Oregon Board of Pharmacy
REVISED BOARD MEETING AGENDA
Meeting Location: Teleconference
February 9-11, 2022

Public Attendance by Phone (503) 446-4951 Phone Conference ID: 776 063 891#
Due to COVID-19, the Portland State Office Building remains closed to the public.

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, February 9, 2022 @ 8:30AM
Thursday, February 10, 2022 @ 8:30AM
Friday, February 11, 2022 @ 8:30AM

- All Board meetings except Executive or Closed Sessions are open to the public. Pursuant to ORS 192.660, Executive Sessions are closed, with the exception of news media and public officials
- No final actions will be taken in Executive Session
- When action is necessary, the Board will return to Open Session
- To sign up for Public Comment, email your request to Karen MacLean by **12:00PM on 2/11/2022**.

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, February 9, 2022

I. OPEN SESSION, Wassim Ayoub RPh, Presiding
- a. Roll Call
- b. 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, February 10, 2022

I. OPEN SESSION, Wassim Ayoub RPh, Presiding
- a. Roll Call

II. EXECUTIVE SESSION – NOT OPEN TO THE PUBLIC, pursuant to ORS 191.660 (1)(L), ORS 192.690(1) ORS 676.165, ORS 676.175.
- a. Deliberation on Disciplinary Cases and Investigations
- b. Contested Case Deliberation *if applicable

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

IV. GENERAL ADMINISTRATION

a. Rules

i. Consider Adoption of Rules – None

ii. Rules in Development – *Davis*

iii. Consider Adoption of Temporary Rules - *Davis*

1. **Div 021/025/110** - Pharmacy Technician Renewal **#A** *Action Necessary*
2. **Div 041/139** - Permanent Pharmacy Closure **#A1** *Action Necessary*

iv. Guest Speakers from Uprise Health - **#C**

v. Rulemaking Policy Discussion Items – Davis

1. **Div 020** – Protocol COVID Antigen Self-Test **#B, #Ba** *Action Necessary*
2. **Div 021/025/110** - Pharmacy Technician (Renewal) **#B1** *Action Necessary*
3. **Div 041/139** - Accurate Hours/Temporary Pharmacy Closure **#B2** *Action Necessary*
4. **Div 006/143** - Pharmacy Prescription Lockers **#B3** *Action Necessary*
5. **Div 006/019/041/139/143** – Interpreters Patient Records **#B4**
6. **Div 021** - CE (Procedural Rule Review) **#B5**
7. **Div 041** – Disclosure of Patient Information **#B6** *Action Necessary*
8. **Div 006/041/139** - Drug Storage (Procedural Rule Review) **#B7** *Action Necessary*
9. **Div 006/020/041/065/139** - Alarm/Audiovisual Communication/Entry/ Surveillance Systems **#B8** *Action Necessary*
10. **Div 080** - Cannabis Exception **#B9** *Action Necessary*
11. **Div 006/041/139** - Definitions Supervision by a Pharmacist **#B10** *Action Necessary*

FRIDAY, February 11, 2022

I. OPEN SESSION, Wassim Ayoub RPh, Presiding

a. Roll Call

II. MOTIONS RELATED TO DISCIPLINARY ACTIONS – *Efremoff* *Action Necessary*

III. GENERAL ADMINISTRATION CONTINUED

i. Policy Discussion Items – *Schnabel*

1. Enforcement Discretion - Telework & PHE Remote Processing *Action Necessary*
2. Safe Pharmacy Practice Conditions Position Statement **#D** *Action Necessary*
3. Recent Board Action Transparency

ii. Rules Advisory Committee & Workgroup Updates – *Davis*

IV. Discussion Items

i. Public Health and Pharmacy Formulary Advisory Committee – *Davis*

ii. Legislative Update – *Schnabel* **#E**

iii. COVID-19 Update – *Schnabel*

iv. Strategic Plan Update – *Schnabel* **#F** *Action Necessary*

v. Financial/Budget Report – *MacLean* **#G**

1. 2023-2025 Budget Development *Action Necessary*

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

c. Reports
   i. Board Members
   ii. Executive Director
   iii. Compliance Director
   iv. Administrative Director
   v. Licensing Manager
   vi. Pharmacist Consultant
   vii. Operations Policy Analyst

2022 Board Meeting Dates

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

2023 Board Meeting Dates

- February 8-9, 2023 Portland
- April 12-14 2023* Portland
- June 7-8, 2023 Portland
- August 9-10, 2023 Portland
- October 11-13, 2023* Portland
- November 8-9, 2023 TBA (Strategic Planning)
- December 13-14, 2023 Portland

Rulemaking Hearing Dates

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

- March 29, 2022
- May 24, 2022
- November 22, 2022

Upcoming Conferences/Meetings - Schnabel

1. OSPA Lane County Mid-Winter Seminar – February 26-27, 2022 @ The Graduate Hotel Eugene, OR
2. OSHP 2022 Annual Seminar – April 22-24, 2022 @ Sunriver Resort, Sunriver, OR

V. APPROVE CONSENT AGENDA* *Action Necessary*

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

a. License/Registration Ratification - **# CONSENT-1**
b. Board Meeting Minutes – December 2021 **# CONSENT-2**

VI. PUBLIC COMMENT

Adjourn *Action Necessary*

Division 021/025/110: Pharmacy Technicians and Certified Oregon Pharmacy Technician Licensure (PT Renewal)

Filing Caption per ORS 183.335(2)(a)(A) (max 15 words): Amends Pharmacy Technician and Certified Oregon Pharmacy Technician Licensure Rules

Need for Rules per ORS 183.335(2)(b)(C) (Describes what we are changing in rule): Clarifies licensure qualifications, elements of a complete application and renewal/reinstatement requirements for Pharmacy Technicians (PT) and Certified Oregon Pharmacy Technicians (COPT); Revises PT license fees; Allows PT to renew or reinstate their license; Adds CE requirements for PT.

Justification of Temporary Filing per ORS 183.403(2)(b)(C) (Statement of findings that prompt action needed to avoid serious prejudice with specific reasons, valid for 180 days): During the COVID-19 pandemic, pharmacies are experiencing a shortage of licensed personnel to assist in the practice of pharmacy. In addition, the current PT and COPT rules present unintended barriers to licensure by requiring those who have never held a national certification to obtain it to remain licensed. A shortage of licensed personnel reduces timely access to prescription medication. Inability to access prescription medications and records in a timely manner is a danger to public health and safety.

Adopting this Temporary rule now will allow current PT licensees to plan ahead and determine if they want to apply for a COPT license.

Documents Relied Upon per ORS 183.335(2)(b)(D):

- Pharmacy Technician Certification Board- CPhT certification renewal
- National Healthcareer Association- CPhT certification renewal

855-025-0005

Licensure: Qualifications- ~~for Licensure~~ as a Pharmacy Technician or Certified Oregon Pharmacy Technician

(1) To qualify for licensure as a Pharmacy Technician or Certified Oregon Pharmacy Technician, an applicant must demonstrate that the applicant is at least 18 years of age and has ~~obtained~~ **completed** ~~a~~ high school **(or equivalent)** ~~diploma or GED~~.

(2) ~~Section one does not apply to persons under the age of 18 licensed by the Board as a Pharmacy Technician prior to January 1, 2015.~~ **To qualify for licensure as a Certified Oregon Pharmacy Technician, the applicant must also demonstrate that the applicant has taken and passed a national pharmacy technician certification examination offered by:**

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

(b) National Healthcareer Association (NHA).

~~(3) An applicant for licensure as a Pharmacy Technician or Certified Oregon Pharmacy Technician must complete an application for licensure, provide the Board with a valid e-mail address and furnish documentation required to conduct a criminal background check.~~

(~~4~~**3**) No person whose license has been denied, revoked, suspended or restricted by any healthcare professional regulatory Board may be licensed as a Pharmacy Technician or Certified Oregon Pharmacy Technician unless the Board determines that licensure will pose no danger to patients or to the public interest.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & **ORS** 689.486

855-025-0010
Licensure: Application- ~~as a~~ Pharmacy Technician

(1)~~The license of a Pharmacy Technician expires the second June 30 from the date of issue and is not to exceed two years, except that due to the COVID-19 declared public health emergency, Pharmacy Technician (PT) licenses set to expire June 30, 2020, will instead expire on 12/31/2020~~ **An application for licensure as a Pharmacy Technician may be accessed on the board website**.

(2) Failure to completely, accurately and honestly answer all questions on the application for licensure or renewal of licensure is grounds for discipline;

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

(~~2~~**4**) ~~The Pharmacy Technician license is not renewable.~~ **The board may issue a license to a qualified Pharmacy Technician after the receipt of:**

(a) A completed application;

(b) Payment of the fee prescribed in OAR 855-110;

(c) A current, passport regulation size photograph (full front, head to shoulders);

(d) Personal identification or proof of identity; and

(e) A completed national fingerprint-based background check.

(~~3~~**5**) ~~A time limited extension of a Pharmacy Technician license may be granted once by petition to the Board. The written completed petition must be received by the Board prior to the expiration of the PT license~~ **The license of a Pharmacy Technician expires June 30 in even numbered years and may be renewed biennially.**

~~(4) An individual may reapply for a Pharmacy Technician license if the previous PT license is lapsed for a period greater than five years.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

855-025-0011

Licensure: Renewal or Reinstatement- Pharmacy Technician

(1) An applicant for renewal of a Pharmacy Technician license must:

(a) Pay the biennial license fee required in OAR 855-110.

(b) Complete the continuing pharmacy education requirements as directed in OAR 855-021;

(c) Be subject to an annual criminal background check.

(2) A Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may apply to renew their license and must pay a late fee required in OAR 855-110.

(3) A Pharmacy Technician or who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate their license as follows:

(a) Must apply per OAR 855-025-0010; and

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

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

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

(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(D) Seven other hours of pharmacy technician-specific continuing education.

POLICY DISCUSSION: Retain CE requirement, CCCE

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225, ORS 689.486, ORS 413.450

855-025-0012

Licensure: Application- ~~as a~~ Certified Oregon Pharmacy Technician

(1) ~~To qualify for licensure as a Certified Oregon Pharmacy Technician, the applicant must demonstrate that he or she has taken and passed a national pharmacy technician certification examination offered by:~~ **An application for licensure as a Pharmacy Technician may be accessed on the board website**.

(~~a~~**2**) ~~The Pharmacy Technician Certification Board (PTCB); or~~ **Failure to completely, accurately and honestly answer all questions on the application for licensure or renewal of licensure is grounds for discipline.**

(~~b~~**3**) ~~The National Healthcareer Association (NHA).~~ **Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.**

(~~24~~) ~~The license of a Certified Oregon Pharmacy Technician expires June 30 in even numbered years and must be renewed biennially.~~ **The board may issue a license to a qualified Certified Oregon Pharmacy Technician after the receipt of:**

(a) A completed application;

(b) Payment of the fee prescribed in OAR 855-110;

(c) A current, passport regulation size photograph (full front, head to shoulders);

(d) Personal identification or proof of identity;

(e) A completed national fingerprint-based background check; and

(f) Proof that the applicant has taken and passed a national pharmacy technician certification offered by the PTCB or the NHA.

(5) The license of a Certified Oregon Pharmacy Technician expires June 30 in even numbered years and may be renewed biennially.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & **ORS** 689.486

855-025-0015
~~Renewal of~~ Licensure: Renewal or Reinstatement- ~~as a~~ Certified Oregon Pharmacy Technician

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

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

(a) Pay the biennial license fee required in OAR 855-110~~.~~**;**

(b) Complet**e**~~ion of~~ **the** continuing pharmacy education requirements as directed in OAR 855-021; **and**

(c) Be subject to an annual criminal background check.

(3) Continued national certification is not required to renew a license as a Certified Oregon Pharmacy Technician.

(4) A Certified Oregon Pharmacy Technician who fails to renew ~~his or her~~ **their** license by the expiration date and whose license has been lapsed for ~~less than~~ one year **or less** may renew ~~his or her~~ **their** license **and must pay a late fee required in OAR 855-110.** ~~as follows:~~

~~(a) Complete the renewal process;~~

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

~~(c) Pay a late fee; and~~

~~(d) Complete the required continuing pharmacy education pursuant to OAR 855-021.~~

(5) A Certified Oregon Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate their license as follows:

(a) Must apply per OAR 855-025-0010; and

(b) Provide certification of completion of 10 continuing education hours. These hours may not be counted toward renewal and must include:

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

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

(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(D) Seven other hours of pharmacy technician-specific continuing education.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225, ORS 689.486, **ORS 413.450**

~~855-025-0060~~
~~Reinstatement of a Certified Oregon Pharmacy Technician License~~

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

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

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

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

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

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

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

~~(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and~~

~~(D) Seven other hours of pharmacy technician-specific continuing education.~~

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

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

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

~~(B) National Healthcareer Association (NHA).~~

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

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.225, ORS 689.486~~

855-110-0003
General

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

(2) Fees cannot be prorated.

(3) Fees for initial licensure as a Pharmacist**, Pharmacy Technician** or Certified Oregon Pharmacy Technician ~~may~~ **will** be reduced to one-half of a biennial rate, if the application is received within 180 days of expiration.

(4) A late fee must be paid**:**

(a) When a renewal application is received after the date specified in these rules; or

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

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.135

855-110-0005
Licensing Fees

(1) Pharmacist license examination (NAPLEX) fee - $50.

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

(3) Pharmacist licensing by reciprocity fee - $100.

(4) Pharmacist licensing by score transfer fee - $50.

(5) Intern license fee. Expires November 30 every two years - $100.

(6) Pharmacist:

(a) Biennial license fee. Expires June 30 each odd numbered year. The biennial license fee is - $250. Late renewal fee (received after June 30) - $50.

(b) Electronic Prescription Monitoring Fund fee. Due by June 30 biennially - $70. (This is a mandatory fee, required by ORS 431A.880 that must be paid with the pharmacist license renewal fee).

(c) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Pharmacist license renewal fee.)

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

(8) Pharmacy Technician license fee ~~- $100.~~**:**

(a) Expires June 30 each even numbered year. The biennial license fee is - $100. Late renewal fee (received after June 30) - $20.

(b) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Pharmacy Technician license renewal fee.)

(9) Certified Oregon Pharmacy Technician:

(a) Biennial license fee. Expires June 30 each even numbered year - $100. Late renewal fee (received after June 30) - $20.

(b) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Certified Oregon Pharmacy Technician license renewal fee.)

Statutory/Other Authority: ORS 689.205, ORS 291.055, ORS 183.705
Statutes/Other Implemented: ORS 689.135, ORS 676.410, ORS 431A.880

855-021-0009

Continuing Pharmacy Education Required for Pharmacy Technician or Certified Oregon Pharmacy Technician License Renewal

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

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

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

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

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

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

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

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

(5) If a license renewal is submitted after June 30th of the license renewal cycle, continuing pharmacy education must be completed prior to submission of the license renewal.

(6) Section (1) does not apply to a Pharmacy Technician applying for the first renewal of their license prior to 7/1/2022.

POLICY DISCUSSION: Same CE requirement

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450 & ORS 676.850

Division 041/139: Operation of Pharmacies (Permanent Pharmacy Closures)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Creates requirements for pharmacies to complete for permanent closure.

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): During the COVID-19 pandemic, there has been an increase in permanent pharmacy closures. Registrants need clear direction on orderly disposition of pharmacy records and drugs when a pharmacy permanently closes. The proposed rule provides a list of items that must be completed prior to, on the date of and within 10 days of the permanent pharmacy closure.

Justification of Temporary Filing per ORS 183.403(2)(b)(C) (Statement of findings that prompt action needed to avoid serious prejudice with specific reasons, valid for 180 days):

If a pharmacy permanently closes, Oregonians need to be made aware of options for receiving their prescriptions. Failure to adopt this temporary rule will continue to result in patients and healthcare providers being unable to access medications prior to a permanent closure and locate prescription records after a pharmacy closure. Inability to access prescription medications and records in a timely manner is a danger to public health and safety.

Documents Relied Upon per ORS 183.335(2)(b)(D): None

Resources:

Other State Regulations: ME 392-13-9 Permanent Closing of a Pharmacy; TX 291.5 Closing a Pharmacy; WA 246-945-480 Facility Reporting Requirements

Oregon Medical Board: OAR 847-012-0000 Patient's Access to Medical Records; Philosophy: Ending the Patient-Physician Relationship; Topic: Ending Oregon Practice

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): The proposed rules require pharmacies to post accurate hours and to update operating hour information in the event of a closure. Accurate pharmacy operating hours must be available to patients and prescribers so they can seek alternate sources of prescription medication when a pharmacy is closed.

855-041-1090

Registration: Change of Business Name~~, or Closure~~ (Both Retail and Institutional Drug Outlets)

~~(1)~~ A A~~ny change of business name of a~~ pharmacy must ~~be reported to~~ **notify** the board ~~within~~ **a minimum of** 15 days **prior to any change of business name of a pharmacy. The change must be reported** by filing a new application for which no fee is required.

~~(2) Any closure of a pharmacy shall be reported to the Board within 15 days and include notification of the disposition of controlled substances, dangerous, legend, and restricted drugs.~~

Statutory/Other Authority: ORS 475.035 & **ORS** 689.205
Statutes/Other Implemented: ORS 689.205

855-041-1092

Pharmacy Closures

POLICY DISCUSSION: Temporary vs. permanent rule

(1) Temporary Closing. Unless subject to an exemption in OAR 855-041-1092(3), when a pharmacy is temporarily closed to the public the pharmacy must:

(a) Post notification of closure on each building entrance and each pharmacy entrance as soon as the need to deviate from the posted hours is known by the pharmacy, but no later than 2 hours after the temporary closure begins. The posting must include:

(A) Estimated period of time the pharmacy will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:

(A) Estimated period of time the pharmacy will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(c) If the pharmacy is temporarily closed greater than 2 consecutive business days, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure.

~~(2)~~ **(d)** Federal and state holidays are exempt from the requirements of (1).

~~(3) Emergency closing. If pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances and the pharmacist-in-charge cannot provide notification as required in (1), the pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.~~

(2) Permanent Closing. If a pharmacy is permanently closing to the public, the pharmacy must:

(a) Prior to closing, the pharmacy must comply with the following:

(A) Provide notification to patients with active prescriptions on file a minimum of 30 days prior to closing. The notification must include:

POLICY DISCUSSION: active prescriptions, # of days

(i) The last day the pharmacy will be open;

(ii) Name, address and telephone number of the pharmacy to which prescription records will be transferred or the Oregon licensed Pharmacist who will serve as the custodian of records;

(iii) Instructions on how patients can arrange for transfer of their prescription records to a pharmacy of their choice; and

(iv) The last day a transfer may be initiated.

(B) The notification must be made via:

(i) Distribution by direct mail;

(ii) Public notice in a newspaper of general circulation in the area served by the pharmacy; and

(iii) Posting a closing notice at each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).

(iv) In addition to (i), (ii) and (iii), the pharmacy may also provide notification via email or text.

POLICY DISCUSSION: Methods

(C) Provide any new patients filling prescriptions during the 30-day period prior to the pharmacy closing with written notification that includes:

(i) The last day the pharmacy will be open;

(ii) Name, address and telephone number of the pharmacy to which prescription records will be transferred or the Oregon licensed pharmacist who will serve as the custodian of records;

(iii) Instructions on how patients can arrange for transfer of their prescription records to a pharmacy of their choice; and

(iv) The last day a transfer may be initiated.

(D) Notify DEA of any controlled substances being transferred to another registrant as specified in 21 CFR 1301.52 (04/01/2021).

(b) On the date of closing or up to 24 hours after the permanent closure begins, the pharmacist-in-charge must comply with the following:

POLICY DISCUSSION: # hours

(A) Complete and document an inventory of all drugs and devices.

(B) If the pharmacy dispenses prescriptions:

(i) Transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy or to an Oregon licensed pharmacist who will serve as the custodian of records;

(ii) Update the pharmacy operating status with each electronic prescribing vendor; and

(iii) Remove all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g. website, social media, mobile applications).

(c) After closing. Within 10 days after the closing of the pharmacy, the pharmacist-in-charge must:

POLICY DISCUSSION: # of days

(A) Remove all prescription drugs from the pharmacy by one or a combination of the following methods:

(i) Return prescription drugs to manufacturer or supplier (for credit/disposal);

(ii) Transfer (sell or give away) prescription drugs to a licensed healthcare provider or outlet who is legally authorized to possess drugs (e.g. physician, drug outlet); or

(iii) Destroy and document the destruction of prescription drugs in the presence of two board licensed staff.

(B) Provide the board a written notice of the closing on a board prescribed form which includes the following information:

(i) Date of closing to the public and discontinuance of the business;

(ii) Date and time the inventory of all prescription drugs and devices was conducted;

(iii) Name, address, phone number and applicable registration number where all legend and controlled substances possessed by the pharmacy were transferred or disposed;

(iv) If drugs were destroyed, name and license numbers of individuals that witnessed the destruction;

(v) If the pharmacy is registered to possess controlled substances, confirmation that the pharmacy complied with all applicable federal requirements in 21 CFR 1301.52 (04/01/2021) for discontinuing operation as a pharmacy that dispenses controlled substances.

(vi) If the pharmacy dispenses prescriptions, the name, address and phone number of the pharmacy or Oregon licensed pharmacist who will serve as the custodian of records to which the prescriptions, including refill information, and patient medication records were transferred;

(vii) Confirmation all pharmacy labels and blank prescriptions were destroyed;

(viii) Confirmation all signs and symbols indicating the presence of the pharmacy including pharmacy-operated internet (e.g. website, social media, mobile applications) have been removed; and

(ix) Confirmation that each registration certificate issued to the pharmacy by the board has been mailed to the board office.

POLICY DISCUSSION: Elements

(C) Once the pharmacy has notified the board that the pharmacy is permanently closed, the license may not be renewed. The pharmacy may apply for a new license as specified in OAR 855-041-1080.

(3) Emergency closing. If pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances and the pharmacist-in-charge cannot provide notification as required in (1), the pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.

(4) Non-resident pharmacies are exempt from (1)-(3) and must follow laws and rules in the pharmacy's state of residence pertaining to temporary, permanent and emergency closures. The non-resident pharmacy must provide the board a written notice of the closing within 10 days on a form prescribed by the board which includes the following information:

(a) Date of closing to the public and discontinuance of the business;

(b) If the pharmacy dispenses prescriptions, the name, address and phone number of the pharmacy or Oregon licensed pharmacist who will serve as the custodian of records for Oregon patients to which the prescriptions, including refill information, and patient medication records were transferred; and

(c) Confirmation that each registration certificate issued to the pharmacy by the board has been mailed to the board office.

(5) The board may conduct an inspection to verify all requirements in subsection (1), (2), (3) and (4) of this section have been completed.

Statutory/Other Authority: ORS 475.035 & ORS 689.205
Statutes/Other Implemented: ORS 689.205

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0025
Registration: Change of Business Name ~~or Closure~~

~~(1)~~ A RDSP Affiliated Pharmacy must notify the board **a minimum of** 15 days prior to any change of business name of a Retail Drug Outlet RDSP. The change must be reported by filing a new application for which no fee is required.

~~(2) A RDSP Affiliated Pharmacy must notify the board 15 days prior to discontinuing operation of a Retail Drug Outlet RDSP. Notification must include the:~~

~~(a) Final disposition of drugs stored in the Retail Drug Outlet RDSP including:~~

~~(A) Name and location where the drugs are transferred;~~

~~(B) Name and location where destruction occurred; and~~

~~(C) Name and location of the site that will store all records;~~

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

~~(d) Provide the board with:~~

~~(A) Oregon Board of Pharmacy state license(s); and~~

~~(B) Signed statement giving the effective date of closure; and~~

~~(e) Comply with the requirements of 21 CFR 1301.52 (04/01/2021).~~

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

855-139-0145
Outlet: Closure- Temporary, Permanent and Emergency
NOTE: Language matches rule package concerning Temporary Pharmacy Closures for (1).

