

BOARD MEETING AGENDA

**Oregon Board of Pharmacy
800 NE Oregon Street
Portland, OR 97232
October 5-6, 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, October 5, 2016 @ 8:30 AM, Conference Room 1A

Thursday, October 6, 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, OCTOBER 5, 2016

I. 8:30 AM OPEN SESSION, Kate James, R.Ph, Presiding

A. Roll Call

B. Agenda Review and Approval

Action Necessary

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

IV. OPEN SESSION - PUBLIC MAY ATTEND - At the conclusion of Executive Session, the Board may convene Open Session to begin the scheduled agenda for October 6, 2016. Items that may be covered are marked with an asterisk * in Section VII Issues/Activities of the agenda.

Adjourn

THURSDAY, OCTOBER 6, 2016

Agenda – October 5-6, 2016

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

Page 1 of 4

8:30AM

V. OPEN SESSION, Kate James, R.Ph. Presiding

A. Roll Call

B. Motions for Contested Cases & Disciplinary Action

Action Necessary

9:00AM

VI. GENERAL ADMINISTRATION

A. Rules

1. Review Rulemaking Hearing Report & Comments – none
2. Consider Adoption of Temporary Rules - none
3. Consider Rules and Send to 11/22 Rulemaking Hearing *Action Necessary*

Phase II First look *

Karbowicz/Miner/MacLean

Phase II Second look **

- a) Div 007 & 041 - Drug Room** **#A1**
 - b) Div 019 and 041 - Naloxone****#A3 (Temp)**
 - c) Div 019 - Volunteer Limited Liability** **#A4**
 - d) Div 019 – Pharmacist Exam Waiting Periods* **#A5**
 - e) Div 019 & 041 - Resident PIC** **#A6**
 - f) Div 041 & 080 - Drug Take Back** **#A7**
 - g) Div 041 - Remote Dispensing Machines **#A11**
 - h) Div 043 – Dispensing Practitioner Drug Outlets** **#A8**
 - i) Div 044 - Charitable Pharmacy and REMS Drugs** **#A9**
 - j) Div 080 – Controlled Substances, synthetic opioids and fentanyl analogue chemicals ** **#A10 (Temp)**
4. Consider Adoption of Rules - none
 5. Policy Issues for Discussion - none

B. Discussion Items

1. Waiver Requests – *Karbowicz/Miner*

Action Necessary

- Mylan request **#B**
- RPh CE request **#B1**
- Legacy Good Samaritan request **#B2**
- Legacy Option-Care request **#B3**
- Multnomah County request **#B4**

2. Workplace Survey update- *Watt* **#B5**
3. Technician Discussion update – *Staff*
4. Auto-refill update – *Watt*

Noon - Lunch break

Resume outstanding Discussion items or move on to Issues and Activities

*VII. ISSUES/ACTIVITIES

*A. Reports:

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

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

- Pharmacy Coalition – 9/15/16, 10/18/16
- Professional Practice Roundtable – 9/8/16, 11/10/16
- Health System Outreach Meeting – 8/18/16

*C. Committees/Meetings

1. NABP District 6,7,8 Meeting 9/11-14/2016, Portland, OR – *Watt/MacLean*
2. Urban League of Portland Naloxone outreach – 9/24/16, Portland - *Efremoff*
3. OSPA Annual Mtg. 10/21-23,2016, Clackamas, OR – *Karbowicz/Efremoff/Miner*
4. OSHP Mtg. 11/5/2016, Portland, OR - *Wallace*
5. OSPA Lane Co. Mid-Winter Mtg. 2/18-19/2017, Eugene, OR – *Watt/Karbowicz*

*D. Board Meeting Dates

- November 2-3, 2016 Silverton (*Strategic Planning*)
- December 7-8, 2016 Portland
- February 16-17, 2017 Eugene
- April 5-6, 2017 Portland
- June 7-8, 2017 Portland
- August 9-11, 2017* Portland (** 3 day meeting*)
- October 11-12, 2017 Portland
- November 8-9, 2017 TBA (*Strategic Planning*)
- December 13-14, 2017 Portland

*E. Rulemaking Hearing Dates

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

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

*F. Financial/Budget Report – *Watt/MacLean* **#C**

G. Legislative update – *Watt* (none)

H. Strategic Planning – *MacLean*

- Updates

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 –none
2. MPJE Scores –none
3. License/Registration Ratification - August 10, 2016 – October 4, 2016
4. Extension Requests - none
5. Approval of Board Meeting Minutes – June 9-10, 2016
6. Approval of Board Meeting Minutes – August 10-12, 2016
7. Approval of Board Meeting Minutes - September 2, 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

1 The proposed rule amendments to *Div 007 Public Health Emergency* and *041 Operation of*
 2 *Pharmacies* update rules related to the registration and regulation of Drug Rooms.

3
 4 The rule (1) describes oversight of long-term storage of state and federal emergency medications
 5 in a Drug Room (2) clarifies that secondary storage areas related to Retail Pharmacies can
 6 register as a Drug Room; and (3) allows a Drug Room to be affiliated with an Institutional
 7 Pharmacy.
 8
 9

10 **855-007-0060**

11 **SNS and State Stockpile Emergency Drugs**

12 (1) General: When drugs from the Strategic National Stockpile (SNS) are delivered to the state,
 13 the drugs may be delivered to a state Receipt, Staging and Storage center (RSS) for further
 14 distribution to Points of Dispensing (PODs) selected by OSPHD. State drugs (state stockpile)
 15 may also be delivered to the RSS.

16 (2) **Temporary** storage of drugs from SNS or state stockpile:

17 (a) The RSS, PODs and local health departments (LHD) are authorized to store any drugs from
 18 the SNS or state stockpile prior to and during an emergency without any registration from the
 19 Board.

20 (b) All such drugs must be stored in accordance with manufacturers' guidelines.

21 (c) This authority to possess drugs shall extend beyond the declared emergency until procedures
 22 issued by OSPHD for the return or destruction of unused drugs have been completed.

23 **(3) A long-term drug storage area for state and federal emergency medications not**
 24 **otherwise registered as a drug outlet must be approved by the Board, comply with storage**
 25 **and security requirements, and register as a Drug Room.**

26 Stat. Auth.: ORS 401.065, 433.441 & ~~689.305~~, 689.205

27 Stats. Implemented: ORS 689.155

28

29 **855-041-1001**30 **Definitions**

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

36 (2) “Biosimilar product” means a biological product licensed by the United States Food and
 37 Drug Administration pursuant to 42 U.S.C. 262(k)(3)(A)(i).

38 **(3) “Drug room” is a drug storage area registered with the Board which is secure and**
 39 **lockable.**

40 ~~(3)~~ **(4)** “Interchangeable” means, in reference to a biological product, that the United States Food
 41 and Drug Administration has determined that a biosimilar product meets the safety standards set
 42 forth in 42 U.S.C. 262(k)(4).

43 ~~(4)~~ **(5)** “Reference biological product” means the biological product licensed pursuant to 42
 44 U.S.C. 262(a) against which a biological product is evaluated in an application submitted to the
 45 United States Food and Drug Administration for licensure of a biological product as a biosimilar
 46 product or for determination that a biosimilar product is interchangeable.

47 Stat. Auth.: ORS 689.205 & 2013 OL Ch 342, **ORS 689.522**
 48 Stats. Implemented: ORS 689.155 & 2013 OL Ch 342, **ORS 689.522**

49 **855-041-1036**50 **Proper Storage of Drugs**

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

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

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

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

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

- 60 (2) A pharmacy must store all drugs at the proper temperature according to manufacturer's
61 published guidelines (pursuant to FDA package insert or USP guidelines).
- 62 (a) All drug refrigeration systems must:
- 63 (A) Maintain refrigerated products between 2 to 8 °C (35 to 46 °F); frozen products between -25
64 to -10 °C (-13 to 14 °F); or as specified by the manufacturer.
- 65 (B) Utilize a centrally placed, accurate, and calibrated thermometer;
- 66 (C) Be dedicated to pharmaceuticals only; and
- 67 (D) Be measured continuously and documented either manually twice daily to include minimum,
68 maximum and current temperatures; or with an automated system capable of creating a
69 producible history of temperature readings.
- 70 (b) A pharmacy must adhere to a monitoring plan, which includes, but is not limited to:
- 71 (A) Documentation of training of all personnel;
- 72 (B) Maintenance of manufacturer recommended calibration of thermometers;
- 73 (C) Maintenance of records of temperature logs for a minimum of three years;
- 74 (D) Documentation of excursion detail, including, but not limited to, event date and name of
75 persons(s) involved in excursion responses;
- 76 (E) Documentation of action(s) taken, including decision to quarantine product for destruction,
77 or determination that it is safe for continued use. This documentation must include details of the
78 information source;
- 79 (F) A written emergency action plan; and
- 80 (G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring
81 equipment.
- 82 (3) Vaccine Drug Storage:
- 83 (a) A pharmacy that stores vaccines must comply with section two of this rule and the following:
- 84 (A) Vaccines must be stored in the temperature stable sections of the refrigerator;
- 85 (B) A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads,
86 calibrated within a plus or minus 0.5 °C variance must be utilized;

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

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

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

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

96 Stat. Auth.: ORS 689.205, 689.325

97 Stats. Implemented: ORS 689.155

98

99 **855-041-5005**

100 **Definitions**

101 For purposes of these rules, OAR 855-041-5000 through 855-041-9999 the following definitions
102 apply:

103 (1) "Institutional Facility" means a hospital or other health care facility which is an inpatient care
104 facility referred to in ORS 442.015, which includes long-term care facilities and special inpatient
105 care facilities, and such facility is licensed by the appropriate state agency. For the purpose of
106 this rule, an Institutional Facility is a Residential Drug Outlet.

107 (2) "Institutional Pharmacy" means a pharmacy where medications are dispensed to other health
108 care professionals for administration to institutionalized patients served by an institutional
109 facility, and which is:

110 (a) Located within the institutional facility;

111 (b) Located outside the facility but provides pharmaceutical services to institutionalized patients;
112 and

113 (c) For the purpose of this rule, an Institutional Pharmacy is a Residential Pharmacy.

114 (3) "Drug Room" means a secure and lockable location within an inpatient ~~a~~ care facility that
115 does not have a pharmacy **and is a Board approved location associated with a licensed**
116 **institutional pharmacy.**

117

118

Pharmacist Prescribing of Naloxone

855-019-0450

Purpose

The purpose of OAR 855-019-0450 through 855-019-0460 is to develop standard procedures for the prescribing and recordkeeping of naloxone by a pharmacist in Oregon.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100

855-019-0455

Qualifications

(1) A pharmacist educated in opiate overdose and naloxone rescue can prescribe unit-of-use naloxone and the necessary medical supplies to administer the naloxone for an individual who:

(a) Conducts training that meets that criteria established by the Oregon Health Authority (OHA) so that the person may possess and distribute naloxone and the necessary medical supplies to persons who successfully complete the training; or

(b) Has successfully completed training that meets criteria established by the OHA allowing the person to possess and administer naloxone to any individual who appears to be experiencing an opiate overdose.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100

855-019-0460

Delivery of Care

(1) A pharmacist can prescribe naloxone and the necessary medical supplies for opiate overdose training to an OHA authorized person or organization.

(2) A pharmacist can prescribe naloxone and the necessary medical supplies to an individual who has completed an OHA approved training. The pharmacist shall determine that the individual seeking naloxone demonstrates understanding of educational materials related to opioid overdose prevention, recognition, response, and the administration of naloxone.

(3) The pharmacist may prescribe naloxone in any FDA approved dosage form and the necessary medical supplies needed to administer naloxone.

(4) The pharmacist shall dispense the naloxone product in a properly labeled container identifying the authorized recipient.

(5) Naloxone may not be dispensed without providing oral counseling to the authorized recipient, to include dose, effectiveness, adverse effects, storage conditions, and safety.

(6) The pharmacist must document the encounter and the prescription, and maintain records for three years.

(7) The pharmacy providing naloxone services must establish, maintain, and enforce written procedures including, but not limited to:

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

(b) Documentation and recordkeeping.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100

855-041-2340

Pharmacist Prescribing of Naloxone

(1) A pharmacist educated in opiate overdose and naloxone rescue may prescribe unit-of-use naloxone and the necessary medical supplies to administer the naloxone to an individual who:

(a) Conducts training that meets that criteria established by the Oregon Health Authority (OHA) so that the person may possess and distribute naloxone and the necessary medical supplies to persons who successfully complete the training; or

(b) Has successfully completed training that meets criteria established by the OHA allowing the person to possess and administer naloxone to any individual who appears to be experiencing an opiate overdose.

(2) The pharmacy providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:

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

(b) Documentation and recordkeeping.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305, 689.681 & 2016 OL Ch. 100

1 The proposed rule amendment references new statewide laws related to limited liability for
2 pharmacist volunteers, put forth by ORS 676.340 and ORS 676.345. A pharmacist who has
3 registered and who provides health care services without compensation is not liable for any
4 injury, death or other loss arising out of the provision of those services, unless the injury, death
5 or other loss results from the gross negligence of the health practitioner.

6 The rule states that pharmacists may claim the state liability limitation upon registration with the
7 Oregon Board of Pharmacy.

