Oregon Board of Pharmacy
BOARD MEETING AGENDA
Meeting Location: Conference Call
August 11-12, 2021

Public Attendance by Phone (503) 446-4951 Phone Conference ID: 924 954 666#

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

Wednesday, August 11, 2021 @ 8:30AM
Thursday, August 12, 2021 @ 8:00AM

- All Board meetings except Executive or Closed Sessions are open to the public. Pursuant to ORS 192.660, Executive Sessions are closed, with the exception of news media and public officials.
- No final actions will be taken in Executive Session.
- When action is necessary, the Board will return to Open Session.
- To sign up for **Public Comment**, email your request to Karen MacLean by **12:00PM on 8/12/2021**.

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

WEDNESDAY, August 11, 2021

I. OPEN SESSION, Wassim Ayoub RPh, Presiding

a. Roll Call
b. Installation and introduction of new Board Member Richard Joyce — *Action Necessary*
c. Agenda Review and Approval — *Action Necessary*

II. EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 676.165, ORS 676.175, ORS 192.660(1)(2)(f)(L), ORS 192.690(1)

a. Legal Advice pursuant to ORS 192.660(2)(f)
b. Deliberation on Disciplinary Cases and Investigations
c. Contested Case Deliberation pursuant to ORS 192.690(1)

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

Adjourn — *Action Necessary*

THURSDAY, August 12, 2021

I. OPEN SESSION, Wassim Ayoub RPh, Presiding

a. Roll Call

II. EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 676.165, ORS 676.175, ORS 192.660(1)(L), ORS 192.690(1)

a. Deliberation on Disciplinary Cases and Investigations
b. Contested Case Deliberation pursuant to ORS 192.690(1)

III. OPEN SESSION – PUBLIC MAY ATTEND – At the conclusion of Executive Session, the Board may convene Open Session to review scheduled agenda items as time permits. We will reconvene at approximately 11:15AM.

a. Introduction of New Board Member Richard Joyce

IV. GENERAL ADMINISTRATION

a. Rules
   i. Review Rulemaking Hearing Report & Comments – none
   ii. Consider Adoption of Rules – none
   iii. Consider Adoption of Temporary Rules – *Action Necessary*
      1. Div 010 - Board Policies/Compensation (2021 HB 2992) *Davis* **#A**
   iv. Rulemaking Policy Discussion Items - *Davis*
      1. Div 006/Div 007/Div 041/Div 045/Div 065 - USP Storage Labeling Repackaging **#A1**
      2. Div 010 - Board Administration/Policies **#A2**
      3. Div 041/043/044 - LEP Informational Inserts **#A3**
      4. Div 041 - Remote Dispensing Site Pharmacy/Telepharmacy **#A4**
      5. Div 041 - Prescription Lockers **#A5**
      6. ORS 475.973 - Pseudoephedrine/Ephedrine Classification **#A6**
      7. Div 080 - Pseudoephedrine/Ephedrine **#A7**
   v. Rules Advisory Committee Update – *Davis*

b. Discussion Items:
   i. Public Health and Pharmacy Formulary Advisory Committee – None
   ii. PharmCon Contraception CE Program Review – *Davis*
   iii. Waiver Request – *Efremoff* **#1** *Action Necessary*
   iv. 2021-2023 Affirmative Action Diversity & Inclusion Plan – *Schnabel* **#B**
   v. COVID-19 Update – *Schnabel* **#C**
   vi. Strategic Plan Update – *Schnabel* **#D**
      - Technicians -
      - Technology -
      - Licensing -
      - Regulation -
      - Communication -
   vii. Legislative Update – *Schnabel* **#E**
   viii. Financial/Budget Report – *MacLean* **#F-F1**

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

a. Reports
   - Board Members
   - Executive Director
   - Compliance Director
   - Administrative Director
   - Licensing Manager
   - Pharmacist Consultant
   - Operations Policy Analyst

- Office Manager

2021 Board Meeting Dates

- October 13-14, 2021 Portland
- November 17-18, 2021 Portland (Strategic Planning)
- December 8-9, 2021 Portland

2022 Board Meeting Dates

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

Rulemaking Hearing Dates

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

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

Conferences/Meetings – *Schnabel*

PAST MEETINGS

FUTURE MEETINGS

1. District 6/7/8 NABP Meeting (Carefree, AZ) – August 29 - September 1, 2021
2. OSPA Annual Meeting (Portland, OR) – October 2, 2021

IV. Approve Consent Agenda* *Action Necessary*

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

a. NAPLEX Scores – None
b. MPJE Scores – None
c. License/Registration Ratification - **# CONSENT - 1**
d. Pharmacy Technician Extensions - **# CONSENT - 2**
e. Board Meeting Minutes – June 9-10, 2021 **# CONSENT-3**

V. Motions related to Disciplinary Actions - *Efremoff* *Action Necessary*

VI. Public Comment

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

Adjourn *Action Necessary*

Division 010 – Board Administration and Policies (HB 2992)

Filing Caption (max 15 words):

- Incorporates directives of 2021 HB 2992 modifying compensation of board members.

Temporary Rule Justification & Statement of Need:

- 2021 HB 2992 directive which modifies amount of compensation paid to members of state boards. Proposed rule amendments take effect 9/25/2021 to align with the effective date of 2021 HB 2992, which is prior to the next scheduled rulemaking hearing to be held in November 2021. Delaying implementation would result in the agency being out of compliance with the directives of 2021 HB 2992.

Fiscal Impact:

- 2021-2023 Biennium: Increase of $51 per member per meeting resulting in a total of a $14,841 increase in Board member and Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) member compensation. Note: August 2021 board meeting and September 2021 PHPFAC meeting prior to 2021 HB 2992 effective date of 9/25/2021.

- 2023-2025 Biennium: Increase of $51 per member per meeting resulting in a total of a $16,116 increase in Board member and Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) member compensation.

Documents Relied Upon:

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

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

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

Rules Summary:

Modifies amount of compensation paid to board members and Public Health and Pharmacy Formulary Advisory Committee members of the Oregon Board of Pharmacy. Requires board to pay compensation and expenses to certain members with adjusted gross income below threshold outlined in ORS 292.495. Provides that members may decline to accept compensation or reimbursement.

Division 10
BOARD ADMINISTRATION AND POLICIES

855-010-0016
Board Administration and Policies: Pharmacy Board Member or Formal Advisory Committee Member Compensation

(1) A board member ~~or member of an advisory committee~~ **and Public Health and Pharmacy Formulary Advisory Committee member** of the Oregon Board of Pharmacy who is entitled to compensation under ORS 292.495 is eligible to receive **an amount equal to the per diem amount paid to members of the Legislative Assembly under ORS 171.072** ~~up to $100 compensation~~ when engaged in the performance of official duties for each day **or portion thereof.** ~~, calculated as whichever amount is the greater of:~~

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

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

(2) For the purpose of compensation, a board member or member of an advisory committee is considered engaged in the performance of official duties when:

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

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

(c) Attending an official advisory committee, such as the Public Health & Pharmacy Formulary Advisory Committee meeting.

(3) Except as otherwise provided by law, all members, including those employed in full-time public service, may receive actual and necessary travel or other expenses actually incurred in the performance of their official duties within the limits provided by law or by the Oregon Department of Administrative services under ORS 292.210 – 292.250.

(4) No board or committee member shall be required to accept compensation or reimbursement of travel expenses while performing their official duties as a board or committee member.

Statutory/Other Authority: ORS 689.115 & ORS 689.205
Statutes/Other Implemented: ORS 689.115, ORS 294.495, ORS 689.175, ORS 689.645**,** ~~& 2017 OL Ch. 106~~ **ORS 689.649 & ORS 171.072**

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

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

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

Fiscal Impact:
None anticipated

Documents Relied Upon:
United States Pharmacopeia -National Formulary <NF> (USP 43-NF38 v. 2021) https://www.uspnf.com/
Homeopathic Pharmacopoeia of the United States (HPUS) (v. 2021): https://www.hpus.com/
Related Federal Statutes/Rules: 21 USC 351 (XX/XX/XXXX), 21 USC 352 (XX/XX/XXXX): https://uscode.house.gov/download/download.shtml

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

Division 6
DEFINITIONS

855-006-0005
Definitions

As used in OAR chapter 855:

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

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

(~~2~~**3**) "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board and has completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for clerical duties, such as recordkeeping, cashiering, bookkeeping and delivery of medications released by the pharmacist are not considered pharmacy technicians.

(~~3~~4) “Clinical Pharmacy Agreement” means an agreement between a pharmacist or pharmacy and a health care organization or a physician that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician.

(4~~5~~) "Collaborative Drug Therapy Management" means the participation by a pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:

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

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

(~~5~~6) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

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

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

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

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

(~~7~~8) "Consulting Pharmacist" means a pharmacist that provides a consulting service regarding a patient medication, therapy management, drug storage and management, security, education, or any other pharmaceutical service.

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

(~~9~~10) "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.

(~~10~~11) "Interpretation and evaluation of prescription orders" means the review of the order for therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug

ordered, its applicability and its relationship to the other known medications used by the patient and determination of whether or not the dose and time interval of administration are within accepted limits of safety. The legal review for correctness of the prescription order includes a determination that the order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose, contains all information required by federal and state law, and is within the practitioner's scope of practice.

(~~11~~**12**) "Labeling" means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or commercially packaged legend drug or device.

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

(~~12~~**14**) "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of the therapeutic or adverse effect of medication upon a patient, including direct consultation with the patient or his agent and review of patient records, as to result and side effect, and the analysis of possible interactions with other medications that may be in the medication regimen of the patient. This section shall not be construed to prohibit monitoring by practitioners or their agents.

(~~13~~**15**) "Medication Therapy Management (MTM)" means a distinct service or group of services that is intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product.

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

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

(~~16~~**18**) "Offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy" means, among other things:

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

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

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

(d) Maintaining confidentiality of patient information.

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

(~~17~~**20**) "Oral Counseling" means an oral communication process between a pharmacist and a patient or a patient's agent in which the pharmacist obtains information from the patient (or agent) and the patient's pharmacy records, assesses that information and provides the patient (or agent) with professional advice regarding the safe and effective use of the prescription drug for the purpose of assuring therapeutic appropriateness.

(~~18~~**21**) Participation in Drug Selection and Drug Utilization Review:

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

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

(A) Over-utilization or under-utilization;

(B) Therapeutic duplication;

(C) Drug-disease contraindications;

(D) Drug-drug interactions;

(E) Incorrect drug dosage;

(F) Incorrect duration of treatment;

(G) Drug-allergy interactions; and

(H) Clinical drug abuse or misuse.

(~~19~~**22**) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes include:

(a) Cure of a disease;

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

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

(d) Prevention of a disease or symptomatology.

(~~20~~**23**) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board but has not completed the specialized education program pursuant to OAR 855-025-0012.

(~~21~~**24**) “Practice of clinical pharmacy” means:

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

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

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

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

(~~23~~**26**) "Prescription released by the pharmacist” means, a prescription which has been reviewed by the pharmacist that does not require further pharmacist intervention such as reconstitution or counseling.

(~~24~~**27**) “Prohibited conduct” means conduct by a licensee that:

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

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

(~~25~~**28**) "Proper and safe storage of drugs and devices and maintenance of proper records therefore" means housing drugs and devices under conditions and circumstances that:

(a) Assure retention of their purity and potency;

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

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

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

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

(~~26~~**29**) “Quality Assurance Plan” is a written set of procedures to ensure that a pharmacy has a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems.

(~~27~~**30**) "Responsibility for advising, when necessary or when regulated, of therapeutic values, content, hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing as required by these rules or federal regulation, of the possible therapeutic response to the medication, the names of the chemicals in the medication, the possible side effects of major importance, and the methods of use or administration of a medication.

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

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

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

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

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

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

(~~29~~**32**) "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action. During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, “supervision by a pharmacist” means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders.

(~~30~~**33**) "Therapeutic substitution" means the act of dispensing a drug product with a different chemical structure for the drug product prescribed under circumstances where the prescriber has not given clear and conscious direction for substitution of the particular drug for the one which may later be ordered.

(~~31~~**34**) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a certified Oregon pharmacy technician.

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

Division 7
PUBLIC HEALTH EMERGENCY

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

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

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

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

(3) Controlled substances damaged, lost or stolen shall be documented and reported to the DEA and the Board on DEA Form 41 or DEA Form 106 as appropriate.

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

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

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

855-041-1001
Definitions

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

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

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

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

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

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

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

Statutory/Other Authority: ORS 689.205, ORS 689.522
Statutes/Other Implemented: ORS 689.155, 689.522, ORS 689.564

855-041-1035
Minimum Equipment Requirements ~~(Both Retail and Institutional Drug Outlets)~~

(1) Each ~~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~~ **must have** the following:

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

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

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

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

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

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

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

(g) Signage in a location easily seen by the public as required by ORS 689.515(4), ORS 689.564(5), OAR 855-041-2100(2), and ORS 689.686(1); and

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

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

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

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

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

855-041-1036
Proper Storage of Drugs

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(3) Vaccine Drug Storage:~~

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

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

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

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

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

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

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

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

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

(3) Each pharmacy must:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(n) Document the following for each temperature excursion:

(i) Date of temperature excursion;

(ii) Start and end time;

(iii) Minimum and maximum temperatures reached;

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

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

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

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

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

(B) Name of the representative providing the information;

(C) Manufacturer contact information;

(D) Copy of information provided by manufacturer;

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

(F) Reference number associated with manufacturer contact;

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

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

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

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

855-041-1040
Drug Outlet Procedures

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

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

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

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

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

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

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

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

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

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

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

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

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

855-041-1130
Retail Drug Outlet Pharmacy Prescription Labeling

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

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

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

POLICY DISCUSSION: Fill vs. Dispense

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) Be labeled to identify at a minimum:

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

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

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

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

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

(ii) The manufacturer's expiration date; or

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

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

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

(b) Be labeled to identify at a minimum:

(A) Brand name or generic name;

(B) Strength;

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

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

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

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

855-041-6270
Institutional Drug Outlet Pharmacy Prescription Labeling

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

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

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

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

(c) The strength of the drug.

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

(a) Name and location of patient;

(b) Name and strength of drug;

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

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

(e) Auxiliary labels as needed, and

(f) Expiration date.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Division 45
DRUG COMPOUNDING
855-045-0200
Application

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

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

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

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

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

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

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

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

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

855-045-0220
Personnel and Responsibilities

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

(2) The Pharmacist-in-Charge (PIC) and the drug outlet shall establish, maintain and enforce policies and procedures in accordance with the standards **required** in **OAR 855-045-0200(3)**~~USP Chapters~~ for all

aspects of the compounding operation according to the type of compounding performed and shall include written procedures for:

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

(b) Hand hygiene;

(c) Garbing;

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

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

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

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

(h) Creating compounding records;

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

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

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

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

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

855-045-0240
Labeling **of Compounded Drugs**

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

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

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

(3) The dosage form and route of administration;

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

(5) The total quantity of the drug product;

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

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

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

Division 65
WHOLESALE DRUG OUTLETS

855-065-0005
Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Counterfeit, diverted, or stolen;

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

(c) The subject of a fraudulent transaction; or

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

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

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

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

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

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

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

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

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

(D) The container size;

(E) The number of containers;

(F) The lot number of the product;

(G) The date of the transaction;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~(a) Further sale; or~~

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

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

(a) Potentially counterfeit, diverted, or stolen;

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

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

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

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

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

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

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

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

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

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

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

(A) Emergency medical reasons;

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

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

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

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

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

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

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

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

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

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

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

(m) The distribution of drugs by a manufacturer registered under division 60 of this chapter of rules of its own products to a person other than a patient.

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

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

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

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

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

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

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

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

(D) Oxygen USP and medical gases;

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

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

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

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

Filing Caption (max 15 words):

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

Need for Rules:

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

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

Fiscal Impact:

- 2021-2023 Biennium: Increase of $51 per member per meeting resulting in a total of a $14,841 increase in Board member and Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) member compensation. Note: August 2021 board meeting and September 2021 PHPFAC meeting prior to 2021 HB 2992 effective date of 9/25/2021.

- 2023-2025 Biennium: Increase of $51 per member per meeting resulting in a total of a $16,116 increase in Board member and Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) member compensation.

Documents Relied Upon:

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

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

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

Rules Summary:

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

Division 10
BOARD ADMINISTRATION AND POLICIES

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

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

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

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

855-010-0005
Meetings

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

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

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

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

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

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

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

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

855-010-0015
Individual Commitments

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

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

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

855-010-0016
Board Administration and Policies: Pharmacy Board Member ~~or~~ **and Public Health and Pharmacy Formulary** ~~Formal~~ Advisory Committee Member Compensation

(1) A board member ~~or member of an advisory committee~~ **and Public Health and Pharmacy Formulary Advisory Committee member** of the Oregon Board of Pharmacy who is entitled to compensation under ORS 292.495 is eligible to receive **an amount equal to the per diem amount paid to members of the Legislative Assembly under ORS 171.072** ~~up to $100 compensation~~ when engaged in the performance of official duties for each day **or portion thereof.**~~, calculated as whichever amount is the greater of:~~

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

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

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

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

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

(c) Attending an **authorized** meeting ~~of an official appointed advisory committee, such as the Public Health & Pharmacy Formulary Advisory Committee meeting~~.

(3) Except as otherwise provided by law, all members, including those employed in full-time public service, may receive actual and necessary travel or other expenses actually incurred in the performance of their official duties within the limits provided by law or by the Oregon Department of Administrative services under ORS 292.210**, ORS 292.220, ORS 292.230, and**~~–~~ **ORS** 292.250.

(4) ~~No~~ **A** board **member** or **Public Health and Pharmacy Formulary Advisory** ~~c~~**C**ommittee member ~~shall be~~ **is not** required to accept compensation or reimbursement of travel expenses while performing their official duties as a board or **appointed** committee member.