(1) Temporary Closing. Unless subject to an exemption in OAR 855-041-1092(3), when a RDSP is temporarily closed to the public the RDSP must:

(a) Post notification of closure on each building entrance and each RDSP entrance as soon as the need to deviate from the posted hours is known by the RDSP, but no later than 2 hours after the temporary closure begins. The posting must include:

(A) Estimated period of time the RDSP will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:

(A) Estimated period of time the RDSP will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(c) If the RDSP is temporarily closed greater than 2 consecutive business days, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure.

(d) Federal and state holidays are exempt from the requirements of (1).

(2) Permanent Closing. If a RDSP is permanently closing to the public, the RDSP must:

(a) Prior to closing, the RDSP must comply with the following:

(A) Provide notification to patients with active prescriptions on file a minimum of 30 days prior to closing. The notification must include:

(i) The last day the RDSP will be open;

(ii) Name, address and telephone number of the pharmacy to which prescription records will be transferred or the Oregon licensed Pharmacist who will serve as the custodian of records;

(iii) Instructions on how patients can arrange for transfer of their prescription records to a pharmacy of their choice; and

(iv) The last day a transfer may be initiated.

(B) The notification must be made via:

(i) Distribution by direct mail;

(ii) Public notice in a newspaper of general circulation in the area served by the RDSP; and

(iii) Posting a closing notice at each RDSP entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).

(iv) In addition to (i), (ii) and (iii), the RDSP may also provide notification via email or text.

(C) Provide any new patients filling prescriptions during the 30-day period prior to the RDSP closing with written notification that includes:

(i) The last day the RDSP will be open;

(ii) Name, address and telephone number of the pharmacy to which prescription records will be transferred or the Oregon licensed pharmacist who will serve as the custodian of records;

(iii) Instructions on how patients can arrange for transfer of their prescription records to a pharmacy of their choice; and

(iv) The last day a transfer may be initiated.

(D) Notify DEA of any controlled substances being transferred to another registrant as specified in 21 CFR 1301.52 (04/01/2021).

(b) On the date of closing or up to 24 hours after the permanent closure begins, the pharmacist-in-charge must comply with the following:

(A) Complete and document an inventory of all drugs and devices.

(B) If the RDSP dispenses prescriptions:

(i) Transfer the prescription drug order files, including refill information, and patient medication records to a licensed pharmacy or to an Oregon licensed pharmacist who will serve as the custodian of records;

(ii) Update the RDSP operating status with each electronic prescribing vendor; and

(iii) Remove all signs and symbols indicating the presence of the RDSP including pharmacy-operated internet (e.g. website, social media, mobile applications).

(c) After closing. Within 10 days after the closing of the RDSP, the pharmacist-in-charge must:

(A) Remove all prescription drugs from the RDSP by one or a combination of the following methods:

(i) Return prescription drugs to manufacturer or supplier (for credit/disposal);

(ii) Transfer (sell or give away) prescription drugs to a licensed healthcare provider or outlet who is legally authorized to possess drugs (e.g. physician, drug outlet); or

(iii) Destroy and document the destruction of prescription drugs in the presence of two board licensed staff.

(B) Provide the board a written notice of the closing on a board prescribed form which includes the following information:

(i) Date of closing to the public and discontinuance of the business;

(ii) Date and time the inventory of all prescription drugs and devices was conducted;

(iii) Name, address, phone number and applicable registration number where all legend and controlled substances possessed by the RDSP were transferred or disposed;

(iv) If drugs were destroyed, name and license numbers of individuals that witnessed the destruction;

(v) If the RDSP is registered to possess controlled substances, confirmation that the RDSP complied with all applicable federal requirements in 21 CFR 1301.52 (04/01/2021) for discontinuing operation as a RDSP that dispenses controlled substances.

(vi) If the RDSP dispenses prescriptions, the name, address and phone number of the RDSP or Oregon licensed pharmacist who will serve as the custodian of records to which the prescriptions, including refill information, and patient medication records were transferred;

(vii) Confirmation all RDSP labels and blank prescriptions were destroyed;

(viii) Confirmation all signs and symbols indicating the presence of the RDSP including pharmacy-operated internet (e.g. website, social media, mobile applications) have been removed; and

(ix) Confirmation that each registration certificate issued to the RDSP by the board has been mailed to the board office.

(C) Once the RDSP has notified the board that the RDSP is permanently closed, the license may not be renewed. The RDSP may apply for a new license as specified in OAR 855-041-1080.

(3) Emergency closing. If RDSP is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances and the pharmacist-in-charge cannot provide notification as required in (1), the pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.

(4) The board may conduct an inspection to verify all requirements in subsection (1), (2), and (3) of this section have been completed.

Statutory/Other Authority: ORS 475.035, ORS 689.205 & 2021 SB 629
Statutes/Other Implemented: ORS 689.155& 2021 SB 629

Division 020: Pharmacist Prescriptive Authority (COVID-19 Antigen Self-Test Protocol)

Filing Caption per ORS 183.335(2)(a)(A) (max 15 words): Compendia amended to include COVID-19 Antigen Self-Test

Need for Rules per ORS 183.335(2)(b)(C) (Describes what we are changing in rule): Permanently adopts the COVID-19 antigen self-test protocol for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 of COVID-19.

Documents Relied Upon per ORS 183.335(2)(b)(D):

- ORS 689.645 and 689.649 state that a pharmacist may provide approved patient care services pursuant to a statewide drug therapy management protocol, and adopted by rule of the Board. A statewide protocol consists of a standardized patient assessment process and treatment care plan under which a pharmacist may assess and identify the need for a patient care service, then prescribe and dispense a drug or device to the patient.

- EUA: Instructions for COVID-19 Antigen Self-Test (Home Test)

- OHA Fax to Pharmacies: Fee-for-service coverage of COVID-19 home testing policy update.

- Testing and Medicaid Coverage of Habilitation Services State Health Official letter- Medicaid and CHIP Coverage and Reimbursement of COVID-19 Testing under the American Rescue Plan Act of 2021 and Medicaid Coverage of Habilitation Services

- Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 43 (pg. 6)- FAQs

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The proposed rule may have the fiscal and economic impact of assisting with early confirmation of COVID-19 infection and thus decrease of transmission due to quarantine and treatment options.

Cost of Compliance - (OBOP/Other State Agencies/Units of Local Government/Public or Stakeholders, Effect on Small Businesses):

OBOP: The rulemaking imposes minimal additional requirements regarding professional services and increased administration for maintenance of the protocol and convening the Public Health and Pharmacy Formulary Committee as needed to make updates to the protocol.

Other State Agencies/Units of Local Government/Public or Stakeholders: The rule may have a positive impact on the work of the Oregon Health Authority Public Health Division and County Health Departments along with providing members of the public to access COVID-19 test kits more easily.

Effect on Small Businesses – number & type subject to the rule, expected reporting, recordkeeping, administrative activities cost in order to comply, cost of professional services, equipment supplies, labor, increased administration required for compliance with the rule: None anticipated. The rulemaking imposes no additional mandatory reporting, recordkeeping, or other administrative requirements on small businesses.

Describe how small businesses were involved in the development of the rules: Small businesses were not involved in the development of proposed amendments to these rules.

Was a RAC consulted? If no, why? Per ORS 183.335(2)(b)(G): No, a RAC was not consulted. The Public Health and Pharmacy Formulary Advisory Committee adopted a new protocol and recommended amending the proposed rule to align with the protocol.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Inequity in access to free COVID-19 antigen self-tests is yet another example of the consistent theme of inequities over the course of the COVID-19 pandemic. Compared to their White counterparts, people of color have faced increased risk of exposure to the virus, suffered more illness and death, and faced more barriers to accessing protective equipment, testing, care, and treatment, as well as vaccines. According to the 2019 Oregon Health Insurance Survey (OHIS), 94% of Oregon residents had health insurance coverage (95.2% Asian, 93.3% White, 92.2% Black, 87.7% Two or more/Other, 83.4% Hispanic). By making these self-test kits easily accessible to patients at their local pharmacy and then billed to their health plan for no charge, it may possibly improve access for patients who may not be able to otherwise access or afford the kits.

Rules Summary per ORS 183.335(2)(a)(B) (Indicates the change to the rule and why): Permanently adopts a COVID-19 antigen self-test protocol and amends the current protocol compendia. Increases equitable access to COVID-19 antigen self-tests and reduces barriers to obtaining COVID-19 antigen self-tests.

Division 20
PHARMACIST PRESCRIPTIVE AUTHORITY

855-020-0300
Protocol Compendium

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

(1) Continuation of therapy (v. 06/2021)

(2) Conditions

(a) Cough and cold symptom management

(A) Pseudoephedrine (v. 06/2021);

(B) Benzonatate (v. 06/2021);

(C) Short-acting beta agonists (v. 06/2021);

(D) Intranasal corticosteroids (v. 06/2021);

(b) Vulvovaginal candidiasis (VVC) Protocol (v. 06/2021);

(c) COVID-19 Monoclonal Antibody (mAb) Protocol (v.12/2021)**;** and

(d) COVID-19 Antigen Self-Test Protocol (v. 12/2021).

(3) Preventative care

(a) Emergency Contraception (v. 06/2021);

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

(c) Tobacco Cessation, NRT (Nicotine Replacement Therapy) and Non-NRT Protocol (v. 06/2021);

(d) Travel Medications Protocol (v. 06/2021);

(e) HIV Post-exposure Prophylaxis (PEP) Protocol (v. 12/2021); and

(f) HIV Pre-exposure Prophylaxis (PrEP) Protocol (v. 12/2021).

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

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

DETECTION OF SARS-CoV-2 ANTIGEN: OTC COVID-19 ANTIGEN SELF-TEST

STATEWIDE PATIENT CARE SERVICE PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

➢ Following all elements outlined in OAR 855-020-0110, a pharmacist licensed and located in Oregon may prescribe OTC COVID-19 Antigen Self-Tests.

PRESCRIBING PARAMETERS:

- Product: OTC COVID-19 Antigen Self-Tests listed on either of the following sites:
  - FDA *In Vitro Diagnostics EUAs* - Antigen Diagnostic Tests for SARS-CoV-2 webpage
    - Must have "OTC" designation
  - FDA *Approved OTC Devices* database
- Indication: Must be consistent with the Emergency Use Authorization or FDA approval for the specific product prescribed (e.g. age, symptom onset)

Division 021/025/110: Pharmacy Technicians and Certified Oregon Pharmacy Technician Licensure (PT Renewal)

Filing Caption per ORS 183.335(2)(a)(A) (max 15 words): Amends Pharmacy Technician and Certified Oregon Pharmacy Technician Licensure Rules

Need for Rules per ORS 183.335(2)(b)(C) (Describes what we are changing in rule): Clarifies licensure qualifications, elements of a complete application and renewal/reinstatement requirements for Pharmacy Technicians (PT) and Certified Oregon Pharmacy Technicians (COPT); Revises PT license fees; Allows PT to renew or reinstate their license; Adds CE requirements for PT.

Documents Relied Upon per ORS 183.335(2)(b)(D):

- Pharmacy Technician Certification Board- CPhT certification renewal
- National Healthcareer Association- CPhT certification renewal

Fiscal & Economic Impact per ORS 183.335(2)(b)(E):

Cost of Compliance - (OBOP/Other State Agencies/Units of Local Government/Public or Stakeholders, Effect on Small Businesses):

- OBOP: Collecting the Workforce Data Collection Fee may result in an additional +$3,040 increase in agency revenue. Collecting the National Fingerprint-based Background Check may result in an agency revenue reduction of -$35,228 for a net impact of -$32,188. Both fees are "pass through" fees that are sent to the Oregon Health Authority and Oregon State Police respectively for actual costs.

- **Other State Agencies/Units of Local Government:** None anticipated

- Public or Stakeholders: In Oregon, it is estimated that 1,528 PTs will be impacted by the new continuing pharmacy education (CPE) requirements. CPE is currently available at no cost through various vendors. The exact number of PTs who will opt to renew is unknown. Using 1/2 of current active PT licensees (~760) as an estimate:

- PTs opt to renew their PT license will not be required to apply for and qualify for a COPT license. The Pharmacy Technician Certification Board (PTCB) exam is $129 and the National Healthcareer Association (NHA) is $117.

- PTs who opt to renew their PT license will be subject to the biennial $4 Workforce Data Collection Fee.

- PTs who opt to renew their license will not be subject to an additional National Fingerprint-based Background Check $46.25 in order to apply for a COPT license.

Opting to renew their PT license may result in a $4 Workforce Data Collection Fee, a reduction of -$117 to -$129 for exam fees, and a reduction of $46.25 in National Fingerprint-based Background Check fees for a net impact of -$159.25 to -$171.25 to the licensee.

Describe how small businesses were involved in the development of the rules: Small businesses were not involved in the development of proposed amendments to these rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not consulted. Agency licensing staff proposed amending the rules based on multiple licensee inquiries and complaints related to current technician license renewal or reinstatement restrictions.

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): The proposed rule may reduce barriers to licensure which would positively impact patients, technician applicants, in both urban and rural communities. Pharmacies are currently facing staffing issues due to the ongoing public health emergency and pharmacy technicians have been negatively impacted by existing rules that do not allow for license renewal or reinstatement. This rule may help alleviate staffing issues by increasing employment opportunities for technicians and provide appropriate staffing levels to prevent temporary or permanent pharmacy closures, which would increase patient access for all Oregonians.

Rules Summary per ORS 183.335(2)(a)(B) (Indicates the change to the rule and why): The proposed rule amendments are to assist in alleviating the shortage of licensed personnel remove barriers to licensure of PTs and COPTs by clarifying licensure qualifications, the elements of a complete application and the requirements for renewal/reinstatement. The rules also allow a PT to renew or reinstate their license. As a result, the PT licensee must pay the workforce data collection fee and complete biennial CPE requirements.

855-025-0005

Licensure: Qualifications- ~~for Licensure~~ as a Pharmacy Technician or Certified Oregon Pharmacy Technician

(1) To qualify for licensure as a Pharmacy Technician or Certified Oregon Pharmacy Technician, an applicant must demonstrate that the applicant is at least 18 years of age and has ~~obtained~~ **completed** ~~a~~ high school **(or equivalent)** ~~diploma or GED~~.

(2) ~~Section one does not apply to persons under the age of 18 licensed by the Board as a Pharmacy Technician prior to January 1, 2015.~~ **To qualify for licensure as a Certified Oregon Pharmacy Technician, the applicant must also demonstrate that the applicant has taken and passed a national pharmacy technician certification examination offered by:**

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

(b) National Healthcareer Association (NHA).

~~(3) An applicant for licensure as a Pharmacy Technician or Certified Oregon Pharmacy Technician must complete an application for licensure, provide the Board with a valid e-mail address and furnish documentation required to conduct a criminal background check.~~

(4**3**) No person whose license has been denied, revoked, suspended or restricted by any healthcare professional regulatory Board may be licensed as a Pharmacy Technician or Certified Oregon Pharmacy Technician unless the Board determines that licensure will pose no danger to patients or to the public interest.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & **ORS** 689.486

855-025-0010

Licensure: Application- ~~as a~~ Pharmacy Technician

(1)~~The license of a Pharmacy Technician expires the second June 30 from the date of issue and is not to exceed two years, except that due to the COVID-19 declared public health emergency, Pharmacy Technician (PT) licenses set to expire June 30, 2020, will instead expire on 12/31/2020~~ **An application for licensure as a Pharmacy Technician may be accessed on the board website**.

(2) Failure to completely, accurately and honestly answer all questions on the application for licensure or renewal of licensure is grounds for discipline;

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

(~~2~~4) ~~The Pharmacy Technician license is not renewable.~~ **The board may issue a license to a qualified Pharmacy Technician after the receipt of:**

(a) A completed application;

(b) Payment of the fee prescribed in OAR 855-110;

(c) A current, passport regulation size photograph (full front, head to shoulders);

(d) Personal identification or proof of identity; and

(e) A completed national fingerprint-based background check.

(~~3~~5) ~~A time limited extension of a Pharmacy Technician license may be granted once by petition to the Board. The written completed petition must be received by the Board prior to the expiration of the PT license~~ **The license of a Pharmacy Technician expires June 30 in even numbered years and may be renewed biennially.**

~~(4) An individual may reapply for a Pharmacy Technician license if the previous PT license is lapsed for a period greater than five years.~~

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & ORS 689.486

855-025-0011

Licensure: Renewal or Reinstatement- Pharmacy Technician

(1) An applicant for renewal of a Pharmacy Technician license must:

(a) Pay the biennial license fee required in OAR 855-110.

(b) Complete the continuing pharmacy education requirements as directed in OAR 855-021;

(c) Be subject to an annual criminal background check.

(2) A Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for one year or less may apply to renew their license and must pay a late fee required in OAR 855-110.

(3) A Pharmacy Technician or who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate their license as follows:

(a) Must apply per OAR 855-025-0010; and

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

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

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

(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(D) Seven other hours of pharmacy technician-specific continuing education.

POLICY DISCUSSION: Retain CE requirement, CCCE

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225, ORS 689.486, ORS 413.450

855-025-0012
Licensure: Application- ~~as a~~ Certified Oregon Pharmacy Technician

(1) ~~To qualify for licensure as a Certified Oregon Pharmacy Technician, the applicant must demonstrate that he or she has taken and passed a national pharmacy technician certification examination offered by:~~ **An application for licensure as a Pharmacy Technician may be accessed on the board website**.

(~~a~~**2**) ~~The Pharmacy Technician Certification Board (PTCB); or~~ **Failure to completely, accurately and honestly answer all questions on the application for licensure or renewal of licensure is grounds for discipline.**

(~~b~~**3**) ~~The National Healthcareer Association (NHA).~~ **Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony may result in denial of the application.**

(~~2~~**4**) ~~The license of a Certified Oregon Pharmacy Technician expires June 30 in even numbered years and must be renewed biennially.~~ **The board may issue a license to a qualified Certified Oregon Pharmacy Technician after the receipt of:**

(a) A completed application;

(b) Payment of the fee prescribed in OAR 855-110;

(c) A current, passport regulation size photograph (full front, head to shoulders);

(d) Personal identification or proof of identity;

(e) A completed national fingerprint-based background check; and

(f) Proof that the applicant has taken and passed a national pharmacy technician certification offered by the PTCB or the NHA.

(5) The license of a Certified Oregon Pharmacy Technician expires June 30 in even numbered years and may be renewed biennially.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225 & **ORS** 689.486

855-025-0015
~~Renewal of~~ Licensure: Renewal or Reinstatement- ~~as a~~ Certified Oregon Pharmacy Technician

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

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

(a) Pay the biennial license fee required in OAR 855-110~~.~~**;**

(b) Complet**e**~~ion of~~ **the** continuing pharmacy education requirements as directed in OAR 855-021; **and**

(c) Be subject to an annual criminal background check.

(3) Continued national certification is not required to renew a license as a Certified Oregon Pharmacy Technician.

(4) A Certified Oregon Pharmacy Technician who fails to renew ~~his or her~~ **their** license by the expiration date and whose license has been lapsed for ~~less than~~ one year **or less** may renew ~~his or her~~ **their** license **and must pay a late fee required in OAR 855-110.** ~~as follows:~~

~~(a) Complete the renewal process;~~

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

~~(c) Pay a late fee; and~~

~~(d) Complete the required continuing pharmacy education pursuant to OAR 855-021.~~

(5) A Certified Oregon Pharmacy Technician who fails to renew their license by the expiration date and whose license has been lapsed for greater than one year may apply to reinstate their license as follows:

(a) Must apply per OAR 855-025-0010; and

(b) Provide certification of completion of 10 continuing education hours. These hours may not be counted toward renewal and must include:

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

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

(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and

(D) Seven other hours of pharmacy technician-specific continuing education.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225, ORS 689.486, **ORS 413.450**

~~855-025-0060~~
~~Reinstatement of a Certified Oregon Pharmacy Technician License~~

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

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

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

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

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

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

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

~~(C) One hour of continuing pharmacy education in cultural competency either approved by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and~~

~~(D) Seven other hours of pharmacy technician-specific continuing education.~~

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

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

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

~~(B) National Healthcareer Association (NHA).~~

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.225, ORS 689.486

855-110-0003
General

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

(2) Fees cannot be prorated.

(3) Fees for initial licensure as a Pharmacist**, Pharmacy Technician** or Certified Oregon Pharmacy Technician ~~may~~ **will** be reduced to one-half of a biennial rate, if the application is received within 180 days of expiration.

(4) A late fee must be paid**:**

(a) When a renewal application is received after the date specified in these rules; or

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

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.135

855-110-0005
Licensing Fees

(1) Pharmacist license examination (NAPLEX) fee - $50.

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

(3) Pharmacist licensing by reciprocity fee - $100.

(4) Pharmacist licensing by score transfer fee - $50.

(5) Intern license fee. Expires November 30 every two years - $100.

(6) Pharmacist:

(a) Biennial license fee. Expires June 30 each odd numbered year. The biennial license fee is - $250. Late renewal fee (received after June 30) - $50.

(b) Electronic Prescription Monitoring Fund fee. Due by June 30 biennially - $70. (This is a mandatory fee, required by ORS 431A.880 that must be paid with the pharmacist license renewal fee).

(c) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Pharmacist license renewal fee.)

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

(8) Pharmacy Technician license fee~~ - $100.~~**:**

(a) Expires June 30 each even numbered year. The biennial license fee is - $100. Late renewal fee (received after June 30) - $20.

(b) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Pharmacy Technician o renewal fee.)

(9) Certified Oregon Pharmacy Technician:

(a) Biennial license fee. Expires June 30 each even numbered year - $100. Late renewal fee (received after June 30) - $20.
(b) Workforce Data Collection fee. Due by June 30 biennially - $4. (This is a mandatory fee as required by OAR 409-026-0130 that must be paid with the Certified Oregon Pharmacy Technician license renewal fee.)

Statutory/Other Authority: ORS 689.205, ORS 291.055, ORS 183.705
Statutes/Other Implemented: ORS 689.135, ORS 676.410, ORS 431A.880

855-021-0009
Continuing Pharmacy Education Required for Pharmacy Technician or Certified Oregon Pharmacy Technician License Renewal

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

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

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

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

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

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

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

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

(5) If a license renewal is submitted after June 30th of the license renewal cycle, continuing pharmacy education must be completed prior to submission of the license renewal.

(6) Section (1) does not apply to a Pharmacy Technician applying for the first renewal of their license prior to 7/1/2021.

POLICY DISCUSSION: Same CE requirement

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450 & ORS 676.850

Division 041/139: Operation of Pharmacies/RDSP (Accurate Pharmacy Hours and Temporary & Emergency Pharmacy Closures)

Filing Caption per ORS 183.335(2)(a)(A) (max 15 words): Requires pharmacies to post accurate hours of operation and to update due to closure.

Need for Rules per ORS 183.335(2)(b)(C) (Describes what we are changing in rule): Moves temporary rule for accurate pharmacy hours from pharmacy operations to minimum equipment rules; Permanently adopts temporary rule language concerning temporary & emergency pharmacy closures; Adds requirements for accurate hours and temporary & emergency pharmacy closures to Remote Dispensing Site Pharmacy rules.

Documents Relied Upon per ORS 183.335(2)(b)(D):

Other State Regulations:

ME 392-13-2 Hours of Operation; Posting of Hours

Surescripts: Emergency Response Action Plans

NCPDP: Emergency Preparedness Guidance (v. 1.9)

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): On 1/4/2022 the agency sent out a fiscal impact request to 1,261 interested party email addresses, and 17,645 licensee/registrant email addresses. We asked for an estimate of costs associated with compliance, implementation and operation related to both temporary and permanent closure for items such as: displaying accurate hours, updating telephone greeting or website, etc. We received 2 responses; one registrant estimated costs for some items to be **$0** or no additional cost while another licensee estimated each of the costs ranging from **$800 to $1million** but didn't provide an explanation on how costs were calculated. A detailed breakdown is shown below:

• **Estimate of fiscal impact associated with compliance implementation & operation related to:**

• Displaying accurate hours of operation at each building and pharmacy entrance = **$0** "Internal process, supported locally. A change can be made and uploaded within minutes, provided the owners of this work are available." = **$800** no explanation provided.

• Indicating accurate hours of operation on each pharmacy telephone greeting = **$0** no additional cost, and = **$3500** "time and paying someone to re-record voicemail due to changing seasonal hours etc."