8 Board staff has begun development the required registration process – see Limited Liability
9 Form

10

11 **855-019-0123**12 **Liability Limitations for Volunteers**

13 **(1) A pharmacist may register with the Board for the limitation on liability provided by**
14 **ORS 676.340, which provides a licensee with specific exemptions from liability for the**
15 **provision of pharmacy services without compensation under the terms of the law.**

16 **(2) A no cost registration may be issued by the Board upon receipt of a completed**
17 **application. Registration requires submission of a signed form provided by the Board in**
18 **accordance with ORS 676.345(2).**

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

22 **(4) Nothing in this section relieves licensee from the responsibility to comply with Board**
23 **regulations and still may be subject to disciplinary actions.**

24 **(5) Pharmacists providing care under the provisions of ORS 676.340 and 676.345 remain**
25 **subject to the Board complaint investigation process articulated in ORS 676.175.**

26 **Stat. Auth.: ORS 676.340, 689.205**

27 **Stats. Implemented: ORS 676.340, 676.345**



Limited Liability Registration
OREGON BOARD OF PHARMACY

Registry for Limited Liability for Pharmacists

Name: _____ License Number: _____

Primary Practice Location Address: _____

City: _____ State: _____ Zip: _____

I certify that:

1. Before providing pharmacy services to the patient, I will obtain the signature of the patient, or the patient’s legal agent, acknowledging receipt of a written statement that notifies the patient that services are provided without compensation. The statement will include notification that my liability is limited and that I may not be held liable for any injury, death or other loss arising out of the provision of those services, unless caused by gross negligence.
2. I will provide pharmacy services to patients without compensation, except for reimbursement for laboratory fees, testing services, and other out-of-pocket expenses, which must be authorized by the patient prior to incurring the expense.
3. I will provide without compensation only those services that are within the scope of my active Oregon Pharmacist license.
4. I understand that this registration is effective until the due date of my next renewal, and I must renew biennially for this limited liability to remain in effect.
5. I wish the Board to acknowledge receipt of this form by:
 - A telephone call to: _____
 - An email to: _____

Signature _____ Date: _____

Keep a copy for your files

Mail to: Oregon Board of Pharmacy, 800 NE Oregon St, Ste 150, Portland, OR 97232

676.340 Limitations on liability of health practitioners providing health care services without compensation, requirements; exceptions; attorney fees; applicability. (1) Notwithstanding any other provision of law, a health practitioner described in subsection (7) of this section who has registered under ORS 676.345 and who provides health care services without compensation is not liable for any injury, death or other loss arising out of the provision of those services, unless the injury, death or other loss results from the gross negligence of the health practitioner.

(2) A health practitioner may claim the limitation on liability provided by this section only if the patient receiving health care services, or a person who has authority under law to make health care decisions for the patient, signs a statement that notifies the patient that the health care services are provided without compensation and that the health practitioner may be held liable for death, injury or other loss only to the extent provided by this section. The statement required under this subsection must be signed before the health care services are provided.

(3) A health practitioner may claim the limitation on liability provided by this section only if the health practitioner obtains the patient's informed consent for the health care services before providing the services, or receives the informed consent of a person who has authority under law to make health care decisions for the patient.

(4) A health practitioner provides health care services without compensation for the purposes of subsection (1) of this section even though the practitioner requires payment of laboratory fees, testing services and other out-of-pocket expenses.

(5) A health practitioner provides health care services without compensation for the purposes of subsection (1) of this section even though the practitioner provides services at a health clinic that receives compensation from the patient, as long as the health practitioner does not personally receive compensation for the services.

(6) In any civil action in which a health practitioner prevails based on the limitation on liability provided by this section, the court shall award all reasonable attorney fees incurred by the health practitioner in defending the action.

(7) This section applies only to:

- (a) A physician licensed under ORS 677.100 to 677.228;
- (b) A nurse licensed under ORS 678.040 to 678.101;
- (c) A nurse practitioner licensed under ORS 678.375 to 678.390;
- (d) A clinical nurse specialist certified under ORS 678.370 and 678.372;
- (e) A physician assistant licensed under ORS 677.505 to 677.525;
- (f) A dental hygienist licensed under ORS 680.010 to 680.205;
- (g) A dentist licensed under ORS 679.060 to 679.180;
- (h) A pharmacist licensed under ORS chapter 689; and
- (i) An optometrist licensed under ORS chapter 683. [1999 c.771 §1; 1999 c.771 §3; 2005 c.462 §2; 2012 c.41 §3]

676.345 Registration program for health care professionals claiming liability limitation; program requirements. (1) A health practitioner described in ORS 676.340 (7) may claim the liability limitation provided by ORS 676.340 only if the health practitioner has registered with a health professional regulatory board in the manner provided by this section. Registration under this section must be made:

- (a) By a physician or physician assistant, with the Oregon Medical Board;
- (b) By a nurse, nurse practitioner or clinical nurse specialist, with the Oregon State Board of Nursing;
- (c) By a dentist or dental hygienist, with the Oregon Board of Dentistry;
- (d) By a pharmacist, with the State Board of Pharmacy; and
- (e) By an optometrist, with the Oregon Board of Optometry.

(2) The health professional regulatory boards listed in subsection (1) of this section shall establish a registration program for the health practitioners who provide health care services without compensation and who wish to be subject to the liability limitation provided by ORS 676.340. All health practitioners registering under the program must provide the health professional regulatory board with:

- (a) A statement that the health practitioner will provide health care services to patients without compensation, except for reimbursement for laboratory fees, testing services and other out-of-pocket expenses;
- (b) A statement that the health practitioner will provide the notice required by ORS 676.340 (2) in the manner provided by ORS 676.340 (2) before providing the services; and
- (c) A statement that the health practitioner will only provide health care services without compensation that are within the scope of the health practitioner's license.

(3) Registration under this section must be made annually. The health professional regulatory boards listed in subsection (1) of this section shall charge no fee for registration under this section. [1999 c.771 §2; 1999 c.771 §4; 2005 c.462 §3; 2012 c.41 §4]

855-019-0123

Liability Limitations for Volunteers

(1) A pharmacist may register with the Board for the limitation on liability provided by ORS 676.340, which provides a licensee with specific exemptions from liability for the provision of pharmacy services without compensation under the terms of the law.

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

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

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

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

1 The proposed rule amendments to *Div 019 Pharmacists* address the waiting period between
 2 retakes for the NAPLEX exam. NABP notified the Board that it was changing the waiting
 3 period from 91 days in between retakes to 45 days effective 11/1/16.

4 A new platform for assembling the NAPLEX is affording the ability to manage retakes and
 5 reduce the waiting period so the candidates can re-take the NAPLEX and secure licensure in a
 6 timely manner. Effective November 1, 2016, NABP will be able to decrease the waiting period
 7 for the NAPLEX to 45-days with a limit of three attempts in a 12 month period.

8 **855-019-0120**

9 **Licensure**

10 (1) Before licensure as a pharmacist, an applicant must meet the following requirements:

11 (a) Provide evidence from a school or college of pharmacy approved by the Board that they have
 12 successfully completed all the requirements for graduation and, starting with the graduating class
 13 of 2011, including not less than 1440 hours of School-based Rotational Internships as that term is
 14 defined in OAR 855-031-0005, and that a degree will be conferred;

15 (b) Pass the North American Pharmacist Licensure Examination (NAPLEX) exam with a score
 16 of not less than 75. This score shall remain valid for only one year unless the Board grants an
 17 extension. A candidate who does not attain this score may retake the exam after a minimum of
 18 ~~91~~ **45** days except that a candidate who has failed the exam three times must wait at least one
 19 year before retaking the exam;

- 20 • *NABP's new policy reducing from 91-45 days is effective November 1, 2016. Do we*
 21 *match that?*
- 22 • *Policy question: NABP's policy has allowed a person to take either exam, for a*
 23 *maximum of 5 times, period, with a limit of 3 times in a 12 month period. However,*
 24 *our Board only allows a person to test a total of three times before waiting one year,*
 25 *prior to re-take, with no maximum number of attempts. Do we want to match this as*
 26 *well?*
- 27 • *How does this affect score transferring?*

28 (c) Pass the Multistate Pharmacy Jurisprudence Examination (MPJE) exam with a score of not
 29 less than 75. The applicant may not take the MJPE until they have graduated from a school or
 30 college of pharmacy approved by the Board. A candidate who does not attain this score may
 31 retake the exam after a minimum of 30 days except that a candidate who has failed the exam
 32 three times must wait at least one year before retaking the exam. The MJPE score shall be valid
 33 for 6 months unless extended by the Board;

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

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

38 Stat. Auth.: ORS 689.205

39 Stats. Implemented: ORS 689.151

40

DRAFT

1 The proposed rule amendments to *Div 019 Pharmacists* and *Div 041 Operation of Pharmacies* update
2 regulations related to PIC expectations in Oregon Pharmacies.

3 The rule (1) states that a pharmacy must employ a Pharmacist-in-Charge; (2) permits a pharmacist to be
4 PIC of up to two Oregon Pharmacies; and (3) clarifies reporting requirements of an Oregon Pharmacy.

6 **855-019-0300**

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

8 (1) In accordance with Division 41 of this chapter of rules, a pharmacy must, ~~at all times~~ have
9 one Pharmacist-in-Charge (PIC) employed ~~on a regular basis~~ **at that location who is**
10 **responsible for the daily operation of the pharmacy.**

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

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

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

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

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

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

24 (b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within
25 15 days of becoming PIC;

26 (c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the
27 pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may
28 be granted as specified in OAR 855-041-0120 **-6310**;

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

- 32 ~~(e) A pharmacist designated as PIC for more than one pharmacy shall personally conduct and~~
 33 ~~document a quarterly compliance audit at each location. This audit shall be on the Quarterly PIC~~
 34 ~~Compliance Audit Form provided by the Board;~~
- 35 ~~(f)~~~~(e)~~ If a discrepancy is noted on a Board inspection, the PIC must submit a plan of correction
 36 within **15 days for a Non-Compliance Notification and** 30 days of receiving a **Deficiency**
 37 **Notification.** ~~notice.~~
- 38 ~~(g)~~ **(f)** The records and forms required by this section must be filed in the pharmacy, made
 39 available to the Board for inspection upon request, and must be retained for three years.
- 40 (5) The PIC is responsible for ensuring that the following activities are correctly completed:
- 41 (a) An inventory of all controlled substances must be taken within 15 days before or after the
 42 effective date of change of PIC, and must be dated and signed by the new PIC. This inventory
 43 must be maintained in the pharmacy for three years and in accordance with all federal laws and
 44 regulations;
- 45 (b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all
 46 pharmacy personnel who are required to be licensed by the Board;
- 47 (c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form
 48 provided by the Board, by February 1 each year. The completed self-inspection forms must be
 49 signed and dated by the PIC and maintained for three years from the date of completion;
- 50 (d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;
- 51 (e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.
- 52 (f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such
 53 training should include an annual review of the PIC Self-Inspection Report;
- 54 ~~(g) Implementing a~~ **Overseeing the Continuous Quality Assurance** ~~Plan~~ **Plan** for the pharmacy.
- 55 (h) The records and forms required by this section must be filed in the pharmacy, made available
 56 to the Board for inspection upon request, and must be retained for three years.
- 57 (6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in
 58 compliance with all state and federal laws and rules governing the practice of pharmacy ~~and that~~
 59 ~~all controlled substance records and inventories are maintained in accordance with all state and~~
 60 ~~federal laws and rules.~~
- 61 Stat. Auth.: ORS 689.205
 62 Stats. Implemented: ORS 689.151, 689.155

63 855-041-1010

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

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

- 70 • *Board discussion: Because the PIC position is still considered essential, Staff is*
71 *concerned with a large gap (i.e. 45 days, as suggested in August) in rule as a*
72 *minimum standard.*

73 **In the absence of the PIC during a Board approved period, the outlet will be responsible**
74 **for completion of PIC requirements, such as the annual inventory and PIC Self-Inspection**
75 **Report.**

76 **(2) A resident pharmacy that terminates or allows a Board licensee to resign in lieu of**
77 **termination must report the termination or resignation to the Board within 10 working**
78 **days.**

79 **(3) (2) The A pharmacy must ensure that it is in compliance with all state and federal laws and**
80 **rules governing the practice of pharmacy and that all controlled substance records and**
81 **inventories are maintained in conformance with the keeping and inventory requirements of**
82 **federal law and board rules.**

83 Stat. Auth.: ORS 689.205

84 Stats. Implemented: ORS 689.151, 689.155, 689.305

85

1 The proposed rule amendments to *Div 041 Operation of Pharmacies* and *Div 080 Schedule of Controlled*
2 *Substances* put forth the requirements for a pharmacy to lawfully participate in Drug Take Back
3 initiatives. Congress adopted the Secure & Responsible Drug Disposal act in 2010 and DEA published its
4 Final Rule on Disposal of Controlled Substances in 2014. Additional information is available:
5 http://www.deadiversion.usdoj.gov/drug_disposal/

6 The rule (1) states that a pharmacy must comply with all DEA regulations for secure and responsible drug
7 disposal (2) directs a pharmacy to notify the Board of its Take Back program (3) outlines the minimum
8 policies and procedures to be established by the pharmacy, including recordkeeping; and (4) prohibits
9 pharmacy staff from handling collected drugs and using the receptacles to dispose of pharmacy stock.

10

11 **855-041-1045**12 **Returned Drugs and Devices**

13 (1) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians may only
14 accept the return of controlled substances upon receiving a waiver from the Board of Pharmacy.

15 (2) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians may
16 accept the return of drugs or devices as defined by ORS 689.005 once the drugs or devices have
17 been removed from the pharmacy only if;

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

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

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

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

26 (a) The drug is in an unopened, tamper-evident unit;

27 (b) The drugs or devices have remained at all times in control of a person trained and
28 knowledgeable in the storage and administration of drugs in long term care facilities or
29 supervised living groups using the services of a consultant pharmacist;

30 (c) The drug or device has not been adulterated or misbranded and has been stored under
31 conditions meeting United States Pharmacopeia standards.