Statutory/Other Authority: ORS 689.115 & ORS 689.205
Statutes/Other Implemented: ~~ORS 689.115~~, ORS 29~~4~~**2**.495, ORS 689.175, ORS 689.645**,** ~~& 2017 OL Ch. 106~~ **ORS 689.649 & ORS 171.072**

855-010-0021
Adoption by Reference

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

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

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

855-010-0035
Board Compliance Program

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

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

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

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

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

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

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

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

(c) The ~~B~~**b**oard may require additional information from the applicant or licensee, such as, but not limited to, proof of identity, previous names, residential history or additional criminal, judicial or other background information.

(4) In making licensing fitness determinations **subject to the requirements of ORS 670.280**, the ~~B~~**b**oard will consider the following:

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

(A) Drug or alcohol offense;

(B) Felony;

(C) Misdemeanor;

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

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

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

(G) Offense requiring registration as a sex offender;

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

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

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

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

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

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

(D) The subsequent commission of another relevant crime;

(E) Whether the conviction was set aside and the legal effect of setting aside the conviction; and

(F) A recommendation of an employer**.**

(c) The facts that support the conviction or indictment, or that indicate the making of a false statement;

(d) The relevancy, if any, of the crime or the false statement to the specific requirements of the subject individual's license or registration; and

(e) Any false statement or omission made to the ~~B~~**b**oard regarding the individual's criminal history.

(f) Any refusal to submit or consent to a criminal record check including a refusal to provide fingerprint identification;

(g) Any other pertinent information obtained as part of an investigation.

(h) The ~~B~~**b**oard ~~shall~~**must** evaluate a crime or offense on the basis of the law of the jurisdiction in which the crime or offense occurred.

(i) The following are examples of crimes likely to result in denial unless there are significant mitigating circumstances:

(A) Aggravated murder;

(B) Murder;

(C) Rape I;

(D) Sodomy I;

(E) Unlawful sexual penetration I;

(F) Sexual abuse I

(j) Under no circumstances ~~shall~~**must** an applicant be denied under these rules because of a juvenile record that has been expunged or set aside pursuant to ORS 419A.260 ~~to~~ **and ORS** 419A.262.

(k) Under no circumstances ~~shall~~**must** an applicant be denied under these rules due to the existence or contents of an adult record that has been set aside pursuant to ORS 137.225.

(5) Criminal offender information is confidential. Dissemination of information received under this rule may only be made to people with a demonstrated and legitimate need to know the information. When the information is part of the investigation of an applicant or licensee, it is confidential pursuant to ORS 676.175. Any fingerprint cards used to conduct a check ~~shall~~**must** be destroyed by either the Federal Bureau of Investigation or the **Oregon** Department of State Police as specified in ORS 181A.195.

(6) The ~~B~~**b**oard will permit the subject individual for whom a fingerprint-based criminal records check was conducted to inspect the individual's own state and national criminal offender records and, if requested by the subject individual, provide the individual with a copy of the individual's own state and national criminal offender records.

(7) If an applicant, licensee or registrant is denied a license, they are entitled to a contested case hearing pursuant to ORS 183.413, ORS 183.415, ORS 183.417**, ORS 183.425, ORS 183.430, ORS 183.435, ORS 183.440, ORS 183.445, ORS 183.450, ORS 183.452, ORS 183.453, ORS 183.457, ORS 183.458, ORS 183.459, ORS 183.460, ORS 183.462, ORS 183.464,** ~~to~~ **and ORS 183.**470 and in accordance with OAR 855-001-0005**, OAR 855-001-0012, OAR 855-001-0016,** ~~to~~ **and OAR 855-001-**0017.

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

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

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

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

855-010-0110
State and Nationwide Criminal Background Checks for Employees, Volunteers and Employment Applicants

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

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

(a) To complete the criminal records check and fitness determination, the ~~B~~**b**oard may require additional information from the employee, volunteer or applicant, such as, but not limited to, proof of identity or additional criminal, judicial or other background information.

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

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

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

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

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

855-010-0120
Criminal Background Checks – **Costs** ~~Fees~~

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

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

855-010-0130
Military Spouse or Domestic Partner

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

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

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

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

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

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

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

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

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

(a) Two years after the date of issuance;

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

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

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.265, **ORS 670.400 & ORS 670.403** ~~2019 OL Ch. 142 & 2019 OL Ch. 626~~

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

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

Clarifies the definition and requirements for an informational insert

Need for Rules:

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

Fiscal Impact:

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

Documents relied upon include:

ORS 689.505 Labeling requirements; rules

Rules Summary:

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

Division 41
OPERATION OF PHARMACIES

855-041-1001
Definitions
(1) "Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.

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

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

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

(4**5**) "Interchangeable" means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 U~~.~~S~~.~~C~~.~~ 262(k)(4) **(12/26/2020)**.

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

(~~5~~**7**) "Reference biological product" means the biological product licensed pursuant to 42 U~~.~~S~~.~~C~~.~~ 262(a) **(12/26/2020)** against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

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

855-041-1132
Limited English Proficiency and Accessibility

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

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

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(**l**) Nepali;

(m) Amharic; and

(n) Pashtu.

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

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

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

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

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

(b) Identifying number;

(c) Name of patient;

(d) Name of drug and strength; and

(e) Date of fill.

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

Division 43
PRACTITIONER DISPENSING

855-043-0002
Definitions

In this division of rules:

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

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

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

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

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

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

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

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

(~~5~~**7**) "Supervising Physician Dispensing Outlet" (SPDO) means any clinic, office, health care center, treatment center, or other establishment from which a physician assistant dispenses drugs, but that is not otherwise registered with the Board in the category of Retail Drug Outlet.

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

855-043-0436
Supervising Physician Dispensing Outlet - Limited English Proficiency and Accessibility

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

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

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

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

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

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

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

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

(b) Identifying number;

(c) Name of patient;

(d) Name of drug and strength; and

(e) Date of fill.

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

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

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

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

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

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

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

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

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

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

(b) Identifying number;

(c) Name of patient;

(d) Name of drug and strength; and

(e) Date of fill.

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

Division 44
CHARITABLE PHARMACIES

855-044-0005
Definitions

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

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

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

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

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

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

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

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

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

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

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

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

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

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

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

(b) Identifying number;

(c) Name of patient;

(d) Name of drug and strength; and

(e) Date of fill.

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

Division 041– Operation of Pharmacies (Remote Dispensing Site Pharmacy/Telepharmacy)

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

Need for Rules:

Revisions to Division 006 and 041 are necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location.

Fiscal Impact:

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

Documents relied upon include:

2021 SB 629 and related statutes

May 2021 Rules Advisory Committee- Pharmacy Technicians minutes

Rules Summary:

Revisions to Divisions 006 and 041 are necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

855-041-XXX1
Remote Dispensing Site Pharmacy- Purpose and Scope

The purpose of OAR 855-041-XXX1 through 855-041-XX10 is to provide minimum requirements for the locations where telepharmacy services are conducted.

855-041-XXX2
Remote Dispensing Site Pharmacy- Definitions

The following words and terms, when used in OAR 855-041-XXX1 through 855-041-XX10, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section has the definition set out in OAR chapter 855, division 006.

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

(2) "Remote Dispensing Site Pharmacy" means an Oregon location registered as a Retail Drug Outlet Remote Dispensing Site Pharmacy staffed by a Certified Oregon Pharmacy Technician under the supervision, direction and control of an Oregon licensed Pharmacist using a telepharmacy system.

(3) "Telepharmacy" means the delivery of pharmacy services by an Oregon licensed Pharmacist through the use of a telepharmacy system to a patient at a remote location staffed by a Certified Oregon Pharmacy Technician.

(4) "Telepharmacy system" means a system of telecommunications technologies that enables monitoring, documenting and recording of the delivery of pharmacy services at a remote location by an electronic method which must include the use of audio and video, still image capture, and store and forward.

(5) "Still image capture" means a specific image captured electronically from a video or other image capture device.

(6) "Store and forward" means a video or still image record which is saved electronically for future review.

855-041-XXX3
Remote Dispensing Site Pharmacy- Registration

(1) A location that delivers pharmacy services by an Oregon licensed Pharmacist through the use of a telepharmacy system to a patient at a remote location staffed by a Certified Oregon Pharmacy Technician must be registered in Oregon as a Retail Drug Outlet Remote Dispensing Site Pharmacy.

(2) A Retail Drug Outlet Remote Dispensing Site Pharmacy cannot operate without an Affiliated Pharmacy that is registered as a Retail Drug Outlet Pharmacy.

(3) A change of ownership of the Affiliated Pharmacy or location of the Retail Drug Outlet Remote Dispensing Site Pharmacy requires the submission of a new Retail Drug Outlet Remote Dispensing Site Pharmacy application and registration fee within 15 days of occurrence.

(4) An Affiliated Pharmacy must notify the board as specified within 15 days of discontinuing operation of a Retail Drug Outlet Remote Dispensing Site Pharmacy. Notification must include the final disposition of prescriptions stored in the Retail Drug Outlet Remote Dispensing Site Pharmacy.

855-041-XXX4
Remote Dispensing Site Pharmacy- General Requirements

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

POLICY DISCUSSION: Limitation

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

POLICY DISCUSSION: Distance

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

(a) Have the same owner; or

(b) Have a written contract that specifies:

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

(B) The responsibilities of each licensee and registrant; and

(C) The accountabilities of each licensee and registrant.

(c) Utilize a shared telepharmacy system;

(d) Ensure each prescription is dispensed in compliance with chapter 855, divisions 19, 25 and 41;

(e) Use a camera for verification of prescriptions that is of sufficient quality and resolution so that the Oregon licensed Pharmacist from the Affiliated Pharmacy can visually identify the source container, dispensed product and prescription container at the Remote Dispensing Site Pharmacy.

(f) Ensure prescription drugs are not dispensed at the Remote Dispensing Site Pharmacy if an Oregon licensed Pharmacist is not supervising the Certified Oregon Pharmacy Technician utilizing the telepharmacy system, or if the telepharmacy system is not fully operational.

(g) Utilize an Oregon licensed Pharmacist from the Affiliated Pharmacy to perform the professional tasks of interpretation, evaluation, DUR, verification and counseling before the prescription is dispensed;

(h1) Utilize an Oregon licensed Pharmacist and real-time audio-visual communication to offer and provide counsel or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed and document the interaction

-OR-

(h2) Utilize an Oregon licensed Pharmacist and real-time audio-visual communication to provide counseling or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed when counseling is required under OAR 855-019-0230 or when requested and document the interaction.

POLICY DISCUSSION: Counseling

(i) Designate in writing the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians authorized to access the Remote Dispensing Site Pharmacy and operate the telepharmacy system;

(j) Train the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians in the operation of the telepharmacy system and Remote Dispensing Site Pharmacy;

(k) Comply with all applicable federal and state laws and rules;

(L) Test the telepharmacy system and document that it operates properly before providing pharmacy services;

(m) Ensure an Oregon licensed Pharmacist continuously supervises, directs and controls each Certified Oregon Pharmacy Technician at the Remote Dispensing Site Pharmacy using audio and visual technology which must be recorded, reviewed and stored;

(n) Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising a Certified Oregon Pharmacy Technician at the Remote Dispensing Site Pharmacy;

(o) Develop, implement and enforce a plan for routine maintenance of the telepharmacy system;

(p) Develop, implement and enforce a continuous quality improvement program for dispensing services from the Retail Drug Outlet Prescription Locker designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, to improve patient care, to establish the root cause, resolve identified problems, prevent reoccurrence, document errors and irregularities;

(q) Utilize a controlled substance perpetual inventory system of controlled substances that are stocked at the Remote Dispensing Site Pharmacy if allowed by the DEA;

POLICY DISCUSSION: Controlled substances

(r) Provide a telephone number that a patient, patient's agent or prescriber may use to contact the Pharmacist from the Affiliated Pharmacy;

(s) Print the address and telephone number of the Affiliated Pharmacy on the label of each prescription container.

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

(u) Develop, implement and enforce a process for an in person physical inspection of the Remote Dispensing Site Pharmacy by an Oregon licensed Pharmacist at least once every 2 weeks or more frequently as deemed necessary by the Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy. The inspection must utilize the Remote Dispensing Site Pharmacy self-inspection form, be documented and records retained.

855-041-XXX5
Remote Dispensing Site Pharmacy- Personnel Requirements

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

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

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

(4) When providing pharmacy services at the Affiliated Pharmacy the Oregon licensed Pharmacist supervising the Remote Dispensing Site Pharmacy may only supervise one Remote Dispensing Site Pharmacy and must:

(a) Determine and document how many people the pharmacist is capable of supervising, directing and controlling, but no more than a total of four pharmacy technicians between both sites.

(b) Determine and document how the pharmacist will meet the supervision requirements while performing the various services.

(5) When providing pharmacy services only for a Remote Dispensing Site Pharmacy the Oregon licensed Pharmacist may supervise up to two Remote Dispensing Site Pharmacies and must:

(a) Determine and document how many people the pharmacist is capable of supervising, directing and controlling, but no more than a total of four Certified Oregon Pharmacy Technicians between both sites.

(b) Determine and document how the pharmacist will meet the supervision requirements while performing the various services.

(6) The Affiliated Pharmacy is required to comply with the pharmacist's determination in (3) and (4) and retain records.

POLICY DISCUSSION: Supervision

(7) Prior to working at a Remote Dispensing Site Pharmacy, the Certified Oregon Pharmacy Technician, intern and the Oregon licensed Pharmacist supervising the Remote Dispensing Site Pharmacy must have completed a training program on the proper use of the telepharmacy system

855-041-XXX6
Remote Dispensing Site Pharmacy- Security

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

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

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

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

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

(c) Any component of the telepharmacy system is not functioning.

(4) A record must be maintained with the name and license number of each person entering the pharmacy area of the Remote Dispensing Site Pharmacy.

(5) No one may be in the prescription area of a Remote Dispensing Site Pharmacy unless authorized in real-time by an Oregon licensed Pharmacist who is supervising the Remote Dispensing Site Pharmacy and from the Affiliated Pharmacy.

(6) Minimum security methods must include a properly functioning:

(a) Alarm system with an audible alarm at the Remote Dispensing Site Pharmacy and real-time notification to a designated licensee of the Affiliated Pharmacy;

(b) Electronic keypad or other electronic entry system that records the:

(A) Identification of the Oregon licensed Pharmacist authorizing access and securing the Remote Dispensing Site Pharmacy;

(B) Identification of the Certified Oregon Pharmacy Technician accessing and securing the Remote Dispensing Site Pharmacy; and

(C) Date and time of each activity.

(c) Surveillance system that utilizes continuously accessible and recorded two-way audiovisual link between the Affiliated Pharmacy and the Remote Dispensing Site Pharmacy. The system must provide a clear view of:

(A) Dispensing site entrances;

(B) Preparation areas;

(C) Drug storage areas;

(D) Pick up areas; and

(E) Office areas.

855-041-XXX7
Remote Dispensing Site Pharmacy- Policies and Procedures

(1) In addition to the requirements of OAR 855-041-1040, the Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy and the Affiliated Pharmacy drug outlet is accountable for establishing, maintaining, and enforcing written policies and procedures for the Remote Dispensing Site Pharmacy. The written policies and procedures must be maintained at the Affiliated Pharmacy and the Remote Dispensing Site Pharmacy and must be available to the board upon request.

(2) The written policies and procedures must include at a minimum the responsibilities of the Affiliated Pharmacy and each Remote Dispensing Site Pharmacy including;

(a) Security;

(b) Operation, testing and maintenance of the telepharmacy system;

(c) Sanitation;

(d) Storage of drugs;

(e) Dispensing;

(f) Oregon licensed Pharmacist supervision, direction and control of pharmacy technicians;

(g) Drug and/or device procurement;

(h) Receiving of drugs and/or devices;

(i) Delivery of drugs and/or devices;

(j) Counseling

(k) Recordkeeping;

(L) Patient confidentiality;

(m) On-site inspection by an Oregon licensed Pharmacist;

(n) Continuous quality improvement; and

(o) Plan for discontinuing and recovering services if telepharmacy system disruption occurs.

(3) If controlled substances are stored at the Remote Dispensing Site Pharmacy, the policies and procedures must:

(a) Outline the process by which controlled substance prescriptions are verified for both accuracy and legitimacy by the Oregon licensed Pharmacist-in-charge during inspection visits; and

(b) Outline the process for maintaining an accurate controlled substance perpetual inventory for all controlled substances that are stocked at the Remote Dispensing Site Pharmacy.

(4) An Affiliated Pharmacy that provides remote pharmacy services through a telepharmacy system at a Remote Dispensing Site Pharmacy must review its written policies and procedures every 12 months, revise them if necessary, and document the review.

855-041-XXX8

Remote Dispensing Site Pharmacy- Records

(1) The recordkeeping requirements OAR 855-041-XXX1 through 855-041-XX10 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) The Remote Dispensing Site Pharmacy must maintain all required records unless these records are maintained in the Affiliated Pharmacy.

(3) Each step in the filling process must be documented and must include the name, initials, or unique identification code and specific activity of each Oregon licensed Pharmacist or Certified Oregon Pharmacy Technician who performed any portion of the process including transmission, filling, dispensing and delivery of information.

855-041-XXX9
Remote Dispensing Site - Prescription Processing

(1) The Remote Dispensing Site Pharmacy and Affiliated Pharmacy must ensure adequate staffing at both the Remote Dispensing Site Pharmacy and Affiliated Pharmacy.

(2) When the patient receives a prescription at the Remote Dispensing Site Pharmacy, the Oregon licensed Pharmacist must use real-time audio-visual communication to counsel or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed and document the interaction.

(3) A prescription for a controlled substance may be processed by a Remote Dispensing Site Pharmacy and verified by the Affiliated Pharmacy when permitted by federal law.

POLICY DISCUSSION: Controlled substances

855-041-XX10
Remote Dispensing Site Pharmacy- Prohibited Practices

(1) A Remote Dispensing Site Pharmacy may not deliver a prescription.