• Indicating accurate hours of operation on pharmacy-operated internet (e.g. website, social media, mobile applications) = **$0** "No additional cost, this is internal and supported at the national level (weekdays/regular business hours). A change can be made within 1-2 days of request." = **$100,000** "develop and maintain website, social media, mobile app that would otherwise be unnecessary for pharmacy operations"

• **Fiscal impact associated with notifying patients with of a temporary pharmacy closure by:**

• Displaying accurate hours of operation at each building and pharmacy entrance that provides:

• The estimated period of time the pharmacy will be closed = **$2800** no explanation provided.

• Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions). = **$9500** "waiting on hold with pharmacies that may also be closed, waiting on hold with prescribers' offices, having to hire pharmacists to come onsite so prescriptions can be reversed etc."

• Updating each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) with:

• The estimated period of time the pharmacy will be closed = **$7500** no explanation provided.

• Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions). = **$0** "No additional cost, IVR phone broadcast messaging (telephone greeting) can be made and uploaded within minutes, provided the owners of this work are available, informing phone-in members of closure(s) as well as other pharmacy options." = **$0** "No additional cost, Website/Social Media/Apps is internal and supported at the national level (weekdays/regular business hours). A message can be added within 1-2 days of request. Depending on the type of message to be conveyed via this means, what is included may be limited by space available." = **$12,500** no explanation provided.

• Indicate if additional fees would be incurred if the above must be completed within 2, 4, 8, 12 or 24 hours = **N/A** and = **2-24 hours: $155,000** "hiring pharmacist to be on call all year to make sure employees can access pharmacy at will based on closure".

Cost of Compliance (including small businesses): May have a fiscal impact for all Oregon pharmacies. Because all Oregon pharmacies are required to comply with these rules, small businesses are impacted including independently owned pharmacies; however, no fiscal impact was received from these outlets or licensees upon request.

- Number/Type: 113 independently owned pharmacies.

- Reporting, Recordkeeping and Administrative Activities Cost:

- Professional Services, Equipment/ Supplies, Labor Cost:

Was a RAC convened? If no, why? per ORS 183.335(2)(b)(G): No. Rules straightforward and necessary to provide the public with accurate information of pharmacy hours of operation to allow access to medication.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule will positively impact people in both urban and rural areas of Oregon by mitigating multiple issues identified by complaints received by the agency. All communities regardless of race have been negatively impacted statewide due to issues such as pharmacies closing without notification or not having an alternate process in place for patients to access medication from another source. The proposed rule will allow patients from all communities to be informed in a timely manner and make alternative arrangements to access medication if the pharmacy they utilize closes temporarily.

Rules Summary per ORS 183.335(2)(a)(B) (Indicates the change to the rule and why): During the COVID-19 pandemic, pharmacies are experiencing an increase in temporary closures due to extenuating circumstances (e.g. illness, staffing shortages). Accurate pharmacy hours of operation must be available to patients and providers to ensure timely access to prescription medication.

855-041-1015

Operation of Pharmacy (Both Retail and Institutional Drug Outlets)

(1) Supervision. A pharmacy may only be operated when a pharmacist licensed to practice in this state is present. This means that the pharmacist must be physically present in the pharmacy or institutional facility.

(2) Sanitation:

(a) Pharmacies shall be kept clean.

(b) Persons working in a pharmacy shall practice appropriate infection control.

~~(3) A Pharmacy must conspicuously display accurate hours of operation at each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (e.g. website, social media, mobile applications).~~

Statutory/Other Authority: ORS 689.305
Statutes/Other Implemented: ORS 689.305

855-041-1035

Minimum Equipment Requirements

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

(a) Appropriate and current pharmaceutical references (e.g. pharmacology, injectables, and veterinary drugs) based on services offered by the outlet;

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, 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;

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

(d) 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;

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

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

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

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

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

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

(E) Providing notification of accurate hours of operation at each building entrance and each pharmacy entrance; and

(h) Accurate hours of operation on each telephone greeting and pharmacy-operated internet (e.g. website, social media, mobile applications).

(~~h~~i) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge.

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

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

855-041-1092
Pharmacy Closures: Temporary or Emergency

NOTE: This is the exact language in the current temporary rule.

(1) Temporary Closing. Unless subject to an exemption in OAR 855-041-1092(3), when a pharmacy is temporarily closed to the public the pharmacy must:

(a) Post notification of closure on each building entrance and each pharmacy entrance as soon as the need to deviate from the posted hours is known by the pharmacy, but no later than 2 hours after the temporary closure begins. The posting must include:

(A) Estimated period of time the pharmacy will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:

(A) Estimated period of time the pharmacy will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(c) If the pharmacy is temporarily closed greater than 2 consecutive business days, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure.

(2) Federal and state holidays are exempt from the requirements of (1).

(3) Emergency closing. If pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances and the pharmacist-in-charge cannot provide notification as required in (1), the pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.

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

855-139-0145
Outlet: Closure- Temporary or Emergency

(1) Temporary Closing. Unless subject to an exemption in OAR 855-041-1092(3), when a RDSP is temporarily closed to the public the RDSP must:

(a) Post notification of closure on each building entrance and each RDSP entrance as soon as the need to deviate from the posted hours is known by the RDSP, but no later than 2 hours after the temporary closure begins. The posting must include:

(A) Estimated period of time the RDSP will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(b) Post notification of closure on each telephone greeting and pharmacy operated internet (e.g. website, social media, mobile applications) as soon as possible. The posting must include:

(A) Estimated period of time the RDSP will be closed; and

(B) Options for prescription pick-up (e.g. another local pharmacy, contact prescriber for new prescription, reverse processed prescriptions).

(c) If the RDSP is temporarily closed greater than 2 consecutive business days, notify the board office as soon as possible but no later than 72 hours after the temporary closure begins with the date and time the closure began, anticipated date and time of re-opening, and the reason for the temporary closure.

(2) Federal and state holidays are exempt from the requirements of (1).

(3) Emergency closing. If RDSP is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances and the pharmacist-in-charge cannot provide notification as required in (1), the pharmacist-in-charge must comply with the provisions of (1) as far in advance or as soon after the closing as allowed by the circumstances.

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

855-139-0155
Outlet: Minimum Equipment Requirements

(1) Each Oregon Retail Drug Outlet RDSP must have the following:

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

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, 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;

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

(d) 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;

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

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

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

(B) Providing notification in each of the languages required in OAR 855-139-0410 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Providing written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy if naloxone services are provided by the pharmacy per OAR 855-139-0720; ~~and~~

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

(E) Providing notification of accurate hours of operation at each building entrance and each pharmacy entrance; and

(h) Accurate hours of operation on each telephone greeting and pharmacy-operated internet (e.g. website, social media, mobile applications).

(~~h~~i) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge.

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

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

Division 006/143–Pharmacy Prescription Lockers

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Establishes new registration for Pharmacy Prescription Lockers (PPLs)

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Proposes rules that establish a new registration type for Pharmacy Prescription Lockers (PPL). Adds new Division 143 which contains requirements for the operation of a PPL by a PPL Affiliated Pharmacy.

Documents Relied Upon per ORS 183.335(2)(b)(D): None

Resources: Prescription lockers are the patient facing pick-up units that hold prescription, non-prescription drugs, devices and supplies already prepared by the pharmacy - Parata Wellspot Locker - Scriptcenter LS - iLocalbox

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): The agency sent out a fiscal impact request for estimated costs associated with compliance, implementation and operation of a PPL.

Cost of Compliance - (Stakeholders): On 1/24/2022 a fiscal impact request was sent to 1,419 interested party email addresses and 1,444 PIC email addresses. The agency received 1 response with the following estimates:

- Locker purchase: $40,000- $80,000
- Locker lease: $500-1,000 per month
- Surveillance systems: $10,000 initially, then $100-500 per month for data storage

Pharmacies are not required to operate a Pharmacy Prescription Locker (PPL). If a pharmacy chooses to operate a PPL, the PPL Affiliated Pharmacy will be required to apply and pay a registration fee of $225 for the PPL and be required to comply with all Oregon Administrative Rules and Oregon Revised Statutes. We do anticipate that licensed drug outlets may be financially impacted in order to comply with the proposed rules.

Pharmacies that choose to deploy lockers will generate revenue from prescription and over-the-counter drug sales to help offset the cost of compliance with these proposed rules.

OBOP/Other State Agencies/Units of Local Government/Public: Fiscal impact is estimated to be minimal for the agency and limited to administrative and compliance costs. There is no anticipated fiscal impact to other state agencies, units of local government or the public.

Cost of Compliance (including small businesses): There are approximately 113 small business drug outlet pharmacies registered with the board. It is not anticipated that the cost of compliance for small business would be different from that of a non-small business.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of the proposed rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): A RAC was not consulted for the development of these rules. The board held a technology forum during the August 2020 board meeting where vendors presented information and resources for the board's consideration prior to drafting proposed rules.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Large, urban, predominantly white communities usually have multiple pharmacies to choose from, but in smaller, rural, and lower socioeconomic areas, even within cities, it can be much more difficult to find an open pharmacy. The proposed rules may positively impact Oregonian's access to pick up prescriptions without having to physically visit an open pharmacy. No contact delivery/pick-up has become necessary for many health-related services due to the ongoing public health emergency.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL.

Division 6
DEFINITIONS

855-006-0005
Definitions

(x) "Alarm system" means a device or series of devices, which emit or transmit an audible or remote visual or electronic alarm signal, which is intended to summon a response.

(x) "Audiovisual communication system" means a continuously accessible, two-way audiovisual link that allows audiovisual communication in real-time and that prevents unauthorized disclosure of protected health information.

(x) "Entry system" enables control of access to a secured area.

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

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

(x) "Surveillance system" means a system of video cameras, monitors, recorders, and other equipment used for surveillance.

NOTE: Board will motion all changes to Div 006 Definitions in one motion at end of policy discussions.

Division 143
PHARMACY PRESCRIPTION LOCKER

855-143-0001
Purpose and Scope

The purpose of OAR 855-143 is to provide minimum requirements for the operation of a Pharmacy Prescription Locker (PPL) by a PPL Affiliated Pharmacy.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-143-0005
Definitions

The following words and terms, when used in OAR 855-143, have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section has the definition set out in OAR 855-006.

(1) "Pharmacy Prescription Locker Affiliated Pharmacy" or "PPL Affiliated Pharmacy" means a Retail Drug Outlet Pharmacy registered in Oregon that operates a Pharmacy Prescription Locker.

(2) "Pharmacy Prescription Locker" or "PPL" means an Oregon location registered as a Retail Drug Outlet Pharmacy Prescription Locker using a mechanical system that securely stores completed patient-specific prescription and non-prescription drugs, devices, and related supplies for pick up.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-143-0010
Registration: General

(1) Each PPL located in Oregon must be registered as a Retail Drug Outlet PPL.

(2) A controlled substance registration will not be issued for a Retail Drug Outlet PPL.

POLICY DISCUSSION: Controlled substances / DEA Policy & Liaison

(3) A Retail Drug Outlet PPL application must specify the PPL Affiliated Pharmacy and cannot operate without a PPL Affiliated Pharmacy that is registered by the board as a Retail Drug Outlet Pharmacy.

(4) Each registration renewal application must be accompanied by the annual fee and must contain the same information required in OAR 855-143-0015(2) and additional information requested by the board.

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

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

(7) The registration is not transferable.

(8) The registration fee cannot be prorated.

(9) A PPL may not operate until a certificate of registration has been issued by the board.

(10) The Pharmacy registration and PPL registration must be on display at both the PPL Affiliated Pharmacy and at the PPL.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, ORS 689.305, ORS 689.527

855-143-0015
Registration: Application

(1) An application for registration of a new PPL must include a floor plan drawn to scale with the location of the:

(a) PPL at the facility;

(b) Surveillance system cameras; and

(c) Alarm system panel.

(2) The application for registration of new PPL must be approved by the Board prior to opening.

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

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

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

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

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

Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305, ORS 689.527

855-143-0020
Registration: Change of Owner, Location, or PPL Affiliated Pharmacy

(1) A change of location of the PPL Affiliated Pharmacy or location of the PPL requires:

(a) Submission of a new PPL application a minimum of 15 days prior to occurrence;

(b) Registration fee;

(c) Approval of the Board; and

(d) New certificate of registration.

(2) A change in the PPL Affiliated Pharmacy or ownership of the PPL requires:

(a) Submission of a new PPL application a minimum of 15 days prior to occurrence;

(b) Registration fee;

(c) Approval of the Board; and

(d) New certificate of registration.

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

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

(5) A PPL that has changed location or ownership must not operate until the new certificate of registration has been approved and issued.

Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305 ORS 689.527

855-143-0025
Registration: Closure

NOTE: Under review in Div 041/139 currently, will propose amendments at April 2022 board meeting to align Div 139 with any updates to rules in Div 041/139.

A PPL Affiliated Pharmacy must notify the board a minimum of 15 days prior to discontinuing operation of a PPL. Notification must include the:

(a) Final disposition of drugs stored in the PPL including:

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

(B) Name and location where destruction occurred; and

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

(b) Provide the board with:

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

(B) Signed statement giving the effective date of closure.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.305, ORS 689.527

855-143-0030
Non-Resident Affiliated Pharmacies

(1) For the purpose of these rules, a non-resident pharmacy includes a PPL Affiliated Pharmacy located outside of Oregon and providing pharmacy services to a PPL located in Oregon.

(2) Each non-resident PPL Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy as a Retail Drug Outlet Pharmacy.

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

(4) The Oregon licensed Pharmacist-in-Charge (PIC) of the non-resident PPL Affiliated Pharmacy is the PIC for each PPL.

(5) The PIC is responsible for ensuring that the PPL PIC self-inspection form is completed prior to February 1 each year.

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, ORS 689.527

855-143-0050
Personnel

(1) A PPL must have an Oregon licensed PIC at all times.

(2) Prior to utilizing a PPL, the Oregon licensed Pharmacist, Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician must have completed a training program on the proper use of the PPL.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.527

855-143-0100
Security

(1) The PPL Affiliated Pharmacy, the PPL, Oregon licensed PIC of the PPL Affiliated Pharmacy and each Oregon licensed Pharmacist supervising the PPL is responsible for the security of the PPL including provisions for adequate safeguards against loss, theft or diversion of prescription and non-prescription drugs, devices, and related supplies, and records for such drugs, devices and related supplies.

(2) The PPL Affiliated Pharmacy must ensure the PPL:

(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 prescription and non-prescription drugs, devices, and related supplies in compliance with the provisions of OAR 855-139-0125;

(3) The PPL must be secured to prevent access when:

(a) There is no Oregon licensed Pharmacist supervising and authorizing access in real-time to the PPL; or

(b) There is no Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician employed by the PPL Affiliated Pharmacy present at the PPL; or

(c) Any component of the PPL is not functioning.

(4) A record must be maintained with the name and Oregon license number of each person accessing the PPL.

(5) An Intern, Certified Oregon Pharmacy Technician, and Pharmacy Technician may only access the PPL when an Oregon licensed Pharmacist is supervising the licensee and has authorized access to the PPL in real-time.

(6) Unlicensed personnel (e.g. vendor) may only access the PPL when escorted and continuously observed by a licensee who is authorized by the Oregon licensed Pharmacist who is supervising and authorizing access to the PPL in real-time.

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

(a) Alarm system at the PPL and real-time notification to an Oregon licensed Pharmacist of the PPL Affiliated Pharmacy if unauthorized access occurs;

(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 PPL;

(B) Identification of the Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician accessing and securing the PPL; and

(C) Date and time of each activity; and

(c) Surveillance system that utilizes continuously accessible and recorded video between the PPL Affiliated Pharmacy and the PPL. The system must provide a clear view of the entire PPL including its access points.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-143-0120
Drug: Procurement

A PPL may only receive prescription, non-prescription drugs, devices, and related supplies from the PPL Affiliated Pharmacy.

Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-139-0125
Drug: Storage

NOTE: Under review in Div 041/139 currently, will propose amendments at April 2022 board meeting to align Div 139 with any updates to rules in Div 041/139.

(1) A PPL 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 PPL must quarantine drugs which are outdated, adulterated, misbranded or suspect. Cold Storage and Monitoring.

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

(a) All drug refrigeration systems must:

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

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

(C) Be dedicated to pharmaceuticals only;

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

(b) A PPL 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 by an Oregon licensed Pharmacist that it is safe for continued use. This documentation must include details of the information source;

(F) A written emergency action plan;

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

(H) Documentation and review of temperature recordings at least once every 28 days by the Oregon licensed Pharmacist at the time of in person physical inspection.

Statutory/Other Authority: ORS 689.205, ORS 689.325
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-139-0130
Drug: Loss

A PPL and its PPL Affiliated Pharmacy must:

(1) Ensure that disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs or devices are reported to the board immediately.

(2) Ensure that confirmed significant drug loss or any loss related to suspected drug theft is reported to the board within one business day.

Statutory/Other Authority: ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-139-0150
Outlet: Sanitation

A PPL and its PPL Affiliated Pharmacy must ensure the PPL is kept clean.

Statutory/Other Authority: ORS 689.305
Statutes/Other Implemented: ORS 689.305, ORS 689.527

855-139-0155
Outlet: Minimum Equipment Requirements

(1) Each Oregon PPL must have the following:

(a) 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 PPL outlet;

(b) Appropriate equipment to maintain the proper storage of drugs;

(c) Signage in a location easily seen by the public at the PPL where prescription and non-prescription drugs, devices, and related supplies are dispensed:

(A) Stating "The (insert name of PPL Affiliated Pharmacy) may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on this sign must be in block letters not less than one inch in height.

(B) Providing notification in each of the languages required in OAR 855-139-0410 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for

patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;

(C) Stating "This location is a Pharmacy Prescription Locker, supervised by an Oregon licensed Pharmacist from (insert name of PPL Affiliated Pharmacy, address, and telephone number)." The printing on the sign must be in block letters not less than one inch in height; and

(D) Providing notification of accurate hours of operation at each building entrance and each pharmacy entrance; and

(e) Accurate hours of operation on each telephone greeting and pharmacy-operated internet (e.g. website, social media, mobile applications).

(d) Additional equipment and supplies that are determined as necessary by the PPL Affiliated Pharmacy or PIC.

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

Statutory/Other Authority: ORS 689.205, ORS 689.654
Statutes/Other Implemented: ORS 689.155, ORS 689.515, ORS 689.654, ORS 689.527

855-143-0200
Outlet: General Requirements

(1) The PPL Affiliated Pharmacy and its PIC are responsible for all operations and enforcing all policies and procedures of the PPL.

(2) A PPL Affiliated Pharmacy may operate more than one PPL.

(3) A PPL Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the PPL.

(4) A PPL and its PPL 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) Ensure each prescription and non-prescription drugs, devices, and related supplies are dispensed in compliance with OAR 855-019, OAR 855-025, OAR 855-031, OAR 855-041 and OAR 855-143;

(d) Ensure prescription and non-prescription drugs devices, and related supplies are not dispensed from the PPL if an Oregon licensed Pharmacist is not available for patient consultation or if the PPL is not operable and functioning in all aspects;

(e) Ensure that the PPL Affiliated Pharmacy prevents duplicate dispensing of a prescription;

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

(g) Ensure that PPL Affiliated Pharmacy has received and documented consent by the patient or patient's agent for the patient's prescription and non-prescription drugs, devices, and related supplies to be placed in the PPL;

(h) Ensure that there is an Oregon licensed PIC who is responsible for all operations and enforcing all policies and procedures of the PPL;

(i) Designate in writing the Oregon licensed Pharmacists, Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians authorized to access the PPL;

(j) Utilize complete chain of custody tracking;

(k) Train the Oregon licensed Pharmacists, Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians in the operation of the PPL and document the training;

(l) Develop, implement and enforce a continuous quality improvement program for dispensing services from a PPL designed to objectively and systematically:

(A) Monitor, evaluate, document the quality and appropriateness of patient care;

(B) Improve patient care; and

(C) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their reoccurrence;

(m) Provide a toll-free telephone number that a patient, patient's agent or prescriber may use to contact the Oregon licensed Pharmacist from the PPL Affiliated Pharmacy; and

(n) Develop, implement and enforce a process for an in person physical inspection of the PPL by an Oregon licensed Pharmacist at least once every 28 days or more frequently as deemed necessary by the Oregon licensed PIC of the PPL Affiliated Pharmacy. The inspection must utilize the PPL self-inspection form, be documented, and records retained.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-143-0205
Outlet: Technology

A PPL and its PPL Affiliated Pharmacy must:

(1) Utilize a shared computer system and have appropriate technology or interface to allow access to information required to dispense a prescription and non-prescription drugs, devices, and related supplies and counsel the patient or patient's agent;

(2) Utilize barcode, radio-frequency identification or quick response code technology for stocking, destocking and dispensing of the PPL;

(3) Test the PPL and verify the unit is operable and functioning in all aspects in accordance with minimum acceptable system or unit design specifications before dispensing prescription and non-prescription drugs, devices, and related supplies and after an upgrade or change is made to the system. The PPL Affiliated Pharmacy must make the results of such testing available to the board upon request; and

(4) Develop, implement and enforce a plan for routine maintenance of the PPL.

(5) Develop, implement and enforce a plan for responding to and recovering from an interruption of service where the PPL is not fully operational and functioning.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-139-0210
Outlet: Supervision

A PPL and its PPL Affiliated Pharmacy must:

(1) Ensure prescription and non-prescription drugs, devices, and related supplies are only dispensed at the PPL if an Oregon licensed Pharmacist is available for patient consultation and the PPL is fully operational.

(2) Ensure that stocking and destocking of prescription and non-prescription drugs, devices, and related supplies in a PPL is completed under the supervision, direction and control of a pharmacist.

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

(a) All prescription and non-prescription drugs, devices, and related supplies were correctly stocked into the PPL;

(b) All prescription and non-prescription drugs, devices, and related supplies destocked from the PPL were returned to the PPL Affiliated Pharmacy;

(c) Proper storage conditions were maintained during transfer per OAR 855-143-0125; and

(d) Records are maintained per OAR 855-143-0550.

Statutory/Other Authority: ORS 689.205, ORS 689.225
Statutes/Other Implemented: ORS 689.151, ORS 689.155,ORS 689.305, ORS 689.527

855-143-0215
Outlet: Pharmacist Utilization

A PPL and its PPL Affiliated Pharmacy must:

(1) Ensure prescription and non-prescription drugs, devices, and related supplies are not dispensed from the PPL if an Oregon licensed Pharmacist is not available for patient consultation or if the PPL is not operable and functioning in all aspects.

(2) Utilize an Oregon licensed Pharmacist to provide real-time consultation, counseling, or to accept the refusal of counseling from the patient or the patient's agent via audiovisual communication system:

(a) For each prescription and non-prescription drugs, devices, and related supplies being dispensed when counseling is required under OAR 855-019-0230

(b) When the patient or patient's agent requests consultation; and

(c) Document the interaction.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-143-0220
Outlet: Non-Prescription Drugs and Supplies

If non-prescription drugs and related supplies are placed in the PPL, the PPL and its PPL Affiliated Pharmacy must:

(1) Ensure that only an Oregon licensed Pharmacist verifies non-prescription drugs and related supplies that will be placed in the PPL; and

(2) Ensure that an Oregon-licensed Pharmacist is readily available to provide counseling or recommendations involving non-prescription drugs and related supplies.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-143-0225
Outlet: Controlled Substances

Controlled substances may not be stored in the PPL.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-143-0345
Dispensing: General Requirements

The PPL Affiliated Pharmacy must:

(1) Ensure prescription, prescription refill, and drug order must be correctly dispensed by the PPL in accordance with the prescribing practitioner's authorization; and

(2) Ensure the PPL dispenses prescriptions accurately and to the correct party.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527, ORS 689.527

855-143-0500
Policies and Procedures

(1) The Oregon licensed PIC of the PPL Affiliated Pharmacy and the PPL Affiliated Pharmacy drug outlet is accountable for establishing, maintaining, and enforcing written policies and procedures for the PPL. The written policies and procedures must be maintained at the PPL 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 PPL Affiliated Pharmacy and each PPL including;

(a) Security;

(b) Operation, testing and maintenance of the PPL;

(c) Sanitation and cleaning;

(d) Storage of drugs;

(e) Stocking and destocking;

(f) Dispensing;

(g) Preventing duplicate dispensing;

(h) Oregon licensed Pharmacist supervision, direction and control of and control of licensed personnel accessing the PPL;

(i) Documenting the identity, function, location, date and time of the licensed personnel accessing the PPL;

(j) Utilization of Oregon licensed Pharmacist (i.e. Counseling);

(k) Recordkeeping;

(l) Patient consent and confidentiality;

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

(n) Continuous quality improvement;

(o) Plan for discontinuing and recovering services if PPL disruption occurs;

(p) Training: initial and ongoing; and

(q) Interpretation, translation and prescription reader services.

