administer naloxone to any individual who appears to be experiencing an opiate overdose.

(5) A person who has successfully completed the training described in this section is immune from civil liability for any act or omission committed during the course of providing the treatment pursuant to the authority granted by this section, if the person is acting in good faith and the act or omission does not constitute wanton misconduct.

SECTION 3. Section 4 of this 2016 Act is added to and made a part of ORS chapter 689.

SECTION 4. In accordance with rules adopted by the State Board of Pharmacy under ORS 689.205, a pharmacist may prescribe unit-of-use packages of naloxone, and the necessary medical supplies to administer the naloxone, to a person who meets the requirements of ORS 689.681 (4).

SECTION 5. Section 6 of this 2016 Act is added to and made a part of ORS chapter 689.

SECTION 6. (1) For purposes of this section, “social services agency” includes, but is not limited to, homeless shelters and crisis centers.

(2) An employee of a social services agency may administer to an individual a unit-of-use package of naloxone that was not distributed to the employee if:

(a) The employee conducts or has successfully completed opiate overdose training under ORS 689.681;

(b) The unit-of-use package of naloxone was distributed to another employee of the social services agency who conducts or has completed the opiate overdose training under ORS 689.681; and

(c) The individual appears to be experiencing an opiate overdose as defined in ORS 689.681.

(3) For the purposes of protecting public health and safety, the Oregon Health Authority may adopt rules for the administration of naloxone under this section.

SECTION 7. This 2016 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2016 Act takes effect on its passage.

Passed by House February 25, 2016

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Timothy G. Sekerak, Chief Clerk of House

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Tina Kotek, Speaker of House

Passed by Senate February 29, 2016

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Peter Courtney, President of Senate

Received by Governor:

.....M,....., 2016

Approved:

.....M,....., 2016

.....
Kate Brown, Governor

Filed in Office of Secretary of State:

.....M,....., 2016

.....
Jeanne P. Atkins, Secretary of State

OREGON BOARD OF PHARMACY STRATEGIC PLAN

APRIL 2016 / G

THE MISSION OF THE OREGON STATE BOARD OF PHARMACY

TO PROMOTE, PRESERVE AND PROTECT THE PUBLIC HEALTH, SAFETY AND WELFARE BY ENSURING HIGH STANDARDS IN THE PRACTICE OF PHARMACY AND BY REGULATING THE QUALITY, MANUFACTURE, SALE AND DISTRIBUTION OF DRUGS.

STRATEGIC OBJECTIVES			
Licensees' operating excellence: "At the top of their license."	No adverse impact on patient safety due to the workplace environment	An adequate and safe drug supply for the State of Oregon.	
Objectives 2014 – 2016 / Priority Outcomes			
Technician licensing that is streamlined and workable, resulting in fewer administrative errors by technicians	A valid framework from which to take workplace safety actions that meet the intent of patient safety	A strategy is in place to insure critical drug shortages are avoided	Non-pharmacy dispensing issues are resolved in support of patient safety.
Strategies & Tactics			
<ul style="list-style-type: none"> • Hold an informational hearing on the technician licensing process. If "go": • Draft and adopt administrative rules. • Create a graphic representation to clearly illustrate how technician licensing works. 	<ul style="list-style-type: none"> • Conduct proactive outreach to licensees outlining concerns and issues, and providing prevention advice and education on conditions that could trigger an action / mitigation. • Create a graphic representation of the paths to workplace action. • Draft and adopt administrative rules. 	<ul style="list-style-type: none"> • Staff work with FDA to insure Oregon has/retains the ability to use compounders for shortage drugs. • Obtain a root-cause analysis of drug shortage causes as they relate to Oregon. • Open Division 45. • Establish and implement the strategy. 	<ul style="list-style-type: none"> • Conduct outreach and debrief feedback with stakeholders. Compile and document stakeholders' interests and concerns. • Refine and share our plan and timeline. • Obtain support from legislators, boards and associations. •

Oregon Board of Pharmacy 2014 – 2016 Strategic Plan: MILESTONE CHART

	2014			2015				2016				2017
	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Technician Licensing												
Hearing on the technician licensing process.		◆										
Draft and adopt administrative rules			◆ □									
Graphic representation to illustrate how technician licensing works,				◆								
Data shows fewer administrative errors by technicians												◆
Workplace Environment												
Graphic representation of the paths to workplace action.			◆									
Proactive outreach to licensees with advice and education re action triggers							◆					
Administrative rules drafted and adopted.								◆				
Drug Shortage Strategy												
Work with FDA to insure ability to use compounders for shortage drugs.	◆											
Obtain a root-cause analysis of drug shortage causes			◆									
Open Division 45.			◆									
Establish and implement the strategy.				◆	→	→	→	→	→	→	→	→
Dispensing												
Outreach to collect and compile stakeholder feedback		◆										
Refine and share plan and timeline		◆										
Solicit support of legislators, boards and associations			◆									

K E Y: ◆=milestone/task achievement. →=ongoing ◆=goal achievement