(2) A Certified Oregon Pharmacy Technician may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the Oregon licensed Pharmacist.

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377 POLICY DISCUSSION: Compounding

Division 041– Operation of Pharmacies (Pharmacy Prescription Lockers)
Filing Caption (15 word limit)**:** Establishes new registration for Retail Drug Outlet Pharmacy Prescription Lockers.

Need for Rules:
The revisions to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

Fiscal Impact:
If a pharmacy chooses to operate a Retail Drug Outlet Pharmacy Prescription Locker then the pharmacy will be required to apply and pay a registration fee for the Retail Drug Outlet Pharmacy Prescription Locker.

Documents relied upon include:
None

Rules Summary:
Procedural rule review and revisions to ensure clarity, transparency and promote patient safety. Rules establish a new drug outlet type of Retail Drug Outlet Pharmacy Prescription Lockers and permit a pharmacy to operate a Retail Drug Outlet Pharmacy Prescription Locker.

Resources:
1) Remote dispensing sites utilizing telepharmacy technologies- Telepharm
2) Lockers which are the pick-up units that hold already prepared drugs by the pharmacy - Parata Wellspot Locker - Scriptcenter LS - iLocalbox

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

855-041-XX11
Pharmacy Prescription Locker - Purpose and Scope

The purpose of OAR 855-041-XX11 through 855-041-XX18 is to provide minimum requirements for the operation of a Retail Drug Outlet Pharmacy Prescription Locker by an Affiliated Pharmacy.

855-041-XX12
Pharmacy Prescription Locker – Definitions

The following words and terms, when used in OAR 855-041-XX11 through 855-041-XX18, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section has the definition set out in OAR chapter 855, division 006.

(1) "Affiliated Pharmacy" means a Retail Drug Outlet Pharmacy registered in Oregon that receives, dispenses and delivers the drug or device directly to the Retail Drug Outlet Pharmacy Prescription Locker and is responsible for the operation of the locker.

(2) "Prescription locker" means a mechanical system that securely stores completed patient-specific prescription and nonprescription medications and devices for pick up and maintains related transaction information that is accessible in real-time.

855-041-XX13
Pharmacy Prescription Locker- Registration

(1) Each Affiliated Pharmacy must be registered as a Retail Drug Outlet Pharmacy with the Board.

(2) Each prescription locker must be registered as a Retail Drug Outlet Pharmacy Prescription Locker and must meet all pharmacy drug storage and security requirements.

(3) The Retail Drug Outlet Pharmacy registration and Retail Drug Outlet Pharmacy Prescription Locker registration must be on display at both the Affiliated Pharmacy and at the Retail Drug Outlet Pharmacy Prescription Locker.

(4) An Affiliated Pharmacy must maintain an active Drug Enforcement Administration Controlled Substance Registration Certificate for each Retail Drug Outlet Pharmacy Prescription Locker and comply with appropriate controlled substance regulations if controlled substance prescriptions are stored in the Retail Drug Outlet Pharmacy Prescription Locker.

POLICY DISCUSSION: Controlled substances

(5) A change of ownership of the Affiliated Pharmacy or location of the Retail Drug Outlet Pharmacy Prescription Locker requires the submission of a new Retail Drug Outlet Pharmacy Prescription Locker application and registration fee within 15 days of occurrence.

(6) An Affiliated Pharmacy must notify the board as specified within 15 days of discontinuing use of a Retail Drug Outlet Pharmacy Prescription Locker. Notification must include the final disposition of prescriptions stored in the Retail Drug Outlet Pharmacy Prescription Locker.

855-041-XX14
Pharmacy Prescription Locker - General Requirements

(1) An Affiliated Pharmacy may operate more than one Retail Drug Outlet Pharmacy Prescription Locker.

POLICY DISCUSSION: Limitation

(2) An Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route.

POLICY DISCUSSION: Distance

(3) A Retail Drug Outlet Pharmacy Prescription Locker-and its Affiliated Pharmacy must:

(a) Have the same owner; or

(b) Have a written contract that specifies:

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

(B) The responsibilities of each licensee and registrant; and

(C) The accountabilities of each licensee and registrant.

(4) The Affiliated Pharmacy must:

(a) Ensure the Retail Drug Outlet Pharmacy Prescription Locker:

(A) Is placed in a secure indoor location that is climate controlled and protected from the elements;

(B) Is securely fastened to a permanent structure so that it cannot be removed;

(C) Stores prescriptions in compliance with the provisions of OAR 855-041-1036;

(D) Utilizes barcode, radio-frequency identification or quick response code technology for stocking, destocking and dispensing;

(E) Provides real-time access to an Oregon-licensed Pharmacist for consultation; and

(F) Utilizes complete chain of custody tracking

(b) Ensure each prescription is dispensed in compliance with chapter 855, divisions 19, 25 and 41;

(c) Ensure that drugs are stored under conditions per OAR 855-041-1036.

(d) Maintain the Retail Drug Outlet Pharmacy Prescription Locker in a sanitary and clean condition.

(e) Ensure prescription drugs are not dispensed from the Retail Drug Outlet Pharmacy Prescription Locker if an Oregon licensed Pharmacist is not available for patient consultation or if the Retail Drug Outlet Pharmacy Prescription Locker is not operable and functioning in all aspects.

(f1) Utilize an Oregon licensed Pharmacist and real-time audio-visual communication to offer and provide counsel or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed and document the interaction

-OR-

(f2) Utilize an Oregon licensed Pharmacist and real-time audio-visual communication provide counsel or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed that requires counseling per OAR 855-019-0230 and document the interaction.

POLICY DISCUSSION: Counseling

(g) Designate in writing the Oregon licensed Pharmacists, Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians authorized to access the Retail Drug Outlet Pharmacy Prescription Locker. No unlicensed personnel may access the Retail Drug Outlet Pharmacy Prescription Locker.

(h) Ensure that stocking and destocking of prescriptions in a Retail Drug Outlet Pharmacy Prescription Locker is completed under the supervision, direction and control of a pharmacist.

(i) Ensure that an Oregon-licensed Pharmacist verifies and documents that:

(A) All prescriptions intended for stocking into the Retail Drug Outlet Pharmacy Prescription Locker were stocked into the Retail Drug Outlet Pharmacy Prescription Locker; and

(B) All prescriptions destocked from the Retail Drug Outlet Pharmacy Prescription Locker were returned to the Affiliated Pharmacy and proper storage, records, etc.

(j) Train the Oregon licensed Pharmacists, Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians in the operation of the Retail Drug Outlet Pharmacy Prescription Locker;

(k) Comply with all applicable federal and state laws and rules;

(l) Test the Retail Drug Outlet Pharmacy Prescription Locker and verify the unit is operable and functioning in all aspects in accordance with minimum acceptable system or unit design specifications before dispensing prescriptions and after an upgrade or change is made to the system. The Affiliated Pharmacy must make the results of such testing available to the board upon request.

(m) Develop, implement and enforce a plan for responding to and recovering from an interruption of service where the Retail Drug Outlet Pharmacy Prescription Locker is not fully operational and functioning.

(n) Develop, implement and enforce a plan for routine maintenance of the Retail Drug Outlet Pharmacy Prescription Locker;

(o) Develop, implement and enforce a continuous quality improvement program for dispensing services from the Retail Drug Outlet Pharmacy Prescription Locker designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, to improve patient care, to establish the root cause, resolve identified problems, prevent reoccurrence, document errors and irregularities;

(p) Provide a telephone number that a patient or patient's agent may use to contact the Pharmacist from the Affiliated Pharmacy;

(q) Display a sign easily viewable by the public stating "This location is a prescription locker, supervised by an Oregon licensed Pharmacist from (insert name of Affiliated Pharmacy, address, and telephone number)." The printing on the sign must be in block letters not less than one inch in height.

(r) Develop, implement and enforce a process for an in person physical inspection of the Retail Drug Outlet Pharmacy Prescription Locker by an Oregon licensed Pharmacist at least once every 4 weeks or more frequently as deemed necessary by the Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy. The inspection must utilize the Retail Drug Outlet Pharmacy Prescription Locker self-inspection form, be documented and records retained.

(s) Ensure that the patient or patient's agent has provided consent to the Affiliated Pharmacy for the patient's prescriptions to be placed in the Retail Drug Outlet Pharmacy Prescription Locker.

(t) Ensure that if the prescription is delivered to the locker and then dispensed from the Affiliated Pharmacy prior to being picked up from the locker then the Affiliated Pharmacy must prevent dispensing of the prescription from the locker.

(u) Obtain proper controlled substance registration for the Retail Drug Outlet Pharmacy Prescription Locker prior to placing any controlled substances in the Retail Drug Outlet Pharmacy Prescription Locker if allowed by the DEA;

855-041-XX15
Pharmacy Prescription Locker- Personnel Requirements

(1) The Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy is responsible for all operations of the Retail Drug Outlet Pharmacy Prescription Locker and enforcing policies and procedures.

(2) A Retail Drug Outlet Pharmacy Prescription Locker may not be accessed by unlicensed personnel.

(3) Prior to utilizing a Retail Drug Outlet Pharmacy Prescription Locker, the Oregon licensed Pharmacist, Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician must have completed a training program on the proper use of the Retail Drug Outlet Pharmacy Prescription Locker.

855-041-XX16
Pharmacy Prescription Locker- Security

(1) The Affiliated Pharmacy, Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy and each Oregon licensed Pharmacist is responsible for the security of the Retail Drug Outlet Pharmacy Prescription Locker including provisions for adequate safeguards against loss, theft or diversion of prescription drugs, and records for such drugs.

(2) The Retail Drug Outlet Pharmacy Prescription Locker must be secured to prevent entry when:

(a) There is no Oregon licensed Pharmacist monitoring the Retail Drug Outlet Pharmacy Prescription Locker; or

(b) There is no Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician employed by the Affiliated Pharmacy present at the Retail Drug Outlet Pharmacy Prescription Locker; or

(c) Any component of the Retail Drug Outlet Pharmacy Prescription Locker is not functioning.

(3) No person may access the Retail Drug Outlet Pharmacy Prescription Locker unless authorized in real-time by an Oregon licensed Pharmacist who is monitoring the Retail Drug Outlet Pharmacy Prescription Locker.

(4) Minimum security methods must include a properly functioning:

(a) Alarm system with an audible alarm at the Retail Drug Outlet Pharmacy Prescription Locker and real-time notification to a designated licensee of the Affiliated Pharmacy;

(b) Electronic entry system that is controlled by an Oregon licensed Pharmacist and records the:

(A) Identification of the Oregon licensed Pharmacist authorizing access and securing the Retail Drug Outlet Pharmacy Prescription Locker;

(B) Identification of the Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician accessing the Retail Drug Outlet Pharmacy Prescription Locker; and

(C) Date and time of each activity.

(c) Surveillance system that utilizes continuously accessible and recorded between the Affiliated Pharmacy and the Retail Drug Outlet Pharmacy Prescription Locker. The system must provide a clear view of the Retail Drug Outlet Pharmacy Prescription Locker and its access points;

POLICY DISCUSSION: Surveillance

855-041-XX17
Pharmacy Prescription Locker - Policies and Procedures

(1) In addition to the requirements of OAR 855-041-1040, the Oregon licensed Pharmacist-in-charge of the Affiliated Pharmacy and the Affiliated Pharmacy drug outlet is accountable for establishing, maintaining, and enforcing written policies and procedures for the Retail Drug Outlet Pharmacy Prescription Locker. The written policies and procedures must be maintained at the Affiliated Pharmacy and must be available to the board upon request.

(2) The written policies and procedures must include at a minimum the responsibilities of the Affiliated Pharmacy and each Retail Drug Outlet Pharmacy Prescription Locker including;

(a) Security;

(b) Operation of the Retail Drug Outlet Pharmacy Prescription Locker including stocking and destocking;

(c) Preventative maintenance of the Retail Drug Outlet Pharmacy Prescription Locker;

(d) Sanitation and cleaning;

(e) Storage of drugs;

(f) Oregon licensed Pharmacist supervision, direction and control of personnel accessing the Retail Drug Outlet Pharmacy Prescription Locker;

(g) Preventing duplicate dispensing;

(h) Stocking and destocking;

(i) Counseling;

(j) Record keeping;

(k) Patient consent and confidentiality;

(l) On-site inspection by an Oregon licensed Pharmacist;

(m) Continuous quality improvement;

(n) Training of all personnel involved in operation of the prescription locker; and

(o) Plan for discontinuing and recovering services if Retail Drug Outlet Pharmacy Prescription Locker disruption occurs.

(3) If controlled substances are stored in the Retail Drug Outlet Pharmacy Prescription Locker, the policies and procedures must:

(a) Require tamper evident packaging of the controlled substances placed into the locker

(b) Require controlled substances be re-counted when returned to the Affiliated Pharmacy after destocking.

(4) An Affiliated Pharmacy that provides prescriptions through a Retail Drug Outlet Pharmacy Prescription Locker must review its written policies and procedures every 12 months, revise them if necessary, and document the review.

855-041-XX18
Pharmacy Prescription Locker – Records

(1) The recordkeeping requirements OAR 855-041-XX11 through 855-041-XX18 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) Records of dispensing from a Retail Drug Outlet Pharmacy Prescription Locker must include the:

(a) Location of the Retail Drug Outlet Pharmacy Prescription Locker;

(b) Identification of the patient or patient's agent retrieving the prescription;

(c) Date and time of transaction;

(d) Each prescription number, patient name, prescriber name, drug name, strength, dosage form and quantity;

(e) Name of pharmacist who provided counseling to the patient or patient's agent, if required, and pharmacist documentation that the counseling was performed or that the pharmacist accepted the patient or patient's agent request not to be counseled.

POLICY DISCUSSION: Counseling

(3) Records of stocking and destocking of prescriptions into or from a Retail Drug Outlet Pharmacy Prescription Locker must include the:

(a) Date and time;

(b) Each prescription number, patient name, prescriber name, drug name, strength, dosage form and quantity

(c) Name and license number of the person stocking or destocking prescriptions from the system; and

(d) Identity of the Oregon licensed Pharmacist who verifies that the system has been accurately stocked or destocked;

(4) The Retail Drug Outlet Pharmacy Prescription Locker must electronically record:

(a) All transactions involving drugs stocked, stored, destocked, or dispensed from the system including the identity of the individual who performed each function.

(b) A digital image of the individual to whom the prescription was dispensed.

SBAR: ORS 475.973

Rulemaking authority regarding products containing ephedrine, pseudoephedrine and phenylpropanolamine; records

S

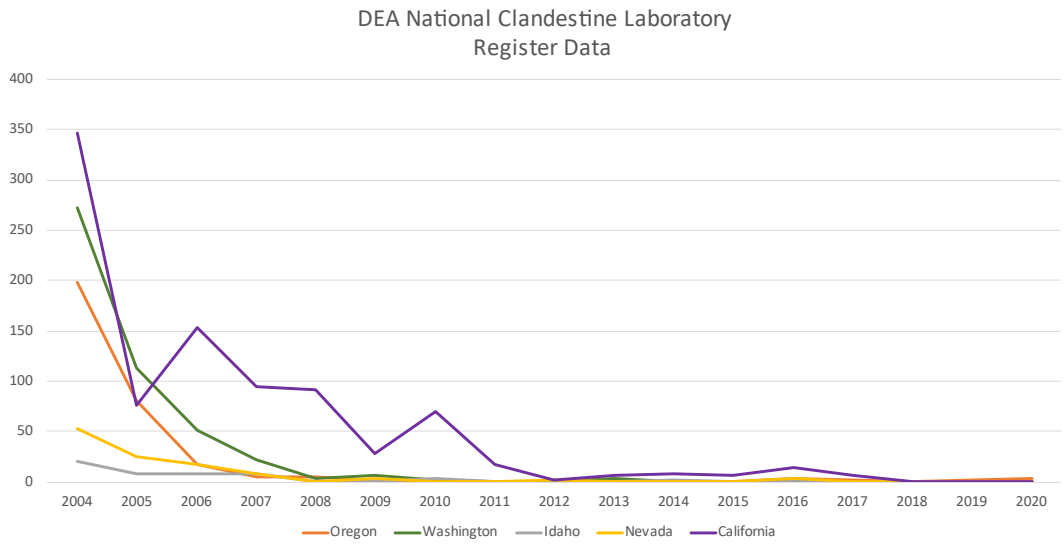
Situation:

- 2021 HB 2648 allows for transfer of drug containing pseudoephedrine or ephedrine without prescription to person who is at least 18 years of age and presents person's valid government-issued photo identification.
- 2021 HB 2648 did not repeal ORS 475.973(1)(a) The State Board of Pharmacy may not adopt rules that exempt a product containing ephedrine or pseudoephedrine from classification as a controlled substance.
- ORS 475.973 requires that if the Board of Pharmacy modifies ephedrine, pseudoephedrine or phenylpropanolamine from a schedule III to another schedule (ie. V) the board must find that restrictions on products containing ephedrine, pseudoephedrine or phenylpropanolamine does not significantly reduce the number of methamphetamine laboratories within the state.

B

Background:

- In 2006, Oregon became the first state in the country to schedule pseudoephedrine, ephedrine and phenylpropanolamine as a schedule III controlled substance.



https://www.dea.gov/clan -lab
Accessed 7/26/202 1

- In 2012, the National Precursor Log Exchange (NPLEx) was developed. The system monitors proposed purchases of pseudoephedrine and ephedrine products in real time by electronically receiving ID and product information from pharmacies and blocks the illegal sale of pseudoephedrine and ephedrine at the point-of-sale and across state lines. Use of the NPLEx system is mandated by 36 states nationwide. Two states (California and New York) allow its use voluntarily and greater than 80% of pharmacies in those states are utilizing the technology.