(3) If non-prescription drugs or supplies are placed in the PPL, the policies and procedures must outline the process for the Oregon licensed Pharmacist counseling and advice.

(4) If compounded preparations are compounded at the PPL Affiliated Pharmacy and placed in the PPL the policies and procedures must meet the requirements of OAR 855-045.

(5) A PPL Affiliated Pharmacy that provides prescription and non-prescription drugs, devices, and related supplies through a PPL must review its written policies and procedures every 12 months, revise them if necessary, and document the review.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-143-0550
Records: General Requirements

(1) The recordkeeping requirements OAR 855-143 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) All required records for the Drug Outlet PPL must be maintained by the PPL Affiliated Pharmacy.

(3) Records retained by the PPL Affiliated Pharmacy must include, but are not limited to:

(a) Date, time and identification of each individual and activity or function performed on the PPL;

(b) Oregon licensed Pharmacist physical inspection of the PPL;

(c) Audiovisual communication system testing;

(d) Licensee training on the proper use of the PPL;

(e) Still image capture and store and forward images must be retained according to (1);

(f) Data and surveillance system data must be retained for 6 months; and

(g) Any errors or irregularities identified by the quality improvement program.

(4) Records of dispensing from a PPL must include the:

(a) Physical location of the PPL;

(b) Identification of the patient or patient's agent retrieving the prescription, non-prescription drugs, and supplies;

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

(d) Date and time of transaction;

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

(f) Each non-prescription drug and supply name, UPC or NDC number, and quantity; and

(g) Name of Oregon licensed Pharmacist or Oregon licensed Intern who provided counseling to the patient or patient's agent, if required, documentation that the counseling was performed or that the Pharmacist or Intern accepted the patient or patient's agent request not to be counseled.

(5) Records of stocking and destocking of prescriptions into or from a PPL must include the:

(a) Date and time;

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

(c) Each non-prescription drug and supply name, UPC or NDC number, and quantity;

(d) Name and Oregon license number of the person stocking or destocking prescription, non-prescription drugs and supplies from the system; and

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.508, ORS 689.527

855-139-0600
Prohibited Practices: General

A PPL may not:

(1) Allow unlicensed personnel, Oregon licensed Pharmacy Technicians or Certified Oregon Pharmacy Technicians to ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist;

(2) Advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide pharmacy services unless the person is registered with the board pursuant to ORS 689.305;

(3) Utilize a person to dispense or deliver a prescription and non-prescription drugs, devices, and related supplies directly to the patient;

(4) Dispense drugs that require further manipulation by a prior to administration or dispensing (e.g. reconstitution, compounding, vaccines); and

(5) Store or dispense controlled substances.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-143-0602
Prohibited Practices: Disclosure of Patient Information

A Retail Drug Outlet PPL may not:

(1) Allow a licensee or registrant of the board who obtains any patient information to disclose that information to a third party without the consent of the patient except as provided in (2) of this rule.

(2) A licensee may disclose patient information:

(a) To the board;

(b) To a practitioner, Oregon licensed Pharmacist, Intern, Pharmacy Technician, or Certified Oregon Pharmacy Technician, if disclosure is authorized by an Oregon-licensed Pharmacist who reasonably believes that disclosure is necessary to protect the patient's health or well-being; or

(c) To a third-party when disclosure is authorized or required by law; or

(d) As permitted pursuant to federal and state patient confidentiality laws; or

(e) To the patient or to persons as authorized by the patient.

(3) Allow a licensee or registrant of the board to access or obtain any patient information unless it is accessed or obtained for the purpose of patient care.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305,ORS 689.315
Statutes/Other Implemented: ORS 689.155, ORS 689.527

855-143-0650
Grounds for Discipline

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

(1) Any of the grounds listed in ORS 689.405.

(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not be limited to, advertising or soliciting that:

(a) Is false, fraudulent, deceptive, or misleading; or

(b) Makes any claim regarding a professional service or product or the cost or price thereof which cannot be substantiated by the licensee.

Statutory/Other Authority: ORS 689.151, ORS 689.155, ORS 689.205, ORS 689.225
Statutes/Other Implemented: ORS 689.155, ORS 689.405, ORS 689.527

Division 006/019/041/139/143– RPH/Operation of a Pharmacy/RDSP/Lockers (Interpreters/Patient Records)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Adds requirements for use of interpreters and modifies patient record requirements

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Revisions to Division 006/019/041/139 are necessary to incorporate directives set forth in 2021 HB 2359, related to health care interpreters. Per 2021 HB 2359, pharmacists and interns must work with health care interpreters from health care interpreter registry operated by Oregon Health Authority to provide interpretation services. Modifies patient records requirements to include patient's sex assigned at birth current gender identification, and current chosen name.

Documents Relied Upon per ORS 183.335(2)(b)(D):

- 2021 HB 2359 and related statutes and OHA rules OAR XXX-XXX-XXXX related to health care interpreters

- Providing Inclusive Care and Services for the Transgender and Gender Diverse Community: A Pharmacy Resource Guide March 2021

Resources

- Redfern, Jan S., Jann, Michael W. "The evolving role of pharmacists in transgender health care." Transgender health 4.1 (2019): 118-130.https://www.liebertpub.com/doi/epdf/10.1089/trgh.2018.0038

- Cleveland Clinic: Why Deadnaming is Harmful

- EPIC: More Inclusive Care for Transgender Patients Using Epic

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): To be determined

OBOP/Other State Agencies/Units of Local Government/Public: No anticipated fiscal impact is expected for the agency, other state agencies, units of local government or the public.

Cost of Compliance (including small businesses): To be determined

Number/Type:

Reporting, Recordkeeping and Administrative Activities Cost:

Professional Services, Equipment/ Supplies, Labor Cost:

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, A RAC was not consulted, proposed rules are a legislative directive of 2021 HB 2359 related to health care interpreters. Proposed rules are also designed to provide more inclusive care for transgender and gender diverse patients.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Patients from a variety of racial and ethnic backgrounds are of Limited English Proficiency. Approximately 222,000 Oregonians (1 out of every 17) cannot read the directions for their prescription medications provided in English. Interpreters offer a language and

cultural bridge between a Pharmacist and a LEP patient. Utilizing qualified interpreters will ensure that proper communication occurs to allow the LEP patient to achieve desired health outcomes. The ability to access an interpreter who can speak the patient's preferred language will have a positive impact on patients from a variety of racial and ethnic backgrounds who may have barriers to communication in English.

There is limited data about the health status and health needs of people who identify as lesbian, gay, bisexual or transgender (LGBT). In Oregon, approximately 20,000 Oregonians (1 out of every 171) identify as transgender. Sex assigned at birth is an important, structured variable that is used to facilitate effective patient care that is efficient, equitable, and patient-centered. Sex assigned at birth in a patient's medical record is often used to calculate medication dosages and screen for drug interactions for a patient's typical hormonal history and anatomy. The proposed rules regarding patient records are intended to provide pharmacists with the information they need for accurate dosage calculations and drug interaction screening while also recognizing the importance of recognizing patients by their chosen name and preferred gender identification.

Rules Summary per ORS 183.335(2)(a)(B) (Indicates the change to the rule and why): Proposed amendments are necessary to incorporate directives set forth in 2021 HB 2359, related to health care interpreters. Requires pharmacists and interns to work with health care interpreters from health care interpreter registry operated by Oregon Health Authority to provide interpretation services. In addition, procedural rule review modifying patient records requirements to provide pharmacists with hormonal history and anatomy for accurate drug dosing and interaction screening. Also provides pharmacies with the ability to identify patients by their chosen name and gender identification.

Division 6
DEFINITIONS

855-006-0005
Definitions

(x) "Certified health care interpreter" has the meaning given that term in ORS 413.550.

(x) "Health care interpreter" has the meaning given that term in ORS 413.550.

(x) "Health care interpreter registry" means the registry described in ORS 413.558 that is administered by the authority.

(x) "Individual with limited English proficiency" means a person who, by reason of place of birth or culture, communicates in a language other than English and prefers to communicate in a language other than English.

NOTE: Board will motion all changes to Div 006 Definitions in one motion at end of policy discussions.

Division 19
PHARMACISTS

855-019-0230

Counseling

(1) The pharmacist or intern ~~shall~~ **must** orally counsel the patient or patient's agent on the use of a drug or device as appropriate:

(a) The pharmacist or intern ~~shall~~ **must** counsel the patient on a new prescription and any changes in therapy, including but not limited to a change in directions or strength, or a prescription which is new to the pharmacy;

(b) Only the pharmacist or intern may accept a patient's or patient's agent's request not to be counseled. If, in their professional judgment, the pharmacist or intern believes that the patient's safety may be affected, the pharmacist or intern may choose not to release the prescription until counseling has been completed;

(c) ~~Effective July 1, 2008,~~ ~~t~~**T**he pharmacist or intern that provides counseling or accepts the request not to be counseled ~~shall~~ **must** document the interaction;

(d) A pharmacist ~~shall~~ **must** not allow non-pharmacist personnel to release a prescription that requires counseling, or accept the request not to be counseled;

(e) For a prescription delivered to a patient, except at a pharmacy or a pharmacy prescription locker, the pharmacist ~~shall~~ **must** offer in writing, to provide direct counseling and information about the drug, including information on how to contact the pharmacist;

(f) For each patient, the pharmacist or intern ~~shall~~ **must** determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient~~.~~**; and**

(g) When communicating (e.g. counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English, the Pharmacist or Intern must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the Pharmacist is proficient in the patient's preferred language.

(2) Counseling on a refill prescription ~~shall~~ **must** be such as a reasonable and prudent pharmacist would provide.

(3) A pharmacist may provide counseling in a form other than oral counseling when, in their professional judgment, a form of counseling other than oral counseling would be more effective.

(4) A pharmacist or intern ~~shall~~ **must** initiate and provide counseling under conditions that maintain patient privacy and confidentiality.

(5) For a discharge prescription from a hospital, the pharmacist must ensure that the patient receives appropriate counseling.

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

Division 41
OPERATION OF PHARMACIES

855-041-1165
Patient Medical Record

A patient record system ~~shall~~ **must** be maintained by pharmacies for all patients for whom **a** prescription drug ~~orders are~~ **is** dispensed~~, except for those patients who the pharmacist has good reason to believe will not return to that pharmacy to obtain drugs~~. The patient record system ~~shall~~ **must** provide ~~for readily retrievable~~ information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist ~~shall~~ **must** make a reasonable effort to obtain, record, and maintain the following information:

(1) Full name of the patient **and current chosen name** for whom the drug is intended;

(2) Address and telephone number of the patient;

(3) Patient's ~~age or~~ date of birth;

(4) Patient's **sex assigned at birth and current** gender **identification**;

POLICY DISCUSSION: Board direction

(5) Patient's preferred language for communication and prescription labeling;

(~~5~~**6**) Chronic medical conditions;

(~~6~~**7**) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;

(~~7~~**8**) Known allergies, drug reactions, and drug idiosyncrasies; and

(~~8~~**9**) If deemed relevant in the pharmacist's professional judgment:

(a) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and

(b) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

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

855-041-0XXX
Dispensing: Interpretation

(1) Except as provided in subsection (2) of this section, a Pharmacist or Intern must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 when communicating with a patient who prefers to communicate in a language other than English, unless the Pharmacist is proficient in the patient's preferred language.

(2) A Pharmacist or Intern who is otherwise required to work with a health care interpreter from the health care interpreter registry may work with a health care interpreter who is not listed on the health care interpreter registry only if the Pharmacist or Intern:

(a) Verifies that the Pharmacist or Intern has taken appropriate steps needed to obtain a health care interpreter from the health care interpreter registry in accordance with rules adopted by the authority under ORS 413.558; or

(b) Has offered the patient the services of a health care interpreter from the health care interpreter registry and the patient declined the offer and chose a different interpreter.

(3) A Pharmacist or Intern must provide personal protective equipment, consistent with established national standards, to health care interpreters providing services on-site at no cost to the health care interpreter and may not suggest to the health care interpreter that the health care interpreter should procure the health care interpreter's own personal protective equipment as a condition of working with the Pharmacist or Intern.

(4) A Pharmacist or Intern must maintain records of each patient encounter in which the Pharmacist or Intern worked with a health care interpreter from the health care interpreter registry. The records must include:

(a) The name of the health care interpreter;

(b) The health care interpreter's registry number; and

(c) The language interpreted.

Statutory/Other Authority: ORS 689.205, 2021 HB 2359
Statutes/Other Implemented: ORS 689.155, 2021 HB 2359

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0555
Records: Patient

A patient record system must be maintained by pharmacies for all patients for whom a prescription drug is dispensed. The patient record system must provide information necessary for the dispensing Oregon licensed Pharmacist to identify previously dispensed drugs at the time a prescription is presented for

dispensing. The pharmacist must make a reasonable effort to obtain, record, and maintain the following information:

(1) Full name of the patient **and current chosen name** for whom the drug is intended;

(2) Address and telephone number of the patient;

(3) Patient's ~~age or~~ date of birth;

(4) Patient's **sex assigned at birth and current** gender **identification**;

(5) Patient's preferred language for communication and prescription labeling;

(~~5~~**6**) Chronic medical conditions;

(~~6~~**7**) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;

(~~7~~**8**) Known allergies, drug reactions, and drug idiosyncrasies; and

(~~8~~**9**) If deemed relevant in the pharmacist's professional judgment:

(a) Oregon licensed Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and

(b) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

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

855-139-0XXX
Dispensing: Interpretation

(1) Except as provided in subsection (2) of this section, a Pharmacist or Intern from the RDSP Affiliated Pharmacy must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 when communicating with a patient who prefers to communicate in a language other than English, unless the Pharmacist is proficient in the patient's preferred language.

(2) A Pharmacist or Intern who is otherwise required to work with a health care interpreter from the health care interpreter registry may work with a health care interpreter who is not listed on the health care interpreter registry only if the Pharmacist or Intern:

(a) Verifies that the Pharmacist or Intern has taken appropriate steps needed to obtain a health care interpreter from the health care interpreter registry in accordance with rules adopted by the authority under ORS 413.558; or

(b) Has offered the patient the services of a health care interpreter from the health care interpreter registry and the patient declined the offer and chose a different interpreter.

(3) A Pharmacist or Intern must provide personal protective equipment, consistent with established national standards, to health care interpreters providing services on-site at no cost to the health care interpreter and may not suggest to the health care interpreter that the health care interpreter should procure the health care interpreter's own personal protective equipment as a condition of working with the Pharmacist or Intern.

(4) A Pharmacist or Intern must maintain records of each patient encounter in which the Pharmacist or Intern worked with a health care interpreter from the health care interpreter registry. The records must include:

(a) The name of the health care interpreter;

(b) The health care interpreter's registry number; and

(c) The language interpreted.

Statutory/Other Authority: ORS 689.205, 2021 HB 2359
Statutes/Other Implemented: ORS 689.155, 2021 HB 2359

Division 143
PHARMACY PRESCRIPTION LOCKERS

NOTE: Will bring language for Division 143 Lockers to April Board meeting.

Division 021/135- Continuing Pharmacy Education (Procedural Rule Review)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Procedural rule review amending continuing education rules.

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Amending definitions, requirements for approved providers, applicants, instructors, renewal requirements for licensees and audits to reflect current requirements and standards.

Documents Relied Upon per ORS 183.335(2)(b)(D): Rules Advisory Committee- Continuing Pharmacy Education: May 2021 minutes, October 2021 minutes, and January 2022 minutes.

Resources: Other State Regulations: CA: CCR 1732**,** OH: OAC 4729:1-5**,**TX: TAC 295.8 Continuing Education Requirements, WA: WAC 246-861 Pharmacists—Professional Pharmaceutical Education

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): It is anticipated that state agencies, units of local government, licensees or the public will not be financially impacted by the proposed rules. Applicants and licensees are currently required by statute and rule to complete certain CE based on their license type.

Effect on Small Businesses? No effect anticipated for small businesses.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of the proposed rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): Yes, a RAC was consulted at three separate RAC meetings.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Adopting the proposed rules may increase patient safety for all Oregonians in every community by ensuring that all licensees continue to develop, maintain and enhance their competence in the practice or assistance of the practice of pharmacy.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): The proposed rules clarify definitions, incorporate universally acceptable CPE standards, amend outdated language and streamlines the process and requirements for providers and licensees applying for continuing pharmacy education credit.

NOTE: Statutory Minor Corrections will be filed to change OAR 855-~~021~~ to OAR 855-**135** for the following rule references

855-025-0015(2)(b) and (4)(d)	Renewal of Licensure as a Certified Oregon Pharmacy Technician
855-019-0170(1)(b) and (2)	Reinstatement of License
855-019-0122(1)(a)	Renewal of Licensure as a Pharmacist
855-031-0016(1)(a)	Renewal of Licensure as an Intern

Division ~~21~~**135**
CONTINUING PHARMACY EDUCATION

855-~~021~~135-0001
Continuing Pharmacy Education: Definitions

(1) "Accredited program" means a structured continuing pharmacy education (CPE) program which has been reviewed and approved by a provider of continuing pharmacy education that is accredited by the Accreditation Council on Pharmaceutical Education (ACPE) or approved by the American Medical Association (AMA).

(2) "AMA Category 1 Program" means a structured program reviewed and approved by the AMA as Category 1 Continuing Medical Education (CME) by a provider of continuing medical education accredited by the Accreditation Council for Continuing Medical Education (ACCME).

(3) "Approved provider" means any person, institution, organization, association, corporation, or agency approved either by the board or ACPE to conduct continuing pharmacy education programs.

(4) "Board-approved program" means a structured continuing pharmacy education which has been reviewed and approved by the board or a board-approved provider.

(5) "Certificate of completion" means a certificate or other official document issued to a participant certifying the successful completion of an approved continuing pharmacy education program.

(~~1~~**6**) "Continuing Pharmacy Education" or "CPE" **means an accredited or approved educational activity designed to support the continuing development of pharmacists, interns, or pharmacy technicians to maintain and enhance their competence applicable to the practice of pharmacy or the assistance of the practice of pharmacy**. ~~classes of post graduate studies, informal study group participation, institutes, seminars, lectures, conferences, workshops, extension study, correspondence courses, teaching, planned and professional meetings, self-study courses, cassette or audio visual tape/slides or materials, and other self-instruction units applicable to the practice of pharmacy~~.

(~~2~~**7**) "Contact hour" means ~~fifty~~ **sixty** minutes of continuing pharmacy education.

(8) "CPE Monitor" means the electronic tracking service of the ACPE and the National Association of Boards of Pharmacy (NABP) for monitoring continuing pharmacy education that pharmacists, interns, and pharmacy technicians receive from participating providers;

(~~6~~**9**) "Cultural competence" means the lifelong process of examining the values and beliefs and developing and applying an inclusive approach to health care practice in a manner that recognizes the content and complexities of provider-patient communication and interaction and preserves the dignity of individuals, families, and communities.

(a) Cultural competence applies to all patients.

(b) Culturally competent providers do not make assumptions on the basis of an individual's actual or perceived abilities, disabilities or traits whether inherent, genetic or developmental including: race, color, spiritual beliefs, creed, age, tribal affiliation, national origin, immigration or refugee status, marital

status, socio-economic status, veteran's status, sexual orientation, gender identity, gender expression, gender transition status, level of formal education, physical or mental disability, medical condition or any consideration recognized under federal, state and local law.

(4**10**) "Medication error prevention" means **the prevention of an event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the healthcare professional, patient, or consumer** ~~systems, procedures and processes to prevent and avoid adverse events and to ensure that the correct patient receives the correct drug in the correct dose~~.

(~~3~~**11**) "Patient safety" means **the prevention of healthcare related errors or the elimination or mitigation of patient injury caused by healthcare related errors** ~~systems, procedures and processes that ensure that the correct patient receives the correct drug in the correct dose and is counseled appropriately~~.

(~~5~~**12**) "Pain management education program" means a specific one-hour web-based program developed by the Pain Management Commission of the Oregon Health Authority.

(13) "Pharmacy law" means the body of laws and doctrines relating to pharmacy practice.

(14) "Structured" means the inclusion of defined learning objectives, qualified instructors, learning assessment, and a program evaluation in a continuing pharmacy education program.

Statutory/Other Authority: ORS 689.205 & ORS 676.850
Statutes/Other Implemented: **ORS 689.255,** ORS 689.285, ORS 689.486, ORS 413.450**, ORS 689.490** & ORS 413.590

855-~~02~~135-0010
Continuing Pharmacy Education Programs: General Requirements

(1) CPE programs must consist of subject matter pertinent to pharmacy including:

(a) Socio-economic aspects of healthcare;

(b) Legal aspects of healthcare;

(c) Properties and actions of drugs and dosage forms;

(d) Etiology, characteristics, therapeutics, and prevention of disease states; or

(e) General topics related to pharmacy.

(2) Full CPE credit (hour for hour) is granted when:

(a) Content is delivered by an instructor;

(b) Content is delivered by a panel of instructors;

(c) The program is a structured discussion, workshop or demonstration;

(d) The program is a structured question and answer session;

(e) The program is an accredited or board-approved program;

(f) The program is approved as an AMA Category 1 program. Licensees may earn a maximum of 10 hours of continuing pharmacy education for AMA Category 1 programs per renewal cycle; and

(g) The program provider has granted credit to the participant as authorized by the program accreditor or approval authority.

(3) CPE credit is not granted for:

(a) Welcoming remarks;

(b) Time spent for meals or social functions;

(c) Business sessions (e.g. voting, treasury report, strategic plan);

(d) Unstructured discussion, workshops, and demonstrations;

(e) Unstructured question and answer sessions;

(f) Degree programs;

(g) Non-ACPE approved certificate programs;

(h) Licensing or certification examinations (e.g. MPJE, BPS, CPhT-Adv);

(i) Skills training programs (e.g. CPR, ACLS);

(j) Software training programs (e.g. NPLEx, PDMP, ALERT-IIS, REMS);

(k) Learning assessments;

(l) Program evaluations; and

(m) Attending continuing pharmacy education programs for which credit was not granted by the provider.

(4) For each board-approved program, the licensee must retain a certificate of completion for each completed program that must include:

(a) Licensee name;

(b) Title and activity number of the program;

(c) Topic designation (e.g. law, patient safety, pain);

(d) Name of the program provider;

(e) Date of completion of the program;

(f) Number of contact hours earned by topic designation; and

(g) Statement of credit granted.

(5) For each ACPE-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor.

(6) For each board-approved program, the licensee must ensure that licensee program completion CPE credit was recorded in the CPE Monitor or uploaded to the licensee's Oregon Board of Pharmacy e-Gov profile.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: **ORS 689.255,** ORS 689.285**, ORS 689.490**

855-~~021~~135-0020
Continuing Pharmacy Education Programs: Approved Providers

(1) A provider may apply to the board on forms provided by the board for qualification as an approved provider. If a provider is approved, the board will issue a certificate or other notification of qualification. The approval is effective for a period of two years. Providers who apply to the board for approved provider status must document the following:

(a) Identify the individual responsible for the providers' CPE program;

(b) Provide copies of CPE program material and information used by the provider in the previous two years with each renewal; and

(c) Develop a procedure for establishing:

(A) Educational goals and learning objectives for each program;

(B) Learning assessment component for each program; and

(C) Program evaluation component for each program.