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

35 Stat. Auth.: ORS ~~475 & 689~~ **689.205**

36 Stats. Implemented: **ORS 689.305**

37 **855-041-1046**

38 **Secure and Responsible Drug Disposal**

39 **(1) A pharmacy registered with the DEA as an authorized collector may collect controlled**
40 **and non-controlled drugs for destruction in accordance with all applicable federal laws.**

41 **(2) A pharmacy that operates a drug take-back collection program shall notify the Board in**
42 **writing prior to initiating the program and shall establish and enforce policies and**
43 **procedures, including but not limited to:**

44 **(a) Provision of secure location of the collection receptacle, which must be accessible to the**
45 **public and cannot be placed behind the pharmacy counter; and**

46 **(b) Provision of adequate security measures, including proper installation and maintenance**
47 **of collection receptacle, tracking of liners, and key accountability; and**

48 **(c) Personnel training and accountability.**

49 **(3) Pharmacy personnel shall not count, sort, inventory, or otherwise handle drugs**
50 **collected.**

51 **(4) A pharmacy shall not dispose of quarantined, recalled or outdated drugs from**
52 **pharmacy stock in a collection receptacle.**

53 **(5) A pharmacy shall maintain disposal records for a minimum of 3 years.**

54 **Stat. Auth.: ORS 689.205**

55 **Stats. Implemented: ORS 689.305**

56

57 **855-080-0105**

58 **Disposal of Drugs**

59 (1) Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be
60 quarantined and physically separated from other drugs until they are destroyed or returned to
61 their supplier.

62 (2) Controlled substances which are expired, deteriorated or unwanted shall be disposed of in
63 conformance with ~~21 CFR 1307.21~~. 21 CFR 1317.

64 (3) Expired, deteriorated, discontinued, or unwanted controlled substances in a long-term care
65 facility shall be destroyed and the destruction jointly witnessed on the premises by any two of the
66 following:

67 (a) The consultant pharmacist or registered nurse designee.

68 (b) The Director of Nursing Services or supervising nurse designee

69 (c) The administrator of the facility or an administrative designee

70 (d) A Registered Nurse employed by the facility

71 (4) The destruction shall be documented and signed by the witnesses and the document retained
72 at the facility for a period of at least three years. Copies of the document shall be sent to the
73 consultant pharmacist. Any destruction of controlled substances deviating from this procedure
74 must be approved by the Board prior to implementation.

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

78 Stat. Auth.: ORS ~~475.035~~ & 689.205

79 Stats. Implemented: ORS 689.305

1 For proposed language additions to *Div 043 Practitioner Dispensing*, please see related
 2 documents: DOJ Final Opinion Dispensing Practitioner Drug Outlet Registration 2.6.2013 and
 3 Non-Pharmacy Dispensing Concept Final Version 12.4.2014

4 Dispensing Practitioner ~~Dispensing~~ Drug Outlets

5 855-043-0505

6 Purpose and Scope

7 **These rules are intended to distinguish between traditional and non-traditional dispensing**
 8 **of drugs by a practitioner who has been granted dispensing privileges from their licensing**
 9 **board and dispenses from their practice location. A practitioner who participates in non-**
 10 **traditional dispensing must register the dispensing outlet with the Board as a Dispensing**
 11 **Practitioner Drug Outlet (DPDO).**

12 Stat. Auth.: ORS 689.205

13 Stats. Implemented: ORS 689.155, 689.305

14 ~~855-043-0510~~

16 Definitions

17 ~~(1) Traditional dispensing means the dispensing of a drug to a patient by a practitioner, and is:~~

18 ~~(a) An FDA manufacturer's sample human drug or medication assistance program (MAP) drug;~~

19 ~~(b) A small amount of drugs to start therapy or incidental to a procedure or office visit, up to a 72~~
 20 ~~hour supply; or~~

21 ~~(c) An amount greater than a 72 hour supply if the drug is:~~

22 ~~(A) A drug in the manufacturer's original unit of use packaging, such as a metered-dose inhaler;~~
 23 ~~or~~

24 ~~(B) A full course of therapy, if in the professional judgment of the practitioner would be in the~~
 25 ~~patient's best interest, such as a course of antibiotic therapy.~~

26 ~~(2) Non-traditional dispensing means the dispensing of drugs to a patient and is:~~

27 ~~(a) A drug therapy greater than a 72 hour supply, not contemplated within section (1)(c); or~~

28 ~~(b) Any refill.~~

31 855-043-0515

32 Registration

33 **(1) A practitioner who engages in dispensing drug therapies greater than a 72 hours supply**
34 **or any medication refill dispenses a drug must register their dispensing site as a drug outlet**
35 **with the Board as a DPDO in the category of Retail Drug Outlet on a form provided by the**
36 **Board, and must renew its registration annually on a renewal form provided by the Board.**

37 **(2) A practitioner is exempt from this registration requirement if the practitioner only**
38 **engages in:**

39 **(A) Dispensing FDA approved drug samples; or**

40 **(B) Dispensing Medication Assistance Program (MAP) drugs; or**

41 **(C) Dispensing a small amount of drugs to start therapy or incidental to a procedure or**
42 **office visit, up to a 72 hour supply; or**

43 **(D) An amount greater than a 72 hour supply if the drug is:**

44 **(i) A drug in the manufacturer's original unit-of-use packaging, such as a metered-dose-**
45 **inhaler; or**

46 **(ii) A full course of therapy, if in the professional judgment of the practitioner would be in**
47 **the patient's best interest, such as a course of antibiotic therapy.**

48 ~~(2) A practitioner is exempt from this registration requirement if practitioner only engages in~~
49 ~~traditional dispensing.~~

50 **(3) The initial application must state the location of the DPDO and the name of the person**
51 **applying for registration. When the person applying for registration is not the owner of the**
52 **dispensing site, the application must disclose the name and address of the owner and the**
53 **applicant's affiliation with the owner.**

54 **(a) If more than one individual owns the dispensing site, the names and addresses of the**
55 **partners or persons holding the three largest ownership interests in the dispensing site**
56 **must be disclosed on the application.**

57 **(b) If the owner is a corporation, the application must state the name of the corporation as**
58 **filed with the Corporation Division of the Oregon Secretary of State, including the names**
59 **of the corporation's officers.**

60 **(4) Upon request by the Board, the applicant must furnish such information as required by**
61 **the Board regarding the partners, stockholders, or other persons not named in the**
62 **application.**

63 **(5) An initial application must be accompanied by the fee established in division 110 of this**
64 **chapter. The fee is not to exceed \$100.**

65 **(6) A certificate of registration will be issued upon Board approval of the application.**

66 **(7) All registration renewal applications must be accompanied by the annual renewal fee**
67 **(~~not to exceed \$100~~) established in Division 110 of this chapter and must contain the**
68 **information required in sections (2) and (3) of this rule.**

69 **(8) The DD registration expires December 31, annually. If the annual renewal fee referred**
70 **to in section (5) of this rule is not paid by November 30 of the current year, the applicant**
71 **for renewal must submit the delinquent fee established in division 110 of this chapter with**
72 **the renewal application.**

73 **(9) The registration is not transferable and the registration fee cannot be prorated.**

74 **(10) The registrant must notify the Board, within 15 days, of any substantial change to the**
75 **information provided on the registration application. Substantial change shall include but**
76 **not be limited to: change of ownership; change of business address; change of normal**
77 **business hours; any disciplinary action taken or pending by any state or federal authority**
78 **against the registrant, or any of its principals, owners, directors, officers, consultant**
79 **pharmacist or supervising physician.**

80 **(11) A new registration form is required for a change of ownership or location and must be**
81 **submitted to the Board with the fees as specified in division 110 of this chapter within 15**
82 **days of the change.**

83 **(12) The Board may grant a time-limited waiver exempting DPDO registration when a**
84 **practitioner licensing board submits a request to the Board with a plan to annually inspect**
85 **the dispensing facility to the standards of the Board.**

86 **Stat. Auth.: ORS 689.205**

87 **Stats. Implemented: ORS 689.155, 689.305**

88 **Policies and Procedures**

89 **855-043-0520**

90 **The registered DPDO must maintain written policies and procedures for the management**
91 **of drugs intended for dispensing, to include security, acquisition, storage, dispensing and**
92 **drug delivery, disposal and recordkeeping . BOP will craft a sample set**

93 **Stat. Auth.: ORS 689.205**
94 **Stats. Implemented: ORS 689.155, 689.305**

95

96 **855-043-0525**

97 **Security**

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

101 **(2) A drug dispensing machine can not be placed in a waiting room or an area that is**
102 **accessible by the public.**

103 **Stat. Auth.: ORS 689.205**
104 **Stats. Implemented: ORS 689.155, 689.305,**

105 **855-043-0530**

106 **Drug Acquisition**

107 **The registered DPDO must verify that all drugs are acquired from a registrant of the**
108 **Board.**

109 **Stat. Auth.: ORS 689.205**
110 **Stats. Implemented: ORS 689.155, 689.305,**

111 **855-043-0535**

112 **Drug Storage**

113 **All drugs must be stored according to manufacturer's published guidelines and be stored**
114 **in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and**
115 **space.**

116 **Stat. Auth.: ORS 689.205**
117 **Stats. Implemented: ORS 689.155, 689.305**

118 **855-043-0540**

119 **Labeling**120 **(1) A prescription must be labeled with the following information:**121 **(a) Unique identifier (i.e prescription number);**122 **(b) Name of patient;**123 **(c) Name of prescriber;**124 **(d) Name, address, and phone number of the clinic;**125 **(e) Date of dispensing;**126 **(f) Name and strength of the drug. If the drug does not have a brand name, then the**
127 **generic name of the drug and the drug manufacturer must be stated;**128 **(g) Quantity dispensed;**129 **(h) Directions for use;**130 **(i) Initials of the dispensing practitioner;**131 **(j) Cautionary statements, if any, as required by law; and**132 **(k) Manufacturer's expiration date, or an earlier date if preferable, after which the patient**
133 **should not use the drug; and**134 **(l) Any dispensed prescription medication, other than those in unit dose or unit of use**
135 **packaging, shall be labeled with its physical description, including any identification code**
136 **that may appear on tablets and capsules.**137 **(2) Notwithstanding any other requirements in this rule, when a drug is dispensed in the**
138 **practice of an Expedited Partner Therapy treatment protocol, as described in OAR 855-**
139 **041-4000 through 4005, the name of the patient may be omitted.**140 **Stat. Auth.: ORS 689.205**141 **Stats. Implemented: ORS 689.155, 689.305**

142

143 **855-043-0545**

144 **Dispensing and Drug Delivery**

145 **(1) Drugs dispensed from DPDO by a practitioner ~~must be personally dispensed by the~~**
146 **~~practitioner~~, shall be dispensed in compliance with the practitioner's Board requirements.**

147 **(2) ~~Prior to dispensing a medication a drug utilization review must be performed by the~~**
148 **~~practitioner which includes but is not limited to drug interactions, drug allergies and~~**
149 **~~duplicate drug therapy.~~**

150 **(3) ~~The practitioner must orally counsel the patient concerning all new drugs, unless~~**
151 **~~circumstances would render oral counseling ineffective.~~**

152 **(4) A DPDO must comply with all requirements of State or federal law.**

153 **(5) A DPDO must dispense a drug in a new container that complies with the current**
154 **provisions of the Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S.**
155 **2162) and rules or regulations and with the current United States Pharmacopoeia/National**
156 **Formulary monographs for preservation, packaging, storage and labeling.**

157 **(6) Drugs must be ~~pre~~packaged by the practitioner, a pharmacy, or a manufacturer**
158 **registered with the Board.**

159 **(7) A DPDO may not accept the return of drugs from a previously dispensed prescription**
160 **and must maintain a list of sites in Oregon where drugs may be disposed.**

161 **(8) ~~Must~~ It is recommended that the DPDO have access to the most current issue of at least**
162 **one pharmaceutical reference with current, properly filed supplements and updates**
163 **appropriate to and based on the standards of practice for the setting.**

164 **Stat. Auth.: ORS 689.205**

165 **Stats. Implemented: ORS 689.155, 689.305**

166 **855-043-0550**

167 **Disposal of Drugs**

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

171 **Stat. Auth.: ORS 689.205**

172 **Stats. Implemented: ORS 689.155, 689.305**

173 855-043-0555

174 Record Keeping

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

177 (a) Name of patient;

178 (b) Unique identifier (i.e. prescription number);

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

181 (d) Directions for use;

182 (e) Date of dispensing; and

183 (f) Initials of person dispensing the prescription.

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

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

187 Stat. Auth.: ORS 689.205

188 Stats. Implemented: ORS 689.155, 689.305

189 855-043-0560

190 Inspections

191 (1) The DPDO must complete the Board Self Inspection Form by January 1, annually.

192 (2) Each DPDO will be inspected on a routine basis and shall be scheduled in advance with
193 the practitioner, to occur during normal business hours.

194 (3) The inspection shall focus on the acquisition, storage, labeling and recordkeeping of
195 drugs intended for dispensing and any violation will apply to the DPDO registration and
196 not to the practitioner.

197 **(4) The Board of Pharmacy shall refer any disciplinary action taken against a DPDO to the**
198 **practitioner's licensing Board.**

199 **Stat. Auth.: ORS 689.205**

200 **Stats. Implemented: ORS 689.155, 689.305**

201

202

DRAFT

1 The proposed rule amendments to *Div 044 Charitable Pharmacies* incorporate new statutory
2 language put forth by Senate Bill 1514 (2016), available at this link:

3 <https://olis.leg.state.or.us/liz/2016R1/Downloads/MeasureDocument/SB1514/Enrolled>

4 The rule (1) clarifies that this is an Oregon specific program that allows donations and
5 distribution of donated drugs within Oregon; and (2) prohibits a Charitable Pharmacy from
6 accepting an FDA REMS drug.

8 **DIVISION 44**

9 **CHARITABLE PHARMACIES**

10 **855-044-0001**

11 **Purpose**

12 The purpose of the program is to provide a process to make donated prescription drugs available
13 to needy or uninsured individuals and those with limited access to pharmaceuticals. Under the
14 rules in this Division, a Charitable Pharmacy that is registered with the Oregon Board of
15 Pharmacy (Board) may accept donated drugs for **donation and** distribution **within this state**
16 when the pharmacist can reasonably be assured of the purity and integrity of the drug. The
17 program may not include categories of drugs specified by the Board as excluded from the
18 program.