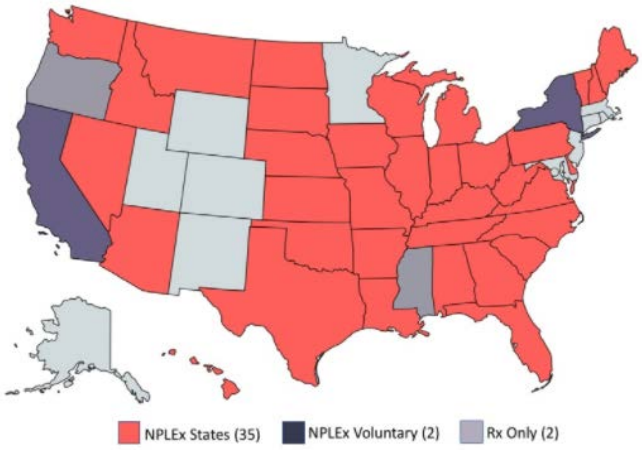


Figure 1- https://apprissinsights.com/solutions/nplex/

Related Resources

- Drug Enforcement Administration National Drug Threat Assessment, March 2021.
  - 2020 National Drug Threat Assessment (NDTA)
- Office of National Drug Control Policy (ONDCP) Oregon-Idaho High Intensity Drug Trafficking Area (HIDTA), April 22, 2021.
  - 2020 Annual Report
- National Association of State Controlled Substance Authorities, April 16, 2016.
  - 2016 White Paper- Impact of State Laws Regulating Pseudoephedrine on Methamphetamine Production and Abuse: A White Paper of the National Association of State Controlled Substance Authorities
- Drug Enforcement Agency, Accessed July 26, 2021
  - DEA National Clandestine Laboratory Register Data

Related Statutes and Rules:

- **ORS 475.973 Rulemaking authority regarding products containing ephedrine, pseudoephedrine and phenylpropanolamine; records.** (1)(a) The State Board of Pharmacy may not adopt rules that exempt a product containing ephedrine or pseudoephedrine from classification as a controlled substance. Except as otherwise provided in this paragraph, the State Board of Pharmacy shall adopt rules to classify ephedrine, pseudoephedrine and phenylpropanolamine as Schedule III controlled substances. The Schedule III classification may be modified by the State Board of Pharmacy if the State Board of Pharmacy finds that restrictions on products containing ephedrine, pseudoephedrine or phenylpropanolamine under a Schedule III designation do not significantly reduce the number of methamphetamine laboratories within the state.

A

Assessment:

- ORS 475.973 requires the Board to find that modifying the schedule of products containing ephedrine, pseudoephedrine or phenylpropanolamine from C-III to C-V does not significantly reduce the number of methamphetamine laboratories within the state.
- Board to discuss if this finding is in best interest of the public health and safety.

	• Board will need to affirm the finding(s) by formal motion and vote as part of the rulemaking process if and when the Board enacts a rule modifying ephedrine, pseudoephedrine or phenylpropanolamine from a schedule III to another schedule (ie. V).
R	**Recommendation:** • Board discussion

Board Review Date: 8/12/2021

Division 080– Controlled Substances (Pseudoephedrine/Ephedrine/Phenylpropanolamine)

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

Allows pharmacist or pharmacy technician to transfer of pseudoephedrine or ephedrine without a prescription

Need for Rules:

Revisions to Division 080 are necessary to allow for the transfer of drug containing pseudoephedrine or ephedrine without prescription to person who is at least 18 years of age and presents person's valid government-issued photo identification pursuant to 2021 HB 2648 and effective 1/1/2022.

Fiscal Impact:

No fiscal anticipated.

Documents relied upon include:

2021 HB 2648 and related statutes

ORS 475.754 Affirmative defense to unlawfully possessing pseudoephedrine

ORS 475.950(2)(f) Failure to report precursor substances transaction.

ORS 475.973 Rulemaking authority regarding products containing ephedrine, pseudoephedrine and phenylpropanolamine; records.

DEA Pharmacists Manual (v.2020) pg. 90-96

21 USC 830 The Combat Methamphetamine Epidemic Act of 2005

21 CFR 1314 Retail Sale of Scheduled Listed Chemical Products

Rules Summary:

Revisions to Division 080 are necessary to allow for the transfer of pseudoephedrine required by 2021 HB 2648.

Division 80
SCHEDULE OF CONTROLLED SUBSTANCES

855-080-0023
Schedule III

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

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

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

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

Statutory/Other Authority: ORS 689.205, ORS 475.973
Statutes/Other Implemented: ORS 475.035

855-080-0026
Schedule V

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

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

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

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

(4) In order to transfer non-prescription pseudoephedrine or ephedrine to a purchaser, a pharmacy must:

(a) Store all pseudoephedrine and ephedrine behind the pharmacy counter in an area that is inaccessible to the public;

(b) Utilize an electronic system meeting the requirements of ORS XXX.XXX; and

(c) Train individuals who are responsible for transferring pseudoephedrine or ephedrine into the custody of purchasers on the requirements of the Combat Methamphetamine Epidemic Act of 2005 (Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177) and use of the electronic system as described in ORS XXX.XXX;

(d) Ensure that only a pharmacist, pharmacy technician or certified Oregon pharmacy technician transfers pseudoephedrine or ephedrine to the purchaser after:

(i) Verifying that the purchaser is 18 years of age or older;

(ii) Verifying the identity of the purchaser with valid government-issued photo identification; and

(iii) Confirming the transfer is allowed via the electronic system

(e) Maintain a written on electronic log for at least three years from the date of the transaction that documents the following elements:

(A) Date and time of the transfer;

(B) Name, address and date of birth of the purchaser;

(C) Form of government-issued photo identification and the identification number used to verify the identity of the purchaser;

(D) Name of the government agency that issued the photo identification in (C);

(E) Name of product sold;

(F) Quantity in grams of product sold;

(G) Signature of the purchaser; and

(H) Name or initials of Pharmacist, Certified Oregon Pharmacy Technician or Pharmacy Technician who transfers the drug.

(f) Rule concerning subpoenas will be inserted after review by AAG

(5) All transfers of pseudoephedrine or ephedrine are subject to the following quantity limits and restrictions:

(a) No more than 3.6 grams in a 24-hour period, or more than 9 grams in a 30-day period without regard to the number of transactions; and

(b) For non-liquids, product packaging is limited to blister packs containing no more than 2 dosage units per blister. Where blister packs are not technically feasible, the product must be packaged in unit dose packets or pouches.

(6) Sections (4) and (5) do not apply to a pseudoephedrine or ephedrine when the drug is transferred pursuant to a prescription.

(7) Pharmacies, Pharmacists, Certified Oregon Pharmacy Technicians and Pharmacy Technicians involved in the transfer of pseudoephedrine or ephedrine must comply with the provisions of 21 CFR 1314.01 (04/01/2020), 21 CFR 1314.02 (04/01/2020), 21 CFR 1314.03 (04/01/2020), 21 CFR 1314.05 (04/01/2020), 21 CFR 1314.10 (04/01/2020), 21 CFR 1314.15 (04/01/2020), 21 CFR 1314.20 (04/01/2020), 21 CFR 1314.25, (04/01/2020); 21 CFR 1314.30 (04/01/2020), 21 CFR 1314.35 (04/01/2020), 21 CFR 1314.40 (04/01/2020), 21 CFR 1314.42 (04/01/2020), 21 CFR 1314.45 (04/01/2020); and 21 CFR 1314.50 (04/01/2020).

Statutory/Other Authority: ORS 689.205, ORS XXX.XXX
Statutes/Other Implemented: ORS 475.035, ORS XXX.XXX

SBAR: Murray's Drug Waiver Request

S	**Situation:** • Murray's Drug (RP# 0000167) in Condon requests to renew their waiver per OAR 855-041-01050(2) to permit the storage and prescription pickup by patients at 2 Asher Federally Qualified Health Center (FQHCs).
B	**Background:** • **OAR 855-041-1050 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.** • First approval in 2015: • No changes in the process have occurred in the past 6 years.
A	**Assessment:** • Per OAR 855-041-1050(2) Will this further public health or safety or the health and safety of a patient? • Per Murry's Drug submission: o The Need: ▪ They are the sole pharmacy service for several remote counties, that have a FQHC in the town of Fossil and Spray. ▪ Their patient base is disproportionally elderly and low income. It is difficult for patient to economically and logistically to drive to the pharmacy to pick up their prescriptions. ▪ Delivering prescriptions to patient home or employment does not work for many of their patients and delivering directly to patients' home is not feasible and during winter is dangerous. ▪ This waiver has helped to improve access to pharmacy services in their rural underserved area. o Safety Parameters: ▪ Prescription drugs are stored in secure storage cabinets at the Asher's clinics. ▪ Cabinets are only accessed by HOPAA trained staff in response to a customer picking up a prescription, as arranged with Murray's pharmacy.

        - The Clinic will have a list of patient names on the exterior of the cabinet to be referenced prior to opening the cabinet.
        - There is a video camera for monitoring of the area.
        - The cabinet is reviewed and prescriptions older than 14 days are returned to Murray's on a weekly basis.
        - The clinic has phone accessible at all times for patient prescription questions.
        - The clinic and prescription list will be available for inspection by BOP at any time.
    - Murray's stated they will continue to deliver directly to patient residences whenever possible.
- Follow up Questions and Responses (in blue):
    - Are prescriptions that require cold drug storage included? If so, how do you ensure that cold drug storage requirements per 855-041-1036 are maintained until the patient receives the prescription, including in transportation to the clinic and at the clinic?
        - Yes there are cold storage meds (lantus, etc) delivered safely in a vaccine cooler to the clinic where they are stored in an approved refrigerator.
    - Are controlled substances included? If so, have you reached out to the DEA to ensure that this is permitted?
        - Yes, there are controlled substances and no, we have not contacted the DEA, we did not know it was needed based on our earlier communications and approval with BOP.
    - Are prescription drugs that are returned to the pharmacy disposed of or used for re-dispensing?
        - If medications are not picked up in a timely manner we do return them to the pharmacy for reuse as they are sealed and never in contact with the patient.
    - To clarify this request is for 2 clinics, 1 in Fossil and 1 in Spray to store prescription drugs for patient pickup?
        - Prescriptions are delivered only from our Condon pharmacy and they go only to the Fossil clinic location. I don't know that in reality it will ever increase to the Spray clinic location.
    - To clarify are prescriptions from any of the 3 Murray's Drug locations (Heppner, Condon and Boardmen) sending prescriptions to the Fossil or Spray clinic for patient pick up?
        - Prescriptions are delivered only from our Condon pharmacy and they go only to the Fossil clinic location. I don't know that in reality it will ever increase to the Spray clinic location.
    - To clarify, the patients that are picking up prescriptions at the clinics may not be patients of that clinic?
        - Yes, there are non-clinic patient prescriptions and hence the need for this waiver. This setup resulted from a joint communication session with Wheeler County on how to improve access to medications for their citizens (there is no pharmacy in Wheeler county).
    - How many prescriptions on a weekly or monthly basis do you deliver to both the Fossil and Spray location for patient pickup?

	▪ Fossil clinic location delivered prescriptions number about 40-50 week.
R	**Recommendation:** • Motion to Grant waiver • Note: o To permit 2 FQHC clinics to securely store prescriptions for patient pickup, per OAR 855-041-1050(2) for 1 year. o This approval ends after one year or if the rule allowing the waiver is repealed, whichever comes first. ▪ If these rules are repealed, staff will work with outlet through the transition process.

Date: 8/4/2021

Murray's Drug

HEPPNER
PO Box 427
Heppner, OR 97836
(541) 676-9158

CONDON
P.O Box 725
Condon, OR 97823
(541) ~~384-2004~~ 256-0200

BOARDMAN
101 Kinkade Road
Boardman, OR 97818
(541) 481-9474

TO OR. Bd of Pharmacy

RE: Murray Condon Pharmacy

RE: Waiver Renewal

RECEIVED
JAN 29 2021
OREGON BOARD OF PHARMACY

Murray's Drug

HEPPNER
P.O Box 427
Heppner, OR 97836
(541) 676-9158

CONDON
P.O Box 725
Condon, OR 97823
(541) 384-2801

BOARDMAN
101 Kinkade Road
Boardman, OR 97818
(541) 481-9474

October 12, 2020

To: Brianne Efremoff
Compliance Director
Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232

Re: Waiver Request

Dear Ms. Efromoff,

Murray's Condon Pharmacy is applying to renew our waiver to OAR 855-041-1050 (Pharmacy Depots).

Since 1963, Murray's Pharmacy in Condon (Gilliam County) has served as the "local" or closest pharmacy for the Wheeler County towns of Fossil and Spray. The distance from Condon to Fossil is 20 miles, and the distance from Condon to Spray is 51 miles. Each of these towns has an Asher Community Health Services FQHC.

For decades, our mutual patients in Fossil and Spray have seen their primary care provider and then driven to our pharmacy for their medications. Our patient base is disproportionately elderly and low income, so this trip has historically been difficult economically and logistically. In addition, our counties experience hazardous driving conditions for months in the wintertime.

Delivery to Board-approved locations (e.g. patients' homes or places of employment) does work for some townspeople, but patients living on farms and ranches may already drive an hour just to get to Fossil and Spray, let alone to the pharmacy. Delivering directly to patients who live out of town is not feasible because of remote access, long distances and dangerous winter driving conditions.

We received a waiver from the Board in 2015 to deliver to secure cabinets in the Fossil and Spray FQHC clinics. In the 5 years since that approval, this service has become an integral part of our community's healthcare system. Our clinics and patients have reported improved access and adherence to prescribed therapies, and we have spared our patients immeasurable time, money, and difficulty.

The system we outlined in our 2015 waiver application to the Board has been working smoothly, and we hope to continue the following practices:

- We will continue to deliver directly to patients' residences whenever possible.
- Secure storage cabinets onsite at Asher Clinic Fossil and Asher Clinic Spray will be managed according to the following standards:
    - Each cabinet will be in a secure, staff-only area of the clinic.

Murray's Drug

HEPPNER
P.O. Box 427
Heppner, OR 97836
(541) 676-9158

CONDON
P.O. Box 725
Condon, OR 97823
(541) 384-2801

BOARDMAN
101 Kinkade Road
Boardman, OR 97818
(541) 481-9474

- Cabinets will only be accessed by HIPAA-trained staff in response to a customer picking up a prescription, as arranged with Murray's Pharmacy
- There will be a list of patient names on the exterior of the cabinet to be referenced prior to opening cabinet
- There will be a video camera for security purposes monitoring the area of the cabinet
- Cabinet will be reviewed and prescriptions returned to Murrays' weekly, all prescriptions older than 14 days will be returned
- The clinic will have a phone accessible at all times for questions patients may have for the Pharmacist when picking up prescriptions
- Cabinet and prescription list will be available for inspection by Board of Pharmacy at any time

This waiver has truly helped us to improve access to pharmacy services in our rural, underserved area. We appreciate the Board's consideration of our renewal request.

Sincerely,

Glenn RPh

Oregon
Kate Brown, Governor

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

December 28, 2015

Murray's Condon Pharmacy
Attn: John Murray, R.Ph
PO Box 725
Condon, OR 97823-0725

Re: Waiver Request

Dear John Murray,

The Oregon Board of Pharmacy reviewed your request for a waiver from OAR 855-041-1050 at their December 2015 meeting. Upon consideration of your request and the issues presented, the Board hereby grants the waiver a period of five (5) years from the date of this letter (until 12/28/2020).

After this date, a new waiver must be requested. A copy of this notification should be kept with your Pharmacist-in-Charge self inspection report.

If you have any questions, or if I can be of further assistance, please contact me at Gary.Miner@state.or.us. Please provide me with your name, your preferred contact method and information, and your concerns. Alternatively, you may contact me at the address and phone number listed above.

Sincerely,

Gary Miner
Compliance Director

CC: Marcus Watt, R.Ph., Executive Director
Oregon Board of Pharmacy Licensing Department

GM/ko

November 23, 2015

Murray's Condon pharmacy waiver request (Prescription Depot)

John Murray's submitted model is similar to the Len's Drug request for a depot site to provide filled prescriptions in a rural area where access to pharmacy services is limit by distance and weather considerations. The submitted model shows a locked cabinet in the practice location which will be secured and out of site to the general population. The proposal addresses security, HIPPA concerns and using a log in and out system for the tracking of the prescriptions.

Staff recommendation is to grant the waiver base on the current request.

855-041-1050

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
Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; BP 9-2011, f. 12-30-11, cert. ef. 1-1-12; BP 1-2012, f. 4-26-12, cert. ef. 5-1-12; Renumbered from 855-041-0095, BP 7-2012, f. & cert. ef. 12-17-12

Gary Miner

Compliance Director

Oregon Board of Pharmacy

800 NE Oregon Street, Suite 150

Portland, OR 97232

Re: Waiver Request

Dear Mr. Miner:

Murray's Condon Pharmacy is applying for a waiver to OAR 855-041-1050 Pharmacy Depots.

Since 1963 Murrays pharmacy in Condon (Gilliam county) has served as the 'local' or closest pharmacy for the Wheeler county towns of Fossil and Spray. Distances between Condon are 20 miles to Fossil and 51 miles to Spray. Each of these towns has an FQHC clinic of Asher Community Health Services.

For decades our common patients have seen their primary care provider and then driven to our pharmacy for their medications, many times in poor winter weather.

We are interested in beginning delivery services to these towns to increase timely access to pharmaceutical services but would like to get a waiver to allow Asher Clinic to securely store prescriptions for all Wheeler county residents some of whom are not their patients.

Delivery to the board approved areas (ex patient homes or places of employment) will work for the townspeople but ranch and farm patients can drive for an hour just to get to Fossil or Spray, let alone the pharmacy. Delivering to farms and ranches is not feasible because of remote access, long distances and dangerous remote roadways in winter.

Our two pharmacies serve 2000 square miles of rural farm, ranch and forest lands in three counties as the only pharmacy. We feel that our patient health would be greatly enhanced by more timely medication administration. Not to mention that many of our patients are served through Oregon Medicaid and Eastern Oregon CCO and do not have access to timely and or affordable transportation.

