Oregon Board of Pharmacy BOARD MEETING AGENDA

Meeting Location: Conference Call February 10-11, 2021

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

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

Wednesday, February 10, 2021 @ 8:30AM Thursday, February 11, 2021 @ 8:30AM

Due to the COVID-19 <u>State of Emergency</u> and Governor Brown's <u>Executive Order 20-67</u>, the Board will meet via teleconference and the public may attend by phone.

- All Board meetings except Executive Session are open to the public. Pursuant to ORS 192.660, Executive Sessions are closed, with the exception of news media and public officials.
- No final actions will be taken in Executive Session.
- When action is necessary, the Board will return to Open Session.
- * To sign up for Public Comment, email your request to <u>Karen MacLean</u> by 12:00PM on 2/11/2021.

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

WEDNESDAY, February 10, 2021

- I. OPEN SESSION, Shannon Beaman 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).
 - a. Deliberation on Disciplinary Cases and Investigations
 - b. Legal Advice pursuant to ORS 192.660(2)(f)
- III. Contested Case Deliberation pursuant to ORS 192.690(1) Not open to the public
- IV. EXECUTIVE SESSION NOT OPEN TO THE PUBLIC, pursuant to ORS 192.660(2)(i) for Employee Performance Review.
- V. OPEN SESSION PUBLIC MAY ATTEND At the conclusion of Executive Session, the Board may convene Open Session to review scheduled agenda items as time permits.

Adjourn Action Necessary

THURSDAY, February 11, 2021

- VI. OPEN SESSION, Shannon Beaman RPh, Presiding
 - a. Roll Call
- VII. EXECUTIVE SESSION NOT OPEN TO THE PUBLIC, pursuant to ORS 676.165, ORS 676.175, ORS 192.660 (1)(2)(f)(L).
 - a. Deliberation on Disciplinary Cases and Investigations
 - b. Legal Advice pursuant to ORS 192.660(2)(f)
- VIII. OPEN SESSION PUBLIC MAY ATTEND
 - a. Motions related to Disciplinary Actions Efremoff

Action Necessary

- IX. GENERAL ADMINISTRATION
 - a. Rules
 - i. Review Rulemaking Hearing Report & Comments none
 - ii. Consider Adoption of Rules none
 - iii. Consider Adoption of Temporary Rules
 - 1. Division 110 Fees Melvin #A

Action Necessary

- iv. Rulemaking Policy Discussion Items Davis
 - 1. Division 019, 021, 025, 031- Cultural Competency CE **#A1**
 - 2. Division 041, 043, 044- LEP (Informational insert) #A2
 - 3. Division 041- Drug Take-back #A3
 - 4. Division 050, 006 Restriction on Retail Sales #A4
- b. Public Health and Pharmacy Formulary Advisory Committee none

Lunch 45-minutes

- c. Discussion Items:
 - i. COVID-19 Update Schnabel
 - ii. Strategic Planning Update Schnabel
 - 1. 2020-2024 Plan Updates
 - Technicians
 - Technology
 - Licensing
 - Regulation
 - Communication
- **X. ISSUES AND ACTIVITIES*** (*Items in this section may occur anytime during the meeting as time allows*)
 - i. Reports:
 - 1. Board President/Members
 - 2. Executive Director
 - 3. Compliance Director
 - 4. Administrative Director
 - 5. Licensing Manager

Agenda – February 10-11, 2021

- 6. Operations Policy Analyst
- 7. Office Manager
- ii. Financial/Budget Report MacLean
 - 1. Financial Update #C-C1
- iii. Legislative Updates *Schnabel*
- iv. Board Meeting Dates

•	April 7-8, 2021	Portland
•	June 9-10, 2021	Portland
•	August 11-13, 2021*	Portland
•	October 13-14, 2021	Portland
•	November 17-18, 2021	Portland (Strategic Planning) date change
•	December 8-9, 2021	Portland

2022 Board Meeting Dates

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

^{*}Note: 3-day meeting

v. Rulemaking Hearing Dates

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

- May 26, 2021
- November 23, 2021
- May 24, 2022
- November 22, 2022
- vi. Conferences/Meetings Schnabel

PAST MEETINGS

1. NABP Interactive Member Forum (virtual) – January 27, 2021

FUTURE MEETINGS

- 1. OSPA Mid-Winter Seminar (virtual) February 20-21, 2021
- 2. OHSP Spring Seminar (virtual) April 29, 2021
- 3. 117th Annual NABP Meeting (virtual) May 13-14, 2021

XI. Approve Consent Agenda*

Action Necessary

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

- a. NAPLEX Scores none
- b. MPJE Scores none
- c. License/Registration Ratification December 9, 2020 February 1, 2021 # CONSENT 1
- d. Pharmacy Technician Extensions July 6, 2020 December 31, 2020 # CONSENT 2
- e. Board Meeting Minutes December 16-17, 2020 # CONSENT 3

PUBLIC COMMENT -

- There will be an opportunity for public comment
- The Board will not deliberate any issues or requests during Public Comment such as formal requests, issues currently under investigation or requests pending before the Board
- To sign-up to provide public comment, email Karen MacLean by 12:00PM on 2/11/2021

Adjourn Action Necessary

Division 110- Fees

The upgraded MyLicense Office / eGov software that was implemented in October 2019, has created many efficiencies for licensees and registrants as well as staff. After evaluation of each renewal cycle it was determined that these efficiencies have eliminated the need for manual processing of each renewing license/registration, and reduced the time required to ensure timely renewal processing. It has been determined that the late fee dates can be amended to match the expiration date.

Need for Rules:

To align late fees for specific Oregon licensees and registrants to match the expiration date.

Fiscal Impact:

This rule amendment has a fiscal impact for specific Oregon licensees and registrants as well as the agency. This rule amendment could potentially result in a savings to licensees and registrants. The agency anticipates a potential revenue reduction of approximately \$90,000-\$95,000 biennially due to a decrease in late fees paid by licensees and registrants.

Rules Summary:

Upgrading the agency licensing software eliminated the need for manual processing of license/registration renewals. The late fees for specific license/registration types can be amended to match the expiration date.

Temporary Rule Justification:

Amendments need to take effect immediately in order to positively impact licensees and registrants for upcoming licensing renewal cycles that occur prior to the next rulemaking hearing. Delaying implementation would negatively impact costs to licensees/registrants.

DIVISION 110 FEES

1 **855-110-0005**

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2 Licensing Fees

- (1) Pharmacist license examination (NAPLEX) and re-examination fee \$50.
- 5 (2) Pharmacist jurisprudence (MPJE) re-examination fee \$25.
 - (3) Pharmacist licensing by reciprocity fee \$250.
 - (4) Pharmacist licensing by score transfer fee \$250.
 - (5) Intern license fee. Expires November 30 every two years \$100.
- 1213 (6) Pharmacist:

15 (a) Biennial license fee. Expires June 30 each odd numbered year. The biennial license fee is 16 – \$250. Delinquent **Late** renewal fee (postmarked received after May 31 **June 30**) — \$50.

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

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(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.)

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

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(8) Pharmacy Technician license fee — \$100.

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(9) Certified Oregon Pharmacy Technician:

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(a) Biennial license fee. Expires June 30 each even numbered year — \$100. Delinquent-Late renewal fee (postmarked received after May 31 June 30) — \$20.

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(b) Workforce Data Collection fee. Due by June 30 biennially — \$4. (This is a mandatory fee as 34 35 required by OAR 409-026-0130 that must be paid with the Certified Oregon Pharmacy 36 Technician license renewal fee.)

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- Statutory/Other Authority: ORS 689.205, **ORS** 291.055 & **ORS** 183.705 38
- Statutes/Other Implemented: ORS 689.135, ORS 431A.972.880 & ORS 676.410 39

- 40 855-110-0007
- 41 Fees for Registration, Renewal, and Reinspection of Drug Outlets

42 43 44 (1) Community Health Clinic. Expires March 31 annually — \$100. Delinquent Late renewal fee (postmarked received after February 28 March 31) — \$25.

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45 (2) Drug Distribution Agent. Expires September 30 annually — \$400. Delinquent Late renewal fee (postmarked received after August 31 September 30) — \$100. 46

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<u>Late</u> renewal fee (postmarked received after February 28 March 31) — \$75. (4) Manufacturers (including Manufacturer Class I, Manufacturer Class II and Manufacturer Class III). Expires September 30 annually — \$525. Delinquent Late renewal fee (postmarked

(3) Drug Room (including correctional facility). Expires March 31 annually — \$100. Delinquent

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received after August 31 September 30) — \$100. (5) Medical Device, Equipment & Gas Class C. Expires January 31 annually — \$75. Delinquent

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58 (6) Nonprescription Class A. Expires January 31 annually — \$75. Delinquent Late renewal fee 59 (postmarked-received after December January 31) — \$25.

<u>Late</u> renewal fee (postmarked received after December January 31) — \$25.

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61 (7) Nonprescription Class B. Expires January 31 annually — \$75. Delinquent-Late renewal fee 62 (postmarked after December January 31) — \$25.

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 64 (8) Nonprescription Class D. Expires January 31 annually \$100. Delinquent Late renewal fee (postmarked after December January 31) \$25.
 - (9) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer \$50. Expires December 31 annually.
 - (10) Re-inspection fee \$100. Applies to any re-inspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.
 - (11) Retail, Institutional, or Consulting/"Drugless" Pharmacy Drug Outlet. Expires March 31 annually \$225. Delinquent Late renewal fee (postmarked received after February 28 March 31) \$75.
 - (12) Wholesalers (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III). Expires September 30 annually \$525. Delinquent Late renewal fee (postmarked received after August 31 September 30) \$100.
 - (13) Remote Dispensing Machine or Remote Distribution Facility. Expires March 31 annually \$120. Due by February 28 March 31 annually.
 - (14) Charitable Pharmacy. Expires March 31 annually \$75. Delinquent <u>Late</u> renewal fee (postmarked received after February 28 March 31) \$25.
 - (15) Home Dialysis. Expires March 31 annually \$225. Delinquent Late renewal fee (postmarked received after February 28 March 31) \$75.
 - (16) Supervising Physician Dispensing Outlet. Expires March 31 annually \$175. Delinquent Late renewal fee (postmarked received after February 28 March 31) \$75.
 - (17) Dispensing Practitioner Drug Outlet. Expires March 31 annually \$100. Delinquent Late renewal fee (postmarked received after February 28 March 31) \$25.
 - Stat. Auth.: ORS 689.205 & ORS 291.055

 Stats. Implemented: ORS 689.135, **ORS** 689.774 & **ORS** 289.305

Revisions to Divisions 019, 021, 025 and 031 are provided to incorporate continuing education requirement directives set forth in 2019 HB 2011, related to cultural competency and CE chapter updates in alignment with the strategic plan.

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

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- 13 **855-019-0170**
- 14 Reinstatement of License
- 15 (1) A pharmacist who fails to renew their license by the deadline may reinstate their license as
- 16 follows:
- 17 (a) By payment of the license fees and delinquency fees for all years during which the license
- 18 was lapsed and for the current year; and
- 19 (b) By providing certification of completion of the continuing **pharmacy** education requirement
- 20 in OAR 855-021 for all years in which the license was lapsed; and
- 21 (c) If their license has been lapsed for more than one year, pass the MPJE with a score of not
- less than 75; and
- 23 (d) Complete an application for licensure, provide the board with a valid e-mail address, and a
- fingerprint card or other documentation required to conduct a criminal background check.
- 25 (2) A pharmacist in good standing who retired from the practice of pharmacy after having been
- licensed for not less than 20 years need only pay the annual license fees for the year in which
- 27 they seek a license, however they must provide certification of completion of continuing
- 28 **pharmacy** education **requirement in OAR 855-021** for all years since their retirement and
- 29 pass the MPJE with a score of not less than 75.
- 30 Statutory/Other Authority: ORS 689.205
- 31 Statutes/Other Implemented: ORS 689.151 & ORS 689.275

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33 **855-019-0205**

34 **Duty to Report**

- 35 (1) Failure to answer completely, accurately and honestly, all questions on the application form
- 36 for licensure or renewal of licensure is grounds for discipline.
- 37 (2) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony
- may result in denial of the application.
- 39 (3) A pharmacist must report to the **Bb**oard within 10 days if they:
- 40 (a) Are convicted of a misdemeanor or a felony; or
- 41 (b) If they are arrested for a felony.
- 42 (4) A pharmacist who has reasonable cause to believe that another licensee (of the **Bb**oard or
- any other Health Professional Regulatory Board) has engaged in prohibited or unprofessional
- conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the
- board responsible for the licensee who is believed to have engaged in the conduct. The
- reporting pharmacist shallmust report the conduct without undue delay, but in no event later
- 47 than 10 working days after the pharmacist learns of the conduct unless federal laws relating to
- 48 confidentiality or the protection of health information prohibit disclosure.
- 49 (5) A pharmacist who reports to a board in good faith as required by section (4) of this rule is
- 50 immune from civil liability for making the report.
- 51 (6) A pharmacist who has reasonable grounds to believe that any violation of these rules has
- occurred, must notify the **b**oard within 10 days. However, in the event of a significant drug loss
- or violation related to drug theft, the pharmacist shallmust notify the Bboard within one (1)
- 54 business day.
- 55 (7) A pharmacist must notify the **Bboard** in writing, within 15 days, of any change in e-mail
- address, employment location or residence address.
- 57 Statutory/Other Authority: ORS 689.205
- 58 Statutes/Other Implemented: **ORS** 689.151, **ORS** 689.155 & **ORS** 689.455
- 60 **855-019-0300**

- 61 Duties of a Pharmacist-in-Charge
- 62 (1) In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have
- one Pharmacist-in-Charge (PIC) employed on a regular basis.
- 64 (2) In order to be a PIC, a pharmacist must have:
- 65 (a) Completed at least one year of pharmacy practice; or
- 66 (b) Completed a **Bb**oard approved PIC training course either before the appointment or within
- 67 30 days after the appointment. With the approval of the **Bb**oard, this course may be employer
- 68 provided and may qualify for continuing education credit.
- 69 (3) A pharmacist may not be designated PIC of more than two pharmacies without prior written
- 70 approval by the **Bb**oard. If such approval is given, the pharmacist must comply with the
- 71 requirements in sub-section (4)(e) of this rule.

- 72 (4) The PIC must perform the following the duties and responsibilities:
- 73 (a) When a change of PIC occurs, both outgoing and incoming PICs must report the change to
- the **Bb**oard within 15 days of the occurrence, on a form provided by the **Bb**oard;
- 75 (b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within
- 76 15 days of becoming PIC;
- 77 (c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the
- 78 pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access
- 79 may be granted as specified in OAR 855-041-0120;
- 80 (d) In a hospital only, the PIC is responsible for providing education and training to the nurse
- supervisor who has been designated to have access to the pharmacy department in the
- 82 absence of a pharmacist;
- 83 (e) A pharmacist designated as PIC for more than one pharmacy shallmust personally conduct
- and document a quarterly compliance audit at each location. This audit shallmust be on the
- 85 Quarterly PIC Compliance Audit Form provided by the **Bb**oard;
- 86 (f) If a discrepancy is noted on a **Bb**oard inspection, the PIC must submit a plan of correction
- within 30 days of receiving notice.
- 88 (g) The records and forms required by this section must be filed in the pharmacy, made
- available to the **Bb**oard for inspection upon request, and must be retained for three years.
- 90 (5) The PIC is responsible for ensuring that the following activities are correctly completed:
- 91 (a) An inventory of all controlled substances must be taken within 15 days before or after the
- 92 effective date of change of PIC, and must be dated and signed by the new PIC. This inventory
- 93 must be maintained in the pharmacy for three years and in accordance with all federal laws and
- 94 regulations;
- 95 (b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all
- 96 pharmacy personnel who are required to be licensed by the **Bb**oard;
- 97 (c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection
- Form provided by the **Bb**oard, by February 1 each year. The completed self-inspection forms
- 99 must be signed and dated by the PIC and maintained for three years from the date of
- 100 completion;
- (d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;
- 102 (e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.
- 103 (f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such
- training should include an annual review of the PIC Self-Inspection Report;
- 105 (g) Implementing a quality assurance plan for the pharmacy.
- 106 (h) The records and forms required by this section must be filed in the pharmacy, made
- available to the **B**board for inspection upon request, and must be retained for three years.

- 108 (6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in 109 compliance with all state and federal laws and rules governing the practice of pharmacy and 110 that all controlled substance records and inventories are maintained in accordance with all state 111 and federal laws and rules.
- Statutory/Other Authority: ORS 689.205
- 113 Statutes/Other Implemented: ORS 689.151 & **ORS** 689.155



Revisions to Divisions 019, 021, 025 and 031 are provided to incorporate continuing education requirement directives set forth in 2019 HB 2011, related to cultural competency and CE chapter updates in alignment with the strategic plan.