19 Stat. Auth.: ORS 689.205

20 Stats. Implemented: ORS 689.772 & 689.774

23 **855-044-0030**

24 **Drug Donation**

25 (1) A charitable pharmacy may not accept:

26 (a) Any controlled substance or any kit, package or blister pack that contains any controlled
27 substance;

28 (b) A non-prescription drug;

29 (c) A drug in a container or package that does not contain a product identification label (PIL),
30 except that a drug in a manufacturer's original container or a manufacturer's blister pack does
31 not need to bear a PIL;

32 **(d) An FDA REMS (Risk Evaluation and Mitigation Strategy) drug;**

33 **(e) A drug donated from another state.**

34 (2) A charitable pharmacy may accept:

35 (a) A prescription drug received in original, sealed, tamper-evident packaging that displays the
36 lot number and expiration date of the drug; and

37 (b) Sealed single unit dose packages received in opened packages containing multiple single unit
38 doses.

39 (3) The following are examples of acceptable packaging:

40 (a) Manufacturer's original container;

41 (b) Single-dose blister packs in sealed outer package;

42 (c) Single-dose blister packs in opened outer package;

43 (d) Tamper-evident hospice kit containing manufacturer's original containers.

44 (4) Donated drugs that do not meet the above criteria or are judged by the pharmacist to be
45 unsafe for re-dispensing must be stored separately from the drug supply until they can be
46 destroyed.

47 (5) A charitable pharmacy may accept a drug from:

48 (a) An individual;

49 (b) A long-term care facility;

50 (c) A pharmacy;

51 (d) A practitioner who has been given dispensing privileges by their licensing board and is acting
52 within their scope of practice;

53 (e) Another registered charitable pharmacy;

54 (f) A medical clinic;

55 (g) A drug manufacturer or wholesaler;

56 (h) A Medication Assistance Program (MAP) such as those supported by drug manufacturers.

57 (6) The donor must certify on a Donor Form provided by the Board that the donated drug has
58 been properly stored, in accordance with manufacturer's recommendations, and has never been
59 opened, used, adulterated or misbranded.

60 (7) Upon written request, the Board may waive any of the requirements of this rule if a waiver
61 will further public health and safety. A waiver granted under this section shall only be effective
62 when it is issued in writing.

63 Stat. Auth.: ORS 689.205

64 Stats. Implemented: ORS 689.772 & 689.774

65

66

DRAFT

855-080-0021

Schedule I

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21CFR part 1308.11, and unless specifically excepted or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(a) 1,4-butanediol;

(b) gamma-butyrolactone

(c) Methamphetamine, except as listed in OAR 855-080-0022;

(d) dichloro-N-(2-(dimethylamino)cyclohexyl)-N-methylbenzamide (U-47700)

(e) 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]piperidin-2-ylidene]benzenesulfonamide (W-18) and positional isomers thereof, and any substituted derivative of W-18 and its positional isomers, and their salts, by any substitution on the piperidine ring (including replacement of all or part of the nitrophenylethyl group), any substitution on or replacement of the sulfonamide, or any combination of the above that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility.

(f) Substituted derivatives of cathinone and methcathinone that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or are not FDA approved drugs, including but not limited to,

(A) Methylmethcathinone (Mephedrone);

(B) Methylenedioxypropylvalerone (MDPV);

(C) Methylenedioxymethylcathinone (Methylone);

(D) 2-Methylamino-3',4'-(methylenedioxy)-butyrophenone (Butylone);

(E) Fluoromethcathinone (Flephedrone);

(F) 4-Methoxymethcathinone (Methedrone).

(2) Schedule I also includes any compounds in the following structural classes (2a–2k) and their salts, that are not FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

(a) Naphthoylindoles: Any compound containing a 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the naphthyl ring to any extent. Examples of this structural class include but are not limited to: JWH-015, JWH-018, JWH-019, JWH-073, JWH-081, JWH-122, JWH-200, JWH-210, AM-1220, MAM-2201 and AM-2201;

(b) Phenylacetylindoles: Any compound containing a 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: JWH-167, JWH -201, JWH-203, JWH-250, JWH-251, JWH-302 and RCS-8;

(c) Benzoylindoles: Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Examples of this structural class include but are not limited to: RCS-4, AM-694, AM-1241, and AM-2233;

(d) Cyclohexylphenols: Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring whether or not substituted in the cyclohexyl ring to any extent. Examples of this structural class include but are not limited to: CP 47,497 and its C8 homologue (cannabicyclohexanol);

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

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

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

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

(i) Adamantoylindoles: Any compound containing a 3-(1-adamantoyl)indole structure with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the

indole ring to any extent and whether or not substituted in the adamantyl ring to any extent. Examples of this structural class include but are not limited to: AM-1248 and AB-001;

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

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

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

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

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

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

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

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

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 475.035, 475.059 & 475.065

1 **855-041-4100**

2 **Definitions**

3 (1) "Automated Pharmacy System" (APS) means a mechanical system that performs operations
4 or activities, including but not limited to, those related to the storage, packaging, dispensing, or
5 distribution of medications, but not including compounding or administration, and that collects,
6 controls, and maintains all transaction information.

7 (2) "Remote Dispensing Facility" (RDF) means a facility where drugs are prepared for
8 administration and where requisite pharmacist supervision is provided remotely as approved by
9 the Board.

10 (3) "Remote Dispensing Machine" (RDM) means a component of an Automated Pharmacy
11 System that contains ~~prepackaged~~ drugs for dispensing.

12 (4) "Responsible Pharmacy" means the licensed pharmacy that is responsible for the APS, and
13 RDM.

14 Stat. Auth.: ORS 689.205
15 Stats. Implemented: ORS 689.155

16 **855-041-4120**

17 **Drug Delivery and Control**

18 (1) Each RDM must be registered with the Board, under the control of and connected via
19 computer with a Responsible Pharmacy, but not located in a pharmacy. RDMs must be used only
20 in settings with an established program of pharmaceutical care that ensures prescription orders
21 are reviewed by a pharmacist before release to the patient. The Responsible Pharmacy must
22 establish the policies and procedures necessary to fulfill the requirements of all applicable state
23 and federal laws and regulations.

24 (2) The following must be conspicuously displayed at the site of the RDM:

25 (a) RDM license;

26 (b) DEA registration if required;

27 (c) A certified copy of the Responsible Pharmacy license; and

28 (d) A certified copy of the Pharmacist-In-Charge license.

29 (3) Documentation as to type of equipment, serial numbers, content, policies and procedures, and
30 location shall be maintained in the pharmacy for review by the board. Such documentation must
31 include, but is not limited to:

- 32 (a) Location of RDM(s);
- 33 (b) Manufacturer's name and model for each RDM;
- 34 (c) Description of how the RDM is used;
- 35 (d) Quality assurance procedures to determine continued appropriate use of the automated
36 device; and
- 37 (e) Policies and procedures for training of appropriate personnel, system operation, safety,
38 security, accuracy, patient confidentiality, oral counseling by a pharmacist or pharmacist-intern,
39 access, and malfunction.
- 40 (4) Policies and procedures addressing the operation of the RDM must be maintained in the
41 pharmacy responsible for the APS and at the location at which the RDM has been installed.
- 42 (5) All events involving the contents of the RDM must be recorded electronically. Records must
43 be maintained by the pharmacy for a minimum of three years and must be readily available to the
44 Board. Such records shall include:
 - 45 (a) Identity of RDM accessed;
 - 46 (b) Identification of the individual accessing the RDM;
 - 47 (c) Type of transaction;
 - 48 (d) Date and time of transaction;
 - 49 (e) Name, strength, dosage form, and quantity of the drug accessed;
 - 50 (f) Name of the patient for whom the drug was ordered;
 - 51 (g) Name of the prescribing practitioner
 - 52 (h) Such additional information as the pharmacist-in-charge may deem necessary; and
 - 53

- 54 (6) Only an Oregon ~~registered technician or an Oregon-licensed p~~Pharmacist, Technician, or
55 Board approved use of a Registered Nurse may have access to the RDM.
- 56 (7) Only an Oregon ~~registered technician or an Oregon-licensed p~~Pharmacist, Technician, or
57 Board approved use of a Registered Nurse may stock medications in the RDM.
- 58 (8) All containers of medications stored in the RDM shall be packaged and labeled in accordance
59 with state and federal laws and regulations, including OAR 855-041-1130.
- 60 (9) All aspects of handling controlled substances shall meet the requirements of all state and
61 federal laws and regulations.
- 62 (10) Oral counseling, as required by OAR 855-019-0230, shall be provided by the pharmacist at
63 the time of dispensing by a two-way audio and video hookup with the Responsible Pharmacy.
- 64 (11) The Automated Pharmacy Systems shall provide a mechanism for securing and accounting
65 for wasted, discarded or unused medications in accordance with existing state and federal laws
66 and regulations.
- 67 (12) The RDM must be clearly marked with the name, address, and phone number of the
68 Responsible Pharmacy and Pharmacist-In-Charge.
- 69 (13) A Responsible Pharmacy located outside of Oregon that operates a RDM in Oregon must be
70 currently licensed and in good standing in Oregon. The Pharmacist-In-Charge must also be
71 currently licensed and in good-standing both in Oregon and in the state in which the Responsible
72 Pharmacy is located.
- 73 **(14) A Responsible Pharmacy may apply for the use of an RDM in a licensed residential**
74 **facility that it provides services to, but only when the facility provides 24 hour nursing**
75 **care.**

76 Stat. Auth.: ORS 689.205
77 Stats. Implemented: ORS 689.205

78

October 2016 Board Meeting

Exception and Waiver Request

Mylan Health Management, Retail Drug Outlet applicant

- Request – for a waiver from 855-041-1035, refrigeration letter of exemption
- Mylan Health Management will only be dispensing EpiPen Auto-Injectors, which do not require refrigeration
- Historically the Board has granted a waiver for equipment exemptions when they do not fit the pharmacy's business model.

Staff Recommendation:

- Staff recommends granting the waiver for the requirement to have a refrigerator.

855-041-1035

Minimum Equipment Requirements (Both Retail and Institutional Drug Outlets)

The minimum equipment requirement to open and operate a retail drug outlet and institutional drug outlet in the state of Oregon shall consist of not less than the following:

(1) The most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.

(2) Current and properly filed Oregon Revised Statutes, Chapters 689, and 475; current and properly filed Oregon Administrative Rules, chapter 855; and a minimum of three years of the Board of Pharmacy quarterly newsletters maintained in house or other readily retrievable means.

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

(4) Suitable refrigeration.

(5) A sink with running hot and cold water.

(6) Equipment and supplies appropriate to and based on the standards of practice for the setting as determined by the Pharmacy and Pharmacist-in-Charge.

(7) Failure to have and use equipment necessary to your practice setting constitutes unprofessional conduct for purposes of ORS 689.405(1)(a).

(8) If an outlet files original prescriptions electronically, then the outlet must have a computer and software capable of storing and accessing electronically filed original prescriptions. Exceptions to the above list may be approved by the Board of Pharmacy.

Stat. Auth.:ORS 689.205 & 689.508

Stats. Implemented: ORS 689.205 & 689.508



Mezzanine Floor, Suite 100
2898 Manufacturers Road
Greensboro, NC 27406
Phone: 844-832-2690

May 12, 2016

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232

RE: Mylan Health Management – Refrigeration Letter of Exemption

Dear Sir or Madam:

On behalf of Mylan Health Management, "Mylan", thank you for reaching out and requesting clarification on our Oregon Retail Drug outlet application. Mylan understands that refrigeration is a standard component of the Minimum Equipment Requirements outlined in OAR-855-041-1035. However, Mylan has a unique business model dispensing only EpiPen® Auto-Injector, and will not be filling, dispensing or shipping drugs that will require refrigeration.

Therefore, Mylan respectfully requests an exemption from the minimum standard equipment requirement. Should the nature of our business change in the future, Mylan will attain the necessary requirement, provide notification to the Board of Pharmacy, and comply with any applicable application requirements.

Should you need further information, please feel free to contact me, Deneen Fumich, at 304-554-4519 or deneen.fumich@mylan.com.

Sincerely,

A handwritten signature in black ink that reads "Deneen Fumich". The signature is written in a cursive, flowing style.

Deneen Fumich, R.Ph.
Senior Manager, Regulatory Affairs

Continuing Education Exception Request
RPH Request

- Request – for the Board to grant RPH permission to use 20 CE credits earned on 6/28/2015 towards her 2017 renewal.
- The rule states that 30 credit hours must be completed during July 1 to June 30 of each biennial license renewal cycle. (CE date range of upcoming renewal: 7/1/2015-6/30/2017)
- Circumstances to consider:
 - Historically, the Board is strict with CE dates, however June has always been a ‘confusing’ month.
 - The large transition to biennial has just been completed. Licensees may still be getting familiar with the new rules.
 - The CE was done 3 days outside the acceptable window.

Staff recommendation:

- Staff recommendation granting the request.

855-021-0005

Continuing Pharmacy Education Required for Pharmacist License Renewal

(1) During the period from July 1 through June 30 of each biennial license renewal cycle, each pharmacist must have satisfactorily completed three (3) continuing pharmacy education units (CEU's) in an approved continuing pharmacy education program prior to submission of the license renewal. Ten contact hours equals 1 CEU. Fifty minutes equals 1 contact hour.

(2) Section (1) does not apply to pharmacists applying for the first renewal of their license if they have not been licensed by the Board for at least one year prior to July 1 of the renewal period.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.285

Exception Request

Legacy Good Samaritan Hospital and Medical Center Warehouse, W1-0003650

- Request – to request an exception
- Legacy is not a wholesaler and uses their WHSE registration to hold prescription and non-prescription product delivered by distributors in their own private warehouse.
- Products are for 'own use' and are not resold.

Staff Recommendation:

- Staff recommends re-issuing the waiver.

855-065-0006

Registration Requirements

(1) Every wholesale distributor, wherever located, that engages in wholesale distribution into, out of, or within Oregon must be registered with the Board in accordance with the laws and regulations of Oregon before engaging in wholesale distribution of drugs. Every applicant for registration or renewal of registration must pay the appropriate fee in accordance with OAR 855-110-0007 and 855-110-0010. An applicant must register as a Class I Wholesaler or a Class II Wholesaler unless the applicant qualifies for registration as a Drug Distribution Agent under Division 62 of this chapter of rules.