At this time I estimate there would be approximately 20 prescriptions per week at Asher Clinic Fossil and 8 per week at Asher Clinic Spray.

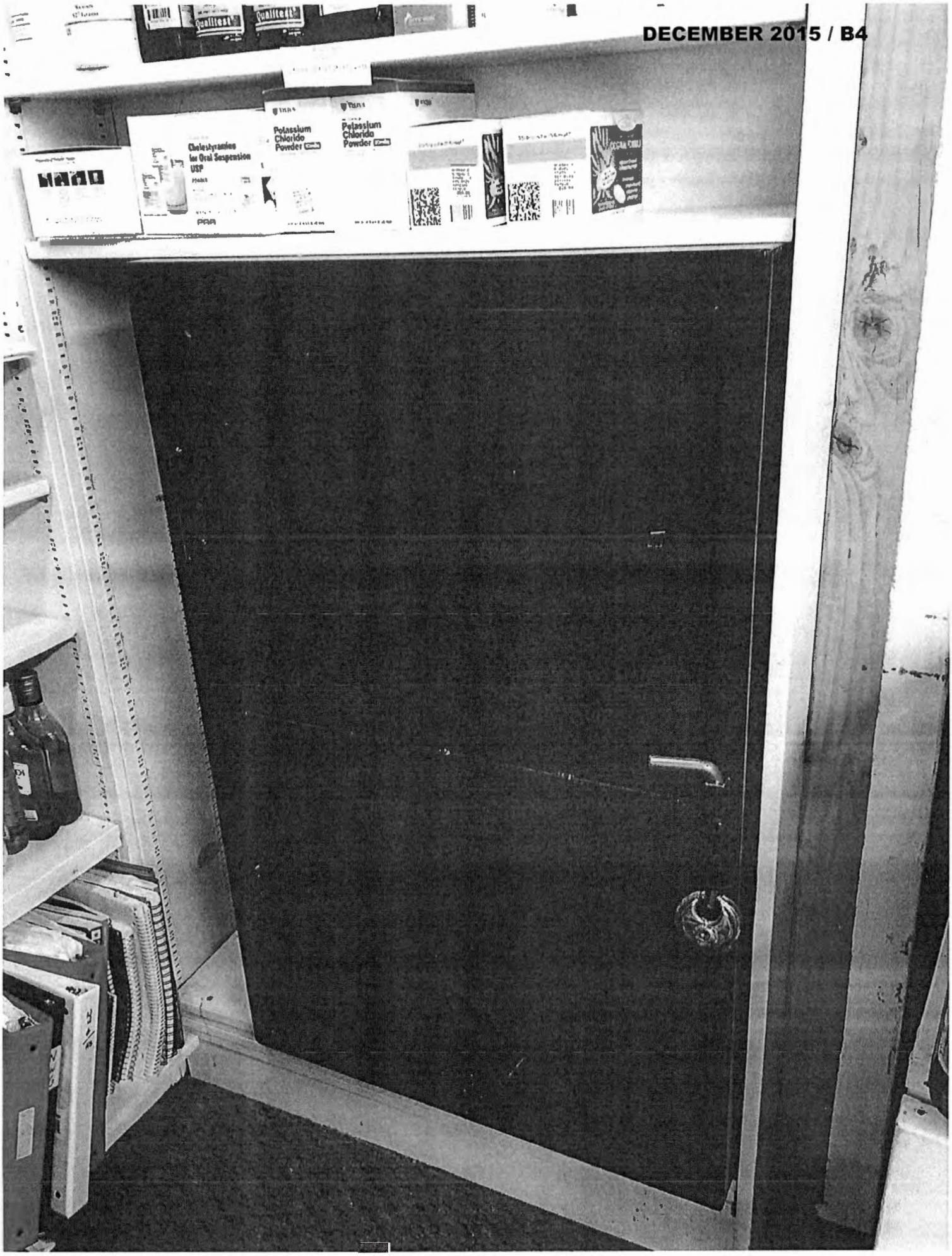
The following is what we propose as a Waiver:

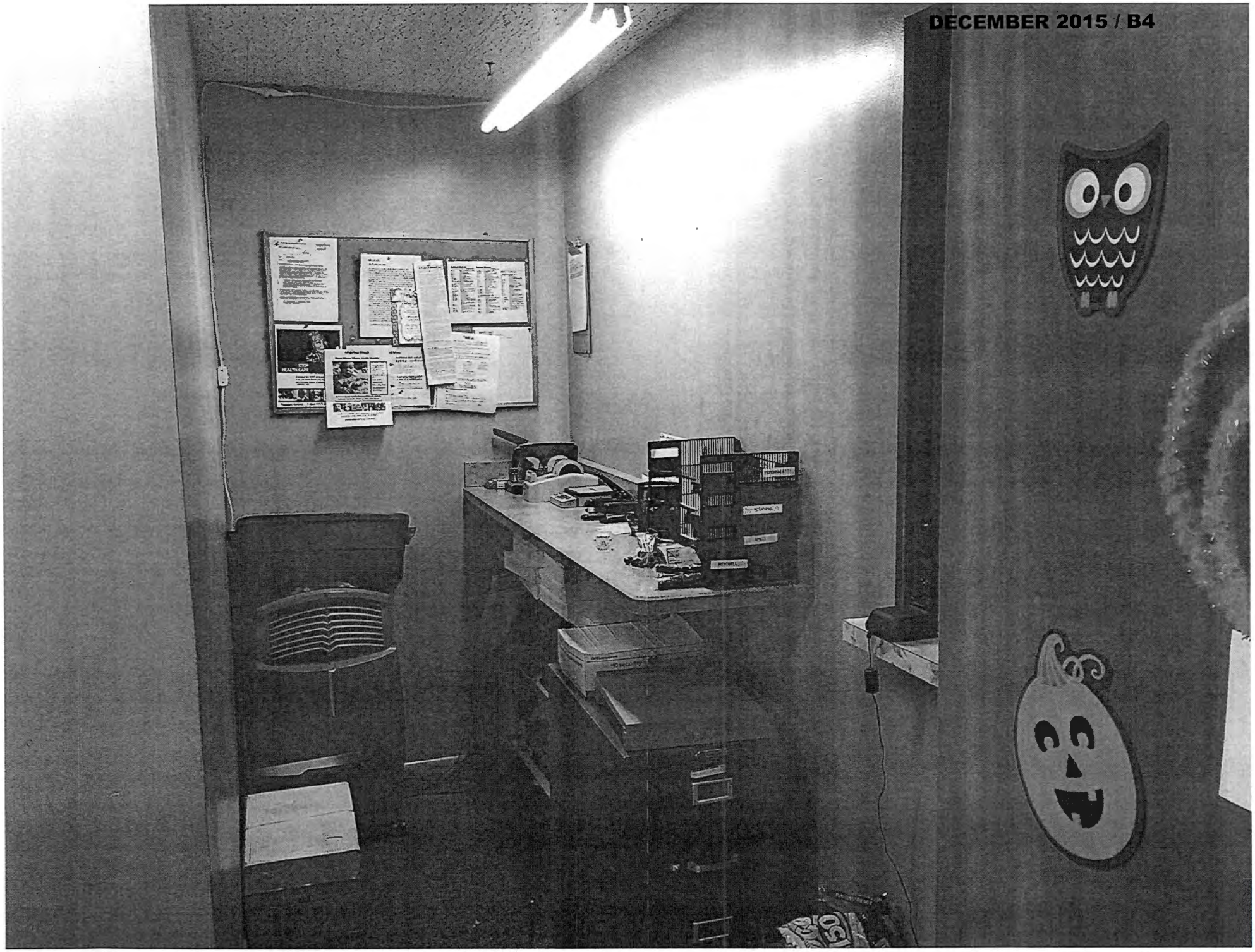
1. Continue to deliver to patient's residence whenever possible.
2. Use a secure storage cabinet onsite at Asher Clinic Fossil and Asher Clinic Spray.
    a. See photos below
    b. Cabinet will be in a secure staff only area of the clinics behind the reception area (photo with glass windows) and in the recessed area in the second picture, a staff area only.

       The cabinet is being built at this time but a photo of our C2 cabinet in the pharmacies is attached showing what it will look like and the locking mechanism. It securely attached to the wall above the small counter on the right.
    c. Cabinet will be accessible only by HIPPA trained staff in response to a customer picking up a prescription as arranged with Murray's Condon Pharmacy.
    d. There will be a list of patient names on the exterior of the cabinet to be referenced prior to opening of cabinet.
    e. There will be a video camera for security purposes monitoring the area of the cabinet.
3. Cabinet will be reviewed and prescriptions returned to Murrays weekly, all prescripions older than 14 days will be returned.
4. Have a phone accessible at all times for questions patients may have for the Pharmacist when picking up prescriptions.
5. Cabinet and prescription list will be available for inspection by Board of Pharmacy at any time.

Sincerely,

John R. Murray, R.Ph.


Cholestyramine for Oral Suspension USP
Potassium Chloride Powder
Potassium Chloride Powder


HEALTH CARE


STOP
HIPAA
PLEASE
CHECK IN WITH THE RECEPTIONIST BEFORE BEING SEATED
COPAYMENT
AS A COURTESY TO OUR PATIENTS
WE WILL BE HAPPY TO BILL YOUR PRIMARY INSURANCE. HOWEVER, PAYMENT for SERVICES IS YOUR RESPONSIBILITY.

Oregon
Kate Brown, Governor

Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland, OR 97232
Phone: 971-673-0001
Fax: 971-673-0002
pharmacy.board@bop.oregon.gov
www.oregon.gov/pharmacy

The Oregon Board of Pharmacy values diversity, equity, and inclusion in its workforce. Therefore, the Board is acting with respect to its affirmative action and diversity, equity, and inclusion programs.

The affirmative action plan that follows represents my personal and professional dedication to upholding our commitment to the citizens of Oregon. The plan also represents our commitment to equal opportunity and affirmative action in employment and public service in compliance with all applicable federal and state laws, including, but not limited to: Executive Order 11246; Title VII of the Civil Rights Act of 1964; Sections 503 and 504 of the Rehabilitation Act of 1974; the Vietnam Era Veterans Readjustment Assistance Act; and the Americans with Disabilities Act. This affirmative action plan has my complete support and authorization.

Joseph Schnabel, Pharm.D., R.Ph.
Executive Director
Oregon Board of Pharmacy
(971) 673-0001

OREGON
BOARD OF PHARMACY

Affirmative Action
Diversity & Inclusion Plan
2021 – 2023 Biennium

Table of Contents

Introduction

Agency

1. Overview

   The Oregon Board of Pharmacy was created by the Oregon State Legislature in 1891. Today, the Board consists of nine Board Members, five members are licensed pharmacists, two are licensed pharmacy technicians and two are representatives of the public. The Governor appoints each member of the Board for a term of four years, subject to approval by the State Senate, and they may be reappointed.

   The Board of Pharmacy office is in Portland and consists of 22 dedicated staff members who, in addition to supporting the Board, provide services in Licensing, Compliance, Communications, Regulation and Operations.

   The Licensing team process license applications and renewals for 34 license categories, including pharmacists, technicians, interns and multiple types of drug outlets (retail, institutional, nonprescription, wholesaler, manufacturer and others). The Licensing team manage over 30,000 active licenses.

   The Compliance team consists of a talented team of pharmacists with experience in all aspects of pharmacy practice, as well as a support staff of tenured professionals. Pharmacy inspectors conduct inspections of drug outlets to promote public safety, investigate complaints from the public and healthcare personnel and provide compliance consultation with licensees. The team works closely with other State and Federal agencies such as the Oregon Health Authority, Drug Enforcement Agency and Food, and Drug Administration to carry out the mission of the Board.

   The Administrative team consists of tenured professionals who are responsible for compliance with State processes, budget & accounting, rulemaking, records management, personnel management, information technology and public outreach. Download the agency's current Strategic Plan to learn more about the agency's direction and priorities.

2. Mission & Objectives

   Mission - The Oregon Board of Pharmacy serves to promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs. Vision – Partners for a Healthy Oregon.

3. Key Employees

   Executive Director
   Joseph Schnabel, Pharm.D., R.Ph.
   Executive Director, Oregon Board of Pharmacy
   joseph.schnabel@bop.oregon.gov

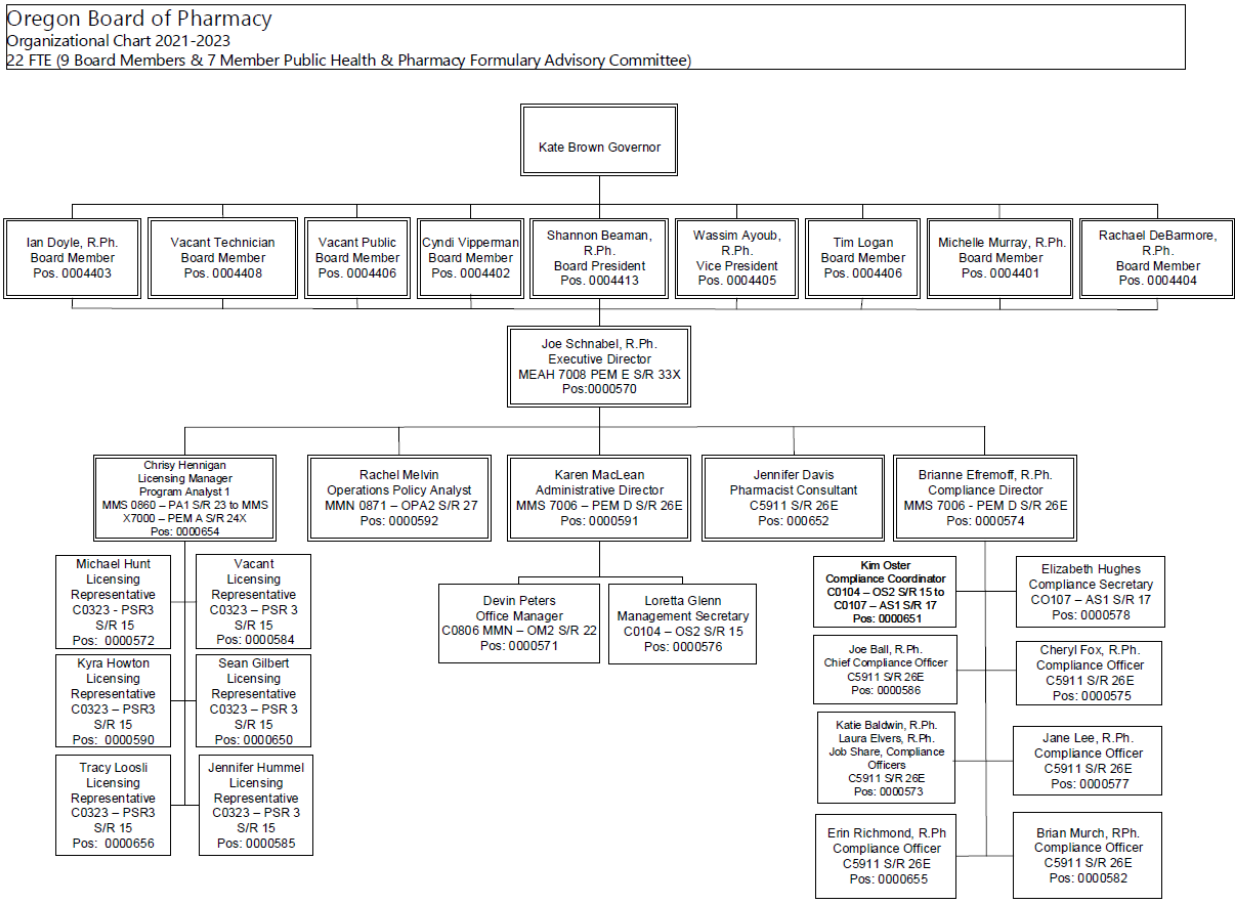
(971) 673-0001

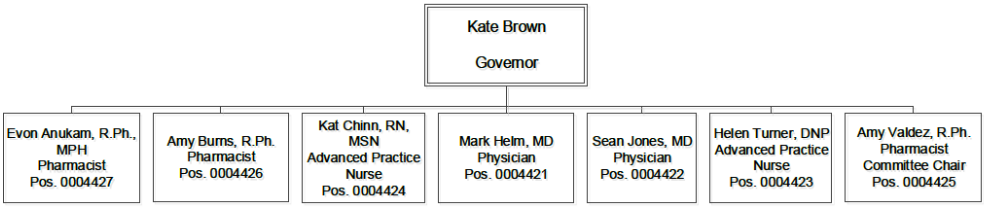
The Governor's Policy Advisor
Jackie Yerby
Deputy Healthcare Policy Advisor, Office of Governor Kate Brown
jackie.yerby@oregon.gov

Affirmative Action Representative
Karen S. MacLean
Administrative Director, Oregon Board of Pharmacy
karen.s.maclean@bop.oregon.gov
(971) 673-0005

Lead for COBID contracting and procurement
Karen S. MacLean
Administrative Director, Oregon Board of Pharmacy
karen.s.maclean@bop.oregon.gov
(971) 673-0005

4. Organization Chart





PUBLIC HEALTH AND PHARMACY FORMULARY ADVISORY COMMITTEE
Established January 1, 2018

Members are appointed by the Governor to make recommendations to the Oregon Board of Pharmacy regarding pharmacist prescriptive authority

Policies, Roles, and Progress Report

Affirmative Action Policies

1. Agency Affirmative Action Policy

Statement:

The Oregon Board of Pharmacy is committed to providing and promoting a respectful, diverse and inclusive environment for all applicants, employees, vendors, licensees, registrants and all people who interact with the agency. The Oregon Board of Pharmacy provides equal employment opportunities to all people and prohibits discrimination and harassment of any type without regard to race, color, religion, sex, national origin, age, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, State or local laws.