(d) A CPE provider must supply each participant with a written program description which lists the topic(s) covered, an assigned activity number, names of instructors, time devoted to the program topic(s), and the learning objectives of the program. The program description must also bear a statement of the number of hours by topic designation of CPE credit assigned by the provider.

(e) The provider must make available to each participant a certificate of completion that must include:

(A) Licensee name;

(B) Title and activity number of the program;

(C) Topic designation (e.g. law, patient safety, pain);

(D) Name of the program provider;

(E) Date of completion of the program;

(F) Number of contact hours earned by topic designation; and

(G) Statement of credit granted.

(2) The provider must retain, for a period of six years, a list of persons to whom a certificate of completion as specified in (1)(e) was supplied.

(3) The board must establish the standards and specifications necessary for a provider to obtain approval.

(4) The board may revoke or suspend an approval of a provider if the provider fails to maintain the necessary standards and specifications required.

POLICY DISCUSSION: Provider-approval

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.285

855-~~021~~135-0030
Continuing Pharmacy Education Programs: Applications for Approval

(1) An application for approval of a CPE program which is not an accredited program or provided by an approved provider using a form provided for this purpose by the board. A complete application includes:

(a) Program provider or sponsor name;

(b) Program name;

(c) Program topic designation;

(d) Licensee type;

(e) Total number of contact hours offered by topic designation;

(f) Description of program goals and learning objectives;

(g) Program format (e.g. interactive discussion, panel, speaker);

(h) Name and qualifications of each instructor;

(i) Dates and location of program;

(j) Learning assessment; and

(k) Program evaluation

(2) The provider must submit an application form a minimum of forty-five days prior to the date the program will be held. Applications submitted less than forty-five days prior to the date the program will be held will not be approved.

(3) Incomplete applications will not be approved.

(4) An application for post-approval of a CPE program will not be approved.

POLICY DISCUSSION: Post-approval, accepting other state board approvals

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.285

855-~~021~~135-0040
Continuing Pharmacy Education Programs: Instructors' Credit Toward CPE Hours

(1) Any pharmacist whose primary responsibility is not the education of health professionals, who instructs a group of health professionals on pharmacy-related topics according to OAR 855-135-0010(1)(a)-(e) in structured CPE may be granted two hours of CPE credit for each hour spent in presenting the initial course or program which has been approved for CPE credit.

(2) Any pharmacist whose primary responsibility is the education of health professionals may be granted CPE credit as in (1) when instructing a group of health professionals on pharmacy-related topics unrelated to their formal course responsibilities in a learning institution.

(3) An instructor may not be granted multiple credit for multiple presentations of the same program of CPE.

(4) An instructor may earn a maximum of 10 hours of CPE for instruction per renewal cycle.

(5) An instructor must submit an application form a minimum of forty-five days prior to the date the program will be held to apply for instructor credit toward CPE hours using a form provided for this purpose by the board. Applications submitted less than forty-five days prior to the date the program will be held will not be approved

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.285

855-~~021~~135-00~~05~~50

Continuing Pharmacy Education: Requirements~~d~~ for Pharmacist License Renewal

(1) During the period from July 1 through June 30 of each biennial license renewal cycle, a pharmacist must have satisfactorily completed at least 30 hours of ~~continuing pharmacy education~~ **CPE**. These hours must include at least:

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

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

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

(d) One hour of ~~continuing pharmacy education~~ **CPE** in pain management, provided by the Pain Management Commission of the Oregon Health Authority; and

(e) Twenty-three additional hours of ~~continuing pharmacy education~~ **CPE in subjects pertinent to pharmacy per OAR 855-135-0010(1)(a)-(e)**.

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

(3) A pharmacist must register with the CPE Monitor for tracking completed ACPE credit hours.

(~~3~~**4**) A pharmacist must retain documentation of completed ~~continuing pharmacy education~~ **CPE** for six years and must provide this documentation if requested by the board.

(~~4~~**5**) ~~continuing pharmacy education~~ **CPE** credit accumulated in excess of the required 30 contact hours for biennial license renewal cannot be carried forward.

Statutory/Other Authority: ORS 689.205 & ORS 676.850
Statutes/Other Implemented: ORS 689.285, **ORS 689.486,** ORS 413.450, ORS 413.590 & 2021 HB 2078

855-~~021~~135-00~~07~~60

Continuing Pharmacy Education: Requirements~~d~~ for Intern License Renewal

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

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

(3) An intern must register with the CPE Monitor for tracking completed ACPE credit hours.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: **ORS 413.450, ORS 689.151, ORS 689.255,** ORS 689.285, ORS 676.850~~, ORS 413.450~~ & ~~ORS 689.151~~

855-~~021~~135-000~~9~~70

Continuing Pharmacy Education: Requirements~~d~~ for Certified Oregon Pharmacy Technician License Renewal

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

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

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

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

(d) Fourteen additional hours of ~~continuing pharmacy education or documented onsite training approved by the board~~ **CPE in subjects pertinent to pharmacy per OAR 855-135-0010(1)(a)-(e)**.

(2) A Certified Oregon Pharmacy Technician must register with the CPE Monitor for tracking completed ACPE credit hours.

(~~2~~**3**) Section (1) does not apply to a Certified Oregon Pharmacy Technician applying for the first renewal of their license if they have not been licensed by the board for at least one year prior to July 1 of the renewal period.

(~~3~~**4**) A Certified Oregon Pharmacy Technician must retain documentation of completed ~~continuing pharmacy education~~ **CPE** for six years and must provide this documentation if requested by the board.

(~~4~~**5**) ~~continuing pharmacy education~~ **CPE** credit accumulated in excess of the required 20 contact hours for biennial license renewal cannot be carried forward.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450 & ORS 676.850

~~**855-021-0010**~~

~~**Continuing Pharmacy Education Programs**~~

~~(1) A continuing pharmacy education program must consist of therapeutics, or pharmacy and drug law or other aspects of health care applicable to the practice of pharmacy.~~

~~(2) Programs must provide for examinations or other methods of evaluation to assure satisfactory completion by participants.~~

~~(3) The person or persons who are to instruct or who are responsible for the delivery or content of the program must be qualified in the subject matter by education and experience.~~

~~(4) Continuing pharmacy education programs must be approved by the Board of Pharmacy. Application for approval must be made on and in accordance with forms established by the board. The forms must require information relating to:~~

~~(a) Name of provider or sponsor;~~

~~(b) Type of program offered;~~

~~(c) Description of subject matter;~~

~~(d) Number of contact hours offered;~~

~~(e) Total number of contact hours in therapeutics or pharmacy and drug law or other aspects of health care applicable to the practice of pharmacy;~~

~~(f) Method of determining satisfactory completion of program;~~

~~(g) Dates and location of program;~~

~~(h) Name and qualification of instructors or other persons responsible for the delivery or content of the program.~~

~~(5) CE programs are not required to carry approval of American Council on Pharmaceutical Education (ACPE). Programs presented by providers approved by the American Council on Pharmacy Education (ACPE) are accepted.~~

~~(6) Providers must provide attendees with proof of attendance that shows the date and number of contact hours provided. Providers must maintain attendance lists for six years.~~

~~(7) A maximum of 10 contact hours may be earned in any licensing cycle by preparing and presenting CE programs. Pharmacists and Certified Oregon Pharmacy Technicians presenting CE programs may earn one contact hour for preparation time of one hour or more, plus credit for the actual contact hour time of the presentation. A pharmacist or Certified Oregon Pharmacy Technician must show content of the course, and a description of the intended audience (e.g., pharmacists, technicians, physicians, nurses). Public service programs, such as presentations to school children or service clubs, are not eligible for continuing education credit.~~

~~(8) Pharmacists or Certified Oregon Pharmacy Technicians taking post graduate studies applicable to graduate or professional degrees may submit the course syllabus and evidence of satisfactory completion of the course for continuing education credit approval by the board.~~

~~(9) The board may approve up to 26 contact hours of CE credit for pharmacists who have successfully completed nationally certified Disease State Management courses.~~

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

~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.285~~

855-~~021~~135-0080
Continuing Pharmacy Education: Requirements for Licensees Licensed in Other Health Professions

A Pharmacist, Intern, or Certified Oregon Pharmacy Technician who is licensed to practice another health profession must meet the same CPE requirements in the same manner as all other board licensees and must otherwise comply with this chapter.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: **ORS 689.255,** ORS 689.285, **ORS 689.490**

855-~~021~~135-004~~5~~85
Continuing Pharmacy Education: Notification of Biennial License Renewal

The board will send a biennial renewal notice to be issued to all licensed pharmacists, interns, and Certified Oregon Pharmacy Technicians at least 60 days prior to the license expiration date that states the biennial license fee, ~~continuing pharmacy education~~ **CPE** requirements and other information necessary for renewal.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: **ORS 689.255,** ORS 689.275 & ORS 689.486**, ORS 689.490**

855-~~21~~135-005~~0~~90
Continuing Pharmacy Education: Audits

(1) The biennial renewal application must be submitted to the board with the appropriate fee and the licensee must attest that they have satisfactorily completed the ~~continuing pharmacy education~~ **CPE** requirements **prior to submitting the application**.

(2) The Board may randomly select and audit applications for renewal to verify completion of ~~continuing pharmacy education~~ **CPE** by pharmacists, interns and Certified Oregon Pharmacy Technicians ~~or documented on-site training by Certified Oregon Pharmacy Technicians~~ reported on the application for renewal.

(a) Pharmacists whose applications for renewal are selected for audit must provide documentation of completion of the ~~continuing pharmacy education~~ **CPE** programs reported. A pharmacist who fails to provide the requested documentation to the board or who fails to complete the biennial ~~continuing pharmacy education~~ **CPE** requirement may be disciplined for unprofessional conduct.

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

(c) Certified Oregon Pharmacy Technicians whose applications for renewal are selected for audit must provide documentation of completion of the ~~continuing pharmacy education~~ **CPE** ~~or documented onsite training reported~~. A Certified Oregon Pharmacy Technician who fails to provide the requested documentation to the board or who fails to complete the biennial ~~continuing education~~ **CPE** requirement may be disciplined for unprofessional conduct.

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

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.275

POLICY DISCUSSION: Implementation with licensure cycles

Division 041: Operation of Pharmacies (Disclosure of Patient Information)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends prohibited practices related to disclosure of patient information

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Permits disclosure of patient information as permitted by federal and state patient confidentiality laws and to the patient or persons authorized by the patient. Also prohibits accessing or obtaining patient information unless it is for the purpose of patient care.

Documents Relied Upon per ORS 183.335(2)(b)(D): OAR 855-139-0602

Cost of Compliance - (OBOP/Other State Agencies/Units of Local Government/Public or Stakeholders, Effect on Small Businesses):

OBOP/Other State Agencies/Units of Local Government/Public or Stakeholders: None anticipated. The rulemaking imposes no additional mandatory reporting, recordkeeping, or other administrative requirements on small businesses.

Effect on Small Businesses – number & type subject to the rule, expected reporting, recordkeeping, administrative activities cost in order to comply, cost of professional services, equipment supplies, labor, increased administration required for compliance with the rule: None anticipated. The rulemaking imposes no additional mandatory reporting, recordkeeping, or other administrative requirements on small businesses.

Effect on Small Businesses? There are no known economic impacts to small businesses or members of the public.

Describe how small businesses were involved in development of the rules: Small businesses were not involved in the development of proposed amendments to these rules.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): No, a RAC was not consulted. Board staff suggests amending the current rule for transparency and clarity for licensees.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Researchers have found links between levels of medical mistrust, race/ethnicity, and people's perception of discrimination. By clarifying the rules concerning disclosure of patient information, all patients can be more confident that their information is being handled appropriately by Oregon Board of Pharmacy licensees.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Proposed amendments are to align Pharmacy Drug Outlet rules concerning disclosure of patient information with Remote Dispensing Site Pharmacy Drug Outlet rules in OAR 855-139-0602 adopted by the board in December 2021. Permits disclosure of patient information as permitted by federal and state patient confidentiality laws and to the patient or persons authorized by the patient. Also prohibits accessing or obtaining patient information unless it is for the purpose of patient care.

1 Division 41
2 OPERATION OF PHARMACIES

855-041-1055

~~Confidentiality~~ Prohibited Practices: Disclosure of Patient Information

A Retail Drug Outlet or Institutional Drug Outlet may not:

(1) ~~No~~ **Allow a** licensee or registrant of the ~~B~~**b**oard who obtains any patient information ~~shall~~ **to** disclose that information to a third party without the consent of the patient **except as provided in (2) of this rule**.

(2) ~~Section (1) of this rule does not apply to:~~ **A licensee may disclose patient information:**

(a) ~~Any disclosure made t~~**T**o the Board;

(b) ~~Any disclosure made t~~**T**o a practitioner ~~or to another pharmacist when the~~**, Oregon licensed Pharmacist, Intern, Pharmacy Technician, or Certified Oregon Pharmacy Technician,** if disclosure is authorized by an Oregon-licensed ~~p~~**P**harmacist **who** reasonably believes that disclos**ure**~~ing such information~~ is necessary to protect the patient's health or wellbeing; or

(c) To a third party when disclosure is ~~otherwise~~ authorized or required by law**; or**

(d) As permitted pursuant to federal and state patient confidentiality laws; or

(e) To the patient or to persons as authorized by the patient.

(3) Allow a licensee or registrant of the board to access or obtain any patient information unless it is accessed or obtained for the purpose of patient care.

Statutory/Other Authority: ~~ORS 689.155 &~~**,** ORS 689.205**, ORS 689.305 & ORS 689.315**
Statutes/Other Implemented: **ORS 689.155**

Division 006/041/139– Definitions/Drug Storage

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends drug storage requirements for pharmacies

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): The proposed rules amend pharmacy requirements for drug storage, drug storage monitoring, and response to drug storage excursion. In addition, the proposed rules 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). Proper drug storage is essential to maintain medication purity, potency and safety.

Documents Relied Upon per ORS 183.335(2)(b)(D):
United States Pharmacopeia -National Formulary <NF> (USP 43-NF38 v. 2021): https://www.uspnf.com/
National Institute of Standards and Technology (NIST):
- Optimizing Data Logger Setup and Use for Refrigerated Vaccine Temperature Monitoring (2015)
- Thermal Analysis of Refrigeration Systems Used for Vaccine Storage: Report on Pharmaceutical Grade Refrigerator and Household Refrigerator/Freezer (2010)
- Accurate Cold Chain Temperature Monitoring Using Digital Data Logger Thermometers (2012)
Oregon: VFC Vaccine Management Guide
CDC: Vaccine Storage and Handling Toolkit

Fiscal & Economic Impact per ORS 183.335(2)(b)(E):

Cost of Compliance - (OBOP/Other State Agencies/Units of Local Government/Public): It is anticipated that state agencies, units of local government and the public will not be financially impacted by the proposed rules. We do anticipate that licensed drug outlets may be financially impacted in order to comply with the proposed rules.

Cost of Compliance - (Stakeholders): A fiscal impact request was sent to approximately 678 email addresses which includes board meeting and rulemaking interested parties. OBOP received 1 response with the following estimates:

In 2019, the respondent received a quote of $10,000 for continuous temperature monitors to be installed at seven pharmacies ($1,429 for one outlet) which included one year of service. This vendor also charges for ongoing annual fees; however, that information was not provided.

Thus, it is estimated that in order for a licensed outlet to comply with the proposed rules, could potentially cost $2,858 ($1,429 x 2 thermometers) for procurement and 1 year of service plus additional annual service fees. As of 12/2/2021 there are currently 1,898 registered outlets.

Effect on Small Businesses – (number & type subject to the rule, expected reporting, recordkeeping, administrative activities cost in order to comply, cost of professional services, equipment supplies,

labor, increased administration required for compliance with the rule): There are approximately 113 small business drug outlet pharmacies registered with the board. It is not anticipated that the cost of compliance for small business would be different from that of a non-small business.

Describe how small businesses were involved in the development of the rules: Small businesses were not involved with the development of the proposed rules.

Was a RAC consulted? If no, why? Per ORS 183.335(2)(b)(G): No, a RAC was not consulted. Rule amendments are necessary to incorporate standards of reference per the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (07/2019).

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) Since the proposed rules provide clarity, transparency and promote patient safety by ensuring drugs are properly stored, no effects on racial equity are anticipated. Ensuring proper drug storage positively impacts all Oregonians in all communities.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): As part of procedural rule review, it was identified that pharmacy requirements for drug storage, drug storage monitoring, and response to drug storage excursion were outdated and needed clarification. In addition, incorporated standards (e.g. USP) need to be adopted by reference.

Division 6
DEFINITIONS

855-006-0005
Definitions

As used in OAR chapter 855:

(x) "Temperature excursion" means an event in which a drug is exposed to a temperature outside of the manufacturer's required storage conditions. If the drug's manufacturer does not include required storage conditions, "temperature excursion" means an event in which a drug is exposed to a temperature outside of that required in an official compendium to ensure that the drug identity, strength, quality, and purity are not adversely affected.

NOTE: Board will motion all changes to Div 006 Definitions in one motion at end of policy discussions.

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

855-041-1036
Proper Storage of Drugs

(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 required 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 to 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:

(i) Has a buffered probe (glycol, glass beads, or similar) that is:

(A) Centrally located;

(B) Contained in a tray with a solid base and solid sides without perforations to maintain the probe in a stable position to minimize temperature fluctuations;

(C) Records the temperature of each drug storage area at least every 15 minutes; and

(D) Accurate and calibrated on a schedule determined by the manufacturer within a plus or minus 0.5°C (1 °F) variance. A copy of the calibration certificate must be retained that includes:

(i) Model/device name or number;

(ii) Serial number;

(iii) Calibration date (report or issue date); and

(iv) Confirmation that the instrument passed testing (or instrument is in tolerance).

(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 (i.e. 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 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:

(A) Date of temperature excursion;

(B) Start and end time;

(C) Minimum and maximum temperatures reached;

(D) 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);

(E) 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; and

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

(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 and case number if 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; and

(p) Have at least one accurate and calibrated back-up buffered temperature probe.

(q) In case the device in use breaks or malfunctions, place a back-up buffered temperature probe in the storage unit to determine the temperature.

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

~~(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.~~

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

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0125
Drug: Storage

(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 required 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 to 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:

(i) Has a buffered probe (glycol, glass beads, or similar) that is:

(A) Centrally located;

(B) Contained in a tray with a solid base and solid sides without perforations to maintain the probe in a stable position to minimize temperature fluctuations;

(C) Records the temperature of each drug storage area at least every 15 minutes; and

(D) Accurate and calibrated on a schedule determined by the manufacturer within a plus or minus 0.5°C (1 °F) variance. A copy of the calibration certificate must be retained that includes:

(i) Model/device name or number;

(ii) Serial number;

(iii) Calibration date (report or issue date); and

(iv) Confirmation that the instrument passed testing (or instrument is in tolerance).

(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:

(A) Date of temperature excursion;

(B) Start and end time;

(C) Minimum and maximum temperatures reached;

(D) 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);

(E) 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; and

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

(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;

(D) Copy of information and case number if 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; and

(p) Have at least one accurate and calibrated back-up buffered temperature probe.

(q) In case the device in use breaks or malfunctions, place a back-up buffered temperature probe in the storage unit to determine the temperature

(r) Maintain all records required by OAR 855-139-0032 for a minimum of three years.

~~(1) A RDSP 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 RDSP must quarantine drugs which are outdated, adulterated, misbranded or suspect. Cold Storage and Monitoring.~~

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

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

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

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

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

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

~~(b) A RDSP 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 by an Oregon licensed Pharmacist that it is safe for continued use. This documentation must include details of the information source;~~

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

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

~~(H) Documentation and review of temperature recordings at least once every 28 days by the Oregon licensed Pharmacist at the time of in person physical inspection.~~

~~(3) Vaccine Drug Storage:~~

~~(a) A RDSP 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.~~

Statutory/Other Authority: ORS 689.205, ORS 689.325
Statutes/Other Implemented: ORS 689.155

Division 006/020/041/065/139: Alarm/ Audiovisual Communication/ Entry / Surveillance Systems

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Adds definitions for alarm, audiovisual communication, entry and surveillance systems; Procedural rule review.

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): Adds definition for alarm system, audiovisual communication system, entry system, and surveillance system; Amends use of these terms in promulgated rules. Removes references to a security system.

Documents Relied Upon per ORS 183.335(2)(b)(D): None

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated

Cost of Compliance- OBOP/Other State Agencies/Units of Local Government/Public: None anticipated

Cost of Compliance- Small Businesses: None anticipated

-Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of the proposed rule amendment.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): A RAC was not consulted, board staff proposed rule amendments to ensure clarity.

Racial Equity statement per ORS 183.335(2)(b)(F) (identifying how adoption of rule might impact one group of people differently than others): Since the proposed rules provide clarity for currently promulgated rules, no effects on racial equity are anticipated.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Adds definition for surveillance system, communication system, alarm system and entry system; Removes references to a security system. Amends use of these terms in promulgated rules to ensure clarity to registrants as to when each system is required.

Division 6

DEFINITIONS

855-006-0005
Definitions

(x) "Alarm system" means a device or series of devices, which emit or transmit an audible or remote visual or electronic alarm signal, which is intended to summon a response.

(x) "Audiovisual communication system" means a continuously accessible, two-way audiovisual link that allows audiovisual communication in real-time and that prevents unauthorized disclosure of protected health information.

(x) "Entry system" enables control of access to a secured area.

(x) "Surveillance system" means a system of video cameras, monitors, recorders, and other equipment used for surveillance.

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

NOTE: Board will motion all changes to Div 006 Definitions in one motion at end of policy discussions.

Division 20

PHARMACIST PRESCRIPTIVE AUTHORITY

855-020-0110
Prescribing Practices

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

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

(a) Patient inclusion and exclusion criteria;

(b) Explicit medical referral criteria;

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

(d) Patient education; and

(e) Provider notification; and

(f) Maintaining confidentiality.

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

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

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

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

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

(d) Provide notification to the patient's identified primary care provider or other care providers when applicable within five business days following the prescribing of a Compendia drug or device.

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

(6) If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use **an** ~~real-time~~ audio-visual communication **system** to conduct the consultation.

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

Division 41

OPERATION OF PHARMACIES

855-041-1020
Security of Prescription Area

(1) The area in a registered pharmacy where legend and/or controlled substances are stored, possessed, prepared, manufactured, compounded, or repackaged shall be restricted in access, in such a manner as to ensure the security of those drugs.

(2) The pharmacist-in-charge and each pharmacist while on duty shall be responsible for the security of the prescription area including provisions for adequate safeguards against theft or diversion of prescription drugs, and records for such drugs.

(3) When there is no pharmacist present, the pharmacy shall be secured to prevent entry. All entrances to the pharmacy shall be securely locked and any keys to the pharmacy shall remain in the possession of the pharmacist-in-charge and other employee pharmacists as authorized by the pharmacist-in-charge. When there is no pharmacist present, and it is necessary for non-pharmacist employees or owners to

have access to the pharmacy, the prescription area shall be secured from entry as described in OAR 855-041- 2100.

(4) Prescription drugs and devices and non-prescription Schedule V controlled substances shall be stored within the prescription area or a secured storage area.

~~(5) Any security system deviating from the requirements of this section, except as provided in OAR 855-041- 6310, shall be approved by the Board prior to implementation. Requests for such approval shall be in writing and provide a detailed description of the proposed system. A written description of such security system, as approved by the Board, shall be maintained in the pharmacy.~~

Statutory/Other Authority: ORS 475.035 & **ORS** 689.205
Statutes/Other Implemented: ORS 689.205

855-041-3220
Telework: Supervision Requirements

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the supervising Oregon licensed Pharmacist from the Drug Outlet must:

(1) Utilize ~~technology that enables real-time~~ **an** audio ~~and~~ visual **communication system** ~~connection~~ and have appropriate technology or interface to allow access to information required to complete assigned duties;

(2) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by Certified Oregon Pharmacy Technicians and Interns;

(3) Ensure an Oregon licensed Pharmacist is supervising, directing and controlling each Intern and Certified Oregon Pharmacy Technician and that the ~~continuous~~ audio~~/~~visual **communication system** ~~connection~~ is fully operational;

(4) Ensure that an Oregon licensed Pharmacist using professional judgment, determines the frequency of "check-ins" for each licensee being supervised via the ~~real-time~~ audio ~~and~~ visual **communication system** ~~connection~~ with a minimum of at least once per work shift to ensure patient safety, compliance with federal and state laws, and documents the interaction;

(5) Be readily available to answer questions and fully responsible for the practice and accuracy of the licensee; and

(6) Ensure the Intern or Certified Oregon Pharmacy Technician knows the identity of the Oregon licensed Pharmacist who is providing supervision, direction and control at all times.