2019 HB 2011 requires specified health professional regulatory boards to require people authorized to practice the profession regulated by the board to complete cultural competency continuing education as a condition of renewal of the authorization to practice. Makes these continuing education requirements operative on July 1, 2021.

2019 HB 2011 requires continuing competency every other renewal. The Board, under its authority in ORS 689.285 and ORS 689.486, is requiring continuing competency CE every renewal, which will also satisfy the requirements of 2019 HB 2011.

Impacts: In Oregon, it is estimated that 8,787 pharmacists, 5,997 Certified Oregon Pharmacy Technicians, and 780 Interns will be impacted by these new requirements.

Documents relied upon include: OHA Cultural Competence Continuing Education (CCCE)

Related statutes:

ORS 676.850 Authority of regulatory boards to require cultural competency continuing education; documentation of participation; rules

ORS 413.450 Continuing education in cultural competency

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

- 1 Division 21
- 2 CONTINUING PHARMACY EDUCATION
- 3 **855-021-0001**
- 4 Definitions
- 5 (1) "Continuing Pharmacy Education" or "CPE" means classes of post graduate studies,
- 6 informal study group participation, institutes, seminars, lectures, conferences,
- 7 workshops, extension study, correspondence courses, teaching, planned and
- 8 professional meetings, self-study courses, cassette or audio visual tape/slides or
- 9 materials, and other self-instruction units applicable to the practice of pharmacy.
- 10 (2) "Contact hour" means fifty minutes of continuing pharmacy education.
- 11 (3) "Patient safety" means systems, procedures and processes that ensure that the
- 12 correct patient receives the correct drug in the correct dose and is counseled
- 13 appropriately.
- 14 (4) "Medication error prevention" means systems, procedures and processes to prevent
- and avoid adverse events and to ensure that the correct patient receives the correct drug
- 16 in the correct dose.

- 17 (5) "Pain management education program" means a specific one-hour web-based
- 18 program developed by the Oregon Pain Commission, in addition to six accredited hours
- of continuing education in pain management, end of life care or a combination of both.
- 20 (6) "Cultural competence" means the lifelong process of examining the values and
- 21 <u>beliefs and developing and applying an inclusive approach to health care practice in a</u>
- 22 <u>manner that recognizes the content and complexities of provider-patient communication</u>
- 23 and interaction and preserves the dignity of individuals, families, and communities.
- 24 (a) Cultural competence applies to all patients.
- 25 (b) Culturally competent providers do not make assumptions on the basis of an
- 26 <u>individual's actual or perceived abilities, disabilities or traits whether inherent, genetic or</u>
- 27 <u>developmental including: race, color, spiritual beliefs, creed, age, tribal affiliation,</u>
- 28 <u>national origin, immigration or refugee status, marital status, socio-economic status,</u>
- veteran's status, sexual orientation, gender identity, gender expression, gender
- 30 transition status, level of formal education, physical or mental disability, medical
- 31 condition or any consideration recognized under federal, state and local law.
- 32 Statutory/Other Authority: ORS 689.205, ORS 676.850
- 33 <u>Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450, ORS 413.590</u>

- 36 **855-021-0005**
- 37 Continuing Pharmacy Education Required for Pharmacist License Renewal
- 38 (1) During the period from July 1 through June 30 of each biennial license renewal cycle, each-a
- 39 pharmacist must have satisfactorily completed three (3) 30 hours of continuing pharmacy
- 40 education units (CEU's) in an approved continuing pharmacy education program prior to
- 41 submission of the license renewal. Ten contact hours equals 1 CEU. Fifty minutes equals 1
- 42 contact hour. These hours must include:
- 43 (a) Two hours of continuing pharmacy education in pharmacy law;
- 44 (b) Two hours of continuing pharmacy education in patient safety or medication error
- 45 **prevention**;
- 46 (c) Two hours of continuing pharmacy education in cultural competency either approved
- 47 by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and
- 48 (d) Twenty-four additional hours of continuing pharmacy education.
- 49 (2) Prior to the second license renewal, a pharmacist licensed under these rules must
- 50 complete seven hours of continuing education in pain management as detailed in the
- 51 following sub-sections.
- 52 (a) A one-hour pain management course, specific to Oregon, provided by the Pain
- 53 Management Commission of the Oregon Health Authority; and

- 54 **(b) A minimum of six hours of continuing education in pain management. This**
- 55 <u>requirement may be fulfilled by any combination of continuing education coursework</u>
- 56 focusing on pain management including but not limited to the treatment of terminally ill
- 57 <u>and dying patients, and those with chronic, non-malignant pain.</u>
- (c) The pain management continuing education required under this rule may count
- towards the required 30 continuing pharmacy education contact hours.
- 60 (3) Section (1) does not apply to pharmacists applying for the first renewal of their
- 61 <u>license, if they have not been licensed by the board for at least one year prior to July 1 of</u>
- 62 the renewal period.
- 63 (4) A pharmacist must retain documentation of completed continuing pharmacy
- 64 <u>education for six years and must provide this documentation if requested by the board.</u>
- 65 (5) Continuing pharmacy education credit accumulated in excess of the required 30
- 66 contact hours for biennial license renewal cannot be carried forward.
- 67 Statutory/Other Authority: ORS 689.205, **ORS 676.850**
- 68 Statutes/Other Implemented: ORS 689.285 ORS 413.450, ORS 413.590
- 70 **855-021-0007**

- 71 Continuing Pharmacy Education Required for Intern License Renewal
- 72 (1) During each license renewal cycle, an intern must have satisfactorily completed 2
- 73 contact hours of *approved continuing pharmacy education in cultural
- 74 competency either approved by the Oregon Health Authority under ORS 413.450 or any
- 75 <u>cultural competency CPE; and</u>
- 76 (2) An intern must retain documentation of completed continuing pharmacy
- 77 education for six years and must provide this documentation if requested by the board.
- 78 Statutory/Other Authority: ORS 689.205
- 79 Statutes/Other Implemented: ORS 689.285, ORS 676.850, ORS 413.450, ORS 689.151
- 81 **855-021-0009**
- 82 Continuing Pharmacy Education Required for Certified Oregon Pharmacy Technician
- 83 License Renewal
- 84 (1) During the period from July 1 through June 30 of each biennial license renewal cycle,
- 85 a Certified Oregon Pharmacy Technician must have satisfactorily completed 20 contact
- 86 hours of continuing pharmacy education. These hours must include:
- 87 (a) Two hours of continuing pharmacy education in pharmacy law;
- 88 **(b)** Two hours of continuing pharmacy education in patient safety or medication error
- 89 **prevention**;

- 90 (c) Two hours of continuing pharmacy education in cultural competency either approved
- 91 by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and
- 92 (d) Fourteen additional hours of continuing pharmacy education or documented onsite
- 93 training approved by the board.
- 94 (2) Section (1) does not apply to a Certified Oregon Pharmacy Technician applying for the
- 95 <u>first renewal of their license, if they have not been licensed by the board for at least one</u>
- year prior to July 1 of the renewal period.
- 97 (3) A Certified Oregon Pharmacy Technician must retain documentation of completed
- 98 continuing pharmacy education for six years and must provide this documentation if
- 99 requested by the board.
- 100 (4) Continuing pharmacy education credit accumulated in excess of the required 20
- 101 contact hours for biennial license renewal cannot be carried forward.
- 102 Statutory/Other Authority: ORS 689.205
- 103 <u>Statutes/Other Implemented: ORS 689.285, ORS 689.486, ORS 413.450, ORS 676.850</u>

- 105 **855-021-0010**
- 106 Continuing Pharmacy Education **Programs**
- 107 (1) In this rule the terms below have the meanings given: As used in OAR 855-021:
- 108 (a) "Patient Safety" means procedures and processes that ensure that the correct patient
- 109 receives the correct drug in the correct dose, and is counseled appropriately.
- 110 (b) "Medication error prevention" means procedures and processes to prevent and avoid
- 111 adverse events and to ensure that the correct patient receives the correct drug in the correct
- 112 dose.
- 113 (2) A continuing pharmacy education program means classes of post graduate studies, informal
- 114 study group participation, institutes, seminars, lectures, conferences, workshops, extension
- 115 study, correspondence courses, teaching, planned and professional meetings, self study
- 116 courses, cassette or audio visual tape/slides or materials, and other self instruction units:
- 117 (a1) A continuing pharmacy education program shallmust consist of therapeutics, or
- pharmacy and drug law or other aspects of health care applicable to the practice of
- 119 pharmacy. A minimum of at least two hours of continuing education credit must be earned in
- 120 the area of pharmacy and drug law. A minimum of two hours of continuing education credit must
- be earned in the area of patient safety or medication error prevention.
- 122 (b2) Programs shallmust provide for examinations or other methods of evaluation to assure
- satisfactory completion by participants.
- 124 (e3) The person or persons who are to instruct or who are responsible for the delivery or content
- of the program shallmust be qualified in the subject matter by education and experience.

- 126 (34) Continuing pharmacy education programs shallmust be approved by the Board of
- Pharmacy. Application for approval shallmust be made on and in accordance with forms
- 128 established by the **b**Board. The forms shallmust require information relating to:
- 129 (a) Name of provider or sponsor;
- 130 (b) Type of program offered;
- 131 (c) Description of subject matter;
- 132 (d) Number of contact hours offered;
- (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;
- 136 (g) Dates and location of program;
- (h) Name and qualification of instructors or other persons responsible for the delivery or content
- of the program.
- 139 (45) CE programs are not required to carry approval of American Council on Pharmaceutical
- 140 Education (ACPE). Programs presented by providers approved by the American Council on
- 141 Pharmacy Education (ACPE) are generally accepted, however, the Board reserves the right to
- 142 determine the number of hours allowed or to disapprove such programs.
- 143 (56) Providers shallmust provide attendees with proof of attendance that shows the date and
- number of contact hours provided. Providers must maintain attendance lists for three years.
- 145 (6) Continuing pharmacy education credit accumulated in excess of the required 30 contact
- 146 hours for biennial license renewal cannot be carried forward.
- 147 (7) A maximum of 120 contact hours (2.0 CEU) may be earned in any licensing cycle by
- preparing and presenting CE programs. Pharmacists and Certified Oregon Pharmacy
- 149 **Technicians** presenting CE programs may earn one contact hour (0.1 CEU) for preparation
- time of one hour or more, plus credit for the actual contact hour time of the presentation. A
- pharmacist or Certified Oregon Pharmacy Technicians 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.
- 155 (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 **b**Board.
- 158 (9) The **b**Board may approve up to 26 contact hours of CE credit for pharmacists who have
- 159 successfully completed nationally certified Disease State Management courses.
- (10) Board members or staff may attend CE programs for the purpose of evaluating content,
- 161 format and appropriateness of material for Continuing Pharmacy Education credit. Subsequent
- programs by CE providers whose current programs are deemed deficient by on-site evaluation

163 164	may be required to obtain prior approval by the b Board. The b Board will provide feedback to CE providers regarding evaluated CE presentations.
165	
166 167	855-021-0016 Continuing Education in Pain Management
168 169	(1) A pharmacist licensed under these rules must complete seven hours of continuing education in pain management as detailed in the following sub-sections. This is a one-time requirement:
170 171	(a) A one-hour pain management course, specific to Oregon, provided by the Pain Management Commission of the Oregon Health Authority; and
172 173 174 175	(b) A minimum of six hours of continuing education in pain management. This requirement may be fulfilled by any combination of continuing education coursework focusing on pain management including but not limited to the treatment of terminally ill and dying patients, and those with chronic, non-malignant pain.
176 177	(2) A pharmacist must complete the required continuing education within 24 months of their first license renewal.
178 179	(3) A pharmacist must retain for three years, documentation showing they have met the requirement of this rule, and must provide this documentation if requested by the Board.
180 181 182	(4) The pain management continuing education required under this rule shall count towards the 3.0 continuing pharmacy education units required under OAR 855-021-0005, in the license cycle in which the pain management continuing education is completed.
183	
184 185	855-021-0025 Continuing Pharmacy Education — Reciprocity
186 187	A pharmacist reciprocating into Oregon will not be required to submit proof of continuing pharmacy education during the initial license cycle.
188	
189 190	855-021-0030 Continuing Pharmacy Education — Non-Resident — Dual Licensees
191 192	(1) Any Oregon licensed pharmacist residing in another state shall, in order to receive Oregon license renewal, meet Oregon requirements for continuing pharmacy education.
193 194	(2) The Board shall accept for CE credit programs for out of state pharmacists that have been approved by that state's Board of Pharmacy.
195 196	(3) Upon request, the Board may certify to another state's licensing authority the status of a licensee's continuing education participation in Oregon.
197 198	(4) The Board may request certification from another state's licensing authority regarding the status of an applicant's continuing education.

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- 200 855-021-0045
- 201 Notification of Annual Biennial License Renewal
- 202 (1) The Bboard will develop an appropriate send a biennial renewal notice to be issued to all
- 203 licensed pharmacists, interns, and Certified Oregon Pharmacy Technicians at least 60 days
- 204 prior to May 1 of each odd numbered year the license expiration date that states the
- 205 biennial license fee, continuing pharmacy education requirements and other information
- 206 necessary for renewal.
- 207 (2) The notice will state the biennial pharmacist license fee and the continuing pharmacy
- 208 education fee due for license renewal.
- 209 (3) The notice will include the continuing pharmacy education time requirement and any other
- 210 information considered pertinent for the licensee's understanding of the renewal requirements.
- 211 Statutory/Other Authority: ORS 689.205
- 212 Statutes/Other Implemented: ORS 689.275, ORS 689.486

- 214 **855-021-0050**
- 215 Renewal Application Continuing Pharmacy Education Audits
- 216 (1) The biennial renewal application must be submitted to the **b**Board with the appropriate fee
- and the pharmacist licensee must attest that he/she they hasve satisfactorily completed the
- 218 continuing pharmacy education requirements.
- 219 (2) The Board may randomly select and audit applications for renewal to verify completion of the
- 220 CE programs continuing pharmacy education by pharmacists, interns and Certified
- 221 Oregon Pharmacy Technicians or documented onsite training by Certified Oregon
- 222 **Pharmacy Technicians** reported on the application for renewal.
- 223 (a) Pharmacists whose applications for renewal are selected for audit must provide
- documentation of completion of the CE continuing pharmacy education programs reported. A
- 225 pharmacist who fails to provide the requested documentation to the **b**Board or who fails to
- 226 complete the biennial CE continuing pharmacy education requirement may be disciplined for
- 227 unprofessional conduct.
- 228 (b) Interns whose applications for renewal are selected for audit must provide
- 229 documentation of completion of the cultural competency continuing pharmacy
- education. An intern who fails to provide the requested documentation to the board or
- 231 who fails to complete the biennial continuing education requirement may be disciplined
- 232 for unprofessional conduct.
- 233 (c) Certified Oregon Pharmacy Technicians whose applications for renewal are selected
- for audit must provide documentation of completion of the continuing pharmacy
- 235 education or documented onsite training reported. A Certified Oregon Pharmacy
- 236 Technician who fails to provide the requested documentation to the board or who fails to
- 237 <u>complete the biennial continuing education requirement may be disciplined for</u>
- 238 unprofessional conduct.

240 241	(3) The board may utilize the National Association of Boards of Pharmacy CPE Monitor service when auditing licensees.
242 243 244	Statutory/Other Authority: ORS 689.205 Statutes/Other Implemented: ORS 689.275
245 246	855-021-0055 Reinstatement
247 248 249	(1) Any person petitioning for reinstatement of a pharmacist license as provided within ORS 689.445 shall produce certification of the continuing education requirements of all years in which the license has been inactive prior to restoration of the license.
250 251	(2) Retired pharmacists who wish to reinstate their license should refer to OAR 855-019-0170(2).
252	

Revisions to Divisions 019, 021, 025 and 031 are provided to incorporate continuing education requirement directives set forth in 2019 HB 2011, related to cultural competency and CE chapter updates in alignment with the strategic plan.