Policy:

All Oregon Board of Pharmacy staff shall adhere to the Affirmative Action Policy and Plan. Management staff shall assure that the intent as well as the stated requirements are implemented in all employee relationships and personnel practices. All personnel actions of Board staff, all licensing actions and disciplinary actions concerning licensees, shall be administered according to this policy. In addition, it is the duty of every employee of the Oregon Board of Pharmacy to create an office environment which is conducive to non-discrimination policies and free of any form of discrimination or harassment. The application of this policy is the individual responsibility of all administrative and supervisory staff and each

shall be evaluated on his/her performance in achieving Affirmative Action Plan goals. Failure to meet the agency's Affirmative Action standards will be subject to disciplinary actions.

The Affirmative Action Plan is posted on the agency's website, a hard copy is placed in the reception area, as well as in the Executive and Administrative Director's offices. All newly appointed board and committee members, new employees and vendors are provided with the link to the plan and must sign an acknowledgment that they reviewed the policy. All employees shall be advised of the procedure for lodging a formal or in-formal complaint. All staff will be provided with contact information and available resources and will be encouraged to bring all complaints to the attention of the Executive Director.

2. Diversity Equity and Inclusion (DEI) - Focused Plans or Policies

   The Oregon Board of Pharmacy currently does not have any DEI-focused plans or policies.

3. State Employment Law Documents

   The following links connect to the relevant state law and documentation:

   - ADA and Reasonable Accommodation Policy (Statewide Policy 50.020.10)
   - Discrimination and Harassment Free Workplace - (Statewide Policy No. 50.010.01)
   - Employee Development and Implementation of Oregon Benchmarks for Workforce Development (Statewide Policy 50.045.01)
   - Veterans Preference in Employment (Statewide Policy 40-055-03)
   - Equal Opportunity and Affirmative Action Rule (OAR 105-040-0001)
   - Executive Order 16-09: Relating to Affirmative Action and Diversity & Inclusion
   - Executive Order 17-11: Relating to Affirmative Action, Equal Employment, Opportunity, Diversity, Equity, and Inclusion
   - Executive Order 19-08: Ensuring Equal Treatment Under Law to Oregon's LGBT+ Community

4. Federal Employment Law Documents

   The following link leads to a pdf with the documents listed below:
   https://www.oregon.gov/gov/policy/Documents/Federal_Affirmative_Action_TitleVII.pdf

   - Age Discrimination in Employment Act of 1967 (ADEA)
   - Disability Discrimination Title I of the Americans with Disability Act of 1990
   - Equal Pay and Compensation Discrimination Equal Pay Act of 1963, and Title VII of the Civil Rights Act of 1964
   - Genetic Information Discrimination Title II of the Genetic Information Nondiscrimination Act of 2008 (GINA)
   - National Origin Discrimination Title VII of the Civil Rights Act of 1964
   - Pregnancy Discrimination Title VII of the Civil Rights Act of 1964
   - Race/Color Discrimination Title VII of the Civil Rights Act of 1964

- Religious Discrimination Title VII of the Civil Rights Act of 1964
- Retaliation Title VII of the Civil Agency Affirmative Action Policy
- Sex-Based Discrimination Title VII of the Civil Rights Act of 1964
- Sexual Harassment Title VII of the Civil Rights Act of 1964

5. Documentation in Support of the agency's Affirmative Action Plan

The agency will work collectively to provide equal opportunities for all applicants and staff while continuing to implement and achieve the agency's goals of creating and maintaining a diverse and inclusive environment. The agency believes that current methods utilized have been effective, but realize that the agency's office culture is organic and is influenced by progress and best practices that grow and evolve.

The agency's current best practices in the areas of training, education and professional development are a work in progress. The agency's Affirmative Action Coordinator attends the regular Governor's Office of Diversity, Equity, and Inclusion & Affirmative Action meetings as often as possible and the agency relies on meeting notes to stay up to date on State practices. The agency was fortunate to encourage all staff to participate for at least one day of the 2020 Virtual Diversity, Equity, and Inclusion Conference; some were able to attend two or three of the days as schedules allowed.

I. Employees:
   a. All new employees are informed during new hire orientation about their rights and responsibilities under the Board's Affirmative Action Plan and are required to sign an acknowledgment upon reviewing the current plan/policy.
   b. Staff participate in an annual exercise presented by the agency Affirmative Action Representative during an all staff meeting.
   c. Directors attend annual Diversity & Inclusion Conference hosted by the state.

II. Board Members/Volunteers:
   a. Newly appointed Board Members, Committee Members and existing Board Members are provided with the link to the current agency Affirmative Action Plan on our website and are required to sign an acknowledgement upon reviewing the plan.

III. Contractors/Vendors
   a. When contracts are established or renewed, all contractors/vendors are provided with the weblink to the agency's current Affirmative Action Plan.

In addition to the above, the Oregon Board of Pharmacy has posted a statement on health equity, found on the agency's website. In summary, thirteen national pharmacy associations, including the National Association of Boards of Pharmacy, have signed a joint statement in support of racial justice. The Oregon Board of Pharmacy fully supports this statement and the

agency's goal will be to address health care disparities in impacted communities, educate those licensed by the board on social injustices and systemic bias, and continue to implement and support strategies to address health care disparities.

6. Additional Federal Documentation
   The Oregon Board of Pharmacy has no additional Federal documentation.

7. Agency Specific Federal Reporting Requirements
   The Oregon Board of Pharmacy has no additional Federal reporting requirements.

8. Executive Order 11246 (OFCCP Regulations)
   Please refer to the below link for information on the Office of Federal Contract Compliance Executive Order 11246 – Equal Employment Opportunity.

   https://www.dol.gov/agencies/ofccp/executive-order-11246/ca-11246

9. State and Federal Affirmative Action Policies Availability
   The Affirmative Action Plan is posted on the agency's website, a hard copy is placed in the reception area, as well as in the Executive and Administrative Director's offices. All newly appointed board members, committee members and new employees and vendors are provided with the link to the plan and must sign an acknowledgment that they reviewed the policy.

   Additional resources and the current Affirmative Action Plan can be found on the Board's Health Equity page:

   https://www.oregon.gov/pharmacy/pages/Health-Equity.aspx

10. Complaint options
    The Oregon Board of Pharmacy has several options to file complaints:

    - Collective bargaining grievance procedures
      http://seiu503.org/contact-us/
    - Filing a complaint with BOLI's Civil Rights Division
      https://www.oregon.gov/boli/CRD/Pages/C_Crcompl.aspx
    - File a complaint with the Federal Equal Employment Opportunity Commission (EEOC)
      https://www.eeoc.gov/federal/fed_employees/filing_complaint.cfm
    - File a civil suit in State Circuit Court
      https://www.courts.oregon.gov/how/Pages/file.aspx
    - File a civil suit in Federal District Court
      http://www.uscourts.gov/about-federal-courts/types-cases/civil-cases

Roles for Implementation of Affirmative Action Plan

1. Roles and Responsibilities; and 2. Accountability Mechanisms
   Executive Director:

   - Foster and promote to employees the importance of a diverse and discrimination and harassment-free workplace. Participate in cultural diversity trainings, orientations, and be a living example of cultural sensitivity. For example, addressing racial justice in all-staff emails and promoting educational opportunities on equity.
   - Meet annually, or more often as needed, with the Board's Human Resource Manager to review equal employment opportunities, evaluate affirmative action and diverse work environment progress, and identify problems. Approve strategies and timetables for meeting goals.
   - Held accountable through annual performance evaluations. Annual performance reviews will include ratings on the Director's support and effectiveness of the agency's Affirmative Action Plan.
   - Hold managers accountable for participating in and promoting affirmative action activities and for communicating this same responsibility to their subordinate supervisors and employees. The effectiveness of managers and supervisors in promoting the affirmative action activities, goals, and objectives for OBOP will be included in their annual performance appraisals. ORS 659.025(1) states:

     "*To achieve the public policy of the State of Oregon for persons in the State to attain employment and advancement without discrimination because of race, religion, color, sex, marital status, national origin, handicap or age, every State agency shall be required to include in the evaluation of all management personnel the manager's or supervisor's effectiveness in achieving affirmative action objectives as a key consideration of the manager's or supervisor's performance*."

   Managers & Supervisors

   - Foster and promote to employees the importance of a diverse and discrimination - and harassment-free workplace. Look for ways to increase the skills of current employees using mentoring, job rotations, and formal training to prepare them for higher level positions within the organization and the State.
   - Managers and supervisors will receive an orientation on the Board's affirmative action goals, understand their own responsibilities, and evaluate how well they are achieving the Board's affirmative action goals and objectives. They will attend cultural competency training, attend orientations, and promote cultural awareness.
   - Subordinate supervisors will be evaluated on their effectiveness in carrying out the responsibilities they have for participating in and promoting affirmative action activities.

- In undertaking these evaluations, managers will consider how well the supervisor fosters and promotes a diverse workforce, how well they promote the affirmative action goals and objectives, and that their staff are knowledgeable about OBOP policies and procedures that encourage an inclusive environment.
- Inform applicants for vacant positions that the Board is an equal opportunity employer committed to workforce diversity. Have a copy of the Board's Affirmative Action Plan available for applicants to review upon request.
- Work with human resources to utilize State of Oregon procedures and rules in filling vacancies. Attend equal opportunity, affirmative action, and other diversity-related training in order to be informed of current issues.
- Display the Board's Affirmative Action Policy Statement and have available a hard copy of the Affirmative Action Plan. An electronic copy of the Board's Affirmative Action Policy Statement will also be maintained on the OBOP website.
- Act decisively and in a timely manner if they become aware of any Board employee engaging in any type of harassment.

Affirmative Action Representative

- Work with the Executive Director, managers, and supervisors to promote a diverse workforce and inclusive work environment to help attain the Affirmative Action goals of the Board. Encourage the retention of existing employees and create new learning opportunities for them.
- Report Affirmative Action activities to the Executive Director, as well as staff meetings. Obtain support for proposed changes to the Affirmative Action Plan to reach goals and objectives. Attend Affirmative Action meetings.
- Encourage opportunities for advancement through cross-training, job rotations and job shadowing as appropriate. Inform employees of career development opportunities and explain any options employees may have for meeting the minimum requirements for promotional job classifications through education and/or experience. Assist employees in the application process for State jobs and how interview skills can be improved.
- Keep management informed of the latest law and rule changes pertaining to EEO/AA.
- Research training opportunities and topics for presentation to all staff. Actively participate in those trainings.
- Have hard copies and/or electronic copies of the Board's Affirmative Action Policy Statement and Plan available for review by all managers, supervisors and employees. Make hard or electronic copies available to applicants for employment on request. Recommend changes to the Plan and update it as required. Compile statistics and keep management informed of the Board's Affirmative Action status during management meetings.
- Discuss the State of Oregon/Board Affirmative Action Plan and Policy in New Employee Orientation. Make the orientation as welcoming as possible. Include in the discussion:

    - The agency's expectations surrounding a respectful workplace and talk about what that means to the agency as well as the employee.
    - The agency's commitment to supporting the personal and professional growth of our employees.
    - The agency's encouragement to contribute and participate in agency activities that will assist the agency in meeting its objectives.
    - The agency's doors are always open for questions and concerns.
- Train and inform managers, supervisors and employees at New Employee Orientation as to their rights and responsibilities under the Board's affirmative action policy and other Board policies to eliminate any harassment based on any protected class status.
- Evaluate revised and new policies for possible adverse impact on the Board's commitment to affirmative action and equal employment opportunities.
- Ensure agency training opportunities are offered free of discrimination based on race, religion, national origin, age, gender, sexual orientation, veteran status, or disability.

2. Executive Staff
   See Executive Director and Affirmative Action Representative sections above.

3. Management Staff
   See Managers and Supervisors section above.

4. Other Staff
   All employees are responsible for reading and understanding our policies and procedures and acting accordingly. They are held accountable for their actions.

2019-2021 Affirmative Action Plan Progress Report

1. Increase agency diversity and inclusion awareness.
   Progress:

   Due to the declared state of emergency for COVID-19, most of the agency's efforts and focus have been on addressing the public health emergency; therefore, the agency did not make specific progress in this area. Social justice events that have occurred in 2020 have impacted, challenged or awakened all persons to issues of diversity and inclusion.

2. Expand opportunities for diversity and inclusion training for all management level staff.
   Progress:

   Management level staff have had the opportunity to participate in diversity and inclusion training during the 2019-21 biennium. All staff had the opportunity to participate in the 2020 virtual Diversity Equity and Inclusion Conference "Amplifying the Voices of Equity" in October 2020. Many staff participated and appreciated the opportunity to learn and grow during this challenging season of racial injustice.

3. Seek Board input on how the agency Affirmative Action plan and goals can be incorporated into agency strategic plan.
   Progress:

   As part of the Board's 2019 Strategic Planning Meeting, the Board discussed how the Affirmative Action Plan and goals can be incorporated into the Board's Strategic Plan through its communications strategy. This is demonstrated in the new Health Equity page highlighted on the agency's website. The Executive Director also added a new priority goal to make tangible steps to increase diversity, equity, and inclusion in agency staffing, the board, and committee membership.

Demographic Analysis

Supervisors

Executive Director: Joseph Schnabel, Pharm.D., R.Ph.

Supervisors:

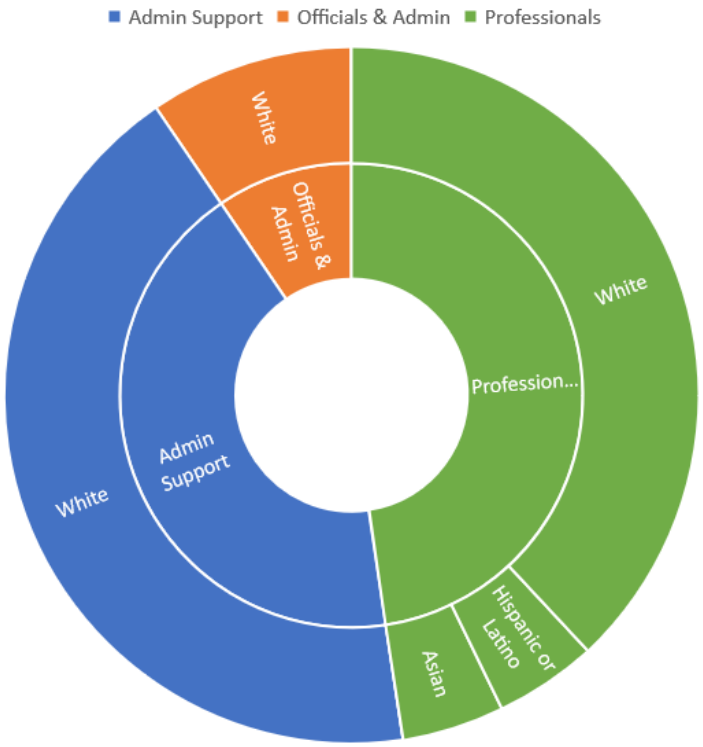
Brianne Efremoff, Pharm.D., R.Ph. – Compliance Director
Chrisy Hennigan – Licensing Manager
Karen MacLean – Administrative Director

Management:

Rachel Melvin – Operations Policy Analyst
Devin Peters – Office Manager

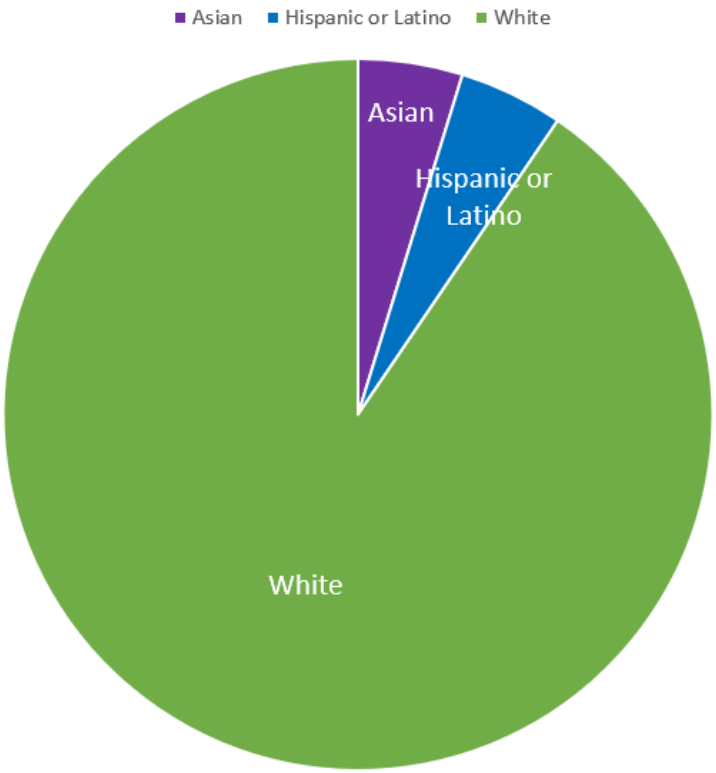
Workforce Tables

1. Demographics of Employees in Each Job Classification



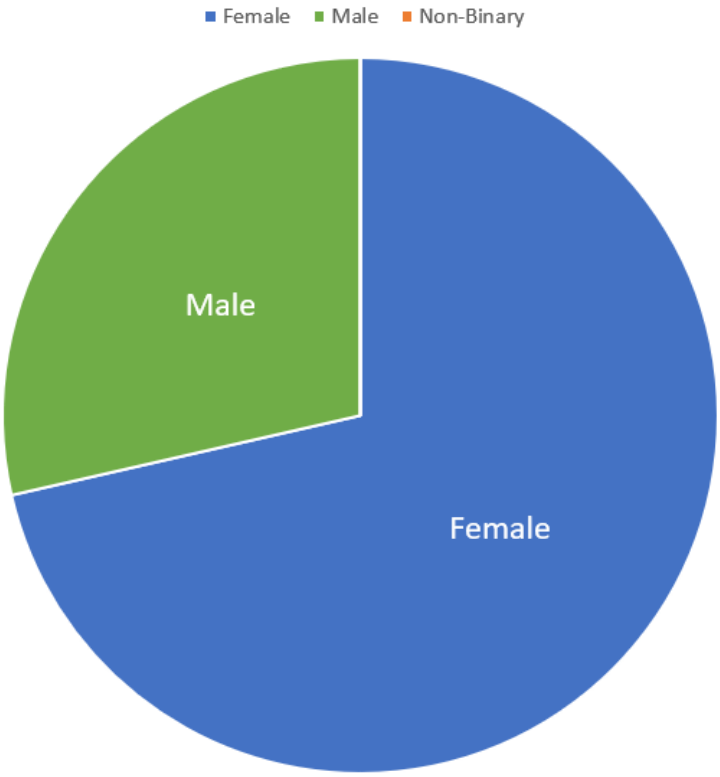
Job Categories		Asian		Hispanic or Latino		White	
	Number	Number	Percent	Number	Percent	Number	Percent
Administrative Support (Including Clerical Sales)	9	0	0%	0	0%	9	100%
Officials & Administrators	2	0	0%	0	0%	2	100%
Professionals	10	1	10%	1	10%	8	80%
Totals	**21**	**1**	**4.76%**	**1**	**4.76%**	**19**	**90.48%**