(7) The Oregon licensed Pharmacist who is supervising an Intern or Certified Oregon Pharmacy Technician at a Telework Site must:

(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 5% of patient interactions observed or reviewed;

(b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;

(c) Document the following within 24 hours of the review in (b):

(A) Number of each licensee's patient interactions;

(B) Number of each licensee's patient interactions pharmacist is reviewing;

(C) Date and time of licensee patient interaction pharmacist is reviewing;

(D) Date and time of pharmacist review of licensee's patient interaction; and

(E) Pharmacist notes of each interaction reviewed; and

(d) Report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 24 hours of discovery and to the board within 10 days.

(8) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination in (7)(a), employ adequate staff to allow for completion of the review within 48 hours, and retain records.

Statutory/Other Authority: ORS 689.135, ORS 689.151 & ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3230
Telework: Technology

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the Pharmacist from the Drug Outlet must:

(1) Use still image capture or store and forward for verification of prescriptions with a camera that is of sufficient quality and resolution so that the Oregon licensed Pharmacist from the Oregon registered Drug Outlet Pharmacy can visually identify each:

(a) Source container including manufacturer, name, strength, lot, and expiration;

(b) Dispensed product including the imprint and physical characteristics;

(c) Completed prescription container including the label; and

(d) Ancillary document provided to patient at the time of dispensing.

(2) Test the ~~continuous~~ audio ~~and~~ visual **communication system** ~~connection~~ and document that it operates properly before engaging in telework.

(3) Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising, directing and controlling the Intern and Certified Oregon Pharmacy Technician at the Telework Site.

(4) Ensure access to:

(a) Appropriate and current pharmaceutical references based on the services offered; and

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, 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.

(5) Train the Oregon licensed Pharmacists, Interns and Certified Oregon Pharmacy Technicians in the operation of ~~continuous~~ audio ~~and~~ visual **communication system** ~~connection~~.

Statutory/Other Authority: ORS 689.135, ORS 689.151 & ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3235
Telework: Personnel

(1) The Oregon licensed Pharmacist-in-charge of the Drug Outlet Pharmacy is responsible for all operations at Drug Outlet Pharmacy including responsibility for the ~~continuous~~ audio ~~and~~ visual **communication system** ~~connection~~ and enforcing policies and procedures.

(2) A Drug Outlet Pharmacy may not utilize Pharmacy Technicians, or unlicensed personnel at Telework Sites.

(3) An Intern or Certified Oregon Pharmacy Technician working at a Telework Site is required to have at least one year experience performing similar services for an Oregon registered Drug Outlet Pharmacy during the three years preceding the date the Intern or Certified Oregon Pharmacy Technician begins teleworking.

(4) The Oregon licensed Pharmacist from the Drug Outlet Pharmacy who is supervising a licensee at a Telework Site must determine and document how many licensed individuals the pharmacist is capable of supervising, directing and controlling based on the services being provided.

(5) When supervising an Intern or Certified Oregon Pharmacy Technician working at a Telework Site, the Oregon licensed Pharmacist may supervise no more than four licensees among all locations, including the Drug Outlet Pharmacy.

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

(7) Prior to working at a Telework Site, the Intern or Certified Oregon Pharmacy Technician and the Oregon licensed Pharmacist supervising the Telework Site must have completed a training program on the use of all equipment necessary for secure operation of the Telework Site.

Statutory/Other Authority: ORS 689.135, ORS 689.151 & ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3240
Telework: Environment and Security

(1) Telework Sites must be located in a designated area where:

(a) All equipment is stored;

(b) All work is performed; and

(c) Confidentiality is maintained such that patient information cannot be viewed or overheard by anyone other than the Pharmacist, Intern or Certified Oregon Pharmacy Technician.

(2) The Pharmacist-in-charge of the Drug Outlet Pharmacy and each Oregon licensed Pharmacist supervising a Telework Site is responsible for ensuring the Telework Site has a designated work area that is secure and has been approved and documented by an Oregon licensed Pharmacist prior to utilization.

(3) All computer equipment used at the Telework Site must:

(a) Establish and maintain a secure connection to the pharmacy and patient information;

(b) Utilize equipment that prevents unauthorized access to the pharmacy and patient information; and

(c) Be configured so that the pharmacy and patient information is not accessible when:

(A) There is no Oregon licensed Pharmacist actively supervising the Intern or Certified Oregon Pharmacy Technician who is assisting in the practice of pharmacy from a Telework Site; or

(B) There is no Pharmacist, Intern or Certified Oregon Pharmacy Technician present at the Telework Site; or

(C) Any component of the ~~real-time~~ audio ~~and~~ visual **communication system** ~~connection~~ is not functioning; and

(d) Comply with all security and confidentiality requirements.

(4) A record must be maintained with the date, time and identification of the licensee accessing patient or pharmacy records from a Telework Site.

(5) Interns and Certified Oregon Pharmacy Technicians may only work from a Telework Site when authorized in real-time by an Oregon licensed Pharmacist who is supervising the licensee at the Telework Site.

(6) All records must be stored in a secure manner that prevents access by unauthorized persons.

Statutory/Other Authority: ORS 689.135, ORS 689.151 & ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3245
Telework: Policies and Procedures

(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the Drug Outlet Pharmacy and the Oregon licensed Pharmacist-in-charge is accountable for establishing, maintaining, and enforcing written policies and procedures for the licensees working from a Telework Site. The written policies and procedures must be maintained at the Drug Outlet Pharmacy and must be available to the board upon request.

(2) The written policies and procedures must include at a minimum the services, responsibilities and accountabilities of the licensee engaging in telework including;

(a) Security;

(b) Operation, testing and maintenance of the audio ~~and~~ visual **communication system** ~~connection~~;

(c) Detailed description of work performed;

(d) Oregon licensed Pharmacist supervision, direction and control of Interns and Certified Oregon Pharmacy Technicians;

(e) Recordkeeping;

(f) Patient confidentiality;

(g) Continuous quality improvement;

(h) Plan for discontinuing and recovering services if **the** audio ~~and~~ visual **communication system** ~~connection~~ **is** disrupt**ed**~~ion occurs~~;

(i) Confirmation of dedicated, secure Telework Sites;

(j) Documenting the identity, function, location, date and time of the licensees engaging in telework;

(k) Written agreement with licensees engaging in telework outlining specific functions performed, conditions and policies governing the operation of the Telework Site; and

(l) Equipment.

Statutory/Other Authority: ORS 689.135, ORS 689.151 & ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-3250

Telework: Records

(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the recordkeeping requirements OAR 855-041-3205 through OAR 855-041-3250 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 created at Telework Sites must be stored at the Drug Outlet 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 must be stored at the Telework site in a manner that prevents unauthorized access.

(3) Records must include, but are not limited to:

(a) Patient profiles and records;

(b) Patient contact and services provided;

(c) Date, time and identification of the licensee accessing patient or pharmacy records from a Telework Site;

(d) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;

(e) List of employees working from Telework Sites that includes:

(A) Name;

(B) License number;

(C) Verification of each license;

(D) Address of Telework Site; and

(E) Name of the Oregon licensed Pharmacist who verified each licensure, approved licensee to telework and approved each Telework Site;

(f) Audio ~~and~~ visual communication system testing and training;

(g) Still image capture and store and forward images must be retained according to (1);

(h) Data and telephone audio must be retained for 6 months; and

(i) Any errors or irregularities identified by the quality improvement program.

Statutory/Other Authority: ORS 689.135, ORS 689.151 & ORS 689.205
Statutes/Other Implemented: ORS 689.155

855-041-5055

Remote Distribution Facility (RDF)

The purpose of these rules is to provide for the use of a Certified Oregon Pharmacy Technician functioning outside of a pharmacy to prepare drugs only for administration to a patient by another healthcare provider, and where requisite pharmacist supervision and verification is provided remotely by an Oregon licensed pharmacist via ~~real-time~~ **an** audio~~-~~ visual **communication system** ~~technology~~.

(1) A pharmacy physically located in Oregon may make written application to operate a RDF.

(2) The Board may approve an application for registration as a RDF which includes the following:

(a) An operation plan;

(b) Policies and Procedures;

(c) A training plan;

(d) A quality assurance plan for ensuring that there is a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems; and

(e) The fee specified in Division 110.

(3) Notwithstanding the definition of "supervision by a pharmacist" in Division 006, supervision in a RDF may be accomplished by a pharmacist via an audio~~-~~ visual **communication system** ~~technology~~ from the applying pharmacy.

(4) Notwithstanding rules in this Division and in Divisions 019 and 025, a Certified Oregon Pharmacy Technician who works in a RDF may have access to the facility without the physical presence of a pharmacist, but may only perform Board approved functions when under the supervision of a pharmacist.

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

855-041-6410

Emergency Department Distribution

(1) A practitioner or associate practitioner with prescriptive authority in Oregon who is a member of the hospital's medical staff may dispense an emergency supply of drugs to a patient examined by them or by an associate practitioner subject to the following requirements:

(a) The prescriber shall offer the patient the option of being provided a prescription that may be filled at the pharmacy of the patient's choice.

(b) During consultation with the patient or the patient's caregiver, the prescriber shall clearly explain the appropriate use of the drug supplied and the need to have a prescription for any additional supply of the drug filled at a pharmacy of the patient's choice.

(c) The patient must be given instructions on the use and precautions for taking the drug;

Labeling

(d) The drug is in a manufacturer's unit-of-use container, such as an inhaler, or hospital pre-pack that has been labeled by the pharmacy with:

(A) Name of drug, strength, and number of units. When a generic name is used, the label must also contain the identifier of the manufacturer or distributor;

(B) Accessory cautionary information as required for patient safety;

(C) Product identification label if the drug is not in unit-of-use packaging;

(D) An expiration date after which the patient should not use the drug; and

(E) Name, address and phone number of the hospital pharmacy.

(e) The following information must be added to the drug container by the practitioner or nurse before dispensing to the patient:

(A) Name of patient;

(B) Directions for use by the patient;

(C) Date of issue;

(D) Unique identifying number as determined by policy and procedure;

(E) Name of prescribing practitioner; and

(F) Initials of the dispensing nurse or practitioner.

Distribution Record

(f) A prescription or record of the distribution must be completed by the practitioner or nurse. This record must contain:

(A) Name of patient;

(B) Date of issuance;

(C) Drug name and strength distributed;

(D) Units issued;

(E) Name of practitioner;

(F) Initials of the dispensing nurse or practitioner; and

(G) Instructions given to the patient as labeled.

(g) Any additional information required by state and federal laws and regulations for the distribution of a drug to an outpatient;

(h) The record must be reviewed and documented by a pharmacist for accuracy and completeness. The pharmacist shall review the record of dispensing of drugs within 24 hours. However, if the pharmacy is closed, records shall be reviewed during the first day the pharmacy is open but not to exceed 72 hours following the dispensing; and

(i) Errors and discrepancies will be included in hospital and pharmacy QA review process and available to the Board.

(2) A controlled substance may only be distributed or dispensed to an outpatient by the examining practitioner after the patient has been examined by the practitioner and a legitimate medical purpose for a controlled substance has been determined. Distribution of a controlled substance must comply with all applicable state and federal laws and regulations.

(3) The CPO or PIC and appropriate hospital committee will establish a limited selection and quantity of drugs to be included in the Emergency Department formulary and the amount contained in each prepak that may be distributed to meet only the acute care needs of a patient; for example, an emergency supply of drugs. The amount dispensed may not exceed a 48 hour supply except for:

(a) A drug in the manufacturer's unit-of-use packaging such as an inhalant or a topical drug;

(b) A full course of therapy that may be dispensed if in the professional judgment of the pharmacist or practitioner this would be in the patient's best interest such as an antibiotic;

(4) Any additional preparation for use of the medication must be completed prior to discharge; for example, reconstituting antibiotics;

Automated Dispensing Machine

(5) For the purpose of this rule an Automated Dispensing Machine (ADM) is a machine or contrivance which will prepare a completed and labeled prescription which is ready for dispensing to the patient or patient's representative.

(6) An Automated Dispensing Machine; may only be located within the Emergency Department in a secure environment that has no direct public access, and when used, must be part of the discharge procedure;

(7) When the patient or patient's representative receives the prescription from an ADM;

(a) A registered nurse or practitioner or pharmacist must be present at the time of dispensing; and

(b) A registered nurse or practitioner or pharmacist will grant access to the ADM for the release of the drugs to be dispensed using a password protected or biometric **access code** ~~security system~~; and

(c) The patient or patient's representative will obtain the drug using a specific patient access code.

(8) Only a pharmacy technician, certified pharmacy technician, intern or pharmacist may access the drug supply in the ADM.

(9) The CPO or PIC will establish policies and procedures for use of the ADM including, but not limited to emergency access and down time procedures for the ADM.

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

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

Division 65

WHOLESALE DRUG OUTLETS

855-065-0012
Storage of Drugs

(1) As a condition for receiving and retaining a wholesale distributor registration issued under these rules, an applicant must satisfy the Board that the applicant has and will continuously maintain acceptable storage and handling conditions and facilities standards for each facility at which drugs are received, stored, warehoused, handled, held, offered, marketed, or displayed, or from which drugs are transported, including:

(a) Suitable construction of the facility and appropriate monitoring equipment to ensure that drugs in the facility are maintained in accordance with labeling or in compliance with official compendium standards.

(b) Suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations.

(c) Adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.

(d) A quarantine area for the separate storage of drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, suspected counterfeit, otherwise unfit for distribution, or contained in immediate or sealed secondary containers that have been opened.

(e) Maintenance of the facility in a clean and orderly condition.

(f) Maintenance of the facility in a commercial, nonresidential building.

(g) Freedom of the facility from infestation by insects, rodents, birds or vermin of any kind.

(2) The facility must be equipped with appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and logs to document proper storage of drugs.

(3) The facility must meet security standards including but not limited to:

(a) ~~Access controls~~ **An entry system** that restrict**s** access to areas where drugs are held, to authorized personnel.

(b) An after-hours central alarm **system** or a comparable entry detection system.

(c) Adequate outside perimeter lighting.

(d) Safeguards against theft and diversion, including employee theft and theft or diversion facilitated or hidden by tampering with computers or electronic records.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155 & **ORS** 689.305

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0100
Security

(1) The area in a registered RDSP where legend and/or controlled substances are stored, possessed, prepared, compounded 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 RDSP Affiliated Pharmacy, the RDSP, Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy and each Oregon licensed Pharmacist supervising the RDSP 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 RDSP must be locked and the ~~security~~ **alarm** system armed to prevent**, deter and detect** entry when:

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

(b) There is no Certified Oregon Pharmacy Technician present in the RDSP~~.~~**; or**

(c) Any component of the surveillance 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 RDSP.

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

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

(a) Alarm system ~~with an audible alarm~~ at the RDSP and real-time notification to a designated licensee of the RDSP Affiliated Pharmacy **if unauthorized access occurs**;

(b) Electronic ~~keypad or other 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 RDSP;

(B) Identification of the Certified Oregon Pharmacy Technician accessing and securing the RDSP; and

(C) Date and time of each activity.

(c) Surveillance system that utilizes continuously accessible and recorded ~~audiovisual link~~ **video** between the RDSP Affiliated Pharmacy and the RDSP. The system must provide a clear view of:

(A) Dispensing site entrances;

(B) Preparation areas;

(C) Drug storage areas;

(D) Pick up areas;

(E) Office areas; and

(F) Publicly accessible areas.

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

855-139-0210
Outlet: Supervision

A RDSP and its RDSP Affiliated Pharmacy must:

(1) Ensure prescription drugs are only dispensed at the RDSP if an Oregon licensed Pharmacist is supervising the Certified Oregon Pharmacy Technician, and the ~~telepharmacy~~ surveillance system is fully operational;

(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each Certified Oregon Pharmacy Technician at the RDSP using **an** ~~continuous~~ audio ~~and~~ visual **communication system** ~~technology~~**. All patient interactions** ~~which~~ must be recorded, reviewed and stored;

(3) The Oregon licensed Pharmacist who is supervising Certified Oregon Pharmacy Technician at a RDSP must:

(a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 10% of patient interactions observed or reviewed;

(b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;

(c) Document the following within 24 hours of the review in (3)(b):

(A) Number of each licensee's patient interactions;

(B) Number of each licensee's patient interactions pharmacist is reviewing;

(C) Date and time of licensee patient interaction pharmacist is reviewing;

(D) Date and time of pharmacist review of licensee's patient interaction; and

(E) Pharmacist notes of each interaction reviewed; and

(d) Report any violation of OAR 855 to the RDSP Affiliated Pharmacy within 24 hours of discovery and to the board within 10 days.

(4) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 48 hours, and retain records.

(5) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the Certified Oregon Pharmacy Technician.

(6) 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 RDSP.

Statutory/Other Authority: ORS 689.205 & ORS 689.225
Statutes/Other Implemented: ORS 689.151, ORS 689.155 & ORS 689.305

855-139-0215
Outlet: Pharmacist Utilization

A RDSP and its RDSP Affiliated Pharmacy must:

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

(2) Utilize an Oregon licensed Pharmacist and ~~real-time~~ **an** audio-visual communication **system** 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 and when requested and document the interaction.

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

855-139-0230
Outlet: Non-Sterile Compounding

If non-sterile preparations are compounded at the RDSP, the RDSP and its RDSP Affiliated Pharmacy must:

(1) Adhere to the requirements of OAR 855-045;

(2) Ensure an Oregon licensed Pharmacist:

(a) Supervises via a**n** ~~real-time~~ audio-visual communication **system** ~~connection~~ all steps of the compounding; and

(b) Documents and visually verifies each item required in OAR 855-139-0205.

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

855-139-0550
Records: General Requirements

(1) The recordkeeping requirements OAR 855-139 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 RDSP must maintain all required records unless these records are maintained in the RDSP Affiliated Pharmacy.

(3) Records retained by the Drug Outlet must include, but are not limited to:

(a) Patient profiles and records;

(b) Date, time and identification of each individual and activity or function performed;

(c) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;

(d) Controlled substance inventory and reconciliation;

(e) Oregon licensed Pharmacist physical inspection of RDSP;

(f) Audio ~~and~~ visual **communication system** ~~connection~~ testing and individual training on use of the audio ~~and~~ visual **communication system** ~~connection~~;

(g) Still image capture and store and forward images must be retained according to (1);

(h) Data, telephone audio and surveillance **system** data must be retained for 6 months; and

(i) Any errors or irregularities identified by the quality improvement program.

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

Division 080: Controlled Substances (Cannabis Exception)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends Schedule I rule by adding exceptions to Marijuana and delta-9-tetrahydrocannabinol (THC).

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule): The proposed amendments include adding the following exceptions to schedule I- Marijuana and delta-9-tetrahydrocannabinol (THC): The plant Cannabis family Cannabaceae; any part of the plant Cannabis family Cannabaceae, whether growing or not; resin extracted from any part of the plant Cannabis family Cannabaceae; the seeds of the plant Cannabis family Cannabaceae; or any compound, manufacture, salt, derivative, mixture or preparation of a plant, part of a plant, resin or seed. Adopted as a result of impacts of the Federal 2018 Farm Bill legalizing cultivation of hemp and marketing of hemp-derived products.

Documents Relied Upon per ORS 183.335(2)(b)(D): ORS 475.005(6)

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): It is not possible to assess the fiscal impact of this rule as there are too many unknowns regarding the hemp products industry.

OBOP/Other State Agencies/Units of Local Government/Public: Minimal fiscal impact.

Cost of Compliance (including small businesses): Unknown, but likely minimal.

Number/Type:

Reporting, Recordkeeping and Administrative Activities Cost: None.

Professional Services, Equipment/ Supplies, Labor Cost: None.

Effect on Small Businesses? Minimal impact on small businesses.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of the proposed rule amendment.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): A RAC was not consulted, board staff proposed rule amendments to ensure clarity.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others) The proposed rule amendments provide clarity for licensees, registrants and the public by listing exceptions to Schedule I (OAR 855-080-0021) related to Marijuana and delta-9-tetrahydrocannabinol (THC) consistent with ORS 475.005(b)(A)-(E). It is anticipated that these amendments will not impact any group of people differently than others.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why): Amends Schedule I rule by adding exceptions to Marijuana and delta-9-tetrahydrocannabinol (THC) which were exempted from Schedule I under the Federal 2018 Farm Bill.

Division 80
CONTROLLED SUBSTANCES

855-080-0021
Schedule I

(1) Schedule I consists of the drugs and other substances, by whatever official, common, usual, chemical, or brand name designated, listed in 21 CFR 1308.11 (04/01/2020), and unless specifically exempt or unless listed in another schedule, any quantity of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(a) 1,4-butanediol;

(b) Gamma-butyrolactone

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

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

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

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

(A) Methylmethcathinone (Mephedrone);

(B) Methylenedioxypyrovalerone (MDPV);

(C) Methylenedioxymethylcathinone (Methylone);

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

(E) Fluoromethcathinone (Flephedrone);

(F) 4-Methoxymethcathinone (Methedrone).

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

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

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

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

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

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

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

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

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

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

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

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

(3) Schedule I also includes any other cannabinoid receptor agonist that is not listed in OARs 855-080-0022 through 0026 (Schedules II through V), ~~or~~ is not an FDA approved drug **or is exempted from the definition of controlled substance in ORS 475.005(6)(b)(A)-(E)**.

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

(5) Schedule I also includes any compounds in the following structural classes (a – b), and their salts, that are not listed in OARs 855-080-0022 through 0026 (Schedules II through V) or FDA approved drugs, unless specifically excepted or when in the possession of an FDA registered manufacturer or a registered research facility, or a person for the purpose of sale to an FDA registered manufacturer or a registered research facility:

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

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

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

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

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

(c) ~~Marijuana and delta-9-tetrahydrocannabinol (THC).~~**The following substances per ORS 475.005(6)(b):**

(A) The plant Cannabis family Cannabaceae;

(B) Any part of the plant Cannabis family Cannabaceae, whether growing or not;

(C) Resin extracted from any part of the plant Cannabis family Cannabaceae;

(D) The seeds of the plant Cannabis family Cannabaceae; or

(E) Any compound, manufacture, salt, derivative, mixture or preparation of a plant, part of a plant, resin or seed described in this paragraph.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: **ORS 475.005**, ORS 475.035, ORS 475.055, ORS 475.065 ~~& ORS 475.005~~

Division 006/041/139– Definitions (Supervision by a Pharmacist/ Move from Div 041/139 to Div 006)

Filing Caption per ORS 183.335(2)(a)(A) (identifies the subject matter of the agency's intended action max 15 words): Amends definition "Supervision by a Pharmacist"; Moves some definitions in Division 041/139 to Division 006.

Need for Rules per ORS 183.335(2)(b)(C) (describes what we are changing in rule):
1. The proposed language amends "supervision by a pharmacist" to include an exception for telework as authorized under OAR 855-041-3200 through OAR 855-041-3250. If permanently adopted, this rule will replace the current temporary rule that was filed on 12/10/2021.

2. Moves definitions for "biological product", "biosimilar", "interchangeable", "reference biological product" and "repackage" from Divisions 041/139 to Division 006. Moves definitions for "still image capture", "store and forward" and "telepharmacy system" to Division 006.

Documents Relied Upon per ORS 183.335(2)(b)(D): None

Fiscal & Economic Impact per ORS 183.335(2)(b)(E): None anticipated.

Describe how small businesses were involved in development of the rules: Small businesses were not involved with the development of the proposed rule amendment.

Was a RAC consulted? If no, why? per ORS 183.335(2)(b)(G): A RAC was not consulted, board staff proposed rule amendments to ensure clarity.