- 1 Division 25
- 2 PHARMACY TECHNICIANS AND CERTIFIED OREGON PHARMACY TECHNICIANS
- 3 **855-025-0015**
- 4 Renewal of Licensure as a Certified Oregon Pharmacy Technician
- 5 (1) A person who has taken and passed a national pharmacy technician certification
- examination listed in OAR 855-025-0012(1)(a)–(b) may use the following title, and is referred to
- 7 in these rules as, and is licensed as a "Certified Oregon Pharmacy Technician."
- 8 (2) An applicant for renewal of a Certified Oregon Pharmacy Technician license must:
- 9 (a) Pay the biennial license fee prescribed required in OAR 855-110.
- 10 (b) Completion of continuing pharmacy education requirements as directed in OAR 855-
- 11 021; Satisfactorily complete a minimum of 20 continuing pharmacy educating hours during the
- 12 period from July 1 through June 30, of each license renewal cycle. These hours must include:
- 13 (A) Two hours of continuing pharmacy education in pharmacy law;
- 14 (B) Two hours of continuing pharmacy education in patient safety or error prevention; and
- 15 (C) Sixteen other hours of continuing pharmacy education or documented onsite training
- 16 approved by the Board.
- 17 (c) OAR 855-025-0015(2)(b) does not apply to a Certified Oregon Pharmacy Technician
- 18 applying for the first renewal of their license, if they have not been licensed by the Board for at
- 19 least one year prior to July 1 of the renewal period.
- 20 (cd) Be subject to an annual criminal background check.
- 21 (3) The Board may randomly select and audit applications for renewal to verify completion of
- 22 continuing education or documented onsite training reported on the application for renewal. A
- 23 Certified Oregon Pharmacy Technician whose application for renewal is selected for audit must
- 24 provide documentation of completion of the continuing pharmacy education reported.
- 25 (4) Effective January 1, 2015, nContinued national certification is not required to renew a
- 26 license as a Certified Oregon Pharmacy Technician.
- 27 (5) A Certified Oregon Pharmacy Technician who fails to renew his or her license by the
- expiration date and whose license has been lapsed for less than one year may renew his or her
- 29 license as follows:
- 30 (a) Complete the renewal process:
- 31 (b) Pay the biennial license fee as prescribed in OAR 855-110;
- 32 (c) Pay a delinquent fee; and

- 33 (d) Complete the required continuing **pharmacy** education pursuant to OAR 855-025-
- 34 0015(2)(b).**021**.
- 35 Statutory/Other Authority: ORS 689.205
- 36 Statutes/Other Implemented: ORS 689.225 & 689.486

- 38 **855-025-0020**
- 39 Recordkeeping Responsibilities of Pharmacy Technicians and Certified Oregon
- 40 Pharmacy Technicians
- 41 Duty to Report
- 42 (1) Failure to answer completely, accurately and honestly, all questions on the application form
- 43 for licensure or renewal of licensure is grounds for discipline.
- 44 (2) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony
- 45 may result in denial of the application.
- 46 (3) A Pharmacy Technician or Certified Oregon Pharmacy Technician must report to the **Bb**oard
- 47 within 10 days if they:
- 48 (a) Are convicted of a misdemeanor or a felony; or
- 49 (b) If they are arrested for a felony.
- 50 (4) A Pharmacy Technician or Certified Oregon Pharmacy Technician who has reasonable
- cause to believe that another licensee (of the **Bb**oard or any other Health Professional
- Regulatory Board) has engaged in prohibited or unprofessional conduct as these terms are
- defined in OAR 855-006-0005, must report that conduct to the board responsible for the
- licensee who is believed to have engaged in the conduct. The reporting Pharmacy Technician
- or Certified Oregon Pharmacy Technician shallmust report the conduct without undue delay,
- but in no event later than 10 working days after the reporting Pharmacy Technician or Certified
- 57 Oregon Pharmacy Technician learns of the conduct unless federal laws relating to
- 58 confidentiality or the protection of health information prohibit disclosure.
- 59 (5) A Pharmacy Technician or Certified Oregon Pharmacy Technician who reports to a **Bb**oard
- in good faith as required by section (4) of this rule is immune from civil liability for making the
- 61 report.
- 62 (6) A Pharmacy Technician or Certified Oregon Pharmacy Technician who has reasonable
- 63 grounds to believe that prescription drugs or records have been lost or stolen, or any violation of
- these rules has occurred, must notify the **Bb**oard within 1 day.
- 65 (7) A Pharmacy Technician or Certified Oregon Pharmacy Technician must notify the **Bb**oard in
- writing, within 15 days, of any change in email address, employment location or residence
- 67 address except that a Pharmacy Technician who is employed at more than one pharmacy need
- only report the name and address of the pharmacy at which the technician normally works the
- 69 most hours.

- 70 (8) A Certified Oregon Pharmacy Technician must obtain certificates of completion that show
- 71 the date and number of hours earned to document continuing pharmacy education credit earned
- 72 and must keep the certificates of completion for three years from the date of the program.
- 73 Statutory/Other Authority: ORS 689.205
- 74 Statutes/Other Implemented: ORS 689.155 & Ch. 536 OL 2009 ORS 689.486
- 75 **855-025-0060**
- 76 Reinstatement of a Certified Oregon Pharmacy Technician License
- 77 (1) A Certified Oregon Pharmacy Technician who fails to renew their license by the deadline
- 78 and whose license has been lapsed for greater than one year may reinstate their license as
- 79 follows:
- 80 (a) Complete a new application for licensure and provide the **Bb**oard with a valid e-mail
- 81 address:
- 82 (b) Pay the biennial license fee as prescribed in OAR 855-110;
- 83 (c) Submit to a national fingerprint background check; and
- (d) Provide certification of completion of 10 continuing education hours. These hours may not be
- 85 counted toward renewal; and must include:
- 86 (A) One hour of continuing pharmacy education in pharmacy law;
- 87 (B) One hour of continuing pharmacy education in patient safety or error prevention; and
- 88 (C) One hour of continuing pharmacy education in cultural competency either approved
- 89 by the Oregon Health Authority under ORS 413.450 or any cultural competency CPE; and
- 90 (CD) Eight Seven other hours of pharmacy technician-specific continuing education.
- 91 (2) A Certified Oregon Pharmacy Technician whose license has been lapsed greater than five
- 92 vears must:
- 93 (a) Re-take and pass a national pharmacy technician certification examination offered by:
- 94 (A) The Pharmacy Technician Certification Board (PTCB); or
- 95 (B) National Healthcareer Association (NHA).
- 96 (b) Satisfy reinstatement requirements pursuant to OAR 855-025-0060(1).
- 97 Statutory/Other Authority: ORS 689.205
- 98 Statutes/Other Implemented: ORS 689.225, ORS 413.450, & ORS 689.486

Revisions to Divisions 019, 021, 025 and 031 are provided to incorporate continuing education requirement directives set forth in 2019 HB 2011, related to cultural competency and CE chapter updates in alignment with the strategic plan.

- 1 Division 31
- 2 INTERNSHIP REGULATIONS
- 3 **855-031-0005**
- 4 Definitions
- 5 (1) An "intern" means any person who:
- 6 (a) Is enrolled in a course of study and is in good academic standing at a school or college of
- 7 pharmacy that is approved by the Oregon Board of Pharmacy (Board); or
- 8 (b) Is a graduate of a school or college of pharmacy that is approved by the **Bb**oard; or
- 9 (c) Is a foreign pharmacy graduate and holds a certificate from the Foreign Pharmacy Graduate
- 10 Equivalency Committee (FPGEC); and
- 11 (d) Is licensed with the **Bb**oard as an intern.
- 12 (2) A "preceptor" means a pharmacist or a person licensed by the **₿b**oard to supervise the
- internship training of an intern.
- 14 (3) "Internship" means a professional experiential program or work experience.
- 15 (a) "Traditional Pharmacy-practice Internship (TPI)" means experience toward achieving
- competency in the practice of pharmacy for which no academic credit is granted to the intern.
- 17 (b) "School-based Rotational Internship (SRI)" means experience toward achieving competency
- in the practice of pharmacy in programs developed and administered by a school of pharmacy.
- 19 (c) "Other Internship" means experience toward achieving competency in the practice of
- 20 pharmacy, other than in an internship as defined in (a) or (b), in a program approved by a
- 21 school of pharmacy or the **Bb**oard.
- 22 (4) "School of pharmacy": In this division of rules, "school of pharmacy" means a school or
- 23 college of pharmacy that is approved by the **Bb**oard.
- 24 Statutory/Other Authority: ORS 689.151 & **ORS** 689.205
- 25 Statutes/Other Implemented: **ORS** 689.255
- 27 **855-031-0010**

- 28 Intern License Application
- 29 (1) Applications for licensure as an intern may be obtained from the Board office or from the
- 30 **Bb**oard website.
- 31 (a) Failure to completely, accurately and honestly answer all questions on the application form
- 32 for licensure or renewal of licensure is grounds for discipline;

- 33 (b) Failure to disclose any arrest for a felony or misdemeanor, or any indictment for a felony
- may result in denial of the application.
- 35 (2) The **B**<u>b</u>oard may issue a license to a qualified intern after the receipt of:
- 36 (a) A completed application;
- 37 (b) Payment of the fee prescribed in OAR 855-110;
- 38 (c) A current, passport regulation size photograph (full front, head to shoulders);
- 39 (d) Furnish documentation required to conduct a national fingerprint-based background check;
- 40 and
- (e) Confirmation from a school of pharmacy that the applicant is enrolled in a course of study,
- 42 except for foreign pharmacy graduates who must:
- 43 (A) Provide a copy of a valid visa permitting full-time employment;
- 44 (B) Provide a copy of the original certificate issued by the Foreign Pharmacy Graduate
- 45 Equivalency Examination Committee; and
- 46 (C) Provide evidence that they have passed the Test of English as a Foreign Language
- 47 (TOEFL) Internet-based Test (IBT).
- 48 (3) The **Bb**oard may issue an intern license after processing the application, however unless the
- 49 applicant is a foreign graduate or an applicant for licensure by reciprocity, it is not valid until the
- 50 intern has started a course of study. The initial license is valid until the last day of November
- following the second anniversary of issue unless terminated automatically by any one of the
- 52 following events. Renewed licenses are valid for two years unless terminated automatically by
- any one of the following events:
- 54 (a) Licensure to practice pharmacy is granted in any state; or
- (b) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by
- 56 reciprocity, fails to maintain enrollment or active registration in a pharmacy degree program for a
- 57 period greater than one year; or
- 58 (c) The licensee, other than a foreign pharmacy graduate or an applicant for licensure by
- 59 reciprocity, has been graduated from a school of pharmacy for 12 months;
- 60 (d) The intern is dismissed, terminated or expelled by the school of pharmacy, or withdraws
- from the program.
- 62 (4) An intern must surrender their license to the Board within 30 days of one of the above
- 63 events.
- 64 (5) Notwithstanding the requirements of section (3) above, upon written request the **Bb**oard may
- waive any of the requirements of this rule if a waiver will further public health and safety. A
- 66 waiver granted under this section shallmust only be effective when it is issued in writing.
- 67 [Publications: Publications referenced are available from the agency.]

- 68 Statutory/Other Authority: ORS 689.151 & ORS 689.205
- 69 Statutes/Other Implemented: ORS 689.207, ORS 689.255 & ORS 689.455

- 71 **855-031-0016**
- 72 Renewal of Licensure as an Intern
- 73 (1) An application for renewal of an intern license must include documentation of:
- 74 (a) Completion of continuing pharmacy education requirements as directed in OAR 855-
- 75 **021; and**
- 76 **(b) Payment of the license fee required in OAR 855-110.**
- 77 (2) An intern will be subject to an annual criminal background check.
- 78 Statutory/Other Authority: ORS 689.205
- 79 Statutes/Other Implemented: ORS 689.151

- 82 **855-031-0020**
- 83 Intern Requirements and Responsibilities
- 84 (1) A licensed intern may practice in any one or a combination of the following approved
- 85 internship experience areas:
- 86 (a) Traditional Pharmacy-practice Internship (TPI): an intern may not work in a TPI until after
- satisfactorily completing the first academic year in a school of pharmacy. An intern working in a
- 88 TPI must be supervised by a licensed pharmacist or pharmacist preceptor;
- 89 (b) School-based Rotational Internship (SRI): an intern must be supervised by a licensed
- 90 pharmacist or other person approved by a school of pharmacy to obtain credit for SRI hours;
- 91 (c) Other Internship.
- 92 (2) An intern may not work more than 48 hours per week in SRIs and must comply with all
- 93 supervision and ratio requirements.
- 94 (3) An intern must verify that their preceptor is currently licensed with the **Bb**oard.
- 95 (4) An intern may not work in the practice of pharmacy unless supervised by a licensed
- 96 pharmacist, except when an intern is working in a federal facility, however, to obtain credit for
- 97 SRI experience in a federal facility located in Oregon, the intern must be licensed with the
- 98 Bboard.
- 99 (5) An intern who is working in a pharmacy or other place of business must conspicuously
- display their intern license in the pharmacy or place of business and must be clearly identified
- 101 as an intern at all times.
- 102 (6) An intern may perform only the duties listed in Division 025 of this Chapter before completion
- of the first academic year in a school of pharmacy.

- 104 (7) An intern may, after successful completion of their first academic year, perform the duties of
- an intern listed in Division 019 of this Chapter, but only after successful completion of
- 106 coursework corresponding to those duties at their school of pharmacy and only with the
- 107 permission of their supervising pharmacist.
- 108 (8) An intern is responsible for his or her own actions and must comply with all **B**<u>b</u>oard
- 109 regulations.
- 110 (9) An intern must notify the **Bb**oard within 15 days of any change in their academic status that
- might affect their eligibility to work as an intern.
- 112 (10) An intern must notify the **Bb**oard in writing within 15 days of a change in permanent
- 113 residence and TPI site.
- 114 (11) An intern must report to the **Bb**oard within 10 days if they are:
- (a) Convicted of a misdemeanor or a felony; or
- 116 (b) Arrested for a felony.
- 117 (12) An intern who has reasonable cause to believe that another licensee (of the **B**board or any
- other Health Professional Regulatory Board) has engaged in prohibited or unprofessional
- conduct as these terms are defined in OAR 855-006-0005, must report that conduct to the
- board responsible for the licensee who is believed to have engaged in the conduct. The intern
- shallmust report the conduct without undue delay, but in no event later than 10 working days
- after the intern learns of the conduct unless federal laws relating to confidentiality or the
- protection of health information prohibit disclosure.
- 124 (13) If needed by an intern for compliance with another **Bb**oard's requirement, an intern must
- maintain written or electronic records that support the number of TPI hours claimed by an intern
- and have those hours certified by a preceptor.
- 127 (14) An intern may make a voluntary report to the Board on any preceptor's aptitude and
- professionalism in performing the duties of a preceptor. An intern must make such a report upon
- 129 request by the **Bb**oard.
- 130 Statutory/Other Authority: ORS 689.151 & **ORS** 689.205
- 131 Statutes/Other Implemented: ORS 689.255 & 2009 OL Ch. 536 ORS
- 133 **855-031-0026**

- 134 Ratio & Supervision
- (1) A pharmacist may not supervise more than one intern at a time at a TPI site who performs
- the duties of an intern as listed in OAR 855-019-0200(3)(g). A pharmacist may supervise more
- than one intern if only one intern performs the duties of an intern as listed in OAR 855-019-
- 138 0200(3)(g) and if other interns supervised by the pharmacist perform the duties listed in OAR
- 139 855-025-0040.
- 140 (2) A preceptor may not supervise more than two interns simultaneously during a shift at an SRI
- site where patient specific recommendations for care or medications are provided without prior
- written authorization of the **Bb**oard. Through the 2020-2021 academic year, a preceptor may

- monitor as many interns as they believe in their professional judgement is appropriate to
- achieve desired experiential outcomes for non-direct patient care learning opportunities only,
- while also preserving and assuring patient safety. The preceptor must retain documentation of
- all interns monitored during this timeframe.
- (3) With the written approval of a school of pharmacy, and when in their professional judgment it
- is appropriate, a preceptor may supervise up to 10 interns at public-health outreach programs
- such as informational health fairs that provide general information but not direct patient care.
- 150 (4) For immunization clinics, an immunizing pharmacist may supervise up to two immunizing
- 151 interns.
- 152 (5) A licensed preceptor may delegate the preceptor responsibilities to another licensed
- 153 pharmacist or preceptor.
- 154 (6) The majority of an intern's overall experience must be with a licensed pharmacist preceptor.
- 155 Statutory/Other Authority: ORS 689.151 & ORS 689.205
- 156 Statutes/Other Implemented: ORS 689.255
- 157
- 158 **855-031-0030**
- 159 Out-of-State Internship Experience
- (1) In order for an Oregon intern to obtain credit for SRI experiences outside the State of
- 161 Oregon, an intern must:
- (a) Be licensed as required by state laws and rules in the state in which they will practice;
- 163 (b) Meet or exceed the minimum SRI requirements of the **Bb**oard;
- 164 (2) In order for an out-of-state intern to practice in the State of Oregon, the intern must meet all
- 165 requirements of these rules.
- 166 Statutory/Other Authority: ORS 689.151 & **ORS** 689.205
- 167 Statutes/Other Implemented: **ORS** 689.255
- 168
- 169 **855-031-0045**
- 170 School and Preceptor Registration and Responsibilities
- 171 (1) A preceptor license may be issued by the **Bb**oard upon receipt of a completed application.
- 172 (2) A pharmacist preceptor must have been an actively practicing pharmacist for at least one
- 173 year immediately prior to supervising an intern.
- 174 (3) A preceptor license must be renewed biennially and will expire on June 30 in odd numbered
- 175 years.
- 176 (4) The preceptor may report to the **Bb**oard voluntarily, the progress and aptitude of an intern
- under the preceptor's supervision, or must do so upon request of the **Bb**oard.