(2) Application for registration must be on a form approved by the Board and must include, but not be limited to, the following information:

(a) The name, business address, social security number and federal tax identification number of each owner, officer, and stockholder owning more than 10 per cent of the stock of the company, unless the stock of the company is publicly traded;

(b) All trade or business names used by the applicant including any businesses outside Oregon;

(c) The names, addresses and telephone numbers of the designated representatives for all facilities used by the applicant that engage in wholesale distribution into, out of, or within Oregon;

(d) The normal business hours for the applicant; and

(e) Any disciplinary action taken by any state or federal authority against the applicant or any other wholesale distributor under common ownership or control, or any owner, principal or designated representative of the applicant, in connection with the drug laws or regulations of any state or the federal government.

(3) The Board may require a criminal history and financial background check of each principal, owner, officer and designated representative of the applicant prior to initial registration and prior to any renewal. Any such checks shall be at the applicant's expense.

(4) The Board may require a physical inspection of each facility prior to initial registration and prior to any renewal.

(5) Any wholesale distributor located outside the boundaries of Oregon, applying for registration or re-registration, as a Class I Wholesaler, must provide evidence of one of the following:

(a) A current license or registration as a wholesale distributor in a state that has a license or registration procedure approved by the Board that included a physical inspection within the past three years; or

(b) A current accreditation by a process approved by the Board such as The National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor (VAWD) program or other nationally recognized accreditation program or contract inspection service.

(6) Any wholesale distributor located inside the boundaries of Oregon, applying for registration or re-registration, as a Class I Wholesaler, must provide evidence of one of the following:

(a) A current accreditation by a process approved by the Board such as The National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor (VAWD) program or other nationally recognized accreditation program or contract inspection service; or

- (b) That it is a small business as defined in ORS 183.310(10); and
 - (A) The applicant has no affiliation with any out-of-state pharmaceutical company; and
 - (B) All owners and principals of the applicant are Oregon residents; and
 - (C) No owner or principal, or close family member of an owner or principal, has a controlling or business interest in any other pharmaceutical company; and
 - (D) Neither the applicant, nor any of its owners or principals, has ever been found to be in violation of any drug law or regulation in this or any other state.
- (7) In addition to the above registration requirements, an applicant for registration as a Class I wholesaler under this rule, that has not received VAWD accreditation, must provide evidence that it has obtained a bond or equivalent means of security of at least \$100,000 that provides direct access to the Oregon Board of Pharmacy as a beneficiary to secure payment of any administrative penalties that may be imposed by the Board and any fees and costs that may be incurred by the Board and that:**
- (a) Are related to a registration held by the wholesale distributor; and**
 - (b) Are authorized under Oregon law; and**
 - (c) The wholesale distributor fails to pay less than thirty days after the penalties, fees, or costs become final.**
- (8) The Board may make a claim against a bond or security posted under section (7) of this rule within one year after the wholesale distributor's registration is no longer valid or sixty days after the conclusion of whichever occurs later:
- (a) An administrative or legal proceeding before or on behalf of the Board that involves the wholesale distributor and results in penalties, fees or costs; or
 - (b) An appeal of such a proceeding.
- (9) Where operations are conducted at more than one location by a single wholesale drug outlet, each such location that does business in Oregon must be registered by the Board.
- (10) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but not be limited to: change of ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, or designated representatives.
- (11) The registration certificate is issued to a specific person and is non-transferable. Additions or deletions of an owner or partner shall be considered as a change of ownership.
- (12) A new registration form is required for a change of ownership or location and must be submitted to the Board with the fees as specified in OAR 855-110-0007 within 15 days of the change.
- (13) Upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety. A waiver granted under this section shall only be effective when it is issued in writing.
- Stat. Auth.: ORS 689.205
Stats. Implemented: ORS 689.155

Fiona Karbowicz

From: Loper, Donald C :LSO Mgr Materials Transportation <DLoper@LHS.ORG>
Sent: Monday, August 29, 2016 3:15 PM
To: Fiona Karbowicz
Cc: Arinda Wong
Subject: Surety Bond waiver request RE: LIC# W1-0003650

Fiona,

I'm writing to request a waiver from the surety bond requirement for the Wholesaler Class 1 License #W1-0003650 issued to: Legacy Good Samaritan Hospital and Medical Center Warehouse. Located at, 2850 NW 31st St Portland OR 97210.

Renewal forms and address correction forms have been submitted with payment to Oregon Board of Pharmacy.

Arinda Wong has informed me that our Surety Bond Waiver has expired. "Legacy Health submitted a request in 2011 and was granted exemption until October 2016. Prior to expiration of the current waiver request, please resubmit a request for exemption of the surety bond requirement or provide a copy of your VAWD accreditation to meet the requirements as a Wholesaler Class I registrant."

Legacy Health, includes Legacy Good Samaritan, Legacy Emanuel, Legacy Meridian Park, Legacy Mt Hood medical centers and the Randall Childrens Hospital @ Legacy Emanuel. All have inpatient pharmacies. The reason we have a Wholesaler Class 1 license is so we can receive and store IV Solutions like Lactated Ringers and Normal Saline in our warehouse facility for emergency response back up supplies. These items are brought in leading up to the flu season and held in reserve then when the season has passed they are distributed to the hospitals for use.

If additional forms or documents are required please let me know

Respectfully submitted

Donald Loper
Mgr, Materials Transportation
Legacy Health
Ph: 503-413-6256
Cell: 503-953-0104
FAX: 503-413-6948
dloper@lhs.org



Oregon

John A. Kitzhaber, MD, Governor

OCTOBER 2016 / B2

Board of Pharmacy

800 NE Oregon Street, Suite 150

Portland, OR 97232

Phone: 971/673-0001

Fax: 971/673-0002

Email: pharmacy.board@state.or.us

Web: www.pharmacy.state.or.us

October 18, 2011

Legacy Health
1310 NW 22nd Ave
Portland, OR 97210

Re: Legacy Health Surety Bond Waiver Request

Dear Ms. Flynn,

At the Board's October 12, 2011 meeting, the Board reviewed and approved your request to waive the \$100,000.00 surety bond requirement for Legacy Health located at 1310 NW 22nd Ave Portland, OR 97210.

This waiver is valid until October 2016. At which time a request will need to be submitted for Board consideration.

Please attach and retain this determination with your records.

Sincerely,

Gary Miner, R.Ph.
Compliance Director

Cc: Karen MacLean, Administrative Director
Courtney Frank, Licensing Representative





Legacy Health
1919 N.W. Lovejoy Street
Portland, Oregon 97209
www.legacyhealth.org

September 29, 2011

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232

Re: Waiver request for Surety Bond

To Whom It May Concern;

Please use this document as a formal request to waive evidence of a \$100,000 Surety Bond required as part of the Wholesaler Class I registration.

Legacy Health is not a wholesaler. We will be using this registration to hold prescription and non-prescription product delivered by distributors in our private warehouse. The products are for our own use in our facilities, nothing will be resold.

Sincerely,

Megar Flynn
Buyer II
Legacy Health

Exception Request

Option Care at Legacy Health LLC, RP-0001173

- Request – to request an exception to OAR 855-041-1045(3) & (4)
- A prescription for Fabrazyme (enzyme-replacement therapy) was delivered to the wrong house and Option Care is asking for permission to re-dispense the product to a different patient.
- The incorrect person who initially received it called to notify pharmacy of the error and the delivery driver immediately returned to pick it up. It was in the person's home for less than 30 minutes and remained in the original packaging.
- Fabrazyme is only available via patient-specific distribution from the manufacturer and is valued at \$11,000. Option Care states that they can ensure that there was not a period of time where the drug was stored outside the necessary parameters.

Staff Recommendation:

- Staff recommends Board discussion.

855-041-1045

Returned Drugs and Devices

(1) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians may only accept the return of controlled substances upon receiving a waiver from the Board of Pharmacy.

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

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

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

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

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

(a) The drug is in an unopened, tamper-evident unit;

(b) The drugs or devices have remained at all times in control of a person trained and knowledgeable in the storage and administration of drugs in long term care facilities or supervised living groups using the services of a consultant pharmacist;

(c) The drug or device has not been adulterated or misbranded and has been stored under conditions meeting United States Pharmacopeia standards.

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

Gary Miner

From: LaGrotta, Kristen [kristen.lagrotta@optioncare.com]
Sent: Saturday, August 06, 2016 11:00 AM
To: Gary Miner
Cc: Johnson, Kristen; Scovell, Jennifer
Subject: Request for exception under ORS 855-041-1045(4)

Hello Gary,

I am writing to request an exception under ORS 855-041-1045(4) on behalf of Option Care at Legacy Health, LLC.

One of our drives inadvertently delivered medication to the incorrect patient's home last weekend. The patient who received the medication opened the box, realized it was not hers, and immediately called us to report the error. The driver immediately returned to the home to retrieve the medication, which was in the patient's home less than half an hour.

The medication in question is an enzyme-replacement therapy (Fabrazyme) only available in patient-specific distribution from the manufacturer. The dose that was delivered incorrectly is valued at \$11,000. In addition, the medication was delivered in the original manufacturer vials and returned to the pharmacy with the caps in place, ensuring that no tampering occurred with the medication. The medication is required to be stored under refrigeration, but was still cold and on ice when it arrived back at the pharmacy. Further, the medication is stable for more than half an hour (the time it was in the other patient's home) at room temperature.

The medication was brought back to the pharmacy, sequestered, and has since been stored appropriately under refrigeration. We are requesting permission to redispense this very expensive and rare medication to this patient as we can ensure that proper storage occurred and that no tampering occurred with the vials. We are filing necessary paperwork for the HIPAA breach as required by law and have notified and discussed the error with the patient. However, as these vials are in tamper-evident packaging and we can ensure that there was not a period of time where they were stored outside the necessary parameters, we would prefer to conserve resources and redispense the vials.

Thank you for your attention to this matter. I look forward to your response.

Kristen LaGrotta, Pharm.D.
Pharmacist
Optioncare at Legacy Health, LLC
503-536-8331
503-536-8313 fax

October 2016

Multnomah County Charitable Pharmacy waiver request

Waiver request:

Multnomah County Charitable Pharmacy is requesting a waiver for 855-044-0070 to exempt the requirement of tracking lot numbers and use the waiver clause in 855-044-0050 to accept donated drugs with an expiration date of less than nine months. The proposal also includes a distribution and dispensing model using donated medications repackaged by another charitable pharmacy.

Discussion:

The rule limits the drugs which can be donated to a Charitable Pharmacy to drugs which have a minimum expiration date of nine months. This was used to prevent a Charitable Pharmacy (CP) from receiving a large number of drugs, which are close to expiring. Multnomah County Charitable Pharmacy (MCCP) will be receiving and will use the drugs without an accumulation of outdated drugs. The requirement for the lot number was not anticipated as a problem when the rules was written as the Board intended to allow the repackaged drugs from long term care pharmacies to be use by the CPs. When the medications are repacked by the long term care pharmacies the lot number is usually not include in the labeling. MCCP will destroy any drugs that are recalled eliminating the need to use the lot number for tracking purposes. The third request was to use medications that have been repackaged from the blister packs at the Sirum Charitable Pharmacy would be sent to MCCP in individual containers.

Recommendations:

We would recommend approval of the waivers for the nine month requirement and the exclusion of the lot numbers. The issue of the repackaging may be more problematic. We did allow this to occur for a small charitable pharmacy with limited staff to accept the repackaged drugs base on a shared service contact. This proposal seems to be on a much larger scale approaching wholesaler volume levels, though the Oregon legislature adopted 2016 SB 1514 which does allow this practice. Staff is unsure of how FDA's DQSA regulations co-exist with the new Oregon law. Prior to approving this request, the Board should approach this request with caution and discussion on the DQSA implications.

Below are the applicable rules for these discussions. Please see 2016 SB 1514 as well.

DIVISION 44

CHARITABLE PHARMACIES

855-044-0030

Drug Donation

(1) A charitable pharmacy may not accept:

(a) Any controlled substance or any kit, package or blister pack that contains any controlled substance;

(b) A non-prescription drug;

(c) A drug in a container or package that does not contain a product identification label (PIL), except that a drug in a manufacturer's original container or a manufacturer's blister pack does not need to bear a PIL.

(2) A charitable pharmacy may accept:

(a) A prescription drug received 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.

(3) The following are examples of acceptable packaging:

(a) Manufacturer's original container;

(b) Single-dose blister packs in sealed outer package;

(c) Single-dose blister packs in opened outer package;

(d) Tamper-evident hospice kit containing manufacturer's original containers.

(4) Donated drugs that do not meet the above criteria or are judged by the pharmacist to be unsafe for re-dispensing must be stored separately from the drug supply until they can be destroyed.

(5) A charitable pharmacy may accept a drug from:

(a) An individual;

(b) A long-term care facility;

(c) A pharmacy;

(d) A practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice;

(e) Another registered charitable pharmacy;

(f) A medical clinic;

(g) A drug manufacturer or wholesaler;

(h) A Medication Assistance Program (MAP) such as those supported by drug manufacturers.

(6) The donor must certify on a Donor Form provided by the Board that the donated drug has been properly stored, in accordance with manufacturer's recommendations, and has never been opened, used, adulterated or misbranded.

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

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.772 & 689.774

855-044-0050

Drug Distribution

(1) A charitable pharmacy may not distribute a donated prescription drug that:

(a) Fails to meet the requirements of the program;

(b) Has not been stored in accordance with manufacturer's recommendations;

(c) Has been repackaged, except that a drug that has been repackaged for a long-term care pharmacy may be distributed;

(d) Bears an expiration date that is less than nine months from the date the drug is donated;

(e) Is adulterated or misbranded;

(f) Is a controlled substance;

(g) Is a drug that requires a special registration for dispensing;

(h) Is an over-the-counter drug;

(i) Requires specialty storage or handling;

(j) Requires refrigeration;

(k) Is a compounded drug; or

(L) In the pharmacist's professional judgment, may be unfit for dispensing.