2. Employees by Race/Ethnicity



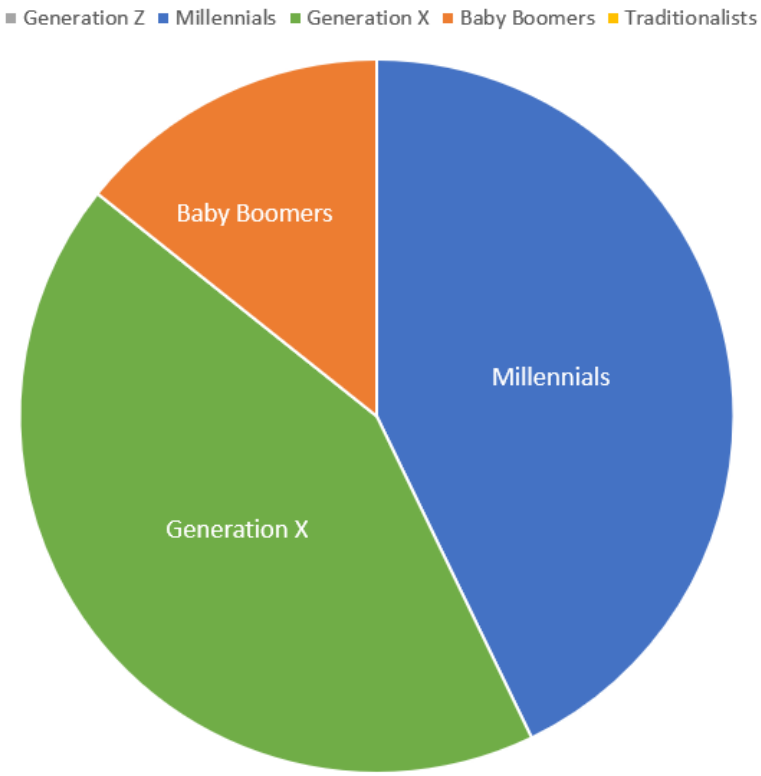
Race/Ethnicity	Total	
	Percent	Number
Asian	4.8%	1
Hispanic or Latino	4.8%	1
White	90.5%	19
Total	**100.0%**	**21**

3. Employees by Gender Identity



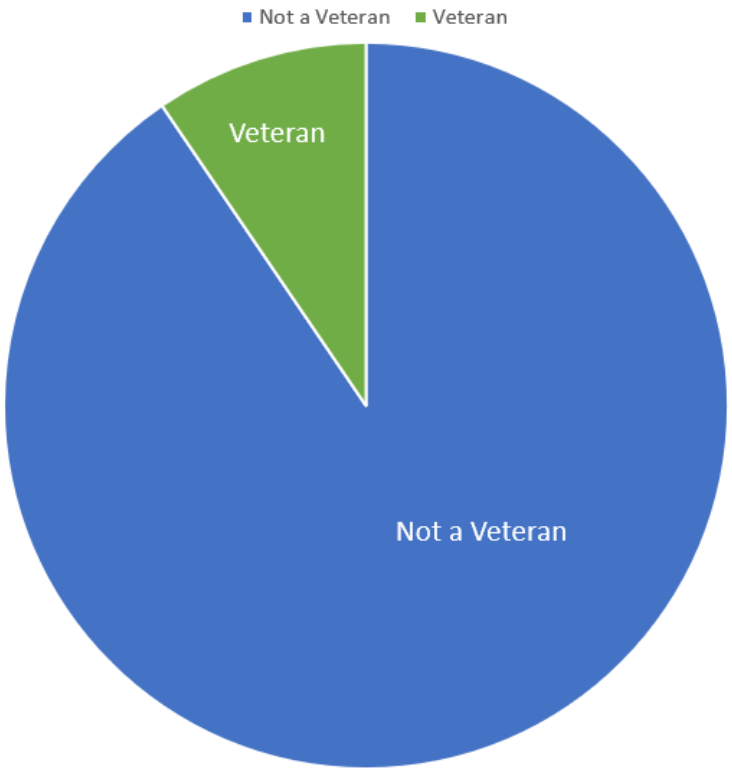
Gender Identity	Total	
	Percent	Number
Female	71.4%	15
Male	28.6%	6
Non-Binary	0.0%	0
Total	**100.0%**	**21**

4. Employees by Generation



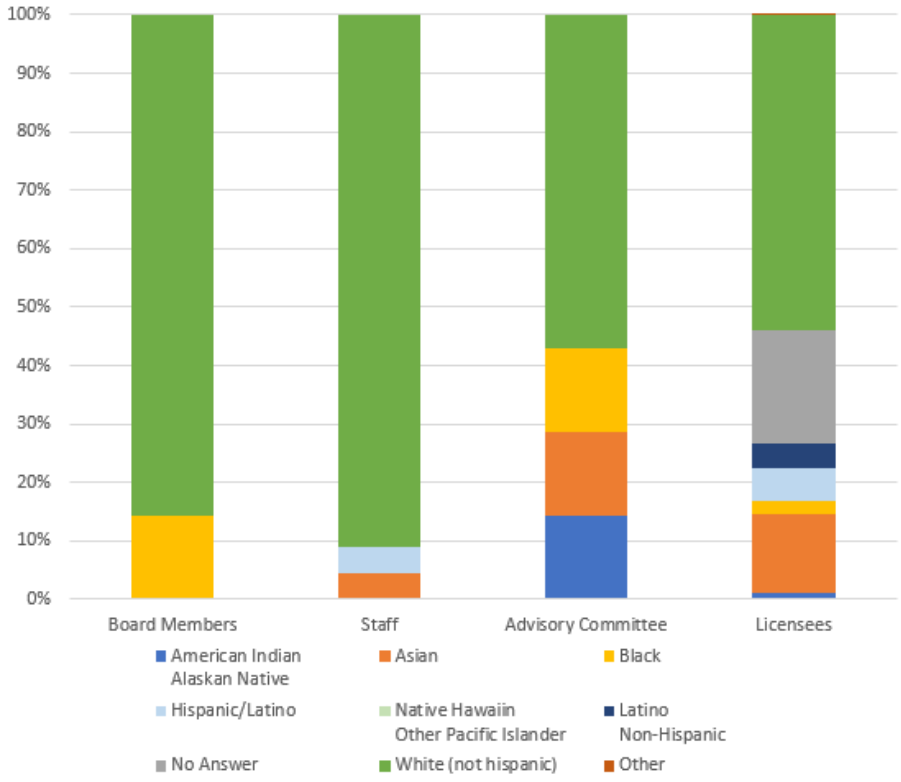
Generation	Total	
	Percent	Number
Generation Z (1997 - Current)	0.0%	0
Millennials (1981 - 1996)	42.9%	9
Generation X (1965 - 1980)	42.9%	9
Baby Boomers (1947 - 1964)	14.3%	3
Traditionalists (1917 - 1946)	0.0%	0
Total	**100.0%**	**21**

5. Employees by Veteran Status



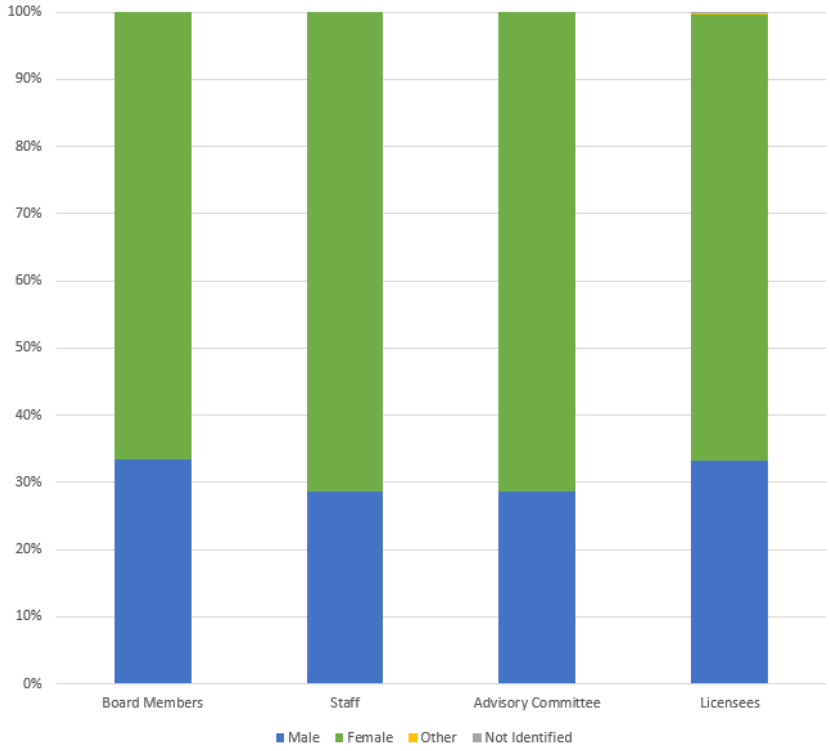
Veteran Status	Total	
	Percent	Number
Not a Veteran	90.5%	19
Veteran	9.5%	2
Total	**100.0%**	**21**

6. Race & Ethnicity Comparisons of Workforce, Board, Committee, and Licensees



	Total	American Indian Alaskan Native	Asian	Black African American	Hispanic/ Latino	Native Hawaiin Other Pacific Islander	Latino or Non-Hispanic	No Answer	White (not hispanic)	Other
Board Members	9	0	0	1	0	0	0	0	8	0
Staff	21	0	1	0	1	0	0	0	19	0
Advisory Committee	7	1	1	1	0	0	0	0	4	0
Licensees	17,528	205	2,343	392	994	26	717	3,405	9,424	22

7. Gender Comparison of Workforce, Board, Committee, and Licensees



	Total	Male	Female	Other	Not Identified
Board Members	9	3	6	0	0
Staff	21	6	15	0	0
Advisory Committee	7	2	5	0	0
Licensees	17,528	5,835	11,634	20	39

Promotions

1. Supervisor Promotion by Racial Categories & Gender
   No promotions to supervisory roles were made as of June 30th, 2020.

2. Non-Supervisor Promotion by Racial Categories & Gender
   No promotions to non-supervisory roles were made as of June 30th, 2020.

Affirmative Action Plans

2021-2023 Affirmative Action Strategies and Goals

1. Issue
   The agency would like to increase its efforts to hire and retain underrepresented groups.

2. Goals

   The agency will increase outreach to job fairs and resources that target underrepresented groups to improve the agency's hiring of qualified candidates from these groups.

3. Outcome

   The agency will work with the entities to ensure jobs are posted in venues that increase posting views by candidates in underserved populations.

4. Measures

   The agency will ensure that it has funding to participate in job fairs and outreach opportunities to underrepresented groups. Success will be measured by change in metrics over this biennium.

5. Implementation

   Agency resources such as funding and staff time will be necessary to meet these goals. Quarterly check-in meetings with HR will assist in maintaining sight on the goal. The Executive Director is supportive of these goals and will continue to emphasize the agency's organizational value of equity in hiring, retention, and promotion of staff.

   The Affirmative Action representative will advise on where new jobs get posted to better assist the hiring manager in recruiting a diverse pool of applicants.

2021-2023 Affirmative Action Strategies

1. Recruitment

   The agency will continue to seek diverse candidate pools in the agency's Board, staff, and committee membership, utilizing tools provided by the State.

2. Selection

   In order to provide accessible interviews, the agency will continue to utilize video conferencing to perform interviews and interview panels. This allows for the candidate to be exposed to a variety of staff members, allows staff to be more involved in the interview process and have a voice in the composition of their team.

   Additionally, the agency has begun to include an interview question in the final round of interviews that addresses the agency's commitment to equity and asks the candidate to define what equity means to them. This allows interviewers to assess the alignment of the candidate's values with the agency's organizational values, with the hope of increasing the possibility of a good fit and a commitment to equity among the team.

3. Retention

   The agency will provide staff with development and training opportunities both within and outside of the agency. In addition, the agency will foster an environment of acceptance and open communication that allows all staff to feel comfortable in each other's company.

4. Employee Engagement
   The agency takes advantage of staff meetings to allow time to discuss issues employees are facing. Due to the COVID-19 pandemic, these meetings have been minimized, but will continue once it is safe to do so or will be held in virtual format.

Management

Leadership Evaluation

ORS 659A.012 requires agencies *"to achieve the public policy of the State of Oregon for persons in the State to attain employment and advancement without discrimination because of race, religion, color, sex, marital status, national origin, disability or age, every State agency shall be required to include in the evaluation of all management personnel the manager's or supervisor's effectiveness in achieving affirmative action objectives as a consideration of the manager's or supervisor's performance."*

1. Compliance with Above Requirement
   This requirement is met through quarterly check-ins with all supervisory roles to ensure that this is kept as a focus.

Succession Plan

1. Succession Planning
   In an agency of 22 FTE, it can be challenging to develop succession planning. Over the last six years, cross training has been actively implemented and standard work documentation is being created to better document established practices. Outside of the recruitment process and encouraging training opportunities, the agency has not yet been able to implement a more formalized succession planning process.

COVID-19 Update

COVID-19 continues to have significant impact on board operations, with the Delta variant introducing a new round of uncertainty. We issued a COVID-19 communication to licensees this week regarding new guidance for vaccination of healthcare workers. Compliance Officers continue to field correspondence about immunization, face covering, and workplace conditions. Licensing is currently in the manufacturer, wholesaler and drug distribution agent renewal window, with a deadline of September 30th.

The Governor's office is asking that state agencies begin to prepare for reopening of state buildings to the public on September 1st. We have continued to limit in-office staffing to approximately 50% with a rotating schedule of remote work.

We continue to work with the OHA to distribute information and links to assist pharmacists in navigating the evolving pandemic landscape. With the Delta variant increasing hospitalization throughout the state in primarily unvaccinated people, it continues to be important for pharmacists and technicians to encourage and provide vaccinations to all who qualify.

Strategic Plan Update

We selected Pivotal Resources as facilitators for our strategic planning meeting in November. Planning will begin in September with stakeholder, board and staff interviews. This will be a two-day meeting with a goal of developing a new four-year plan for 2022-2026.

- Technicians - The first technician Rules Advisory Committee Meeting was held on March 18th with the second meeting scheduled for August 25th. Draft rules for remote dispensing site pharmacies (aka Telepharmacy, as detailed in SB 629) and remote work have been presented to the board. We will continue to seek RAC input and refine these rules to protect public health and safety as well as increase access to pharmacy services.

- Technology – We have presented draft rules for self-service prescription lockers for delivery of completed prescriptions and Telepharmacy as outlined in SB 629.

- Licensing - License and registration late fees have been synchronized with their expiration date due to the ability to renew most licenses online. Drug outlet registration statutes and rules are being reviewed to identify consistency in registration categories and guide future rulemaking. Draft rules for drug outlet registration will be forthcoming when full legal assessment has been completed. We are adding additional license categories to online renewal capability to achieve additional efficiencies. The Jasper reporting system has been implemented which has improved licensing database reporting.

- Regulation - We are meeting the goal to provide at least one comprehensive rule review for one division at each board meeting. For this meeting, seven rules have been presented for a first or second look. We are on target to review each division every five years.

- Communication - We continue to proactively communicate with licensees, registrants, and stakeholders. Our Communication Plan is still somewhat hampered by COVID, but we have been communicating with stakeholders and the public through COVID-19 updates and virtual presentations to the associations and colleges of pharmacy. We have a presentation scheduled for the P-1 class at Oregon State on September 16th and a Law Update presentation to the OSPA on October 2. The PIC class has been reinstated in a hybrid format, with the next presentation scheduled for August 24th.