- 178 (5) The preceptor must be responsible for supervision of the majority of the intern's SRI hours
- and must provide the intern with internship experiences, which in the preceptor's judgment will
- increase the intern's competency in the practice of pharmacy.
- 181 (6) Before supervising an intern in an SRI program, a preceptor must complete any training
- program required by the school of pharmacy.
- 183 (7) A preceptor must advise each school of pharmacy when they are supervising students from
- more than one school at the same time. This applies to both in-state and out-of-state schools or
- 185 colleges of pharmacy.
- 186 (8) A preceptor must verify that their intern is currently licensed with the **Bb**oard.
- (9) A pharmacist acting as a preceptor in a federal facility is not required to be licensed as a
- pharmacist in Oregon, but is required to be licensed as a preceptor with the **b**oard.
- (10) The school of pharmacy must maintain a record of each intern's SRIs. This record must be
- 190 made available to the **Bb**oard upon request.
- 191 (11) A school of pharmacy located in Oregon must submit a report on their experiential
- education program to the **Bb**oard at the end of each academic year. This report must include
- the names of students who successfully completed the program and graduated from the school.
- The school must maintain a list of preceptors and SRI sites, in and out-of-state, approved by the
- 195 school and must make this list available to the **₿b**oard upon request.
- 196 (12) All records related to a student must be available for three years after the student
- 197 graduates.
- 198 Statutory/Other Authority: ORS 689.151 & **ORS** 689.205
- 199 Statutes/Other Implemented: ORS 689.255

- 201 **855-031-0050**
- 202 Eligibility for Exams Foreign Pharmacy Graduates
- 203 In addition to the other requirements of this Division, a foreign pharmacy graduate must
- 204 complete 1440 internship hours before applying to take the Multistate Pharmacy Jurisprudence
- 205 Examination (MPJE) and before applying for licensure as a pharmacist as specified in OAR
- 206 855-019-0150. Evidence of completing this requirement must be provided to the **Bb**oard by the
- 207 applicant and must be authenticated by each preceptor.
- 208 Statutory/Other Authority: ORS 689.151 & **ORS** 689.205
- 209 Statutes/Other Implemented: **ORS** 689.255

- 211 **855-031-0055**
- 212 Eligibility for Exams and Pharmacist Licensure
- 213 (1) An intern is eligible to take the North American Pharmacist Licensure Examination
- (NAPLEX) and the MPJE, upon graduation and notification to the Bboard by the school of
- 215 pharmacy that their degree, with not less than 1440 hours of SRI, has been conferred.

- 216 (2) Upon meeting all requirements for pharmacist licensure, and before practicing pharmacy in
- the State of Oregon, a person must:
- 218 (a) Complete an application for licensure including providing any fingerprint card or other
- 219 documentation required by the **Bb**oard to conduct a criminal background check;
- 220 (b) Pay the license fee as prescribed in OAR 855-110; and
- (c) Obtain a license, which will expire on June 30 in odd numbered years.
- 222 Statutory/Other Authority: ORS 689.205
- 223 Statutes/Other Implemented: ORS 689.135, **ORS** 689.207, **ORS** 689.225 & **ORS** 689.275



Division 041, 043 & 044 - Informational Inserts

Proposed language for Divisions 041, 043 & 044 to address directives of 2019 SB 698, which require accessibility services for limited English proficiency (LEP) patients. These rules are intended to clarify the definition and requirements for an informational insert for all prescription drugs dispensed directly to LEP patients. These requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies.

Need for Rules:

These rules are intended to clarify the definition and requirements for an informational insert for all prescription drugs dispensed directly to LEP patients. The requirements apply to pharmacies and dispensing drug outlets.

Fiscal Impact:

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

Rules Summary:

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

1 **855-041-1001**

- 2 **Definitions**
- 3 (1) "Biological product" means, with respect to the prevention, treatment or cure of a disease or
- 4 condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood
- 5 component, blood derivative, allergenic product, protein other than a chemically synthesized
- 6 polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.
- 7 (2) "Biosimilar product" means a biological product licensed by the United States Food and Drug
- 8 Administration pursuant to 42 U.S.C. 262(k)(3)(A)(i).
- 9 (3) "Drug room" is a drug storage area registered with the Board which is secure and lockable.
- 10 (4) "Informational insert" is an auxiliary document that is provided to the patient when directions for
- use by the patient required under OAR 855-041-1130 do not fit on the label affixed to the prescription
- 12 <u>container.</u>
- 13 (45) "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
- 15 U.S.C. 262(k)(4).

16 (6) "Limited English proficiency" means not fluent in the English language. 17 (57) "Reference biological product" means the biological product licensed pursuant to 42 U.S.C. 262(a) 18 against which a biological product is evaluated in an application submitted to the United States Food 19 and Drug Administration for licensure of a biological product as a biosimilar product or for 20 determination that a biosimilar product is interchangeable. 21 **Statutory/Other Authority:** ORS 689.205 & 689.522 22 Statutes/Other Implemented: ORS 689.155 & 342 & ORS 689.522, & ORS 689.564 23 24 855-041-1132 25 **Limited English Proficiency and Accessibility** 26 (1) Upon request of a prescriber, patient or a patient's agent, each drug dispensed by a pharmacy for a 27 patient's self-administration must bear a label in both English and the language requested for an 28 individual with limited English proficiency, defined as a person who is not fluent in the English language. 29 This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare 30 worker. 31 (2) When dispensing a drug under (1), a pharmacy must provide a prescription labels and, when needed, an informational inserts in both English and one of the following languages: 32 33 (a) Spanish; 34 (b) Russian; (c) Somali; 35 36 (d) Arabic; (e) Chinese (simplified); 37 38 (f) Vietnamese; 39 (g) Farsi; 40 (h) Korean; (i) Romanian; 41 42 (j) Swahili; 43 (k) Burmese; 44 (I) Nepali; 45 (m) Amharic; and (n) Pashtu. 46

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

- 48 (4) An informational insert must only be used when the directions for use by the patient required 49 under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container. 50 (5) When an informational insert is provided, the prescription label affixed to the prescription 51 container must state in the language requested by the patient that an informational insert is being 52 used. (6) At a minimum, the informational insert must include the: 53 54 (a) directions for use by the patient; 55 (b) identifying number; (c) name of patient; 56
- (d) name of drug and strength; and(e) dispensing date.
- 59 Statutory/Other Authority: ORS 689.564
 60 Statutes/Other Implemented: ORS 689.205

- 61 **855-043-0002**
- 62 **Definitions**
- 63 In this division of rules:
- 64 (1) "Administer" means the direct application of a drug or device whether by injection, inhalation,
- 65 ingestion, or any other means, to the body of a patient by:
- 66 (a) A practitioner or the practitioner's authorized agent; or
- 67 (b) The patient at the direction of the practitioner.
- 68 (2) "Dispense" or "Dispensing" means the preparation and delivery of a prescription drug pursuant to a
- 69 lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration
- 70 to or use by a patient or other individual entitled to receive the prescription drug.
- 71 (3) "Formulary" means a list of drugs or classes of drugs, or a list of disease states, health conditions or
- 72 preventative measures such as immunization or birth control approved by the Board or by the
- 73 Department of Human Services (DHS).
- 74 (4) "Health Officer" means a physician licensed by the Oregon Medical Board or the Oregon Board of
- Naturopathic Medicine and employed by or under contract with a county or district health department
- 76 or DHS.
- 77 (5) "Informational insert" is an auxiliary document that is provided to the patient when directions for
- 78 use by the patient required under OAR 855-041-1130 do not fit on the label affixed to the prescription
- 79 **container.**
- 80 (6) "Limited English proficiency" means not fluent in the English language.
- 81 (57) "Supervising Physician Dispensing Outlet" (SPDO) means any clinic, office, health care center,
- 82 treatment center, or other establishment from which a physician assistant dispenses drugs, but that is
- 83 not otherwise registered with the Board in the category of Retail Drug Outlet.
- 84 Statutory/Other Authority: ORS 689.205
- 85 Statutes/Other Implemented: ORS 689.155, & ORS 689.564

- 87 **855-043-0436**
- 88 Supervising Physician Dispensing Outlet Limited English Proficiency and Accessibility
- 89 (1) Upon request of a patient or a patient's agent, each drug dispensed by a drug outlet for a patient's
- 90 self-administration must bear a label in both English and the language requested for an individual with
- 91 limited English proficiency, defined as a person who is not fluent in the English language. This does not
- 92 apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.
- 93 (2) When dispensing a drug under (1), a pharmacy must provide a prescription labels and, when
- 94 **needed, an** informational inserts in both English and one of the following languages:
- 95 (a) Spanish;

96	(b) Russian;
97	(c) Somali;
98	(d) Arabic;
99	(e) Chinese (simplified);
100	(f) Vietnamese;
101	(g) Farsi;
102	(h) Korean;
103	(i) Romanian;
104	(j) Swahili;
105	(k) Burmese;
106	(I) Nepali;
107	(m) Amharic; and
108	(n) Pashtu.
109	(3) The board must reassess and update (2) as necessary and at least every ten years.
110 111	(4) An informational insert must only be used when the directions for use by the patient required under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container.
111 112 113	under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container. (5) When an informational insert is provided, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being
111 112 113 114	under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container. (5) When an informational insert is provided, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being used.
111 112 113 114 115	under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container. (5) When an informational insert is provided, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being used. (6) At a minimum, the informational insert, must include the:
111 112 113 114 115 116	under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container. (5) When an informational insert is provided, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being used. (6) At a minimum, the informational insert, must include the: (a) directions for use by the patient;
111 112 113 114 115 116	under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container. (5) When an informational insert is provided, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being used. (6) At a minimum, the informational insert, must include the: (a) directions for use by the patient; (b) identifying number;
111 112 113 114 115 116 117 118	under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container. (5) When an informational insert is provided, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being used. (6) At a minimum, the informational insert, must include the: (a) directions for use by the patient; (b) identifying number; (c) name of patient;
111 112 113 114 115 116 117 118 119	under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container. (5) When an informational insert is provided, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being used. (6) At a minimum, the informational insert, must include the: (a) directions for use by the patient; (b) identifying number; (c) name of patient; (d) name of drug and strength; and
111 112 113 114 115 116 117 118 119 120 121	under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container. (5) When an informational insert is provided, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being used. (6) At a minimum, the informational insert, must include the: (a) directions for use by the patient; (b) identifying number; (c) name of patient; (d) name of drug and strength; and (e) dispensing date. Statutory/Other Authority: ORS 689.564

- 126 (1) Upon request of a patient or a patient's agent, each drug dispensed by a drug outlet for a patient's
- self-administration must bear a label in both English and the language requested for an individual with
- 128 limited English proficiency, defined as a person who is not fluent in the English language. This does not
- apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.
- (2) When dispensing a drug under (1), a pharmacy must provide a prescription labels and, when
- needed, an informational inserts in both English and one of the following languages:
- 132 (a) Spanish;
- 133 (b) Russian;
- 134 (c) Somali;
- 135 (d) Arabic;
- 136 (e) Chinese (simplified);
- 137 (f) Vietnamese;
- 138 (g) Farsi;
- 139 (h) Korean;
- 140 (i) Romanian;
- 141 (j) Swahili;
- 142 (k) Burmese;
- 143 (I) Nepali;
- 144 (m) Amharic; and
- 145 (n) Pashtu.
- 146 (3) The board must reassess and update (2) as necessary and at least every ten years.
- 147 Statutory/Other Authority: ORS 689.564
- 148 Statutes/Other Implemented: ORS 689.205

150 151	855-044-0005 Definitions
152 153	(1) "Charitable Pharmacy" means a facility registered with the Oregon Board of Pharmacy for the purpose of receiving and distributing donated drugs.
154 155 156	(2) "Informational insert" is an auxiliary document that is provided to the patient when directions for use by the patient required under OAR 855-041-1130 do not fit on the label affixed to the prescription container.
157	(3) "Limited English proficiency" means not fluent in the English language.
158 159 160	$(2\underline{4})$ "Point-of-Contact" means an individual designated by a charitable pharmacy who serves as the primary contact person for the charitable pharmacy and who is responsible for managing the charitable pharmacy at that location.
161 162	Statutory/Other Authority: ORS 689.205 Statutes/Other Implemented: ORS 689.772, & ORS 689.774, & ORS 689.564
163	
164 165	855-044-0061 Charitable Pharmacies - Limited English Proficiency and Accessibility
166 167 168 169 170	(1) Upon request of a prescriber, patient or a patient's agent, each drug dispensed by a pharmacy for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency, defined as a person who is not fluent in the English language. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.
171 172	(2) When dispensing a drug under (1), a pharmacy must provide <u>a prescription</u> label s and, <u>when</u> <u>needed, an</u> informational inserts in both English and one of the following languages:
173	(a) Spanish;
174	(b) Russian;
175	(c) Somali;
176	(d) Arabic;
177	(e) Chinese (simplified);
178	(f) Vietnamese;
179	(g) Farsi;
180	(h) Korean;
181	(i) Romanian;
182	(j) Swahili;
102	(J) Swarm,

183	(k) Burmese;
184	(I) Nepali;
185	(m) Amharic; and
186	(n) Pashtu.
187	(3) The board must reassess and update (2) as necessary and at least every ten years.
188 189 190	(4) A pharmacy that dispenses prescriptions for a patient's self-administration must post signage to provide notification of the right to free, competent oral interpretation and translation services for patients who are of limited English proficiency, in compliance with federal and state regulations.
191 192	(5) An informational insert must only be used when the directions for use by the patient required under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container.
193 194 195	(6) When an informational insert is provided, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being used.
196	(7) At a minimum, the informational insert, must include the:
197	(a) directions for use by the patient;
198	(b) identifying number;
199	(c) name of patient;
200	(d) name of drug and strength; and
201	(e) dispensing date.
202 203	Statutory/Other Authority: ORS 689.564 Statutes/Other Implemented: ORS 689.205

Division 041- Drug Take Back

Need for Rules:

To address directives of <u>2019 HB 3273</u> which directs DEQ to adopt any rules necessary for the effective administration of ORS 459A.200 to 459A.266. DEQ requested OBOP to assist DEQ in adopting rules under ORS 459A.200 to 459A.266.

Fiscal Impact:

2019 HB 3273 directs each covered manufacturer of covered drugs that are sold within this state to develop and implement drug take-back program for purpose of collecting from individuals and nonbusiness entities covered drugs for disposal and requires the manufacturers to pay fees for the program; thus, these rules may potentially decrease the start-up and ongoing costs for drug outlet registrants to purchase and maintain necessary equipment for a drug take back program.