(2) A charitable pharmacy may only dispense a drug to a person who:

(a) Has a valid prescription for the drug; and

(b) Is a resident of Oregon; and

(c) Is underinsured or does not have adequate health insurance coverage for the prescription drug requested; or

(d) Is enrolled in a program of public assistance as defined in ORS 411.010;

(3) A drug may only be dispensed by a pharmacist or by a practitioner who has been given dispensing privileges by their licensing board and is acting within their scope of practice, or by a registered nurse subject to the following:

(a) A registered nurse who is an employee of a charitable pharmacy may dispense a drug to a client of the charitable pharmacy; and

(b) Such dispensing by a registered nurse shall be pursuant to the order of a person authorized to prescribe the drug.

(4) The dispensing practitioner must provide the patient with appropriate counseling on the use of the drug and any potential side effects, and may provide written drug information;

(5) A recipient of a drug under this program must sign a Recipient Form, provided by the Board, that attests that the recipient has been notified that:

- (a) The prescription drug was donated to the program;
 - (b) A visual inspection was conducted by a pharmacist to ensure that the drug has not expired, been adulterated or misbranded, and is in its original, sealed packaging;
 - (c) A pharmacist has determined that the drug is safe to distribute based on the accuracy of the Donor's Form and the visual inspection by the pharmacist;
 - (d) Participants in the program are immune from liability as provided in ORS 689.780; and
 - (e) That they are qualified to receive the drug as specified in section (2) of this rule.
- (6) Upon written request the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.772 & 689.774

Hist.: BP 6-2010, f. & cert. ef. 6-29-10

855-044-0070

Records

- (1) A charitable pharmacy must maintain a donation record of all drugs received that includes:
- (a) Donor's name and address;
 - (b) Drug manufacturer, **lot number**, name and strength;
 - (c) Drug quantity;
 - (d) Expiration date of the drug;
 - (e) Date donated; and
 - (f) The unique identifier.
- (2) A charitable pharmacy must maintain a distribution and dispensing record that includes:
- (a) Drug name and strength;
 - (b) Quantity distributed;
 - (c) Name of manufacturer;
 - (d) **Lot number** and expiration date;
 - (e) Date of distribution or dispensing;
 - (f) Name and address of recipient.
- (3) A charitable pharmacy must maintain a record of all drugs that are destroyed.

(4) In addition to the above records, a charitable pharmacy must cross-reference the donation record and the distribution and dispensing record with the appropriate donor and recipient forms.

(5) A charitable pharmacy must make an annual report to the Board by completing a form provided by the Board and submitting it with their application for renewal of registration.

(6) All records required by these rules must be retained for three years and made available to the Board upon request.

(7) Upon written request the Board may waive any of the requirements of this rule if a waiver will further public health and safety. A waiver granted under this section shall only be effective when it is issued in writing.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.774

Pharmacy Depots

(1) Except when delivering directly to a patient, licensed pharmacists may not participate in the transfer of completed prescription medication containers to or from any location that is not a licensed pharmacy, unless the transfer occurs to:

(a) The office of the patient's health care practitioner; or

(b) The location of the patient; or

(A) Patient's primary residence; or

(B) Alternate residence designated by the patient; or

(C) Patient's workplace; or

(c) The hospital or medical care facility in which a patient is receiving care.

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

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689

855-019-0265

Administration of Drugs

(1) In accordance with ORS 689.655, a pharmacist may administer a drug or device as specified in this rule.

(2) A pharmacist who administers a drug or device must:

(a) Observe, monitor, report, and otherwise take appropriate action regarding desired effect, side effect, interaction, and contraindication associated with administering the drug or device; and

(b) Ensure a record is kept for three years of such activities. This record shall include but is not limited to:

- (A) Patient identifier;
 - (B) Drug or device and strength;
 - (C) Route and site of administration;
 - (D) Date and time of administration;
 - (E) Pharmacist identifier.
- (3) The pharmacist must be acting:
- (a) Under the direction of or pursuant to a lawful prescription or order issued by a licensed practitioner acting within the scope of the practitioner's practice or;
 - (b) In accordance with a written protocol or collaborative drug therapy agreement with a licensed practitioner.
- (4) The pharmacist must be able to document that they have received training on the drug or device to be administered and the route of administration. Such training may include a program approved by the ACPE, curriculum based programs from an ACPE-accredited college, state or local health department programs, training by an appropriately qualified practitioner, or programs approved by the Board.
- (5) The pharmacist may administer a drug or device in conjunction with training the patient or the patient's caregiver how to administer or self-administer the drug or device.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.655

Definitions

855-006-0005

(24) "Shared Pharmacy Service" means a written agreement, that has been approved in writing by the board, that exists for the processing by a pharmacy of a request from another pharmacy or a practitioner licensed to prescribe the drug, to fill or refill a prescription or a drug order, or to perform processing functions including but not limited to:

- (a) Dispensing;
- (b) Drug utilization review;
- (c) Claims adjudication;
- (d) Refill authorizations;
- (e) Compounding; and
- (f) Therapeutic interventions

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

RECEIVED

AUG 03 2016

OREGON BOARD OF PHARMACY

Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232-2162

August 1, 2016

Dear Mr. Miner:

Pursuant to ORS 689.772 (3)(b), we respectfully request a the following three (3) waivers from the Board of Pharmacy.

1. Waiver for OAR 689.772 (2)(a) that stipulates "Prescription drugs received in original, sealed, tamper-evident packaging that displays the lot number and expiration date of the drug". We specifically request two waivers for this subsection.
 - a. For "original, sealed, tamper-evident packaging"
 - b. For "lot numbers"

We have been advised that drugs we obtain from SIRUM Charitable Pharmacy will be repackaged at their secure facility and will not contain lot numbers. For recall purposes, all drugs obtained from SIRUM Charitable Pharmacy will be recalled and destroyed based upon a recalled drug's name, strength and manufacturer.

2. Waiver for OAR 689.722 (3)(A) that stipulates the program may not distribute donated prescription drugs that "bear an expiration date that is less than nine (9) months from the date the drug is donated". We have been advised that the drugs we obtain from SIRUM Charitable Pharmacy may bear expiration dates less than nine (9) months from the date of receipt. We intend to distribute the drugs obtained from SIRUM Charitable Pharmacy to uninsured clients who are in acute need of medication therapy for which we dispense a supply that is less than or equal to a thirty (30) day supply. It is our standard operating procedure to check expiration dates on every prescription drug prepared and dispensed to clients assuring that we are not dispensing expired drugs or drugs that would be expire during the expected duration of use.

Thank you for your consideration. Please contact me with any questions.

Sincerely,

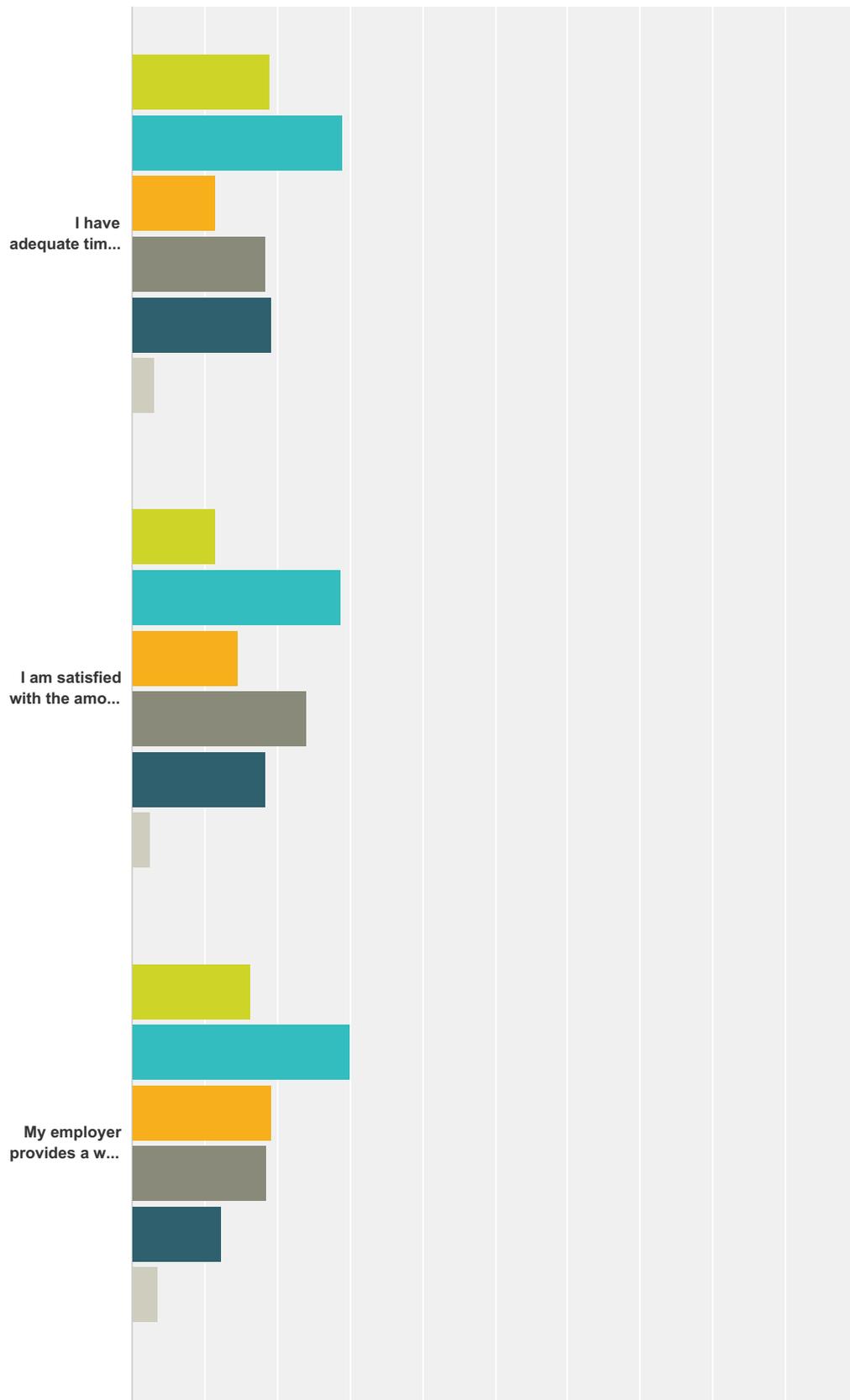


Chris Carter, RPh.
Pharmacy and Lab Services Director
Multnomah County Health Department

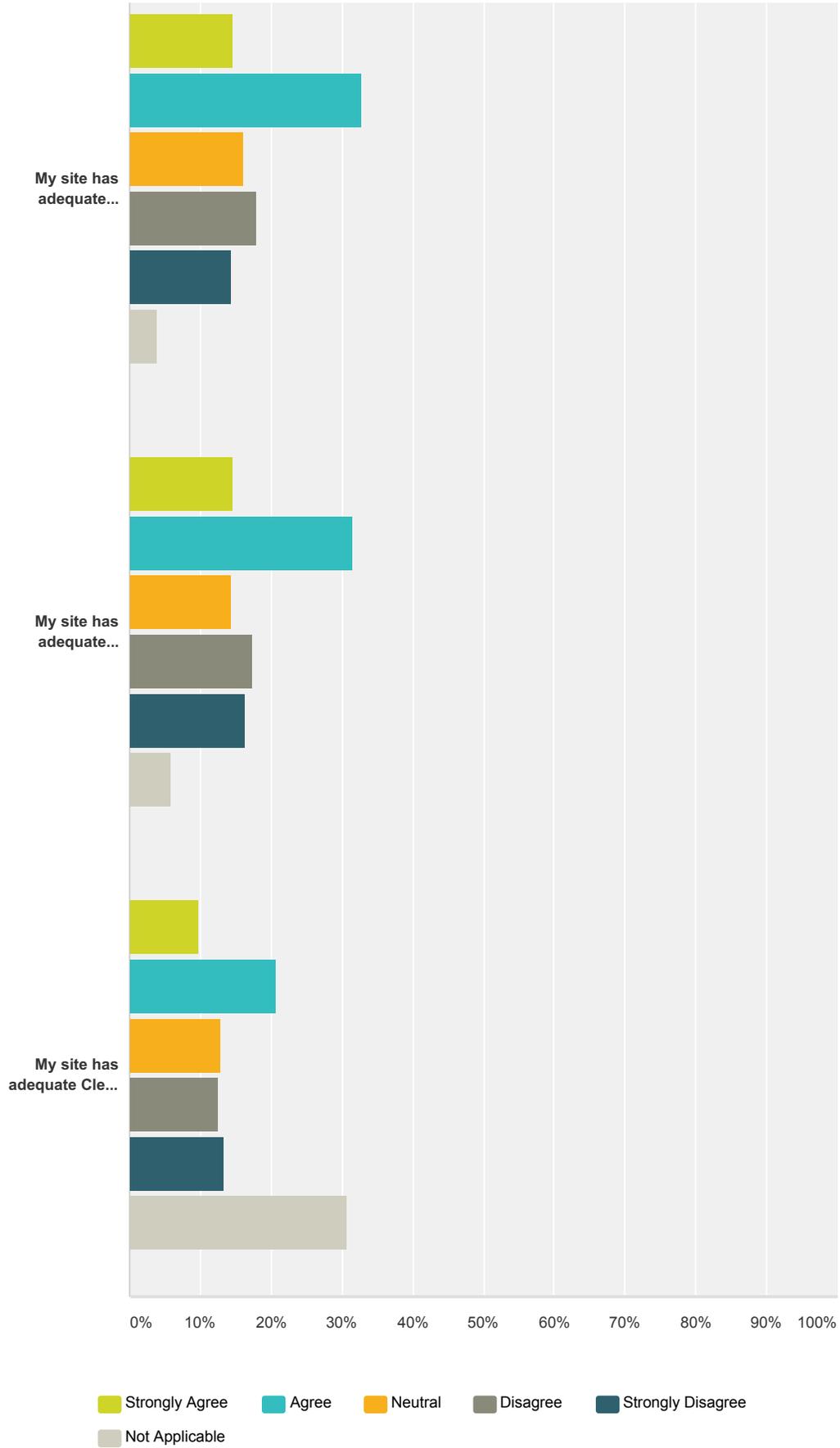
426 SW Stark St, 2nd Floor
Portland, Oregon 97204