End of Session Report

Report Date: July 30, 2021

Oregon Board of Pharmacy

N/A

Bill #	Status	Position	Priority	Effective Date	Last Three Actions
HB 2074 EN	Passed	Watch	1		7/19/2021 - Governor signed. 6/26/2021 - President signed. 6/24/2021 - Speaker signed.
Increases prescription monitoring program fees from $25 to $35.					
HB 2078 EN	Passed	Watch	1	January 1, 2022	6/10/2021 - Chapter 50, (2021 Laws): Effective date January 1, 2022. 5/21/2021 - Governor signed. 5/14/2021 - President signed.
Repeals electronic credentialing information program.					
HB 2132 EN	Passed	Watch	1	June 11, 2021	6/30/2021 - Chapter 213, (2021 Laws): Effective date June 11, 2021. 6/14/2021 - Governor signed. 6/7/2021 - President signed.
Modifies provisions relating to criminal records checks.					
HB 2167 EN	Passed	Watch	3		7/27/2021 - Governor signed. 6/26/2021 - President signed. 6/24/2021 - Speaker signed.
Creates Racial Justice Council within Office of Governor.					
HB 2168 EN	Passed	Watch	3	September 25, 2021	6/30/2021 - Chapter 201, (2021 Laws): Effective date September 25, 2021. 6/14/2021 - Governor signed. 6/7/2021 - President signed.
Establishes Juneteenth as legal state holiday.					
HB 2315 EN	Passed	Watch	4		6/10/2021 - Chapter 114, (2021 Laws): effective on the 91st day following adjournment sine die. 6/1/2021 - Governor signed. 5/25/2021 - President signed.
Directs Oregon Health Authority and specified professional regulatory boards to require licensees regulated by authority or board to complete continuing education					

End of Session Report

Report Date: July 30, 2021

Oregon Board of Pharmacy

N/A

Bill #	Status	Position	Priority	Effective Date	Last Three Actions
related to suicide risk assessment, treatment and management at specified intervals and to report completion of continuing education to authority or board.					
HB 2359 EN	Passed	Watch	1	July 14, 2021	7/27/2021 - Chapter 453, (2021 Laws): Effective date July 14, 2021. 7/14/2021 - Governor signed. 6/26/2021 - President signed.
Requires health care providers to work with health care interpreters from health care interpreter registry operated by Oregon Health Authority to provide interpretation services.					
HB 2508 EN	Passed	Informational	3	June 1, 2021	6/10/2021 - Chapter 117, (2021 Laws): Effective date June 1, 2021. 6/1/2021 - Governor signed. 5/25/2021 - President signed.
Prescribes requirements for reimbursement by Oregon Health Authority and coordinated care organizations of health services delivered using telemedicine.					
HB 2560 EN	Passed	Watch	2	January 1, 2022	6/30/2021 - Chapter 228, (2021 Laws): Effective date January 1, 2022. 6/14/2021 - Governor signed. 6/7/2021 - President signed.
Requires governing body of public body, to extent reasonably possible, to make all meetings accessible remotely through technological means and provide opportunity for members of general public to remotely submit oral and written testimony .					
HB 2646 EN	Pending	Watch	5		6/30/2021 - President signed. 6/29/2021 - Speaker signed. 6/26/2021 - Rules suspended. Third reading. Carried by Frederick. Passed. Ayes, 26; Nays, 2--Boquist, Robinson; Excused, 2--Heard, Manning Jr.
Establishes regulations for kratom products, including testing standards, labeling requirements and minimum age for sale.					
HB 2648 EN	Passed	Watch	1	September 25, 2021	6/30/2021 - Chapter 297, (2021 Laws): Effective date September 25, 2021. 6/15/2021 - Governor signed. 6/8/2021 - Speaker signed.

End of Session Report

Report Date: July 30, 2021

Oregon Board of Pharmacy

N/A

Bill #	Status	Position	Priority	Effective Date	Last Three Actions
Allows pharmacist or pharmacy technician to transfer drug containing pseudoephedrine without prescription to person who is at least 18 years of age and presents person's valid government-issued photo identification.					
HB 2958 EN	Passed	Watch	1	September 25, 2021	7/7/2021 - Chapter 365, (2021 Laws): Effective date September 25, 2021. 6/23/2021 - Governor signed. 6/17/2021 - President signed.
Allows pharmacist to prescribe, dispense and administer preexposure prophylactic antiretroviral therapies and post-exposure prophylactic antiretroviral therapies.					
HB 2970 EN	Passed	Watch	4	June 23, 2021	7/7/2021 - Chapter 366, (2021 Laws): Effective date June 23, 2021. 6/23/2021 - Governor signed. 6/16/2021 - President signed.
Defines "device" for purposes of practice of advanced nonablative esthetics.					
HB 2993 EN	Passed	Watch	1	January 1, 2022	7/27/2021 - Chapter 463, (2021 Laws): Effective date January 1, 2022. 7/14/2021 - Governor signed. 6/26/2021 - President signed.
Provides that advisory committees appointed by agency as part of rulemaking must represent interests of persons and communities likely to be affected by rule.					
HB 3057 EN	Passed	Watch	1	May 24, 2021	6/10/2021 - Chapter 92, (2021 Laws): Effective date May 24, 2021. 5/25/2021 - Governor signed. 5/18/2021 - President signed.
Authorizes Oregon Health Authority to disclose individually identifiable information related to COVID-19 to certain persons and under certain circumstances.					
HB 5027 EN	Passed	Watch	1	July 1, 2021	6/10/2021 - Chapter 168, (2021 Laws): Effective date July 1, 2021. 6/3/2021 - Governor signed. 5/27/2021 - President signed.
Limits biennial expenditures from fees, moneys or other revenues, including Miscellaneous Receipts, but excluding lottery funds and federal funds, collected or received by State Board of Pharmacy.					

End of Session Report

Report Date: July 30, 2021

Oregon Board of Pharmacy

N/A

Bill #	Status	Position	Priority	Effective Date	Last Three Actions
SB 629 EN	Passed	Watch	1	September 25, 2021	6/30/2021 - Effective date, September 25, 2021. 6/30/2021 - Chapter 340, 2021 Laws. 6/15/2021 - Governor signed.
Allows pharmacist to use telepharmacy to deliver pharmacy services to patient at remote location.					
SB 636 EN	Passed	Watch	2	January 1, 2022	6/10/2021 - Effective date, January 1, 2022. 6/10/2021 - Chapter 143, 2021 Laws. 6/1/2021 - Governor signed.
Provides that when state agency is required by statute to mail certain notice to individual, and agency has on file post office box address for individual, agency must mail notice to post office box address if address is individual's last known address on file or address to which individual has requested that notices be sent.					
SB 763 EN	Passed	Watch	3	September 25, 2021	7/14/2021 - Governor signed. 6/26/2021 - Speaker signed. 6/26/2021 - President signed.
Provides that person may not engage in business as pharmaceutical representative without obtaining license from Director of Department of Consumer and Business Services.					

Oregon Board of Pharmacy

Budget Report: May 2021 (Month 23)

Revenue:

Through May, revenue is $1,304,383 (18.5%) **over** budget

Expenditures:

Through May, **total expenditures** are $979,508 (11.3%) **under** budget

Personal services are $536,792 (9.2%) **under** budget

Services and Supplies are $430,787 (18.2%) **under** budget

Special Payments are $11,928 (100%) **under** budget

Revenues less Expenditures: $710,343

Cash Balance:

Cash balance through May is $4,467,993 which represents (11.89 months of operating expense)

Note: This the above is a snap-shot of the biennium to date through May 2021. It does not include projections for the remainder of the biennium.

End of biennium estimated cash balance is $4,583,344, which represents (13.53 months of operating expense)

Cash balance target is $2,031,822, (6.0 months of operating expense)

Note: The end of biennium estimated cash balance is calculated based on the biennium to date plus the remaining months projections for 2019-21.

Oregon Board of Pharmacy				
Total All Funds - LAB 2019-2021				
Actuals through May 2021 month-end-close				
		LAB	**ACTUAL+PROJ**	**VARIANCE**
	BEGINNING CASH BALANCE	**0**	**3,757,650**	**0.00**
REVENUE				
50	GENERAL FUND			
205	OTHER BUSINESS LICENSES	7,146,250.00	8,476,261.25	(1,330,011.25)
210	OTHER NONBUSINESS LICENSES AND FEES	139,296.00	252,398.25	(113,102.25)
505	FINES AND FORFEITS	405,000.00	425,381.28	(20,381.28)
605	INTEREST AND INVESTMENTS	45,000.00	120,752.71	(75,752.71)
975	OTHER REVENUE	57,090.00	65,733.71	(8,643.71)
	TOTAL REVENUE	**7,792,636.00**	**9,340,527.20**	**(1,547,891.20)**
TRANSFERS				
1107	TRANSFER IN FROM DAS	-	35,494.97	(35,494.97)
	TOTAL TRANSFER IN	**0.00**	**35,494.97**	**(35,494.97)**
2010	TRANSFER OUT TO OTHER FUNDS	-	-	-
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	416,146.00	423,040.00	(6,894.00)
	TOTAL TRANSFER OUT	**416,146.00**	**423,040.00**	**(6,894.00)**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	3,890,199.00	3,531,044.74	359,154.26
3160	TEMPORARY APPOINTMENTS	26,180.00	5,148.66	21,031.34
3170	OVERTIME PAYMENTS	-	1,737.31	(1,737.31)
3180	SHIFT DIFFERENTIAL	-	-	-
3190	ALL OTHER DIFFERENTIAL	190,428.00	233,923.42	(43,495.42)
3210	ERB ASSESSMENT	1,281.00	1,139.58	141.42
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	684,570.00	578,066.26	106,503.74
3221	PENSION BOND CONTRIBUTION	200,306.00	201,179.12	(873.12)
3230	SOCIAL SECURITY TAX	313,870.00	273,652.68	40,217.32
3240	UNEMPLOYMENT ASSESSMENT	-	329.26	(329.26)
3250	WORKERS' COMPENSATION ASSESSMENT	1,276.00	854.05	421.95
3260	MASS TRANSIT	24,607.00	22,489.17	2,117.83
3270	FLEXIBLE BENEFITS	774,048.00	706,001.19	68,046.81
3435	Personal Services Budget Adj.	(20,653.00)	-	(20,653.00)
	TOTAL PERSONAL SERVICES	**6,086,112.00**	**5,555,565.44**	**530,546.56**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	113,572.00	45,961.49	67,610.51
4125	OUT-OF-STATE TRAVEL	16,322.00	5,916.69	10,405.31
4150	EMPLOYEE TRAINING	21,400.00	14,789.62	6,610.38
4175	OFFICE EXPENSES	129,018.00	82,067.78	46,950.22
4200	TELECOMM/TECH SVC AND SUPPLIES	48,830.00	47,080.29	1,749.71
4225	STATE GOVERNMENT SERVICE CHARGES	163,176.00	163,522.76	(346.76)
4250	DATA PROCESSING	80,540.00	324,627.96	(244,087.96)
4275	PUBLICITY & PUBLICATIONS	39,583.00	19,627.10	19,955.90
4300	PROFESSIONAL SERVICES	321,394.00	318,205.72	3,188.28
4315	IT PROFESSIONAL SERVICES	652,149.00	280,925.35	371,223.65
4325	ATTORNEY GENERAL LEGAL FEES	525,607.00	524,692.61	914.39
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	653.00	-	653.00
4400	DUES AND SUBSCRIPTIONS	5,195.00	5,459.99	(264.99)
4425	FACILITIES RENT & TAXES	210,941.00	203,074.80	7,866.20
4475	FACILITIES MAINTENANCE	53.00	2,266.00	(2,213.00)
4525	MEDICAL SUPPLIES AND SERVICES	1,152.00	801.36	350.64
4575	AGENCY PROGRAM RELATED SVCS & SUPP	240,152.00	231,610.19	8,541.81
4650	OTHER SERVICES AND SUPPLIES	284,656.00	256,040.48	28,615.52
4700	EXPENDABLE PROPERTY $250-$5000	13,526.00	4,155.60	9,370.40
4715	IT EXPENDABLE PROPERTY	43,363.00	34,179.36	9,183.64
	TOTAL SERVICES & SUPPLIES	**2,911,282.00**	**2,565,005.15**	**346,276.85**
Capital Outlay				
5600	DATA PROCESSING HARDWARE	8,611.00	-	8,611.00
5900	OTHER CAPITAL OUTLAY	-	6,717.34	(6,717.34)
	Total Capital Outlay	**8,611.00**	**6,717.34**	**1,893.66**
Special Payments				
6085	OTHER SPECIAL PAYMENTS	12,447.00	-	12,447.00
	Total Special Payments	**12,447.00**	**0.00**	**12,447.00**
	TOTAL EXPENDITURES	**9,018,452.00**	**8,127,287.93**	**891,164.07**
	PROJECTED BIENNIAL ENDING CASH BALANCE		**4,583,344**	
	End of biennium projected cash balance in months		13.53	
	Cash balance target of 6.0 months (working capital)		2,031,822	

Oregon Board of Pharmacy

Budget Report: June 2021 (Month 24)

Revenue:

Through June, revenue is $1,842,323 (25.0%) **over** budget

Expenditures:

Through June, **total expenditures** are $1,024,863 (11.4%) **under** budget

Personal services are $532,177 (8.7%) **under** budget

Services and Supplies are $480,239 (19.7%) **under** budget

Special Payments are $12,447 (100%) **under** budget

Revenues less Expenditures: $1,225,224

Cash Balance:

Cash balance through June is $4,982,874 which represents (13.26 months of operating expense)

Note: This the above is a snap-shot of the biennium to date through June 2021. It does not include projections for the remainder of the biennium.

End of biennium estimated cash balance is $4,721,529, which represents (14.06 months of operating expense)

Cash balance target is $2,014,448, (6.0 months of operating expense)

Note: The end of biennium estimated cash balance is calculated based on the biennium to date plus the remaining months projections for 2019-21.

Oregon Board of Pharmacy				
Total All Funds - LAB 2019-2021				
Actuals through June 2021 month-end-close				
		LAB	**ACTUAL+PROJ**	**VARIANCE**
	BEGINNING CASH BALANCE	**0**	**3,757,650**	**0.00**
REVENUE				
50	GENERAL FUND			
205	OTHER BUSINESS LICENSES	7,146,250.00	8,546,255.25	(1,400,005.25)
210	OTHER NONBUSINESS LICENSES AND FEES	139,296.00	254,727.75	(115,431.75)
505	FINES AND FORFEITS	405,000.00	425,491.28	(20,491.28)
605	INTEREST AND INVESTMENTS	45,000.00	120,752.71	(75,752.71)
975	OTHER REVENUE	57,090.00	64,593.71	(7,503.71)
	TOTAL REVENUE	**7,792,636.00**	**9,411,820.70**	**(1,619,184.70)**
TRANSFERS				
1107	TRANSFER IN FROM DAS	-	35,494.97	(35,494.97)
	TOTAL TRANSFER IN	**0.00**	**35,494.97**	**(35,494.97)**
2010	TRANSFER OUT TO OTHER FUNDS	-	-	-
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	416,146.00	425,643.00	(9,497.00)
	TOTAL TRANSFER OUT	**416,146.00**	**425,643.00**	**(9,497.00)**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	3,890,199.00	3,529,844.72	360,354.28
3160	TEMPORARY APPOINTMENTS	26,180.00	5,148.66	21,031.34
3170	OVERTIME PAYMENTS	-	1,737.31	(1,737.31)
3180	SHIFT DIFFERENTIAL	-	-	-
3190	ALL OTHER DIFFERENTIAL	190,428.00	233,923.43	(43,495.43)
3210	ERB ASSESSMENT	1,281.00	1,139.58	141.42
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	684,570.00	578,066.28	106,503.72
3221	PENSION BOND CONTRIBUTION	200,306.00	201,153.16	(847.16)
3230	SOCIAL SECURITY TAX	313,870.00	273,260.36	40,609.64
3240	UNEMPLOYMENT ASSESSMENT	-	329.26	(329.26)
3250	WORKERS' COMPENSATION ASSESSMENT	1,276.00	838.28	437.72
3260	MASS TRANSIT	24,607.00	22,492.58	2,114.42
3270	FLEXIBLE BENEFITS	774,048.00	705,996.81	68,051.19
3435	Personal Services Budget Adj.	(20,653.00)	-	(20,653.00)
	TOTAL PERSONAL SERVICES	**6,086,112.00**	**5,553,930.43**	**532,181.57**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	113,572.00	38,375.09	75,196.91
4125	OUT-OF-STATE TRAVEL	16,322.00	2,916.69	13,405.31
4150	EMPLOYEE TRAINING	21,400.00	14,212.62	7,187.38
4175	OFFICE EXPENSES	129,018.00	69,093.88	59,924.12
4200	TELECOMM/TECH SVC AND SUPPLIES	48,830.00	48,909.23	(79.23)
4225	STATE GOVERNMENT SERVICE CHARGES	163,176.00	163,418.16	(242.16)
4250	DATA PROCESSING	80,540.00	324,816.88	(244,276.88)
4275	PUBLICITY & PUBLICATIONS	39,583.00	17,931.61	21,651.39
4300	PROFESSIONAL SERVICES	321,394.00	299,109.63	22,284.37
4315	IT PROFESSIONAL SERVICES	652,149.00	279,177.35	372,971.65
4325	ATTORNEY GENERAL LEGAL FEES	525,607.00	524,567.61	1,039.39
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	653.00	-	653.00
4400	DUES AND SUBSCRIPTIONS	5,195.00	5,719.99	(524.99)
4425	FACILITIES RENT & TAXES	210,941.00	203,074.80	7,866.20
4475	FACILITIES MAINTENANCE	53.00	2,266.00	(2,213.00)
4525	MEDICAL SUPPLIES AND SERVICES	1,152.00	251.36	900.64
4575	AGENCY PROGRAM RELATED SVCS & SUPP	240,152.00	203,573.94	36,578.06
4650	OTHER SERVICES AND SUPPLIES	284,656.00	263,041.72	21,614.28
4700	EXPENDABLE PROPERTY $250-$5000	13,526.00	3,427.80	10,098.20
4715	IT EXPENDABLE PROPERTY	43,363.00	33,261.57	10,101.43
	TOTAL SERVICES & SUPPLIES	**2,911,282.00**	**2,497,145.93**	**414,136.07**
Capital Outlay				
5600	DATA PROCESSING HARDWARE	8,611.00	-	8,611.00
5900	OTHER CAPITAL OUTLAY	-	6,717.34	(6,717.34)
	Total Capital Outlay	**8,611.00**	**6,717.34**	**1,893.66**
Special Payments				
6085	OTHER SPECIAL PAYMENTS	12,447.00	-	12,447.00
	Total Special Payments	**12,447.00**	**0.00**	**12,447.00**
	TOTAL EXPENDITURES	**9,018,452.00**	**8,057,793.70**	**960,658.30**
	PROJECTED BIENNIAL ENDING CASH BALANCE		**4,721,529**	
	End of biennium projected cash balance in months		14.06	
	Cash balance target of 6.0 months (working capital)		2,014,448	