Rules Summary:

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

1 855-041-1045

2 Returned Drugs and Devices

- 3 (1) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians and interns may
- 4 not only accept the return of controlled substances upon receiving a waiver from the Board of
- 5 Pharmacy.
- 6 (2) Pharmacists, pharmacies, pharmacy technicians, and certified pharmacy technicians and interns may
- 7 accept the return of drugs or devices as defined by ORS 689.005 once the drugs or devices have been
- 8 removed from the pharmacy only if;
- 9 (a) The drugs or devices are accepted for destruction or disposal and;
- 10 (b) The drugs or devices were dispensed in error, were defective, adulterated, misbranded, dispensed
- 11 beyond their expiration date, were unable to be delivered to the patient, or are subject of a drug or
- 12 device recall; or
- 13 (c) After consultation, a pharmacist determines that, in the pharmacist's professional judgment, harm
- could result to the public or a patient if the drugs or devices were not accepted for return.
- 15 (3) Not withstanding section (2) of this rule, drugs or devices previously dispensed or distributed may be
- 16 returned and redispensed or redistributed provided all the following conditions are met:
- 17 (a) The drug is in an unopened, tamper-evident unit;
- 18 (b) The drugs or devices have remained at all times in control of a person trained and knowledgeable in
- 19 the storage and administration of drugs in long term care facilities or supervised living groups using the
- 20 services of a consultant pharmacist;

- (c) The drug or device has not been adulterated or misbranded and has been stored under according to
- 22 conditions meeting United States Pharmacopeia standards the manufacturer recommendations.
- 23 (4) Upon written request, the Board may waive any of the requirements of this rule if a waiver will
- 24 further public health or safety or the health and safety of a patient. A waiver granted under this section
- 25 shall only be effective when it is issued by the Board in writing.
- 26 Statutory/Other Authority: ORS 689.205
- 27 Statutes/Other Implemented: ORS 689.305

28

29

- 31 **855-041-1046**
- 32 Secure and Responsible Drug Disposal
- 33 (1) A pharmacy that operates a drug take back collection program or that participates in a drug take-
- 34 <u>back program under ORS 459A.200 to ORS 459A.266 as an authorized collector must be</u> registered
- 35 with the DEA as an authorized collector-may to collect controlled and non-controlled drugs for
- 36 destruction in accordance with all applicable federal laws.
- 37 (2) A pharmacy that operates <u>as</u> a <u>drug take back collection program</u> <u>Drug Enforcement Agency (DEA)</u>
- 38 <u>authorized collector shall must</u> notify the <u>b</u>Board in writing prior to within 30 days of initiating or
- 39 terminating the program and shall must establish and enforce policies and procedures, including but
- 40 not limited to:
- 41 (a) Provision of a secure location of the collection receptacle inside the retail drug outlet, which must
- 42 be is accessible to the public, within view of the pharmacy counter and cannot be must not placed be
- 43 **located** behind the pharmacy counter; and
- (b) Provision of adequate security measures, including proper installation and maintenance of **the**
- 45 collection receptacle, tracking of liners, documentation and key accountability; and
- 46 (c) Personnel training and accountability.
- 47 (3) A pharmacy must inform consumers to directly deposit drugs into the collection receptacle.
- 48 Pharmacy personnel shall-must not count, sort, inventory, or otherwise handle drugs collected.
- 49 (4) A pharmacy shall must not dispose of quarantined, recalled or outdated drugs from pharmacy stock
- in a collection receptacle.
- 51 (5) The liner must be inserted and removed from a locked collection receptacle only by or under the
- 52 supervision of two employees of the pharmacy. Upon removal, the liner must be immediately sealed,
- 53 and the pharmacy employees must document their participation in the insertion and removal of each
- 54 liner from a collection receptacle on a log. Sealed liners must not be opened, analyzed or penetrated
- at any time by the pharmacy or pharmacy personnel.
- 56 (6) Liners that have been removed from a collection receptacle and immediately sealed must be
- 57 <u>directly transferred, or otherwise stored in a secured, locked location in the pharmacy for no longer</u>

- 58 than 7 days prior to be transferred, by two pharmacy personnel to a registered drug distribution agent
- 59 (such as registered UPS, FedEx or USPS) or a reverse wholesaler registered with the DEA and the
- 60 **board.**
- 61 (7) Any tampering with a collection receptacle, liner or theft of deposited drugs must be reported to
- the board in writing within one day of discovery.
- 63 (58) A pharmacy shall-must maintain all drug disposal records for a minimum of 3 years.
- 64 (9) Authorized collectors are required to comply with the following federal and state laws:
- 65 (a) ORS 459A.200, ORS 459A.203, ORS 459A.206, ORS 459A.209, ORS 459A.212, ORS 459A.215, ORS
- 66 459A.218, ORS 459A.221, ORS 459A.224, ORS 459A.227, ORS 459A.230, ORS 459A.233, ORS 459A.236,
- 67 ORS 459A.239, ORS 459A.242, ORS 459A.245, ORS 459A.248, ORS 459A.251, ORS 459A.254, ORS
- 68 <u>459A.257, ORS 459A.260, ORS 459A.263, and ORS 459A.266;</u>
- 69 **(b)** OAR 340-098-0000, OAR 340-098-0010, OAR 340-098-0300, OAR 340-098-0350, OAR 340-098-0370,
- 70 and OAR 340-098-0390;
- 71 (c) 21 CFR 1317.30 (04/01/2021), 21 CFR 1317.35 (04/01/2021), 21 CFR 1317.40 (04/01/2021), 21 CFR
- 72 <u>1317.55 (04/01/2021), 21 CFR 1317.60 (04/01/2021), 21 CFR 1317.65 (04/01/2021), 21 CFR 1317.70</u>
- 73 (04/01/2021), 21 CFR 1317.75 (04/01/2021), 21 CFR 1317.80 (04/01/2021), and 21 CFR 1317.85
- 74 **(04/01/2021)**; and
- 75 (d) 21 USC 822 (XX/XX/XXXX), 21 USC 822a (XX/XX/XXXX).
- 76 Statutory/Other Authority: ORS 689.205 & ORS 459A.266
- 77 Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215, & ORS 495A.218

Division 050- Restriction on Retail Sales

The proposal to repeal these rules is a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

- 1 Division 50
- 2 RESTRICTION ON RETAIL SALES
- 3 **855-050-0035**
- 4 Over-the-Counter Drug Restrictions
- 5 (1) The following items shall be sold only by or under the direct supervision of a licensed pharmacist in
- 6 registered pharmacies. They need not bear the store name and address, if in original container, need
- 7 not be registered, but must be properly labeled. They shall not be available by self-service, but stored in
- 8 or immediately adjacent to the prescription department. Items bearing prescription legend are excepted
- 9 and may be sold only on prescription:
- 10 (a) Ammoniated Mercury ointment, five percent;
- 11 (b) Sulfa drugs Alone or in combination;
- 12 (c) Blue Ointment.
- 13 (2) The following items shall be sold only by a licensed pharmacist(s) in registered pharmacies, must
- 14 bear the store name and address, must be properly labeled with adequate warning, must be registered
- 15 in Official Poison Register, and the purchaser must provide acceptable identification, providing the
- 16 preparations do not bear prescription legend, in which case they may be sold only on prescription:
- 17 (a) Arsenic and its preparations;
- 18 (b) Corrosive sublimate;
- 19 (c) Cyanides and preparations, including hydrocyanic acid;
- 20 (d) Hydrochloric acid and any preparation containing free or chemically unneutralized hydrochloric acid
- 21 (HC1) in a concentration of ten percent or more;
- 22 (e) Nitric acid or any preparation containing free or chemically unneutralized nitric acid (HNO3) in a
- 23 concentration of five percent or more;
- 24 (f) Sulphuric acid and any preparation containing free or chemically unneutralized sulphuric acid (H2SO4)
- 25 in a concentration of ten percent or more;
- 26 (g) Solution of ammonia, U.S.P. 28 percent;
- 27 (h) Carbolic acid.
- 28 Statutory/Other Authority: ORS 689
- 29 History:
- 30 Reverted to PB 4-1988, f. & cert. ef. 7-5-88

- 31 BP 6-2004(Temp), f. 10-15-04 cert. ef. 11-1-04 thru 5-13-05
- 32 PB 4-1988, f. & cert. ef. 7-5-88
- 33 1PB 2-1980, f. & ef. 4-3-80
- 34 Reverted to 1PB 18, f. & ef. 10-14-64
- 35 1PB 2-1979(Temp), f. & ef 10-3-79
- 36 1PB 18, f. & ef. 10-14-64
- 37 855-050-0045
- 38 Organic Silver Salts
- 39 (1) May be sold only by licensed pharmacists in registered pharmacies.
- 40 (2) Solutions must be freshly prepared, unless stabilized.
- 41 (3) Must be adequately labeled, to include name and address of store, date of preparation, and
- 42 percentage content.
- 43 Statutory/Other Authority: ORS 689
- 44 History:
- 45 1PB 2-1980, f. & ef. 4-3-80
- 46 Reverted to 1PB 18, f. & ef. 10-14-64
- 47 1PB 2-1979(Temp), f. & ef. 10-3-79
- 48 1PB 18. f. & cf. 10-14-64
- 49 855 050 0070
- 50 Prescription Drugs
- 51 (1) The following are prescription drugs:
- 52 (a) Drugs required by federal law to be labeled with either of the following statements:
- 53 (A) "Caution: Federal law prohibits dispensing without prescription"
- 54 (B) "Caution: Federal law restricts this drug to be used by or on the order of a licensed veterinarian"; or
- 55 (C) "Rx only"
- 56 (b) Drugs designated as prescription drugs by the Oregon Board of Pharmacy
- 57 (2) The Oregon Board of Pharmacy designates the following drugs as prescription drugs:
- 58 (a) Preparations containing codeine or salts of codeine
- 59 (b) Preparations containing opium/paregoric
- 60 (3) No person shall sell, give away, barter, transfer, purchase, receive or possess prescription drugs
- 61 except upon the prescription of a practitioner.
- 62 (4) The following are exempt from the prohibition of section (3) of this rule:
- 63 (a) Manufacturers
- 64 (b) Wholesalers;

- 65 (c) Institutional and retail drug outlets;
- 66 (d) Practitioners.
- 67 (5) Individuals who purchase, receive, or possess a prescription drug for the purpose of administration
- 68 or delivery to a patient are exempt from the prohibition against purchasing, receiving, or possessing
- 69 prescription drugs contained in section (3) of this rule and ORS 689.765(6).
- 70 Statutory/Other Authority: ORS 689.205
- 71 Statutes/Other Implemented: ORS 689.155 & 689.765
- 72 History:

- 73 BP 1-2007, f. & cert. ef. 6-29-07
- 74 BP 14-2006(Temp), f. 12-29-06, cert. ef. 1-1-07 thru 6-29-07
- 75 BP 4-2006, f. 6-9-06, cert. ef. 7-1-06
- 76 BP 7-2004, f. & cert. ef. 11-8-04
- 77 BP 1-2002, f. & cert. ef. 1-8-02
- 78 PB 4-1991, f. & cert. ef. 9-19-91
- 79 PB 9-1990, f. & cert. ef. 12-5-90
- 80 PB 3-1990, f. & cert. ef. 4-5-90

Division 006– Definitions: Prescription Drug

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

_	*** *** ****
2	Definitions
3	
4	As used in OAR chapter 855:
5	
6	(1) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.
7	
8	(2) "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy
9	who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board and has
10	completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for
11	clerical duties, such as recordkeeping, cashiering, bookkeeping and delivery of medications released by
12	the pharmacist are not considered pharmacy technicians.
13	
14	(3) "Clinical Pharmacy Agreement" means an agreement between a pharmacist or pharmacy and a
15	health care organization or a physician that permits the pharmacist to engage in the practice of clinical
16	pharmacy for the benefit of the patients of the health care organization or physician.
17	
18	(4) "Collaborative Drug Therapy Management" means the participation by a pharmacist in the
19	management of drug therapy pursuant to a written protocol that includes information specific to the
20	dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and
21	initiated upon a prescription order for an individual patient and:
22	
23	(a) Is agreed to by one pharmacist and one practitioner; or
24	
25	(b) Is agreed to by one or more pharmacists at a single pharmacy registered by the board and one or
26	more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group
27	practice, including but not limited to organized medical groups using a pharmacy and therapeutics
28	committee.

29 30

1

855-006-0005

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

313233

34

(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

35 36

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

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

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

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

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

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

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

(11) "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.

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

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

(14) "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.

82	(15) "Non-legend drug" means a drug which does not require dispensing by prescription and which is
83	not restricted to use by practitioners only.
84	(4.6) Official and a final a
85	(16) "Offering or performing of those acts, services, operations or transactions necessary in the conduct,
86	operation, management and control of pharmacy" means, among other things:
87	(ATherese the control of the form of the control of
88	(a) The creation and retention of accurate and complete patient records;
89	(h) Assumating such suits, and responsibility for any dust coloration of during and devices.
90	(b) Assuming authority and responsibility for product selection of drugs and devices;
91	(c) Developing and maintaining a cafe practice cotting for the pharmacist, for pharmacy staff and for the
92	(c) Developing and maintaining a safe practice setting for the pharmacist, for pharmacy staff and for the
93 94	general public;
9 4 95	(d) Maintaining confidentiality of patient information.
96	(u) Maintaining confidentiality of patient information.
97	(17) "Oral Counseling" means an oral communication process between a pharmacist and a patient or a
98	patient's agent in which the pharmacist obtains information from the patient (or agent) and the
99	patient's pharmacy records, assesses that information and provides the patient (or agent) with
100	professional advice regarding the safe and effective use of the prescription drug for the purpose of
101	assuring therapeutic appropriateness.
102	assuming incruped the appropriateriess.
103	(18) Participation in Drug Selection and Drug Utilization Review:
104	
105	(a) "Participation in drug selection" means the consultation with the practitioner in the selection of the
106	best possible drug for a particular patient.
107	
108	(b) "Drug utilization review" means evaluating prescription drug order in light of the information
109	currently provided to the pharmacist by the patient or the patient's agent and in light of the information
110	contained in the patient's record for the purpose of promoting therapeutic appropriateness by
111	identifying potential problems and consulting with the prescriber, when appropriate. Problems subject
112	to identification during drug utilization review include, but are not limited to:
113	
114	(A) Over-utilization or under-utilization;
115	
116	(B) Therapeutic duplication;
117	
118	(C) Drug-disease contraindications;
119	
120	(D) Drug-drug interactions;
121	
122	(E) Incorrect drug dosage;
123	
124	(F) Incorrect duration of treatment;
125	

126 127	(G) Drug-allergy interactions; and
128	(H) Clinical drug abuse or misuse.
129	(11) Chilledi di dig dibase of misase.
130	(19) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of
131	achieving definite outcomes that improve a patient's quality of life. These outcomes include:
132	demonify demonited distances and improve a passence quantity or more masses accounted measures.
133	(a) Cure of a disease;
134	
135	(b) Elimination or reduction of a patient's symptomatology;
136	
137	(c) Arrest or slowing of a disease process; or
138	
139	(d) Prevention of a disease or symptomatology.
140	
141	(20) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the
142	pharmacist in the practice of pharmacy pursuant to rules of the Board but has not completed the
143	specialized education program pursuant to OAR 855-025-0012.
144	
145	(21) "Practice of clinical pharmacy" means:
146	
147	(a) The health science discipline in which, in conjunction with the patient's other practitioners, a
148	pharmacist provides patient care to optimize medication therapy and to promote disease prevention
149	and the patient's health and wellness;
150	
151	(b) The provision of patient care services, including but not limited to post-diagnostic disease state
152	management services; and
153	/ N=1
154	(c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.
155	(22) "Duration of pharmaca," is an defined in ODS COO COO
156	(22) "Practice of pharmacy" is as defined in ORS 689.005.
157 158	(23) "Prescription drug" or "legend drug" is as defined in ORS 689.005 and:
159	(25) Frescription drug of legend drug is as defined in OK3 003.003 and.
160	(a) Required by federal law, prior to being dispensed or delivered, to be labeled with "Rx only"; and
161	tay required by rederal law, prior to being dispensed of delivered, to be labeled with the only , and
162	(b) Required by any applicable federal or state law or regulation to be dispensed on prescription only
163	or is restricted to use by practitioners only.
164	
165	(234) "Prescription released by the pharmacist" means, a prescription which has been reviewed by the
166	pharmacist that does not require further pharmacist intervention such as reconstitution or counseling.
167	
168	(24 <u>5</u>) "Prohibited conduct" means conduct by a licensee that:
169	

170	(a) Constitutes a criminal act against a patient or client; or
171 172	(b) Constitutes a criminal act that creates a risk of harm to a patient or client.
173 174 175	(256) "Proper and safe storage of drugs and devices and maintenance of proper records therefore" means housing drugs and devices under conditions and circumstances that:
176 177 178	(a) Assure retention of their purity and potency;
179 180	(b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;
181 182	(c) Assure security and minimize the risk of their loss through accident or theft;
183 184	(d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;
185 186 187	(e) Protect the health, safety and welfare of the pharmacist, pharmacy staff and the general public from harmful exposure to hazardous substances.
188 189 190	$(26\underline{7})$ "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.
191 192 193 194 195 196	(278) "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.
198 199	(28 <u>9</u>) "Specialized Education Program" means;
200 201 202 203	(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
204 205 206	(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:
207 208	(A) An organization recognized by the board as representing pharmacists or pharmacy technicians;
209 210	(B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or
211 212	(C) A trade association recognized by the board as representing pharmacies.

(2930) "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action. During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders.

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(301) "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.

224 225 226

(312) "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.