Q1 Please rate your level of agreement with the following statements:

Answered: 1,117 Skipped: 3



2016 Follow Up to the 2013 Oregon Board of Pharmacy Working Conditions Survey

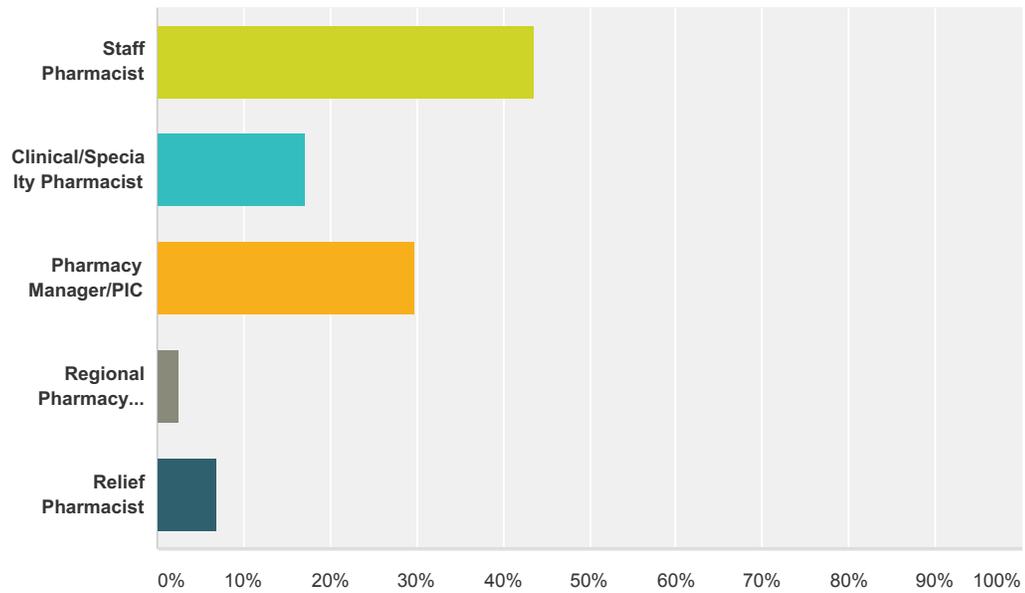


2016 Follow Up to the 2013 Oregon Board of Pharmacy Working Conditions Survey

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Not Applicable	Total
I have adequate time for breaks/lunches at my primary practice site.	18.98% 212	28.92% 323	11.46% 128	18.35% 205	19.16% 214	3.13% 35	1,117
I am satisfied with the amount of time I have to do my job.	11.58% 129	28.73% 320	14.63% 163	24.06% 268	18.40% 205	2.60% 29	1,114
My employer provides a work environment that is conducive to providing safe and effective patient care.	16.25% 181	30.16% 336	19.12% 213	18.67% 208	12.30% 137	3.50% 39	1,114
My site has adequate Pharmacist staff to provide safe and effective patient care.	14.54% 162	32.85% 366	16.07% 179	18.04% 201	14.45% 161	4.04% 45	1,114
My site has adequate Technician staff to provide safe and effective patient care.	14.65% 163	31.45% 350	14.38% 160	17.43% 194	16.26% 181	5.84% 65	1,113
My site has adequate Clerk staff to provide safe and effective patient care.	9.87% 110	20.65% 230	13.02% 145	12.48% 139	13.29% 148	30.70% 342	1,114

Q2 Please select your primary role as a pharmacist:

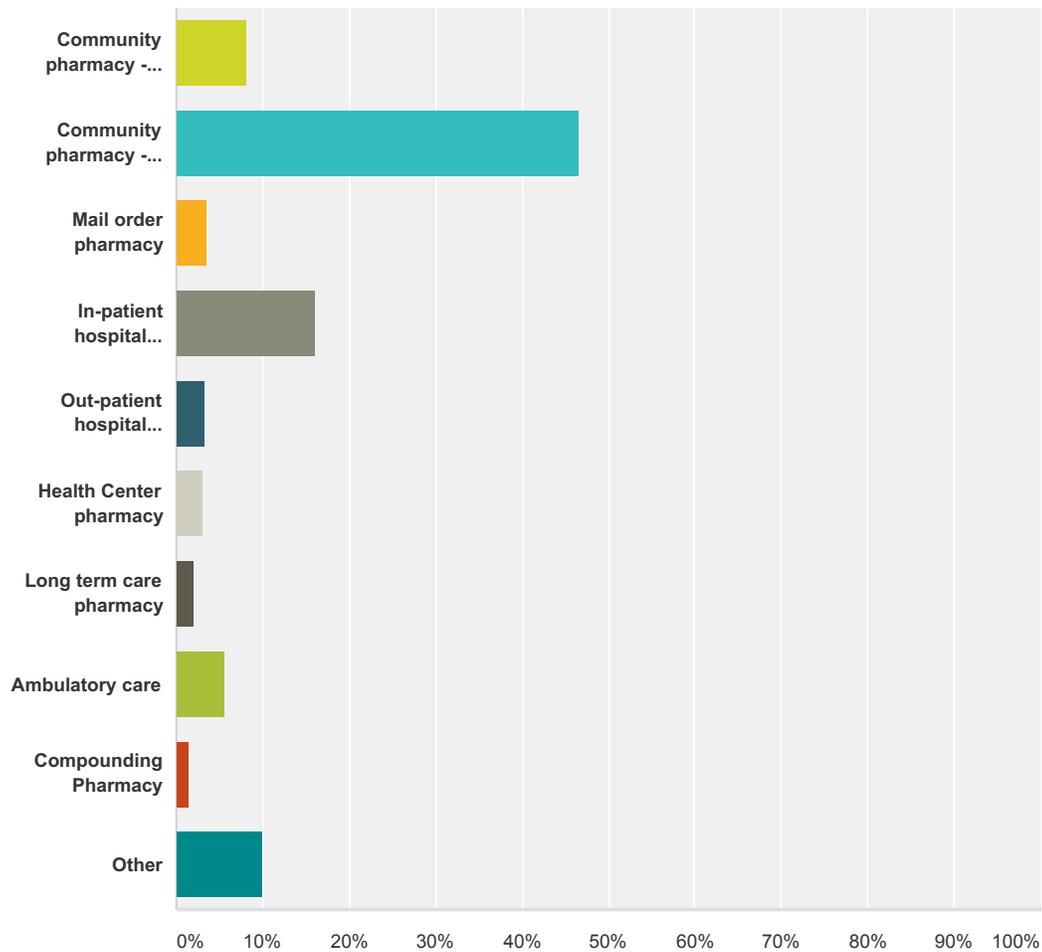
Answered: 1,099 Skipped: 21



Answer Choices	Responses
Staff Pharmacist	43.68% 480
Clinical/Specialty Pharmacist	17.20% 189
Pharmacy Manager/PIC	29.75% 327
Regional Pharmacy Manager/Director/VP	2.46% 27
Relief Pharmacist	6.92% 76
Total	1,099

Q3 Please indicate your primary practice site.

Answered: 1,103 Skipped: 17

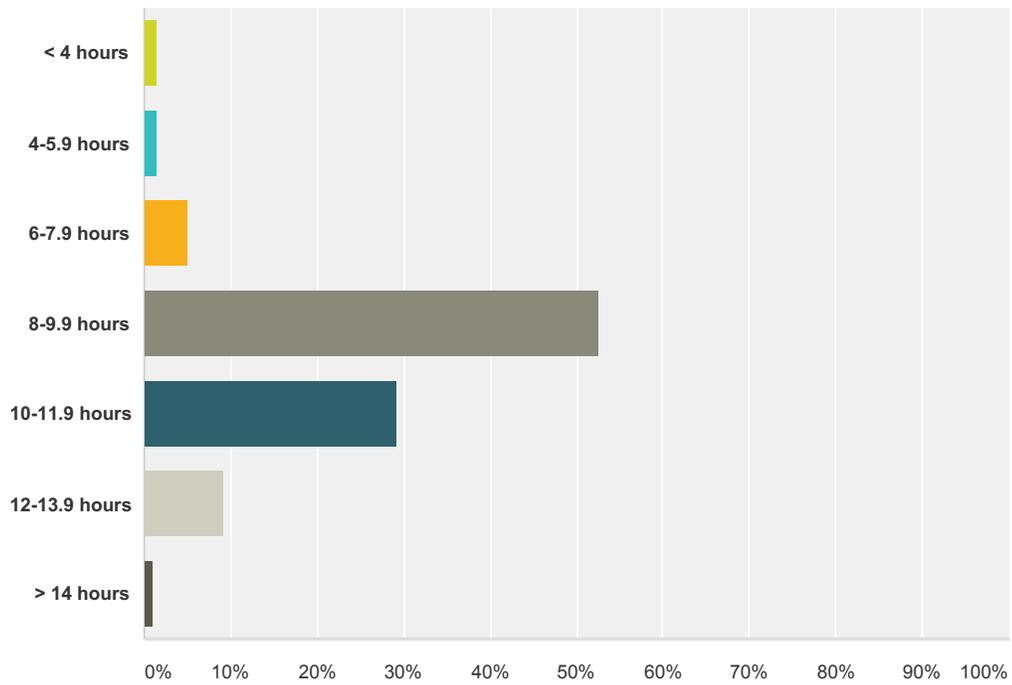


Answer Choices	Responses
Community pharmacy - independent	8.16% 90
Community pharmacy - chain/mass merchandiser	46.60% 514
Mail order pharmacy	3.45% 38
In-patient hospital pharmacy	16.14% 178
Out-patient hospital pharmacy	3.35% 37
Health Center pharmacy	3.17% 35
Long term care pharmacy	1.99% 22
Ambulatory care	5.62% 62
Compounding Pharmacy	1.54% 17
Other	9.97% 110

Total	1,103
-------	-------

Q4 How many hours do you work during a typical shift at your primary practice site?

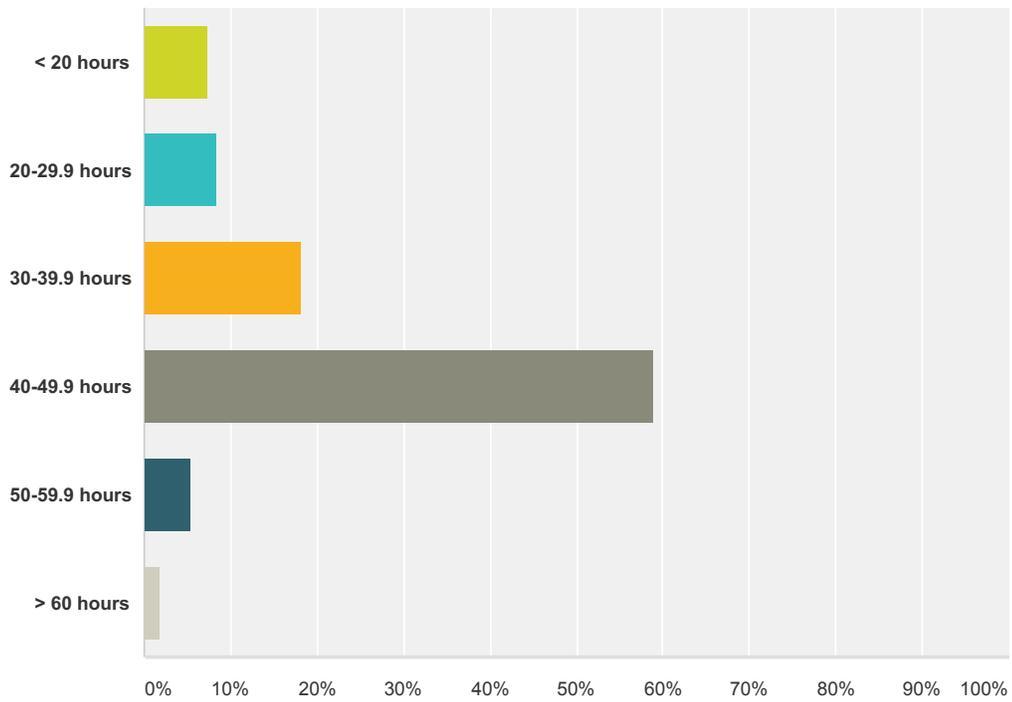
Answered: 1,088 Skipped: 32



Answer Choices	Responses	
< 4 hours	1.38%	15
4-5.9 hours	1.56%	17
6-7.9 hours	4.96%	54
8-9.9 hours	52.57%	572
10-11.9 hours	29.23%	318
12-13.9 hours	9.19%	100
> 14 hours	1.10%	12
Total		1,088

Q5 How many hours do you work in your primary practice site in a typical week?