Racial Equity statement per ORS 183.335(2)(b)(F): (identifying how adoption of rule might impact one group of people differently than others)
1. The ability to work remotely allows employers to hire licensees that do not live in their geographical region; thus, allowing employers to seek out more diverse employees; thus, it is anticipated that these rules will have some potential impact on racial equity. Adoption of this rule may positively impact all licensees throughout Oregon by allowing some work to be performed outside of a traditional brick and mortar pharmacy location, which may also increase employee performance and assist with work life balance.
2. Reorganizing proposed rules may provide clarity, transparency and promote patient safety, no effects on racial equity are anticipated. Ensuring registrants and licensees are able to easily locate definitions will positively impact all Oregonians in all communities.

Rules Summary per ORS 183.335(2)(a)(B) (indicates the change to the rule and why):
1. Due to COVID-19, licensees need the ability to work remotely at a secured off-site, non- pharmacy location. Rule permits Pharmacist to supervise, direct and control the work of Interns and Certified Oregon Pharmacy Technicians who are not stationed within the same work area as the Pharmacist to work remotely at a secured off-site, non-pharmacy location.
2. The proposed reorganization would relocate some definitions in Division 041/139 to Division 006 will streamline definitions and make the definitions easier to locate by registrants, licensees and the public.

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. 12/09/2021)**.**

(2) "Alarm system" means a device or series of devices, which emit or transmit an audible or remote visual or electronic alarm signal, which is intended to summon a response.

In rule package: Div 006 020 041 065 139 Alarm Audiovisual Communication Entry and Surveillance Systems

(3) "Audiovisual communication system" means a continuously accessible, two-way audiovisual link that allows audiovisual communication in real-time and that prevents unauthorized disclosure of protected health information.

In rule package: Div 006 020 041 065 139 Alarm Audiovisual Communication Entry and Surveillance Systems

(4) "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.

Moving: From Division 041 and 139

(5) "Biosimilar" product means a biological product licensed by the United States Food and Drug Administration pursuant to 42 USC 262(k)(3)(A)(i) (12/1/2021).

Moving: From Division 041 and 139

(~~2~~**6**) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.

(7) "Certified health care interpreter" has the meaning given that term in ORS 413.550.

In rule package: Div 006 019 041 139 Interpreters

(~~3~~**8**) "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.

(4**9**) "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.

(~~5~~**10**) "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.

(~~6~~**11**) "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.

(~~7~~**12**) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.

(~~8~~**13**) "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.

(~~9~~**14**) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.

(~~10~~**15**) "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.

(16) "Entry system" enables control of access to a secured area.

In rule package: Div 006 020 041 065 139 Alarm Audiovisual Communication Entry and Surveillance Systems

(17) "Health care interpreter" has the meaning given that term in ORS 413.550.

In rule package: Div 006 019 041 139 Interpreters

(18) "Health care interpreter registry" means the registry described in ORS 413.558 that is administered by the authority.

In rule package: Div 006 019 041 139 Interpreters

(19) "Individual with limited English proficiency" means a person who, by reason of place of birth or culture, communicates in a language other than English and prefers to communicate in a language other than English.

In rule package: Div 006 019 041 139 Interpreters

(20) "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 USC 262(k)(4) (12/01/2021).

Moving: From Division 041 and 139

(~~11~~**21**) "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.

(~~12~~**22**) "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~~**23**) "Misbranded" has the same definition as set forth in 21 USC 352 (v. 12/09/2021).

(~~14~~**24**) "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.

(~~15~~**25**) "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.

(~~16~~**26**) "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.

(~~17~~**27**) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.

(~~18~~**28**) "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~~**29**) “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.

(~~20~~**30**) "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.

(~~21~~**31**) 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.

(~~22~~**32**) "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.

(~~23~~**33**) "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.

(~~24~~**34**) “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.

(~~25~~**35**) “Practice of pharmacy” is as defined in ORS 689.005.

(~~26~~**36**) “Prescription drug” or “legend drug” is as defined in ORS 689.005 and:

(a) Required by federal law, prior to being dispensed or delivered, to be labeled with “Rx only”; or

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

(~~27~~**37**) "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.

(~~28~~**38**) “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.

(~~29~~**39**) "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.

(~~30~~**40**) "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.

(41) "Reference biological product" means the biological product licensed pursuant to 42 USC 262(a) (12/01/2021) 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.

Moving: From Division 041 and 139

(42) "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.

Moving: From Division 041

(~~31~~**43**) "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.

(~~32~~**44**) "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.

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

Moving: From Division 139

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

Moving: From Division 139

(~~33~~**47**) "Supervision by a pharmacist" means being stationed within the same work area, **except as authorized under OAR 855-041-3200 through OAR 855-041-3250**, 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.

In rule package: Div 006 Supervision by a Pharmacist

(48) "Surveillance system" means a system of video cameras, monitors, recorders, and other equipment used for surveillance.

In rule package: Div 006 020 041 065 139 Alarm Audiovisual Communication Entry and Surveillance Systems

(49) "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.

Moving: From Division 139

(50) "Temperature excursion" means an event in which a drug is exposed to a temperature outside of the manufacturer's required storage conditions. If the drug's manufacturer does not include required storage conditions, "temperature excursion" means an event in which a drug is exposed to a temperature outside of that required in an official compendium to ensure that the drug identity, strength, quality, and purity are not adversely affected.

In rule package: Div 041/139 Drug Storage

(~~34~~**51**) "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.

(~~35~~**52**) "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 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 USC 262(k)(3)(A)(i) (12/1/2021).~~

~~(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 USC 262(k)(4) (12/01/2021).~~

~~(5) "Reference biological product" means the biological product licensed pursuant to 42 USC 262(a) (12/01/2021) 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.~~

Statutory/Other Authority: ORS 689.205 & ORS 689.522
Statutes/Other Implemented: ORS 689.155 & ORS 689.522

Division 139
REMOTE DISPENSING SITE PHARMACY

855-139-0005
Definitions

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

~~(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 USC 262(k)(3)(A)(i) (12/01/2021).~~

~~(3) "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 USC 262(k)(4) (12/01/2021).~~

(4**1**) "RDSP Affiliated Pharmacy" means a Retail Drug Outlet Pharmacy registered in Oregon where an Oregon licensed Pharmacist provides pharmacy services through a telepharmacy system.

~~(5) "Reference biological product" means the biological product licensed pursuant to 42 USC 262(a) (12/01/2021) 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~~**2**) "Remote Dispensing Site Pharmacy" or "RDSP" 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.

~~(7) "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.~~

~~(8) "Still image capture" means a specific image captured electronically from a video or other image capture device.~~

~~(9) "Store and forward" means a video or still image record which is saved electronically for future review.~~

(~~10~~**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.

~~(11) "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.~~

Statutory/Other Authority: ORS 689.205, ORS 689.522 & 2021 SB 629
Statutes/Other Implemented: ORS 689.522, ORS 689.564 & 2021 SB 629

Oregon's Health Professionals' Services Program (HPSP)

An Introduction

Oregon Board of Pharmacy
February 10, 2022

Kate Manelis, LMSW
Program Manager

Lori Govar, MSW, MBA
Monitoring Director

uprisehealth

1

Agenda

- Substance Use & the Healthcare Profession
- HPSP History
- HPSP Program Components
- HPSP Outcomes

Uprise Health Monitoring

Protecting public safety while assisting participants with mental health and substance use disorder problems to continue in their professional careers.

2

Substance Abuse in the Healthcare Profession

~10% of the population struggles with addiction

- Studies typically show that Healthcare Practitioners are similar

Increased risk factors:

- High stress
- Long / Varied hours
- Access to prescription medications

Increased risk of danger to the public

- Healthcare Practitioners :
  - 5.5% illicit drug use in past month. (SAMHSA)
  - 4.4% heavy alcohol use in past month. (SAMHSA)
  - 5.7% substance use disorder in past year. (SAMHSA)
- 77% of first time DUII patients have lifetime alcohol abuse or dependence diagnosis (Palmer et al., 2007)

uprisehealth

3

Impact of the Pandemic

Increase in drinking and binge drinking

- 1 in 4 adults increased drinking
- 1 in 3 binge drinking
- 1 in 5 nurses increased drinking

Increase in anxiety and depressive symptoms

- 1 in 4 adults (vs 1 in 10 pre-pandemic)

Increased other substance use

- 3% of nurses

Mental Health Disorder Prevalence

•1 in 5 adults, 51.5 million Americans, experienced mental illness in 2019.
•1 in 20 adults, 13.1 million Americans, experienced serious mental illness in 2019.
•18.4% of adults with mental illness also experienced a substance use disorder in 2019 (9.5 million Americans.)
•Suicide is the 10th leading cause of death.
- NAMI

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7763183/
https://www.apa.org/news/press/releases/2021/03/one-year-pandemic-stress
https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/
https://www.medpagetoday.com/nursing/nursing/96449 accessed 1/18/22

uprisehealth

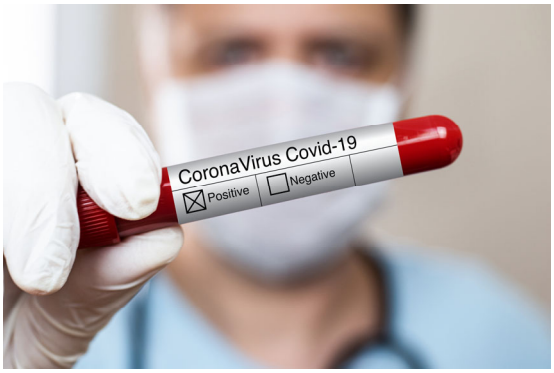
4

Substance Abuse in the Healthcare Profession

Treatable with help
- But less than 10% get help

Fear of discipline and stigma = Hide problems
- Greater treatment gap than general population

Alternative to Discipline (ATD)
- National Effort
- 88% of states = ATD for nurses; 94% for physicians
- Physician suicides led to Oregon's initiation of a PHP in the late 70's



uprisehealth

5

Professional Monitoring Programs

Physician Health Programs; Alternative-to-Discipline Programs

Supported by research
- Uprise Health model based on empirically-based best practices

Providing monitoring allows for:
- Improved workplace and public safety
- Minimized safety and financial risks
- Retention of experienced, trained licensees in their chosen profession

An average of 60-70% of all participants complete program thanks to accountability and structure

Physician Health Programs (PHPs)
•Leading the way
•Federation of PHPs (research & collaboration)
•Most often are a temporary safe-haven for physicians

uprisehealth

6

Oregon: In the News Before HPSP

9/21/06:	Nurse-Monitoring Audit Spurs Senator's Concern
3/22/07:	Nursing Chaos 1 Year Later
9/2/07:	Changes Ahead for Oregon Nursing Board After Reports of Problems
9/7/07:	Oregon State Board of Nursing Protected Nursing Over Patients – Reports
12/9/10:	Doctors Under the Influence

7

Health Professionals' Services Program (HPSP)

Established on July 1, 2010 through direct action of the 2009 Oregon Legislature (HB 2345).

- The Oregon Health Authority (OHA 2010 through 2017), Addictions & Mental Health Division, was given responsibility to contract with an outside vendor to establish a monitoring program

Based on HB 2345: HPSP is the alternative to discipline program in Oregon

Uprise Health (previously RBH / IBH) has served as the provider for Oregon since 7/1/10

Overseen by Advisory Committee currently

4 Participating Boards: Nursing, Dental, Pharmacy, & Medical

uprisehealth

8

Health Professionals' Services Program (HPSP)

Confidential monitoring program for licensed healthcare professionals who have been diagnosed with a substance use disorder and/or mental health disorder.

Offers Boards:

- Retention of Qualified Licensees, Public Safety, Consultation, & Support

Offers Licensees

- Opportunity to stay in their chosen profession

Provides STRUCTURE and ACCOUNTABILITY for licensees

NOT Treatment

- Follow treatment recommendations of evaluator
- Makes sure Licensees complete treatment requirements

Established guidelines reinforced by statute

uprisehealth

9

HPSP - Eligibility

Board of Nursing:

- Advanced Practice Nurses, RNs, CRNAs, and LPNs (NOT CNAs)

Medical Board

- MD, DO, Podiatry (DPM), Physician's Assistant (PA), Acupuncturist (LAc)

Board of Dentistry

- DMD, DDS, Registered Dental Hygienist

Board of Pharmacy

- Registered Pharmacist (RPH) (NOT Pharmacy Techs)

Other Boards

- Have not elected to participate at this time.
- No alternative-to-discipline for Licensees (license must be sanctioned)

uprisehealth

10

HPSP - Eligibility

Board Referred Licensees Must Have:

- Diagnosis of substance use disorder, mental health disorder, or both
- An active state license (must be maintained throughout monitoring)
- Evaluation by approved evaluator
  - Treatment Recommendations
  - Return to Work Recommendations

Self Referred Licensees Must ALSO Have:

- No known active investigations
- No past on the job impairment, patient harm or crimes committed
- Safe Practice Investigation (SPI)

***Dental Board does not allow for self-referrals at this time*

***Identity unknown to board if remain compliant*

Oregon Duty to Report- ORS

676.150 Duty to report prohibited or unprofessional conduct, arrests and convictions; investigation; confidentiality; immunity from liability.

(2) … a licensee who has reasonable cause to believe that another licensee has engaged in prohibited or unprofessional conduct shall report the conduct to the board . . .no event later than 10 working days after . . . learns of the conduct.

Includes licensee, workplace, and colleagues

HPSP Services for the Boards

Program and policy consultation

Training / Outreach
- Board staff, associations, colleges, hospitals, employers

Referral coordination

Reporting:
- Individual status updates, Toxicology (missed and non-negative), Non-compliance, & Program-Wide

Quality Assurance

Local Program Manager

Alternative to Discipline or Non-Discipline	Component of Discipline
Board of Pharmacy (*Self-Referrals)	Board of Pharmacy
Medical Board (*Self-Referrals)	Medical Board
Board of Nursing	Board of Dentistry
Board of Dentistry	

uprisehealth

13

HPSP for the Licensee

Phone intake with Agreement Monitor

Referral for independent ("third party") evaluation with local provider

Monitoring Agreement
- Individualized Program Requirements
- Treatment / Aftercare, Toxicology, Self-Help, Check-ins with Staff, Medication Management

Workplace Monitoring

Annual reviews

Monitor until completion

uprisehealth

14

Monitoring Requirements

Agreement Monitor Check-In

- Weekly:
  - Phone/Video call initially
  - Email/Voicemail with 1x month phone/video call subsequently
- Purpose:
  - Reinforce structure and provide support & coaching
  - Coordination of care
  - Documentation reminders
  - Community recovery support encouragement
  - Assist in problem solving

Agreement Monitors
•Behavioral Health Specialist
•Similar to a case manager
•NOT: board agent/employee

The Role of the Agreement Monitor
•Support licensee's safe practice in a healthcare setting
•Provide structure and support for recovery
•Helping licensees navigate the monitoring process
•NOT therapist, secret keeper or advocate (with some exceptions)

15

Monitoring Requirements

Toxicology

Daily Test Notification

- Smart phone app, phone call, or website
- Participant responsibility

Collection sites

- Near work and home
- Open before and after shift

Randomly scheduled tests may occur any day, even while traveling and on Saturdays

Urine, PEth (blood), hair and nail

Testing Frequency & Panels

Based on diagnosis, severity, history, work environment, compliance AND guideline

Set by Medical Director with input

Minimums:

- Year 1- 36 tests
- Year 2 – 24 tests
- Years 3+ – 18 tests

Increase due to dilutes, concerns, missed tests, etc

uprisehealth

16

Monitoring Requirements

Workplace Monitoring

Onsite monitoring for safe practice

Signed contract

Monthly workplace monitor safe practice reports

Immediate notification of concerns required

Uprise Health:

- Identifies, interviews, and trains workplace monitor
- Outreach to workplace monitor
- Consultation

Medication Management

Prescriptions sent to Uprise Health

Reviewed by agreement monitor and medical director

Watch for addictive-nature of prescribed substances

Watch for doctor shopping

Coordination with toxicology

uprisehealth

17

Monitoring Requirements

Treatment Component:

Aftercare

Individual Counseling

Self Help

Medication Management

Determined by Third Party Evaluator

Board Requirements:

Some HPSP requirements will differ between boards

Monitoring Agreement will include any individual requirement from current board orders or board recommendations

uprisehealth

18

Non-Compliance:

In the event of non-compliance with the monitoring requirements (including non-negative tests), an immediate report is provided to the Board.

uprisehealth

19

Non-Compliance

Statutory outlined in ORS 676.185

Engaged in criminal behavior;

Engaged in conduct that caused injury, death or harm to the public, including engaging in sexual impropriety with a patient;

Was impaired in a health care setting in the course of the licensee's employment;

Received a positive toxicology test result as determined by federal regulations pertaining to drug testing;

Violated a restriction on the licensee's practice imposed by the program or the licensee's board;

Civil commitment for mental illness;

Entered into a diversion agreement, but failed to participate in the program;

Was referred to the program but failed to enroll in the program;

uprisehealth

20

Positive Toxicology

Confirmed by Medical Review Officer (MRO)

AM completes Non-Compliance Report to Board

AM informs Licensee and Worksite Monitor of test result and asks for immediate step down from practice

AM identifies and shares options for third party evaluator with licensee

- With ROI in place, AM discusses referral with evaluator and completes referral packet
- After evaluation is complete, AM confirms return to work, toxicology, and treatment recommendations
- New Monitoring Agreement is created

Goal to return licensee to work as soon as clinically indicated

uprisehealth

21

HPSP Outcomes (Program-Wide)

1065 – Total Enrolled (7/1/10 - 12/31/21)

68% = successfully completed or on track to complete (12/31/21)

83% of completers = no positive toxicology (11/10/20)

- ATD: unique position to identify early signs of relapse due to close monitoring

87% of participants = satisfied with the program (2017-2021 bi-annual surveys)

84% of completers = HPSP improved personal life (2018-2021 annual survey reports)

78% of completers = HPSP improved professional life (2018-2021 annual survey reports)

2020 Audit:

- "Uprise Health met most contractual requirements, generally met required minimal success rate standards, and submitted to the Boards invoices & reports that were accurate and supported by substantiating documentation."
- "[Uprise Health] employed sound controls over licensee monitoring."

uprisehealth

22

HPSP Outcomes - Public Safety

HPSP Workplace Monitors surveyed (Jan 2020– July 2021):

- 98%: "satisfied" or "very satisfied" with Uprise Health's support of their supervision of their licensees
- 99%: Uprise Health ensures safety in the workplace
  - 84%: Uprise Health does an "excellent" or "above average" job of ensuring safety

uprisehealth

23

Thank You!

HPPSP Program Manager — **Kate Manelis, LMSW**
Monitoring Dept. Director — **Lori Govar, MSW, MBA**
Medical Director — **Dr. Robbie Bahl, MD**
Consulting Psychiatrist — **Dr. Joe Autry, MD**

Phone 888.802.2843
Website https://www.hpspmonitoring.com

uprisehealth

24

Sampling of Participant Testimonials

"I want to thank [Uprise Health] and its program for the **stability they have provided** me over the past 4 years. I often share this when I chair AA meetings; I was so broken and afraid when I started this monitoring program. Although monitoring is not enough to keep me sober, it is what I credit with keeping me in AA long enough to integrate it into my life, and that IS what keeps me sober. I am grateful for where I am today, and where life will take me next. I truly consider myself one of the lucky ones."

"In reflecting on the monitoring process I find that instead of feeling ashamed, I feel **empowered**. Every morning when I check to see if I need to test I **embrace the daily reminder** that I am putting my sobriety first, for myself and for my profession. Working in healthcare I made a pledge to protect the public and **with monitoring, I have a paper trail to prove I am standing by that promise."**

"I am so **grateful** for this program. **It gave me a second chance**. I now appreciate other people more, see what I needed in my life and I wouldn't be where I am if I wasn't in the monitoring program. I believe I would have spiraled down and lost my job, family and support system."

uprisehealth

25

Uprise Health Monitoring

- State Licensed Professional Programs
  - Oregon's Health Professionals' Services Program (HPSP)
  - Delaware Professional Monitoring Program (DPHMP)
- Hospital Programs:
  - Christiana Care Monitoring Program
- Extended Monitoring
- Oregon State Lawyers Assistance Committee (SLAC)

uprisehealth

26

Safe Pharmacy Practice statement for licensees

Boards of pharmacy around the US have issued statements to their licensees and registrants on the importance of sufficient staffing of pharmacies for safe delivery of pharmacy services during these challenging times.

The Washington Pharmacy Quality Assurance Commission issued such a statement that we took inspiration from to draft a statement to Oregon Board of Pharmacy licensees and registrants. With the board's consent, staff would like to issue the following statement to licensees and drug outlets:

Providing safe pharmacy practice conditions during the COVID-19 pandemic

The Oregon Board of Pharmacy recognizes the hard work and perseverance of pharmacy personnel in all practice settings who have provided essential care to the residents of Oregon during the COVID-19 pandemic. The board also recognizes that pharmacists, technicians and interns have been challenged by an increase in work demand, a decrease in available staffing and more frequent lapses in civility. In community pharmacy settings, this has adversely impacted pharmacy operating hours, wait times for prescriptions, and opportunities for pharmacists to address their patients' medication-related questions or concerns. The board continues to receive a high number of complaints from licensees and the public about these conditions.

Sufficient staffing of pharmacies is a critical component of protecting public health and safety. The board is updating rules to facilitate communication with the public about hours of pharmacy operation, to remove barriers to Pharmacy Technician licensure, and to allow alternative methods of prescription dispensing with Remote Dispensing Site Pharmacies and Pharmacy Prescription Lockers. The board as also convened a workgroup of Oregon licensed pharmacists, technicians and members of the public to solicit feedback on current practice conditions and make recommendations on rule changes.

Pharmacies are encouraged to employ strategies to provide sufficient staffing to assure that the public can receive their medications, vaccinations, counseling, and other patient care services in a safe and timely manner.

February, 2022

Activity Report

Report Date: February 8, 2022

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
HB 4024 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	2/1/2022 - Referred to Business and Labor. 2/1/2022 - First reading. Referred to Speaker's desk.	
Allows private entity to swipe driver license or identification card to submit information to electronic system for purpose of transferring drug containing pseudoephedrine.				
HB 4025 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	2/1/2022 - Referred to Health Care. 2/1/2022 - First reading. Referred to Speaker's desk.	
Allows pharmacy intern to transfer drug containing pseudoephedrine subject to requirements that apply to transfer by pharmacist and pharmacy technician.				
HB 4034 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	2/11/2022 - Work Session scheduled. 2/9/2022 - Public Hearing scheduled. 2/1/2022 - Referred to Health Care.	3:15 PM 02/09/2022 House Committee Health Care Public Hearing Remote D
Deletes requirement that coordinated care organization collect specified data from members and submit data to Oregon Health Authority.				
HB 4081 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	2/11/2022 - Work Session scheduled. 2/4/2022 - Public Hearing held. 2/1/2022 - Referred to Health Care.	8:00 AM 02/11/2022 House Committee Health Care Work Session Remote D
Requires pharmacist who dispenses opioid prescription to offer prescription for naloxone, or similar drug, and information about naloxone under specified circumstances.				
HB 4096 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	2/11/2022 - Work Session scheduled. 2/9/2022 - Public Hearing scheduled. 2/1/2022 - Referred to Health Care.	3:15 PM 02/09/2022 House Committee Health Care Public Hearing Remote D
Authorizes health care practitioner authorized in another state or United States territory to practice in this state without compensation for specified number of days without obtaining licensure in this state.				
HB 4135 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	2/3/2022 - Public Hearing held. 2/1/2022 - Referred to Judiciary. 2/1/2022 - First reading. Referred to Speaker's desk.	
Provides that "attempted transfer," for purposes of Uniform Controlled Substances Act, includes possession of controlled substance with intent to transfer to another person.				