228 229

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

Oregon Board of Pharmacy

Budget Report: November 2020 (Month 17)

Revenue:

Through November, revenue is \$320,163 (6.1%) over budget

Expenditures:

Through November, total expenditures are \$474,321 (7.7%) under budget

Personal services are \$249,768 (6.1%) under budget

Services and Supplies are \$215,736 (11.6%) under budget

Special Payments are \$8,817 (100%) under budget

Revenues less Expenditures: \$(168,576)

Cash Balance:

Cash balance through November is \$3,589,074 which represents (9.86 months of operating expense)

Note: This the above is a snap-shot of the biennium to date through November 2020. It does not include projections for the remainder of the biennium.

End of biennium estimated cash balance is \$3,937,733, which represents (11.33 months of operating expense)

Cash balance target is \$2,085,545, (6.0 months of operating expense)

Note: The end of biennium estimated cash balance is calculated based on the biennium to date plus the remaining months projections for 2019-21.

FEBRUARY 2021 / C

Total A	III Funds - LAB 2019-2021			
Actuals t	hrough November 2020 month-end-close			
	5			
	CINNUNC CACIL PALANCE	LAB	ACTUAL+PROJ	VARIANCE
REVENUE	GINNING CASH BALANCE	0	3,757,650	0.00
	NERAL FUND			
205 OT	HER BUSINESS LICENSES	7,146,250.00	8,097,081.75	(950,831.7
	THER NONBUSINESS LICENSES AND FEES	139,296.00	208,203.75	(68,907.7
	NES AND FORFEITS TEREST AND INVESTMENTS	405,000.00 45,000.00	405,000.00 127,398.38	(92.209.2
	THER REVENUE	57,090.00	71,032.71	(82,398.3)
	TAL REVENUE	7,792,636.00	8,908,716.59	(1,116,080.5
RANSFER				
	ANSFER IN FROM DAS	-	36,587.93	(36,587.9)
10	TAL TRANSFER IN	0.00	36,587.93	(36,587.9
2010 TR	ANSFER OUT TO OTHER FUNDS	-	-	-
2443 TR	ANSFER OUT TO OREGON HEALTH AUTHORITY	416,146.00	423,040.00	(6,894.00
то	TAL TRANSFER OUT	416,146.00	423,040.00	(6,894.00
	L SERVICES ASS/UNCLASS SALARY & PER DIEM	2 662 669 00	2 502 240 10	70,427.90
	MPORARY APPOINTMENTS	3,663,668.00 26,180.00	3,593,240.10 5,148.66	21,031.3
	/ERTIME PAYMENTS	20,100.00	1,088.84	(1,088.8
	IFT DIFFERENTIAL		-	
3190 AL	L OTHER DIFFERENTIAL	190,428.00	234,006.97	(43,578.9
	B ASSESSMENT	1,281.00	1,151.28	129.7
	IBLIC EMPLOYES' RETIREMENT SYSTEM	647,442.00	587,231.05	60,210.9
	NSION BOND CONTRIBUTION ICIAL SECURITY TAX	200,306.00	206,129.02	(5,823.0
	NEMPLOYMENT ASSESSMENT	296,540.00	280,655.13	15,884.8
	ORKERS' COMPENSATION ASSESSMENT	1,276.00	980.52	295.4
	ASS TRANSIT	23,248.00	22,901.12	346.8
3270 FLE	EXIBLE BENEFITS	774,048.00	728,684.83	45,363.1
	rsonal Services Budget Adj.	(20,653.00)	-	(20,653.0
то	TAL PERSONAL SERVICES	5,803,764.00	5,661,217.52	142,546.48
EDVICES	AND SUPPLIES			
	STATE TRAVEL	113,572.00	68,538.86	45,033.14
	JT-OF-STATE TRAVEL	16,322.00	10,916.69	5,405.3
4150 EN	IPLOYEE TRAINING	21,400.00	19,539.62	1,860.3
4175 OF	FICE EXPENSES	129,018.00	88,984.40	40,033.6
	LECOMM/TECH SVC AND SUPPLIES	48,830.00	43,901.09	4,928.9
	ATE GOVERNMENT SERVICE CHARGES ATA PROCESSING	163,176.00	163,552.76	(376.7)
	IBLICITY & PUBLICATIONS	80,540.00 39.583.00	306,309.95 20,732.98	(225,769.9 18,850.0
	OFESSIONAL SERVICES	321,394.00	353,056.45	(31,662.4
	PROFESSIONAL SERVICES	652,149.00	330,120.00	322,029.0
4325 AT	TORNEY GENERAL LEGAL FEES	525,607.00	525,014.11	592.89
	MPLOYEE RECRUITMENT AND DEVELOPMENT	653.00	-	653.0
	JES AND SUBSCRIPTIONS	5,195.00	7,773.00	(2,578.0
	CILITIES RENT & TAXES CILITIES MAINTENANCE	210,941.00	203,074.80	7,866.2
	EDICAL SUPPLIES AND SERVICES	53.00 1,152.00	1,351.36	53.0
	GENCY PROGRAM RELATED SVCS & SUPP	240,152.00	226,715.44	13,436.5
	THER SERVICES AND SUPPLIES	284,656.00	275,298.01	9,357.9
	PENDABLE PROPERTY \$250-\$5000	13,526.00	5,852.93	7,673.0
	EXPENDABLE PROPERTY	43,363.00	30,231.44	13,131.5
то	TAL SERVICES & SUPPLIES	2,911,282.00	2,680,963.89	230,318.1
Capital Ou	ıtlav			
	ATA PROCESSING HARDWARE	8,611.00	-	8,611.0
	THER CAPITAL OUTLAY			
To	tal Capital Outlay	8,611.00	0.00	8,611.0
pecial Pa	yments HER SPECIAL PAYMENTS	12 447 00		12 447 0
	tal Special Payments	12,447.00 12,447.00	0.00	12,447.0 12,447.0
10	an apacian ayincing	12,747.00	0.00	12,447.0
то	TAL EXPENDITURES	8,736,104.00	8,342,181.41	393,922.5
PR	OJECTED BIENNIAL ENDING CASH BALANCE		3,937,733	
En	d of biennium projected cash balance in months		11.33	
EII	a or premium projected cash baidnes in months		11.33	

Oregon Board of Pharmacy

Oregon Board of Pharmacy 2021-23 Budget Presentation (Governor's Budget)



Joint Ways and Means Education Subcommittee February 1, 2021

8:30 PM - Room H-178 (Remote Meeting)

Presented by: Joseph Schnabel, Pharm D., R.Ph., BCPS Executive Director

Karen S. MacLean Administrative Director

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.

Executive Summary

The Oregon Board of Pharmacy (OBOP), established in 1891 under ORS Chapter 689 regulates the practice of pharmacy and the commerce and quality of all prescription and non-prescription drugs within and into the State. In addition, the Board has authority and responsibilities contained in ORS Chapter 475, the Uniform Controlled Substances Act to oversee drugs with abuse or addiction potential and the research and scheduling of controlled drugs in Oregon. The practice of pharmacy in the State of Oregon is declared a professional practice affecting public health, safety and welfare and is subject to regulation and control in the public interest. The Legislature further declared it to be a matter of public interest and concern that the practice of pharmacy merit and receive the confidence of the citizens of Oregon and that only qualified persons be permitted to engage in the practice of pharmacy in the State of Oregon.

The Board of Pharmacy consists of nine board members appointed by the Governor and confirmed by the State Senate, including two public members, five pharmacists and two pharmacy technicians. In addition, there is a seven-member Public Health and Pharmacy Formulary Advisory Committee made up of three pharmacists, two physicians and two advanced practice nurses. This Committee, appointed by the Governor, was established to review concepts for drugs, devices, and protocols that pharmacists may safely prescribe and to make recommendations to the Board for adoption by rule. The agency's staff currently consists of twenty-two FTE.

The 2021-23 Proposed Organizational Chart is in the Appendix of this presentation on <u>pages</u> <u>16 and 17</u>. A detailed description of ongoing operational tasks can be found in the agency <u>Governor's Budget binder</u>.

Summary of Program

The purpose of the Board of Pharmacy under ORS Chapter 689 is to promote, preserve, and protect the health, safety and welfare of Oregon citizens by control and regulation of the practice of pharmacy and the commerce and quality of drugs through outlets involved in the manufacture, production, sale and distribution of drugs, medications, devices and such other materials as may be used in the diagnosis and treatment of injury, illness and disease.

This is accomplished through:

Examinations: Any individual wishing to practice as a pharmacist in the State must take and pass an entry level competency exam, the North American Pharmacy Licensure Examination (NAPLEX). This exam has been standardized throughout all fifty states. Candidates for licensure in Oregon must also take and pass a pharmacy law exam, the Multistate Pharmacy Jurisprudence Examination (MPJE). These exams are administered by the National Association of Boards of Pharmacy (NABP). The MPJE exam questions are written, maintained and updated by OBOP staff and members through annual review of the exam question pool and psychometric analysis of the questions by NABP.

<u>Licensing</u>: After verification of passing scores on the NAPLEX and MPJE exams, the Board of Pharmacy allows the pharmacist candidate to submit an application for licensure. The Board completes a primary source verification of all credentials and completes an FBI criminal

background check prior to issuing a license. All individual (pharmacist, technician, and intern) licenses must be renewed on a biennial cycle. The OBOP has an online renewal process for most licenses. Pharmacy Technicians must obtain experience and become nationally certified within two years of initial Oregon licensure, then apply to be a Certified Oregon Pharmacy Technician to continue working as a technician. All drug outlet registrations renew annually. Pharmacies, pharmaceutical manufacturers, wholesalers, non-prescription drug outlets and a variety of other drug outlets must also be licensed with the OBOP to do business in the State. Establishments seeking licensure undergo similar scrutiny through primary source verification and vetting of applications and documents for licensure.

<u>Compliance</u>: The OBOP investigates all complaints and allegations of violations of Oregon law (ORS Chapter 689) and corresponding administrative rules (OAR Chapter 855), as well as any violations of state (ORS Chapter 475) or federal laws and rules related to controlled substances.

<u>Communication and Education</u>: Customer Service is one of the Board's highest priorities. All incoming phone calls are answered by a staff member, and then routed to the appropriate personnel for assistance. The OBOP staff receives questions from licensees, other healthcare professionals, the media, and the public. The Board has a philosophy of compliance through education and participates in conferences and educational presentations to professional associations and pharmacy schools regarding pharmacy and drug law and licensing issues. The Board participated in over 30 outreach programs in 2019 and 2020.

<u>Board Administration (Members and Meetings)</u>: The Board is composed of nine volunteer members that serve four-year terms. Onboarding new members requires orientation to procedures and processes for state service and Board meeting procedures. Board members are required to utilize their professional expertise to create a regulatory framework that protects the public health and safety. While Board members may work in the profession and are governed by Board statutes and rules, they must make decisions based solely on the public interest.

Public Health and Pharmacy Formulary Advisory Committee (PHPFAC): The role of the PHPFAC is to evaluate concepts for protocols, drugs and devices for pharmacists to prescribe to Oregon patients and then to submit recommendations for the Board of Pharmacy to adopt by rule. Board staff support the committee's work by preparing the concepts for review, working with subject matter experts to formulate protocols, and assuring compliance with public meeting requirements. If the PHPFAC recommends a protocol, drug or device, the staff presents the recommendation to the Board in the form of draft rules for rulemaking consideration.

Agency Key Performance Measures need to update

Goals

The five strategic goal areas outlined in the Board's <u>2020-2024 Strategic Plan</u> will 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 make sure that desired outcomes are being met and to encourage safe and contemporary pharmacy practice. The five strategic goal areas include: • Technicians • Technology • Licensing • Regulation and • Communication.

The Agency has identified three long-term strategic goals to align with Key Performance Measures (KPM) that are consistent with its mission statement and that will provide direction for ongoing activities and resource allocation. The goals and measures are:

- Goal #1: Protect Oregon consumers by regulating the practice of pharmacy and distribution of drugs
- Goal #2: Provide excellent customer service
- Goal #3: Conduct business in a manner that supports a positive environment for the pharmacy industry

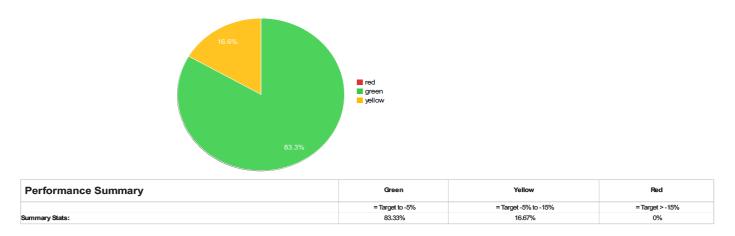
In its ongoing efforts to achieve these goals, the Board will:

- Continue to assure the competency level of pharmacists through testing, peer review, and improved continuing education
- Maximize the use of onsite inspections of the various drug outlets to ensure public safety
- Focus on timely investigation of consumer complaints and allegations of diversion and other drug distribution violations and medication dispensing errors
- Work closely with the Medical, Nursing, Dental, Optometry, Naturopathic and Veterinary Boards and their Associations (i.e. health professions with authority to prescribe drugs), the Oregon State University College of Pharmacy and the Pacific University College of Health Professions School of Pharmacy, and the state and federal drug enforcement agencies in the ongoing effort to eliminate the diversion of drugs from legitimate distribution channels to illegal street markets and harmful recreational use (prescription drug abuse)

The Board has six Key Performance Measures and is proposing to delete and change measure #2 and revise measure #3:

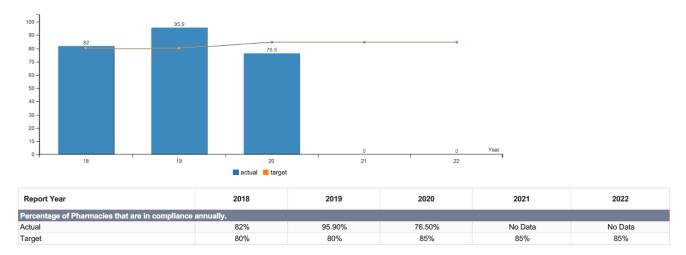
- 1) Percent of annually inspected pharmacies that are in compliance with pharmacy laws and rules.
- 2) Percent of audited pharmacists who have completed their continuing education (CE) on time
- 3) Percent of pharmacies inspected annually.
- 4) Average number of days required to complete an investigation.
- 5) Percent of customers rating their satisfaction with the agency's customer service as "good" or "excellent"; overall, timeliness, accuracy, helpfulness, expertise, availability of information.
- 6) Percent of total best practices met by the Board.

The following is an overall reflection of the agency's performance, our targets and actual performance is very close to the expected outcomes. Note, the results for the 2020 report are based on calendar year 2019.



Measures #1-2 are dependent on the licensee's ability to comply with Agency laws and rules upon inspection or audit.

Measure #1 - Percent of inspected pharmacies that are in compliance annually.

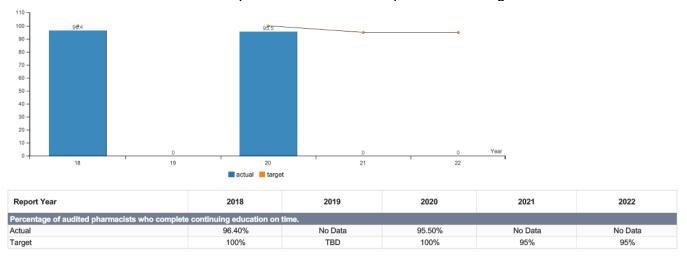


Measures #1 and #3 relate to the number of pharmacies in compliance upon inspection and the number of pharmacies inspected annually. Board Inspectors utilize an annually updated Pharmacy Self-Inspection report as a tool for inspections. Those pharmacies that are not in compliance upon inspection have the opportunity to correct violations of best practices within 30 days. If corrective action is not completed, the Board will review violations for possible disciplinary action. The Board reviews this information throughout the year as a regular activity during the Compliance portion of each regularly scheduled Board meeting.

Many rule changes have been implemented over the past 5 years to account for new legislative authorities for a pharmacist to prescribe and rules related to outlet requirements to ensure cold drug storage integrity. Many outlets were identified to be non-compliant with these rules and needed corrective action follow up to ensure that patient safety is maintained. In the last year, several Rules Advisory Committees were formed to discuss pending large rule changes related to updated compounding rules which went into place in 2019 to meet national standards, as well as new legislation related to dual language prescription label and reader requirements. The new rules contributed to outlets focusing on implementation of large projects which may have contributed to noted deficiencies and non-compliance.

Staff continues to work to communicate effectively with all outlets to improve patient safety by achieving compliance with laws and rules.

Measure #2 - Percent of audited pharmacists who complete continuing education on time.