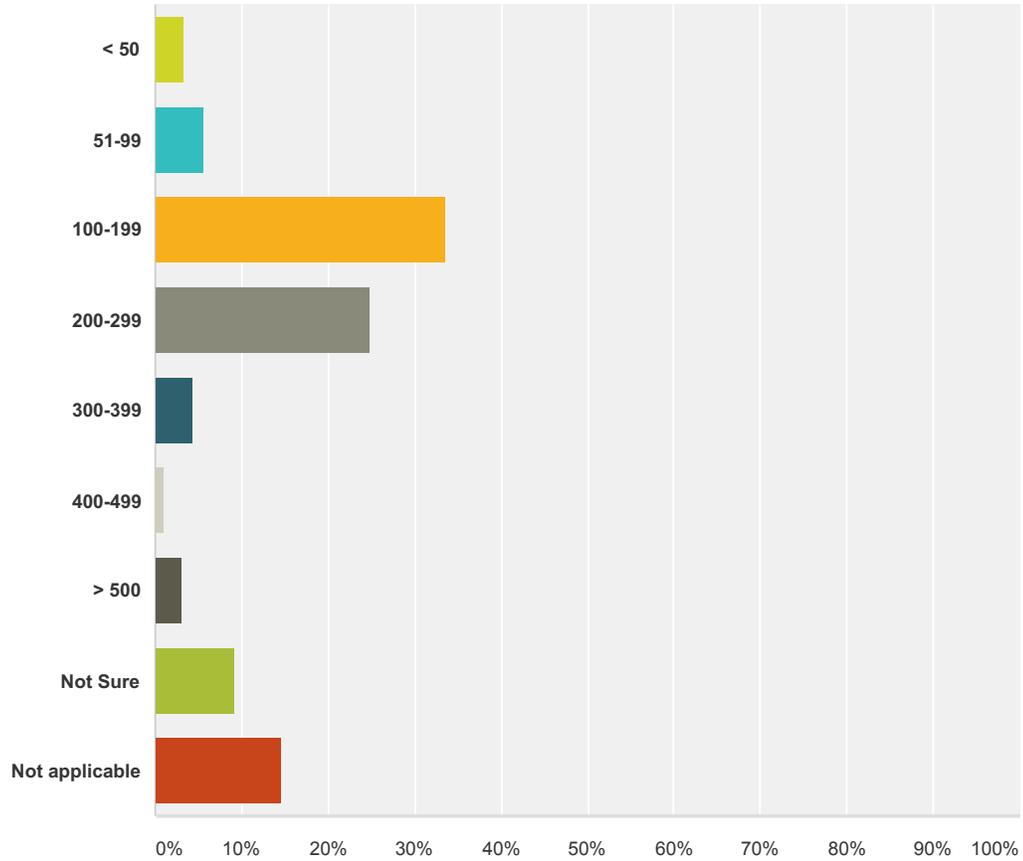
Answered: 1,088 Skipped: 32



Answer Choices	Responses	Count
< 20 hours	7.35%	80
20-29.9 hours	8.36%	91
30-39.9 hours	18.20%	198
40-49.9 hours	58.82%	640
50-59.9 hours	5.33%	58
> 60 hours	1.93%	21
Total		1,088

Q6 Approximately how many prescriptions or orders are processed PER PHARMACIST per day at your site?

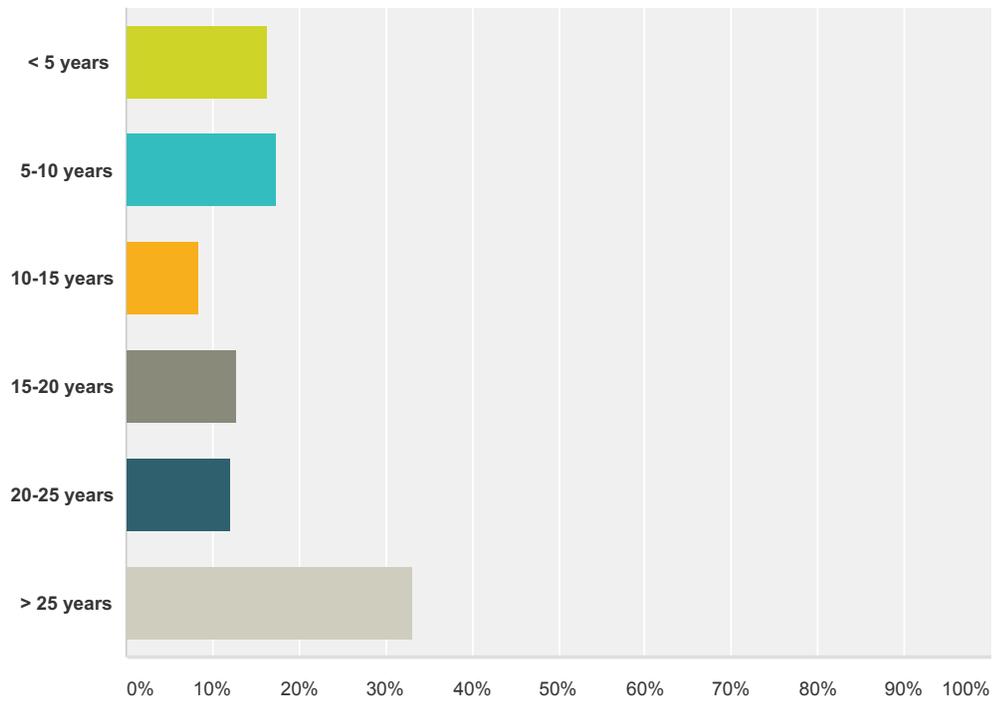
Answered: 1,088 Skipped: 32



Answer Choices	Responses
< 50	3.31% 36
51-99	5.61% 61
100-199	33.64% 366
200-299	24.91% 271
300-399	4.32% 47
400-499	1.10% 12
> 500	3.22% 35
Not Sure	9.19% 100
Not applicable	14.71% 160
Total	1,088

Q7 Please select the number of years you have been a licensed pharmacist.

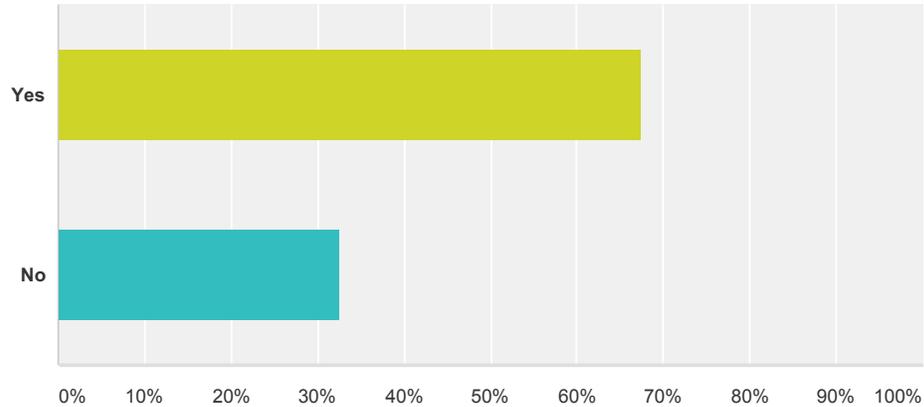
Answered: 1,066 Skipped: 54



Answer Choices	Responses
< 5 years	16.23% 173
5-10 years	17.26% 184
10-15 years	8.44% 90
15-20 years	12.76% 136
20-25 years	12.10% 129
> 25 years	33.21% 354
Total	1,066

Q8 Have you experienced any changes (positive or negative) in your work environment in the past 3 years.

Answered: 1,053 Skipped: 67



Answer Choices	Responses
Yes	67.52% 711
No	32.48% 342
Total	1,053

#	Please explain:	Date
1	Less technician hours. Change to longer shifts of 12 hours per day for pharmacists some days, which is has a negative impact on patient safety.	7/26/2016 11:19 AM
2	Since the implementation of our new pharmacy computer system ePIMS the focus on numbers has gotten worse. It is a lousy system and the company spent a fortune on it, so we are stuck with it. We have had to use a lot of "work arounds" to get our work done. Now that we are "national", "one Kaiser" we are expected to perform like the California Kaiser pharmacies-- yet they don't offer the same services that we do. Our supervisor wants to be better than all of the other regions. Safety isn't the priority. The fewer days it takes to get an order out the door is the motivation. The bar graphs that are sent by national management comparing the regions are a "big deal".	7/21/2016 8:08 PM
3	EPIC (not much else to say about that). Negative. Expectations/speed of info changes.	7/21/2016 5:53 PM
4	Shortened hours per shift. Less technician help. Sometimes no technician in the building.	7/19/2016 7:15 PM
5	Do more with less. Lost a 40 hour/week technician due to his returning to school and was not replaced. New "metrics" to determine clerk/tech hours per week based now on actual scripts SOLD, not just processed per week. Despite making payroll with the additional tech, the hours were actually reduced further. More programs shoved at us to do weekly and new HIGH quota for immunizations this fall. We have no automatic filling machines. Glad I am close to retirement. This is not my idea of pharmacy/patient care.	7/19/2016 4:52 PM
6	I have only been a licensed pharmacist for a few years, but spent many years prior as a technician and in other related capacities. The challenges remain the same: budget cuts in the face of poor reimbursements and increased pressure to complete tasks and responsibilities, as a result of a broken healthcare system.	7/19/2016 12:35 PM
7	Focus of the corporation is profits and not patient safety. They continually understaff and get away with it because there is no regulation. Pharmacists are responsible for too much of the workload and mistakes are made at a higher rate than should be acceptable	7/19/2016 11:53 AM
8	Infrastructure change and Continuous Improvement methodologies are necessary and definitely offer improved patient safety and patient care opportunities. The negative is that support of these take more time than administration is aware of, which impacts patient safety and satisfaction on the back side, (as well as employee satisfaction.)	7/19/2016 10:29 AM

BOARD OF PHARMACY
AY17 CASH FLOW
OF Appn 30235

Budget Objects	REVENUE & EXPENDITURES	LAB ORBITS BUDGET	Rstars Financial Plan	EBoard or Adj Budget or Salary Pot	Adjusted Financial Plan	ACTUALS To Date	Unobligated Balance	% Expended
REVENUE			REV Proj as of 1/31/16					
0205	Other Business Licenses	4,924,832	5,012,583		5,012,583	2,054,986	2,957,598	41%
0210	Other NonBusiness Licenses and Fees	65,855	127,584		127,584	144,553	(16,970)	113%
0505	Fines and Forfeits	270,000	360,573		360,573	309,395	51,177	86%
0605	Interest and Investments	35,000	43,095		43,095	34,351	8,744	80%
0975	Other Revenue	29,700	37,811		37,811	28,888	8,924	76%
SubTotal Revenue		5,325,387	5,581,646	0	5,581,646	2,572,173	3,009,473	46%
TRANSFERS								
2443	Transfer out to OHA--Workforce Data	65,855	65,855		65,855	47,053	18,803	71%
2443	Transfer out to OHA--PDMP program	283,590	283,590	0	283,590	2,520	281,070	1%
SubTotal Transfers		349,445	349,445	0	349,445	49,573	299,873	14%
TOTAL REVENUE & TRANSFERS		5,674,832	5,931,091	0	5,931,091	2,522,600	2,709,600	43%
PERSONAL SERVICES			PS Proj from OSPS Detail					
3110	Regular Employees	2,872,872	2,774,620	142,105	2,916,725	1,333,504	1,612,380.26	46%
	Board Member Stipends		29,160		29,160			
3160	Temporary Appointments	24,322	-		0	-	-	0%
3170	Overtime Payments		-		0	120	(120)	0%
3190	All Other Differential O/Class Lead Work	176,911	174,819		174,819	87,102	87,717	50%
3210	Employment Relations Board Assessment	880	895		895	434	461	48%
3220	Public Employees Retirement Contrib	478,038	434,842	22,438	457,280	202,773	254,507	44%
3221	Pension Bond Contribution	176,574	175,863	2,878	178,741	83,923	94,818	47%
3230	Social Security Taxes	235,168	223,075	10,871	233,946	103,887	130,059	44%
3240	Unemployment Assessment				0	3,298	(3,298)	0%
3250	Workers' Compensation Assessments	1,380	1,308		1,308	587	721	45%
3260	Mass Transit Tax	18,445	17,697	853	18,550	8,511	10,039	46%
3270	Flexible Benefits	610,560	559,693	21,680	581,373	267,481	313,892	46%
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	4,596,718	200,825	4,797,543	2,091,620	2,705,923	44%
SERVICES AND SUPPLIES			Proj all					
4100	InState Travel	106,639	106,639		106,639	49,867	56,772	47%
4125	Out of State Travel	19,985	19,985		19,985	7,210	12,775	36%
4150	Employee Training	48,559	48,559		48,559	11,704	36,855	24%
4175	Office Expenses	119,463	119,463		119,463	60,006	59,457	50%
4200	Telecommunications	36,349	36,349		36,349	18,663	17,686	51%
4225	State Govt. Service Chgs.	72,769	72,769	4,638	77,407	36,477	40,930	47%
4250	Data Processing	56,060	56,060		56,060	25,990	30,070	46%
4275	Publicity & Publications	37,593	37,593		37,593	14,560	23,033	39%
4300	Professional Services	116,711	116,711		116,711	85,325	31,386	73%
4315	IT Professional Services	78,096	78,096		78,096	30,150	47,946	39%
4325	Attorney General	314,038	314,038		314,038	152,551	161,487	49%
4375	Employee Recruitment & Develop	200	200		200		200	0%
4400	Dues & Subscriptions	4,419	4,419		4,419	4,054	365	92%
4425	Facilities Rent & Taxes	217,606	217,606		217,606	96,347	121,259	44%
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	88,718	132,530	40%
4650	Other Services & Supplies	292,293	292,293		292,293	117,478	174,815	40%
4700	Expendable Property	10,124	10,124		10,124	7,559	2,565	75%
4715	IT Expendable Property	40,285	40,285		40,285	10,253	30,032	25%
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	4,638	2,077,271	817,142	1,260,129	39%
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	113,092	63,807	64%
SubTotal Transfers		188,462	188,462	0	188,462	113,092	75,370	64%
Total Expenditures Budget		6,856,245	6,857,813	205,463	7,063,276	3,021,854	4,041,422	43%
					7,057,070			
LAB % PS		67%			68%		Target	100%
LAB % S&S		30%			29%			
LAB % SP		3%			3%			

AY15 Ending Cash Balance	Cash	5,094,726
Revenue less Expenditures		
Total Revenue & Transfers	Actuals	2,522,600
Total Expenditures		(3,021,854)
Total Revenues & Transfers less Expenditures		(499,254)
AY17 Cash Balance after the Fiscal Month Closed		4,595,472
Budgeted Revenues not yet received less Estimated Transfers to OHA-PMP & Workforce Data program to be made		2,709,600
Budgeted Expenditures not yet spent		(4,041,422)
AY17 Estimated Cash Balance		3,263,651
Cash Balance Contingency (Months)		11.42 months