Activity Report

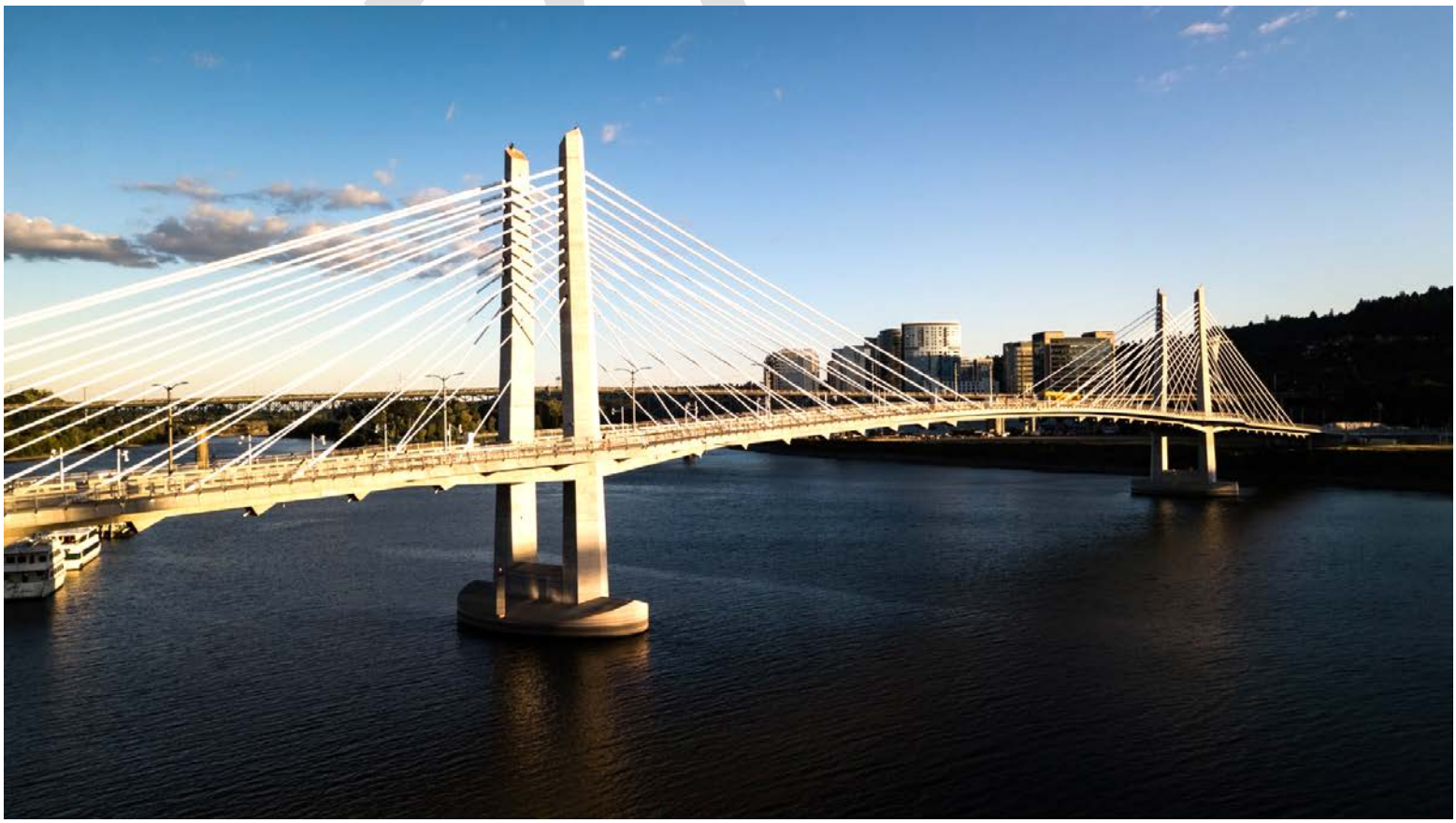
Report Date: February 8, 2022

Bill #	Agency / Position	Agency / Priority	Last Three Actions	Next Hearing
HB 4140 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	2/10/2022 - Public Hearing scheduled. 2/1/2022 - Referred to Rules. 2/1/2022 - First reading. Referred to Speaker's desk.	8:00 AM 02/10/2022 House Committee Rules Public Hearing Remote C
Expands duties of Oregon Government Ethics Commission to conduct investigations, make findings and impose penalties for violations of public meetings law.				
SB 1512 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	2/7/2022 - Public Hearing held. 2/1/2022 - Referred to Judiciary and Ballot Measure 110 Implementation. 2/1/2022 - Introduction and first reading. Referred to President's desk.	8:00 AM 02/08/2022 Senate Committee Judiciary and Ballot Measure 110 Implementation Work Session Remote B
Specifies conditions under which licensing board, commission or agency may suspend or deny occupational or professional license on basis of applicant's or licensee's criminal history, moral character or similar qualification.				
SB 1517 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	2/10/2022 - Public Hearing Scheduled. 2/3/2022 - Informational Meeting held. 2/1/2022 - Referred to Veterans and Emergency Preparedness.	3:15 PM 02/10/2022 Senate Committee Veterans and Emergency Preparedness Public Hearing Remote B
Requires that declarations and extensions of states of emergency under certain statutes be accompanied by written explanations.				
SB 1529 INTRO	Oregon Board of Pharmacy: Watch	Oregon Board of Pharmacy: 1	2/9/2022 - Work Session scheduled. 2/7/2022 - Public Hearing held. 2/1/2022 - Referred to Health Care.	1:00 PM 02/09/2022 Senate Committee Health Care Work Session Remote A
Authorizes pharmacy or pharmacy technician to swipe identification card or driver license of purchaser of pseudoephedrine or ephedrine.				

FEBRUARY 2022/F

Oregon Board of Pharmacy

Strategic Plan 2022-2026



THIS PAGE INTENTIONALLY LEFT BLANK

CONTENTS

INTRODUCTION

On behalf of the Board members and staff of the Oregon State Board of Pharmacy, I am pleased to present the Board's Strategic Plan for 2022-2026. The purpose of this plan is to outline the direction and priorities which have been established by the Board and which will ensure that pharmacy practice is regulated in the interest of public health and safety, result in exceptional service to our licensees and registrants, and advance the health of Oregonians.

Over the past two years, the board and staff have been working to implement the 2020-2024 Strategic Plan that was adopted in early 2020. Little did we know at that time, a global pandemic was beginning that would present extraordinary challenges to the public and the profession and would change pharmacy practice in significant ways. In addition, 2020 brought devastating wildfires to several areas in Oregon that further impacted the public and profession. Pharmacists, interns and pharmacy technicians throughout the state have been asked to go above and beyond their already demanding roles to provide vaccinations, testing, and prescription services. The board and staff are extremely appreciative of the extraordinary professionalism and selflessness of pharmacists and technicians in serving the needs of Oregonians during the ongoing pandemic.

We would like to acknowledge the input of stakeholders who share their views on priorities for pharmacy regulation that allows pharmacists, pharmacy technicians and drug outlets to provide the best possible care to all Oregonians. The practice of pharmacy and pharmaceutical supply chain have continued to undergo profound change due to technological advances, changes in healthcare delivery, increasing complexity in the supply chain, fragmentation of care, remote practice, social and political shifts, drug shortages, health disparities, access issues, opioid abuse, compounding and medication safety, natural disasters, and a variety of political and economic forces. We are committed to continuing to assure that pharmacy services are provided in a way that prevents healthcare disparities and to continue our affirmative action, diversity, equity and inclusion efforts in recruitment and retention of Board and Committee members and staff.

The five strategic goal areas outlined in this Strategic Plan will continue to guide the work of the Board and staff to create the regulatory structure necessary to incorporate and encourage the best pharmacy practices to ensure public health and safety. This plan will be reviewed and updated annually to assess progress and to encourage safe and equitable delivery of pharmacy services. The five strategic goal areas include:

- **Technicians**
- **Technology**
- **Licensing and Registration**
- **Regulation**
- **Communication**

As we begin to implement these initiatives, we encourage continued active engagement with the Board and participation in Board Meetings, Committee Meetings, Rules Hearings, and other Board activities.

Joe Schnabel, Pharm.D., R.Ph.
Executive Director

OUR PURPOSE

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

Values

These values reflect both how our Board and staff strive to conduct ourselves, and the behaviors we seek to instill across the practice of pharmacy in Oregon.

Integrity

We meet commitments to public health & safety and are accountable for our words and actions

Includes …

- Honesty
- Ethics
- Respect

Quality

We strive to deliver a consistent standard of excellence

Includes …

- Excellence
- Value
- Worth

Safety

We are committed to protecting the health, safety and welfare of the public

Includes …

- Protection
- Security
- Care

Accountability

We accept responsibility for our actions, products, decisions and policies

Includes …

- Trust
- Responsibility
- Transparency

Professionalism

We are committed to promoting excellence in pharmacy practice

Includes …

- Expertise
- Commitment
- Competence

PHARMACY STRATEGIC LANDSCAPE

Transformation of healthcare, pharmacy practice and society has occurred since early 2020 due to the COVID-19 pandemic. This will likely be a profoundly pivotal event in each of our lives and will have far-reaching consequences on the delivery healthcare, pharmacy practice, and our way of life.

A variety of changes in how pharmacy services are delivered is impacting the Board's regulatory activities, daily work and strategic priorities. Many of these changes offer potential benefits to the public, the pharmacy profession and health care while others pose clear risks. All, however, require careful monitoring and response from the Board to ensure public safety is maintained and that licensing, regulation, enforcement and outreach efforts reflect the evolving landscape.

Some of the issues facing the Board of Pharmacy include:

Access and distribution: The COVID-19 pandemic has demonstrated the value of pharmacists, pharmacy interns, and pharmacy technicians as the most accessible healthcare professionals able to deliver essential services, such as vaccinations, testing, and therapeutics.

Economic and social impacts: The economics of pharmacy along with pharmacists and pharmacy technicians leaving the profession has resulted in challenges for the public seeking pharmacy services. Pharmacies have been closing and staff have been resigning in numbers that are impacting access to pharmacy services, particularly in rural Oregon.

Regulatory trends: The move to remote practice and telework has impacted pharmacy service models and regulation. Improvements in technology and the need to assure equitable access to pharmacy services for all Oregonians has necessitated new regulatory approaches. The Board supports such rule changes when they result in improved access, efficiency, and protection of the public health, safety and welfare.

STRATEGIC PRIORITIES

At its Strategic Planning meeting in November 2021, the Board, Executive Director and the staff leadership team identified and evaluated a wide range of trends and challenges facing the practice of pharmacy and our agency. This process and deliberation led to agreement that the five critical Strategic Areas of focus identified in 2019 will remain the same for the 2022-2026 period and upon which the board's attention and resources will be focused.

TECHNICIANS

Goal: *Articulate the regulatory structure where the accountabilities of pharmacists and the role of pharmacy technicians are aligned to enhance safety, access, service and efficiency*

TECHNOLOGY

Goal: *Articulate the regulatory structure where the accountabilities of pharmacists and the use of technology are aligned to enhance safety, access, service and efficiency*

LICENSING and REGISTRATION

Goal: *Clarify licensing and registration categories to promote appropriate professional licensure and drug outlet registration*

REGULATION

Goal: *Systematically refresh rules and standardize the rule development approach to improve clarity and compliance*

COMMUNICATION

Goal: *Improve and maintain stakeholder and public engagement through proactive communication strategies*

The Board indicated that meaningful progress has been made in each goal area and additional work remains to be completed over the next two to four years. We will regularly assess progress and refine our goals and resource commitments as we work to achieve these key objectives.

TECHNICIANS

Goal: Articulate the regulatory structure where the accountabilities of pharmacists and the role of pharmacy technicians are aligned to enhance safety, access, service and efficiency

The Board seeks to develop clear rules to ensure that pharmacists understand their legal scope of practice and their accountability to provide patient care services and safe pharmacy practices. Permitting pharmacists to more fully and effectively utilize technician support must be structured to improve safety, access and patient care services.

The Board seeks rule alignment to clearly describe the role of pharmacy technicians and how they assist the pharmacist in the practice of pharmacy. Regulatory structures developed for technician roles should delineate requirements for training, quality assurance, and pharmacist supervision.

Key Actions:

1. Revise rules to make Pharmacy Technician (PT) license renewable indefinitely and remove five-year waiting period for reapplication of lapsed PT licenses. (June 2022)
2. Review technician licensing and training rules to remove barriers to licensure for those wishing to become licensed and renew their license.
3. Evaluate the impact of a single, renewable pharmacy technician license.
4. Evaluate role of national certification as a requirement for licensure and assess those pharmacy technician functions in the assistance of the practice of pharmacy for which national certification would enhance public health and safety.
5. Review and assess applicable statutes for the development of rules that clearly articulate the responsibilities of a pharmacist and functions that only a pharmacist may perform.

Outcome Conditions:

- Adoption of revised rules for pharmacy technician licensure.
- Adoption of revised rules for pharmacy technician training.
- Adoption of revised rules for pharmacist supervision, direction and control of pharmacy technicians
- Evaluation and board decision on the role of national certification in the licensing process.
- Enhanced capacity for pharmacist provision of patient care services while maintaining safety in dispensing services.

TECHNOLOGY

Goal: Articulate the regulatory structure where the accountabilities of pharmacists and the use of technology are aligned to enhance safety, access, service and efficiency

The Board seeks to develop clear rules to ensure that pharmacists understand their scope of practice and their accountability to provide patient care services and safe pharmacy practices while permitting the use of technologies that improve safety, access, service and efficiency. Regulatory structures developed for use of technology should be function-based and delineate pharmacist and drug outlet accountabilities for each critical stage of automated processes.

Key Actions:

1. Implement Remote Dispensing Site Pharmacy (RDSP) rules and amend them as more is learned from experiences of pharmacists, Certified Oregon Pharmacy Technicians, and the public about their effectiveness at maintaining public health and safety while improving access to pharmacy services.
2. Draft and adopt rules for Pharmacy Prescription Lockers (PPL). Amend the PPL rules as more is learned from experiences of pharmacists, technicians, and the public about their effectiveness at maintaining public health and safety while improving access to medications and supplies.
3. Draft and adopt rules for kiosks. Amend the kiosk rules as more is learned from experiences of pharmacists, technicians, and the public about their effectiveness at maintaining public health and safety while improving access to medications and supplies.
4. Amend Remote Dispensing Machine (RDM) and Remote Distribution Facility (RDF) rules to align with RDSP and PPL rules.

Outcome Conditions:

- Number of RDSPs registered in Oregon each year.
- Compliance cases involving RDSPs and their affiliated pharmacies.
- Number of PPLs registered in Oregon each year.
- Compliance cases involving PPLs and their affiliated pharmacies.
- Draft rules for Board consideration that clearly delineate the use of new technology and pharmacist accountabilities in the practice of pharmacy.
- Defined accountabilities for each critical step in automated processes.
- Enhanced capacity for pharmacist provision of patient care services while maintaining safety in dispensing services.
- Effective quality assurance plan applied to all automated pharmacy processes.

LICENSING and REGISTRATION

Goal: Clarify licensing and registration categories to promote appropriate professional licensure and drug outlet registration

The Board promotes patient safety through appropriate licensing and registration of all licensees and drug outlets engaged in the practice of pharmacy or assistance in the practice of pharmacy and in the manufacture, dispensing, delivery or distribution of drugs, devices and supplies. License and registration categories should clearly guide applicants to the appropriate license type.

Key Actions:

1. Review technician licensing and training rules to remove barriers to licensure for those wishing to become licensed and renew their license.
2. Create and implement a consistent, ongoing process to evaluate applicable statutes for each drug outlet registration type and develop rules that clearly outline the appropriate registration type for each outlet.
3. Evaluate legislative and budgetary considerations that may be required to implement changes to drug outlet registration types.

Outcome Conditions:

- Draft rules for Board consideration that clarify the appropriate registration type for each drug outlet.
- Decrease in questions from applicants regarding appropriate registration type for which to apply.

REGULATION

Goal: Systematically refresh rules and standardize rule development to improve clarity and longevity

The Board proactively reviews and updates rules to provide clear expectations to licensees and registrants to promote compliance and patient safety. Rule updates should emphasize clarity and longevity that allows practice variation that improves safety, access, service and efficiency.

Key Actions:

1. Identify and complete process for submitting a legislative concept for board to compel licensees to undergo substance use disorder evaluation for compliance cases involving substance use (June 2023).
2. Update Continuing Pharmacy Education rules to create clear expectations that guide licensees in professional development that improves their ability to safely engage in contemporary pharmacy practice (June 2022).
3. Evaluate current state of pharmacy practice in Oregon and convene Safe Pharmacy Practice Conditions workgroup to develop rules to assure that clearly outline requirements for safe pharmacy practice in all pharmacy settings (December 2023).
4. Create standard procedures and schedule to accomplish five-year rule review that emphasizes clarity and durability.
5. Conduct routine, scheduled, and systematic review of Board of Pharmacy rules by Division and draft revisions for Board consideration.

Outcome Conditions:

- Legislative concept submitted for substance use disorder evaluations for 2023 legislative session.
- Improved compliance rate with Continuing Education audits and reduce resources used to conduct such audits.
- Improved safe pharmacy practice conditions in all pharmacy settings and reduced licensee and public complaints regarding pharmacy practice conditions and services.
- At least four divisions are reviewed, updated and presented to Board for consideration annually.

COMMUNICATION

Goal: Improve and maintain stakeholder and public engagement through proactive communication strategies

The Board communicates through multiple platforms to collaborate, educate, promote patient safety and enhance consumer protection.

Key Actions:

1. Execute the agency's communication plan at all levels to improve access to relevant information and encourage stakeholder engagement.
2. Utilize public records request process to respond to inquiries for agency records and provide training to agency staff to respond in compliance to state law.
3. Continue regular outreach to stakeholder groups, including schools and colleges of pharmacy, pharmacy associations, and the public.
4. Utilize analytics from agency website and listserv platform to improve agency communications.

Outcome Conditions:

- Modern materials for agency communications, including branding and plain language used for presentations and other public documents.
- Agency website updated and maintained to provide current information and focused content, including forms and reference documents.

Oregon Board of Pharmacy

Budget Report: November 2021 (Month 5)

Revenue:

Through November, revenue is $1,992,989 (5.2%) **over** budget

Expenditures:

Through November, **total expenditures** are $1,184,502 (16%) **under** budget

Personal services are $1,292,764 (4.3%) **under** budget

Services and Supplies are $531.738 (16.3) **under** budget

Special Payments are $0 (100%) **under** budget

Revenues less Expenditures: $168,487

Cash Balance:

Cash balance through November is $4,342,407 which represents (11.01) months of operating expense)

Note: This the above is a snap-shot of the biennium to date through November 2021. It does not include projections for the remainder of the biennium.

End of biennium projected cash balance is $6,468,638, which represents (17.25) months of operating expense*)

Cash balance target is $2,250,133, (6.0 months of operating expense)

*Note: The end of biennium projected cash balance is calculated based on the biennium to date plus the remaining months projections for 2021-23.

Oregon Board of Pharmacy
Total All Funds - LAB 2021-2023

Actuals through NOVEMBER 2021

		LAB	ACTUAL+PROJ	VARIANCE
	BEGINNING CASH BALANCE	**3,679,852**	**4,714,145**	**0.00**
REVENUE				
50	GENERAL FUND			
205	OTHER BUSINESS LICENSES	8,716,500.00	10,418,391.75	(1,701,891.75)
210	OTHER NONBUSINESS LICENSES AND FEES	192,995.00	275,550.75	(82,555.75)
505	FINES AND FORFEITS	410,000.00	388,254.66	21,745.34
605	INTEREST AND INVESTMENTS	131,250.00	58,081.03	73,168.97
975	OTHER REVENUE	84,335.00	57,864.45	26,470.55
	TOTAL REVENUE	**9,535,080.00**	**11,198,142.64**	**(1,663,062.64)**
TRANSFERS				
1107	TRANSFER IN FROM DAS	-	-	-
	TOTAL TRANSFER IN	**0.00**	**0.00**	**0.00**
2010	TRANSFER OUT TO OTHER FUNDS	-	-	-
2443	TRANSFER OUT TO OREGON HEALTH AUTHORITY	443,120.00	443,120.00	-
	TOTAL TRANSFER OUT	**443,120.00**	**443,120.00**	**0.00**
PERSONAL SERVICES				
3110	CLASS/UNCLASS SALARY & PER DIEM	4,092,836.00	4,143,841.02	(51,005.02)
3160	TEMPORARY APPOINTMENTS	27,306.00	-	27,306.00
3170	OVERTIME PAYMENTS	-	562.89	(562.89)
3180	SHIFT DIFFERENTIAL	-	-	-
3190	ALL OTHER DIFFERENTIAL	198,616.00	251,647.75	(53,031.75)
3210	ERB ASSESSMENT	1,276.00	1,262.40	13.60
3220	PUBLIC EMPLOYES' RETIREMENT SYSTEM	728,465.00	777,208.83	(48,743.83)
3221	PENSION BOND CONTRIBUTION	246,725.00	240,905.75	5,819.25
3230	SOCIAL SECURITY TAX	319,688.00	293,650.78	26,037.22
3240	UNEMPLOYMENT ASSESSMENT	-	-	-
3250	WORKERS' COMPENSATION ASSESSMENT	1,012.00	997.66	14.34
3260	MASS TRANSIT	25,912.00	26,146.75	(234.75)
3270	FLEXIBLE BENEFITS	841,104.00	776,125.15	64,978.85
3435	Personal Services Budget Adj.	-	-	-
	TOTAL PERSONAL SERVICES	**6,482,940.00**	**6,512,349.00**	**(29,409.00)**
SERVICES AND SUPPLIES				
4100	INSTATE TRAVEL	115,894.00	16,273.51	99,620.49
4125	OUT-OF-STATE TRAVEL	17,024.00	1,032.87	15,991.13
4150	EMPLOYEE TRAINING	22,320.00	13,624.45	8,695.55
4175	OFFICE EXPENSES	134,566.00	70,630.99	63,935.01
4200	TELECOMM/TECH SVC AND SUPPLIES	50,930.00	60,672.28	(9,742.28)
4225	STATE GOVERNMENT SERVICE CHARGES	202,541.00	202,541.00	-
4250	DATA PROCESSING	318,678.00	371,547.42	(52,869.42)
4275	PUBLICITY & PUBLICATIONS	43,329.00	14,717.97	28,611.03
4300	PROFESSIONAL SERVICES	339,713.00	221,024.28	118,688.72
4315	IT PROFESSIONAL SERVICES	134,467.00	48,000.00	86,467.00
4325	ATTORNEY GENERAL LEGAL FEES	621,835.00	561,829.68	60,005.32
4375	EMPLOYEE RECRUITMENT AND DEVELOPMENT	681.00	-	681.00
4400	DUES AND SUBSCRIPTIONS	5,418.00	4,060.00	1,358.00
4425	FACILITIES RENT & TAXES	229,042.00	281,866.27	(52,824.27)
4475	FACILITIES MAINTENANCE	55.00	-	55.00
4525	MEDICAL SUPPLIES AND SERVICES	1,202.00	1,000.00	202.00
4575	AGENCY PROGRAM RELATED SVCS & SUPP	250,479.00	190,263.70	60,215.30
4650	OTHER SERVICES AND SUPPLIES	411,285.00	394,043.06	17,241.94
4700	EXPENDABLE PROPERTY $250-$5000	14,108.00	10,000.00	4,108.00
4715	IT EXPENDABLE PROPERTY	45,228.00	25,053.77	20,174.23
	TOTAL SERVICES & SUPPLIES	**2,958,795.00**	**2,488,181.25**	**470,613.75**
Capital Outlay				
5600	DATA PROCESSING HARDWARE	8,981.00	-	8,981.00
5900	OTHER CAPITAL OUTLAY	-	-	-
	Total Capital Outlay	**8,981.00**	**0.00**	**8,981.00**
Special Payments				
6085	OTHER SPECIAL PAYMENTS	12,982.00	-	12,982.00
	Total Special Payments	**12,982.00**	**0.00**	**12,982.00**
	TOTAL EXPENDITURES	**9,463,698.00**	**9,000,530.25**	**463,167.75**
	PROJECTED BIENNIAL ENDING CASH BALANCE	**3,308,114**	**6,468,638**	
	End of biennium projected cash balance in months		17.25	
	Cash balance target of 6.0 months (working capital)		2,250,133	