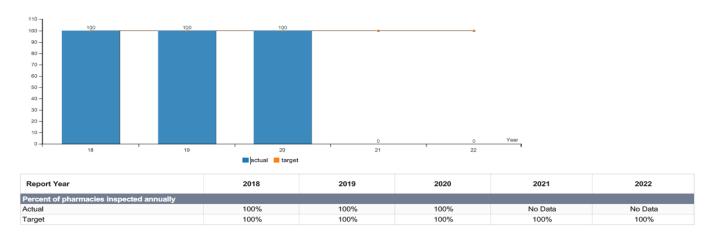


Measure #2 - 704 or 11% of the pharmacists who renewed their license in 2019 were audited. Of those, 675 or 95% completed their continuing education in the timeframe specified. This is a biennial renewal in odd numbered years. The audit was finished in early 2020.

This measure is proposed for deletion and changed for the following reason: The *Percent of audited pharmacists who complete continuing education on time,* is identified to be the responsibility of a licensee, rather than a responsibility or measure of agency performance.

The Agency proposes to change KPM #2 to: *Percentage of individual and facility licenses that are issued in within 30 days* with a proposed target of 75%. This will capture the changes in volume and workflow timeframes throughout the whole licensing process, from receipt of application through investigations and Board member deliberation and approval, when required.

Measure #3 - Percent of pharmacies inspected annually

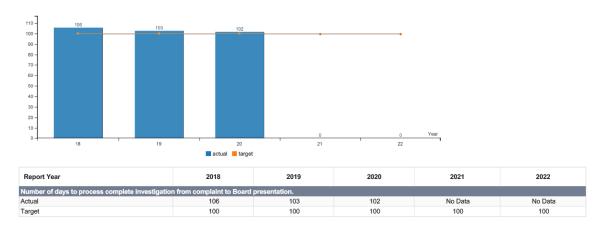


Measure #3 - Board staff strives to complete 100% of retail and institutional pharmacy inspections in Oregon annually; we have reached 100% annually since 2011. While this measure is specific to these two categories, inspectors also inspected 8 additional registration types in 2020 and other in-state outlets are now on a rotating schedule from year to year. Board staff reports progress on the number or percent of outlets inspected at each Board meeting.

This measure is proposed for deletion and changed for the following reason: The Percent of pharmacies inspected annually, is proposed to be changed to biennial.

The Agency proposes to change KPM #3 to: *Percent of pharmacies inspected biennially* (every two years). Proposed target = 100%. This effort is to ensure that our processes are focused on achieving our mission to ensure public safety. This will allow for more intentionality and strategic focus towards high risk locations such as retail and institutional pharmacies and will result in better patient safety outcomes. This measure is also anticipated to reduce travel inspection costs each year.

Measure #4 - Average number of days to complete an investigation from complaint to board presentation.



Measure #4 - The total number of investigations/inspections that resulted in cases from January 1, 2019 - December 31, 2019 was 776 which is a decrease of 26 from 2018. This number is inclusive of all cases, which include those initiated from inspection results, licensee application cases, drug diversion and theft cases, impairment cases, fraud / misrepresentation cases and all consumer complaints. Cases are triaged to ensure that the public's safety is maintained which may cause delays in processing of other types of cases. On average, cases are reported and presented to the Board within 102 days. This is a decrease of 4 days from 2018. Full staffing, continuous process improvement, and case triage are all contributors to ensuring patient safety through timely Board review / action.

Measure #5 – Customer Service – Percent of customers rating their satisfaction with the agency's customer service as "good" or "excellent": Overall customer service, timeliness, accuracy, helpfulness, expertise, and availability of information.

No Data

No Data



Measure #5 – The Board's overall average of 87.7% is a decrease of .55% from 2018 (the 2019 Report). The Board continues to see licensee growth which increases application processing times.

87%

86%

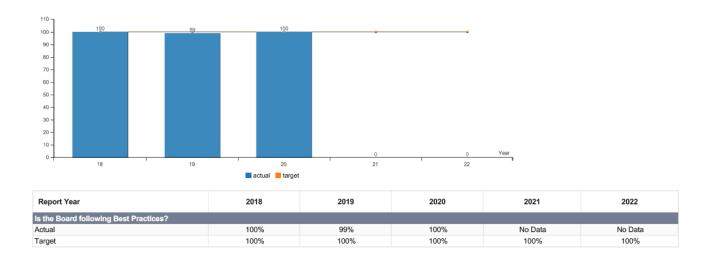
We had several factors that impacted the decreases noted in the results:

88%

Actual Target

- A long-term licensing staff member left the agency to pursue employment outside of state service and an additional FTE was added effective 7/1/2019. Two new staff were hired and started with the Board in the fall. With over 30 different license types, there is a significant learning curve to understand all the nuances and regulations surrounding licensure/registration with the Oregon Board of Pharmacy.
- For several months, national fingerprint-based background check results were taking an average of 20 - 30 days to be received. This caused significant dissatisfaction with applicants but was out of the Board's control.
- In October of 2019, the Board implemented an upgrade to the licensing and compliance database. Included in the implementation was a new licensee interface. The setup, training and implementation of these new systems caused a slow-down in the processing of applications due to staff resources required to for user acceptance testing, training on the new systems and the assistance provided to licensees with the new online processes.

Measure #6 - Percent of total best practices met by the Board.



Measure #6 – The Board regularly works to follow best practices. Staff regularly reports to the Board on many of the best practice items and/or the Board reviews materials throughout the year. This year, eight out of nine members participated in providing feedback to this measure. Of those, three out of nine members were new since February 2020, one of those since July. The opportunity to regularly orient the Board to best practices and answer questions is very useful.

Overall, the 2020 report continues to reflect the Agency is striving to meet all Key Performance Targets. The Board serves its licensees and the people of Oregon. A complete copy of the 2020 Annual Performance Progress Report (linked here) is also available in the Governor's Budget document under Special Reports.

2021-23 Summary of Program

The Agency is budgeted as one Program Unit. For management efficiency, we have broken out the key areas of agency function, which include:

- Operations, Administration, and Communications
- Licensing
- Compliance
- Board member activities
- Public Health and Pharmacy Formulary Advisory Committee activities

All areas are by their nature intricately connected and required to accomplish the statutory mission of the agency.

To Achieve the Agency's Mission and Deliver Services to Oregonians

Agency staff engages is a variety of ongoing operational activities to achieve the Agency's mission of public safety for Oregonians and regulatory oversight of over 30,000 licensees in 34 categories of individuals and drug outlets both in-state and out of state, a chart reflecting these categories is in the Appendix on page 24. The 2021-23 Governor's Budget supports these activities based on current projections. These operational responsibilities and services include:

- Efficient management of office and agency
- Efficient processing of examinations and licenses

- Perform regular pharmacy inspections
- Provide responsive research, information and assistance services
- Provide effective compliance efforts
- Provide responsive consumer and other stakeholder communication
- Provide support to the Board and Formulary Advisory Committee

Boards of pharmacy, unlike other health regulatory boards, are required to collaborate with many other state and federal regulatory agencies including:

- U.S. Food and Drug Administration (FDA), with federal authority over prescription and non-prescription drugs and devices
- U.S. Drug Enforcement Administration (DEA), with federal authority over controlled substances
- State health regulatory Boards for every discipline with the authority to prescribe, dispense, administer or possess drugs and devices

Boards of pharmacy also uniquely differ from other health regulatory Boards in that they:

- regulate the licensed professional individual; and
- regulate the quality, distribution, and commerce of products and services and register the various types of drug outlets

This dual role creates a variety of unique circumstances affecting pharmacy boards which are not shared by the other health regulatory Boards.

Major budget drivers, budget risks, and environmental factors

This 2021-23 budget includes one small policy package related to personnel. The Board implemented fee increases at the beginning of biennium approved in 2019, no new fees are needed. The biggest risk would be any loss of personnel or FTE.

<u>"Personnel Services" costs</u> represent 69% of the agencies budget. What the agency does involves people working with people, licensing, investigations and outreach.

Ongoing expenses for "Services and Supplies" represent 31% of the agencies budget and are inherent and tend to not fluctuate significantly.

Attorney General is the second largest agency expenditure at 6.81%. This is due in part to the flat-rate agreement that is going away in the 2021-23 biennium which was driven by current and past usage, but also the large number of cases and hearing requests we receive associated with notification of Board discipline and the changing practice of pharmacy within the state or nationally In 2019 alone, there were 776 cases, 327 final orders issues (the most ever in one year) and we currently have 42 hearings requested and being managed.

Environmental Factors

COVID-19 Impacts

As with many State agencies, the Board of Pharmacy has been actively involved in helping licensees, registrants and the public navigate and stay safe during the COVID-19 public health emergency. From the beginning of the pandemic in March, the Board has communicated with licensees and registrants to assist them in keeping their staff and the public safe.

- Implemented temporary rules to allow remote work by pharmacists and pharmacy technicians
- Temporarily prohibited dispensing of chloroquine and hydroxychloroquine for COVID-19 to preserve supplies for patients with rheumatoid arthritis and lupus
- Increased the number of interns that a pharmacist may supervise in academic experiences
- Extended Pharmacy Technician license to accommodate lack of testing site availability
- Required licensee/registrant compliance with Governor's Executive Orders
- Temporarily suspended some requirements for training/certification to prevent disruptions of care or increase number of pharmacists available to provide immunizations
- Provided regulations for vaccine storage outside of a registered drug outlet
- Worked with local distilleries, OHA and Moda to facilitate production and distribution of hand sanitizer
- Prioritized processing of applications for vaccine distribution outlets and drug rooms for storage and distribution of vaccines in Oregon
- Communicated with pharmacists on providing emergency prescription services to people impacted by wildfires

Pharmacists will continue to perform essential roles in providing immunization services as the demand for mass vaccination is expected to continue through 2021 and beyond.

Additional environmental factors include expanding technician roles in assisting pharmacists, automation and technology in drug distribution, regulating pharmacist patient care services under statewide protocols and formulary, increasing complexity and scope of investigations, changing pharmacist and pharmacy technician roles and challenges to drug supply chain security and integrity.

<u>Administrative initiatives</u> and projects such as budget preparation, database upgrade, document security and move to electronic documents, business continuity, workforce data and cultural competence are some of the many activities that consume an increasing portion of staff time.

<u>Statutory directives</u> to safeguard public health utilize significant portion of staff time. Recent examples include: revising rules for emergency insulin and naloxone dispensing; prescription labeling for patients with limited English proficiency; prescription readers for the visually impaired; cultural competency continuing education; prescription drug take-back program; pharmacist prescribing under statewide protocols; immunization updates; public health emergencies; opioid abuse reduction efforts; biosimilars; and the Health Professionals Service Program.

<u>Prescription drug abuse or overutilization</u> requires an increasing amount of staff time. Staff investigates illegal Internet drug distribution, local fraudulent prescription scams and diversion and theft of controlled substances from pharmacies. Many drug related issues such as these are also covered by the news media and requests for information, interviews and statements from staff are common. Other issues include working with the Oregon Department of Environmental Quality to implement 2019 HB 3273, the statewide prescription drug take back program and participating in the Oregon Opioid Taper Guidelines Taskforce to address opioid use disorder. Pharmacists are uniquely positioned to have a positive impact in reducing

opioid abuse by utilizing the Oregon Prescription Drug Monitoring Program (PDMP) and communicating with health care providers.

Major Changes in the Last 6 Years

Executive Director, Marcus Watt retired in late 2018 and new Executive Director Joe Schnabel began his tenure with the Board in February 2019.

The Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) was established by 2017 HB 2397 and became effective on January 1, 2018. Committee members were appointed in 2018 and established core elements of pharmacist prescribing practices. To date, the PHPFAC has recommended twelve statewide protocols and eight formulary devices and supplies for pharmacist prescribing, which the Board has adopted by rule. Funding for the Committee was approved in the 2019 Legislatively Adopted Budget.

Implementation of the Shared Academic and Regulatory Fellowship Program for Post-Graduate Learners with Pacific University School of Pharmacy (PUSOP) and the Oregon Board of Pharmacy (OBOP) was started in 2017. This Fellowship established a reoccurring one-year program designed to transition the fellow from a general practitioner to a regulatory pharmaceutical specialist and clinical educator. Upon successful completion of the PUSOP-OBOP Fellowship, graduates will be on track to pursue careers in: 1) Regulatory oversight services at a State Board of Pharmacy, and 2) Academic/faculty positions that involve pharmacy practice, experiential teaching responsibilities, and school service, as well as preceptor development opportunities. This program was initiated in 2017-18, the Fellow did not complete the full year. There was only one candidate for the 2018-19 year and no selection was made. This program was phased out of the 2019-21 budget. It may be evaluated for consideration in the future.

Longtime Compliance Director Gary Miner retired January 2017 and a new director, Brianne Efremoff assumed this position.

All licenses for individuals (pharmacist, technician, intern) were converted from annual licensure to biennial licensure.

The Board participates in the Health Professionals Service Program (HPSP) for impaired professionals. Legislation in 2016 shifted operational management from Oregon Health Authority to a Work Group of Health Boards (Medical, Dental, Nursing, Pharmacy) effective July 1, 2017. A required third-party audit of the HPSP provider was conducted in 2020 and the findings are currently being evaluated by the Work Group.

The Board amended (18), adopted (2) or repealed (8) rules in 2019 and one temporary rule in response to legislative action. In 2020, the Board amended (14), adopted (7) or repealed (2) rules in 2020 in response to legislative action. In 2020, the Board also responded to the COVID-19 Public Health Emergency adopting 6 and amending 4 rules. We will continue to be responsive to the current emergency as needed. Regular review, streamlining efforts or rules in need of updating occurs throughout the biennium.

Process Changes for Efficiency

Examples of changes the Board has implemented in the past few years to save resources and create efficiency include:

- Upgrading the licensing database streamlined the process for licensees to renew online more efficiently and update their profile while ensuring greater security for agency data overall. Individual applicants are able to apply for and renew licensure online. All the larger facilities are now able to renew online, applications are in progress.
- License verifications have been upgraded with the database modernization project, this has simplified the process for making public records available to the public and streamlined staff work in the process.
- The pharmacist licensure process has been streamlined and simplified to improve customer service and faster processing time.
- Upgraded Board website to State standard, greatly improving access and user experience.
- Increasing technology and security changes mandated by the Enterprise Information Services Office (EIS) has allowed the agency to increase security for all systems. This was further highlighted by the impact of COVID-19 on the workplace and the ability to modernize equipment and implement telework options for employees.
- Incorporating LEAN process improvement methods, to increase efficiency and standardization in important agency processes.
- Online forms to submit complaints, public records request, updated all applications
- Newsletter is cleaner and more intuitive
- New Board and Staff Orientation professional development
- Cross-training of staff continues to allow for better resource allocation.
- Developed a Strategic Plan for staff to implement Board priorities for 2020-24
- The Board continues to conduct most of the Board's meetings virtually, rather than in person due to the COVID-19 pandemic. It is likely that virtual meetings will continue for several more months.
- Streamlined investigative case report development and presentations for the Board.

2021-23 Budget Information

The Board's 2021-23 proposed budget includes an Other Fund expenditure limitation request of **\$9,104,052**, a .95% increase over the 2019-21 Legislatively Adopted Budget, this percentage includes limitation added in December 2020 for all agencies for salaries and benefits.

The following packages supports the agencies activities as described, reclassifies two positions and corrects one salary due to COVID timing.

2021-23 Essential Packages include various packages from 010 – 099. These packages make a variety of DAS adjustments (increases, decreases or reductions) and a few agency specific adjustments including Package 022 that phases out funding for the database upgrade that was implemented, \$288,415; Package 090 that reduced three line items included on the agency 10% Reduction Item list totaling \$32,284. The remaining packages relate to Statewide adjustments and include updates to the DAS Price List, State Government Service Charges, and Microsoft 365 Consolidation.

2021-23 Policy Packages

Policy Package 100 Personnel Management

The first part of this package is to reclassify an Office Specialist 2 position to an Administrative Specialist 1. The Compliance Department's responsibilities and case workload have evolved. Establishing the "Compliance Coordinator" role became essential to ensure that Compliance workload is completed on time and in accordance with Board rules, policies, and procedures. The second part of this package is to adjust a salary for a new hire that was delayed due to COVID-19 until June 1, 2020 which was after ORPICS freeze and wasn't included in the Current Service Level calculations. The third part of this package is to reclassify a Program Analyst 1 to a Principal Executive Manager-A. This Licensing Manager position was recently reviewed by the Chief Human Resources Office and approved for a reclassification. Package 100 increases Personal Services expenditures by \$29,851. More details are included in the policy package narrative.

Summary of Proposed Legislation

The agency doesn't have any proposed legislation.

The following are some of the 2021 bills the agency is tracking that are pharmacy related and may impact the agency or have a budgetary impact.

<u>HB 2858</u> - Allows pharmacist to prescribe and dispense preexposure prophylactic antiretroviral drug to patient after completion of patient assessment. Requires OBOP to adopt rules.

<u>HB 2074</u> - Increases prescription monitoring program fees from \$25 to \$35 annually. This impacts pharmacist licensure cost.

HB 2648 / SB 526 – These bills are similar in that they allow the following: pharmacist or pharmacy technician to transfer drug containing pseudoephedrine without prescription to person who is at least 18 years of age and presents person's valid government-issued photo identification. This would require rule revisions for OBOP.

Reduction options in Governor's budget

The Governor's budget does include minor reductions; three from the agency submitted Reduction Options list in the areas of special payments, capital outlay and publicity and publications totaling \$32,284.

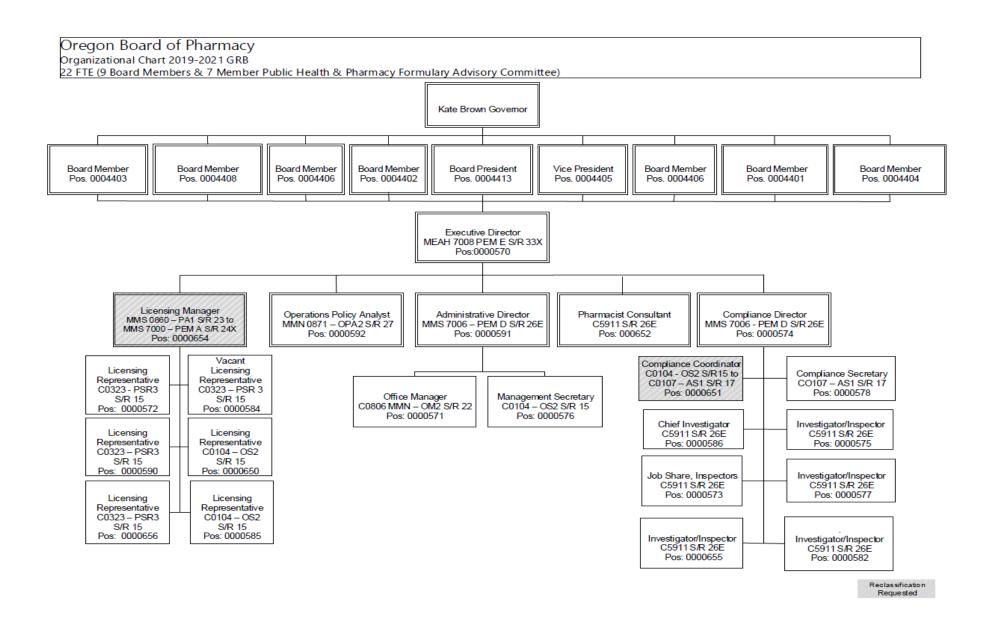
Ending Balance

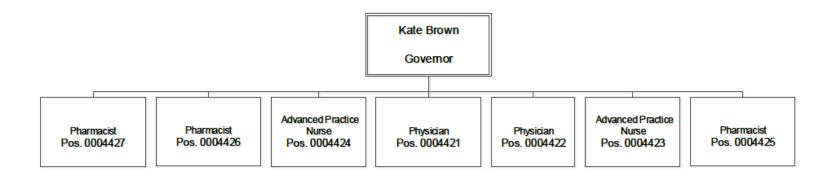
Assuming the Governor's Budget is approved; the Board will have a 9.6 month ending balance at the end of 2021-23 of \$3,667,760, this higher balance was expected as fees were increased in 2019-21. An updated ending balance chart is located on page 25.

APPENDIX

Pages 16-17	- Organizational	Charts
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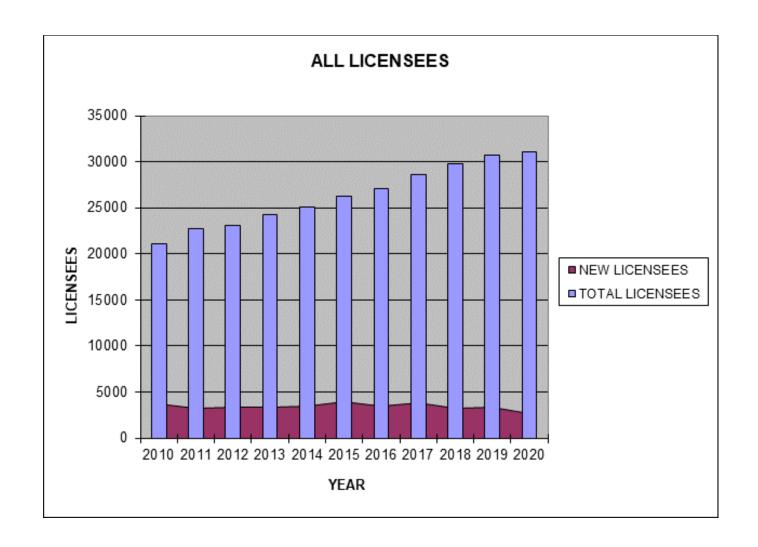
- Page 18 Licensing total/new licensee comparison chart
- Page 19 Licensee count / Funds /FTE
- Page 20 Compliance Case Chart
- Page 21 Inspection Charts
- Page 22 2021-23 Program Allocation
- Page 23 2021-23 Expenditures by type
- Page 24 Licensee Category by type
- Page 25 Ending Balance Information
- Page 26 Program prioritization for 2021-23



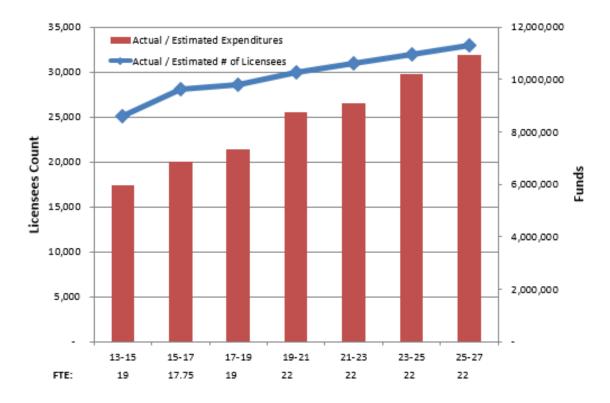


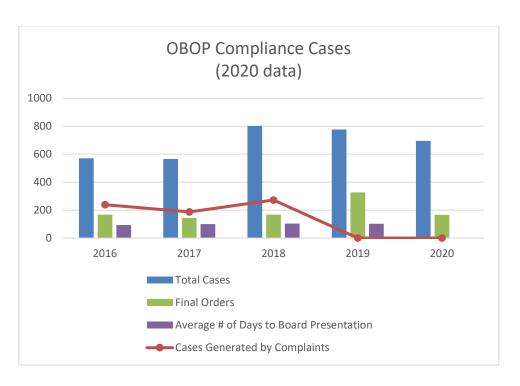
PUBLIC HEALTH AND PHARMACY FORMULARY ADVISORY COMMITTEE Established January 1, 2018

Members are appointed by the Governor to make recommendations to the Oregon Board of Pharmacy regarding pharmacist prescriptive authority

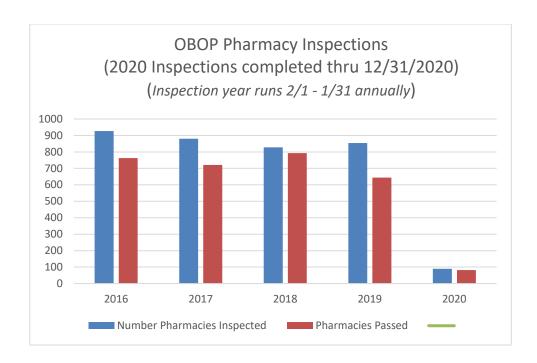


Oregon Board of Pharmacy Comparison Chart Licensees / Funds / FTE



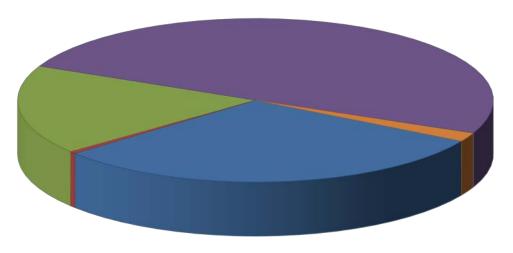


Note, as this chart relates to Key Performance Measure #4, beginning in 2019, "total cases" is inclusive of all case types, which include those initiated from inspection results, licensee application cases, drug diversion and theft cases, impairment cases, fraud / misrepresentation cases and all consumer complaints. Cases are triaged to ensure that the public's safety is maintained which may cause delays in processing of other types of cases. The 2020 data related to the average # of days is not available at this time. That will be reported in the 2021 Annual Performance Progress Report.



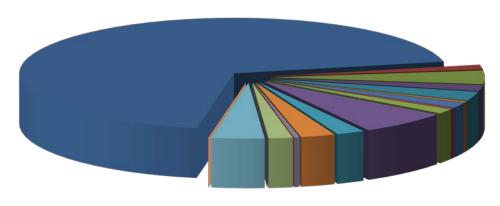
Due to the COVID-19 Public Health Emergency in 2020, limited inspections were completed due to travel restrictions and the safety of our staff. The Board is currently exploring options to conduct inspections virtually until it is safer to travel around the state.

2021-2023 Program Allocation



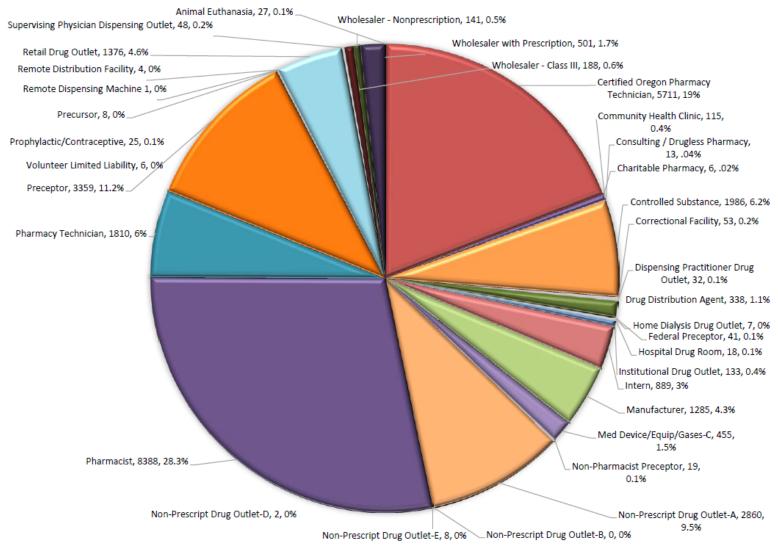
- Operations/Administration/Communications 30.38%
- Board Meeting and Member Activities .45%
- Licensing 17.69%
- Compliance 49.69%
- Public Health & Pharmacy Formulary Advisory Committee .06%
- Health Professionals Service Program (HPSP) 1.73%

2021-2023 Expenditures by Type \$9,104,052



- Personel Services 68.85%
- Travel 1.39%
- Data Processing & Telecommunications 3.98%
- Prof. Services/Hearings Panel 1.73%
- Agency Program Related S & S (Fingerprinting) 2.64%
- IT Expendable Property 0.48%
- IT Professional Services 1.48%
- Publicity & Publications 0.37%
- Office Expenses/Supplies (Includes Storage Fees & Postage) 1.42%
- Attorney General 6.81%
- State Government Service Charges 2.12%
- Facilities & Rent 2.58%
- Employee Training 0.24%
- Expendable Property 0.14%
- Health Professional's Service Program 1.81%
- Other Special Payments 0.00%
- Other Services & Supplies 3.97%
- Medical Services & Supplies 0.01%

Licenses by Category



Ending Balance Information

UPDATED OTHER FUNDS ENDING BALANCES FOR THE 2019-21 & 2021-23 BIENNIA

Agency: 85500 Oregon Board of Pharmacy Contact Person (Name & Phone #): Karen MacLean (971)673-0005

(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)
Other Fund				Constitutional and/or	2019-21 End	ing Balance	2021-23 Endi	ing Balance	
Type	Program Area (SCR)	Treasury Fund #/Name	Category/Description	Statutory reference	In LAB	Revised	In CSL	Revised	Comments
									2019-21 ending balance is higher than anticipated for
									a variety of reasons. 1) Continued owner/location
									changes for facilities are very unpredictable and have
					l		i		generated approx \$292k of revenue to date this
									biennium. 2) We had trouble filling a few positions
									this biennium, both getting candidates and due to
									COVID which resulted in vacancy savings. 3) Travel
	85500-001-00-00-	1171 OF State Board of			!		!		and Office expense savings have also been realized
Limited	00000	Pharmacy Account	Operations	ORS 689.135	1,462,841	3,937,733	3,256,649	3,514,530	due to COVID.

FEBRUARY 2021 / C1

	Program Prioritization for 2021-23																				
	y Name: 3 Bienniur		n Board	l of Pharmacy											Agenc	y Number	. 8==00				
Prograi					Program/D	ivision Pr	rioritie	for 20	21-23 B	liennium	1				rigerie	y ivanibei	. 05500				
1	2	3	4	5	6				10			13	14	15	16	17	18	19	20	21	22
(ran highe	iority ked with st priority ïrst)	Agency Initials	Program or Activity Initials	Program Unit/Activity	Identify Key Performance Measure(s)	Program-	GF	LF	OF	NL-OF	FF	NL-FF	TOTAL FUNDS	Pos.	FTE	New or Enhanced Program (Y/N)		Legal Req. Code (C, D, FM, FO, S)	Legal Citation	Explain What is Mandatory (for C, FM, and FO Only)	Comments on Proposed Changes to CSL included in Agency Request
Agcy	Prgm/ Div	1																			
85500	1	OBOP		Operations/Administration & Communications/Policy - Office & Operational Mgmt, Budget, Clerical, Policy Research, Committees, Administrative Rules, Project Mgmt.	85500 1-6	3			2,884,356				\$ 2,884,356		6.00	N	Y	s	ORS 475 & 689		None unless 10% Reductions are considered. The impact is included on the Reduction form 107bf17.
85500	1	ОВОР		Licensing & Exams	85500 2,5	3			1,679,089				\$ 1,679,089		7.00	N	Y	S	ORS 475 & 689		None unless 10% Reductions are considered. The impact is included on the Reduction form 107bf17.
85500	1	OBOP		Compliance	85500 7, 3-5	3			4,903,530				\$ 4,903,530		9.00	N	Y	S	ORS 475 & 689		Includes HPSP, KPM approval needed for biennial inspections. If 10% Reductions are considered, see 107b17.
85500	1	OBOP		Board Activities	85500 6	3			42,741				\$ 42,741		0.00	N	Y	S	ORS 475 & 689		The Board has 9 members, if in-state or out of state travel is reduced, there will be an impact.
85500	1	ОВОР		Formulary Committee	Agency Mission	3			5,447				\$ 5,447		0.00	N	N	S	ORS 689.645 and .649		This Committee includes 7 members, legislatively authorized and effective 1/1/18. The Committee is meeting approximately 4 times per year.
													\$ - \$ -								
							-	-	9,515,163	-	-	-	\$ 9,515,163	0	22.00						

Document criteria used to prioritize activities:	
The agency is budgeted as one Program Unit. For the purpose of this exercise, we have broken out the key areas of agency function. However, all areas are required to accomplish the statutory mission of the agency.	

Pharmacy Te	chnician Exter	nsions 12/9/2020-12/31/	2020					
Date					New Expiration			
Requested:	Lic#	Name:	Date Granted:	Issue Date	Date:	<u>Notes</u>	<u>Employer</u>	<u>Location</u>
7/6/2020	T-0023664	Celestine, Maria	Not Granted	8/16/2018	12/31/2020	Not eligible due to 2 year rule		
9/30/2020	T-0024423	Ayala, Dalia	Not Granted	5/30/2019	12/31/2020	Had not yet applied to take exams		
10/8/2020	T-0024205	Cortez, Faradiva	Not Granted	2/27/2019	12/31/2020	Had not yet applied to take exams		
10/12/2020	T-0023958	Brown, Jennifer	Not Granted	11/30/2018	12/31/2020	Not eligible due to 2 year rule		
10/12/2020	T-0024016	Okonkwo, Lawrence	Not Granted	12/12/2018	12/31/2020	Not eligible due to 2 year rule		
10/30/2020	T-0023984	Harlin, Andrew	Not Granted	12/11/2018	12/31/2020	Not eligible due to 2 year rule		
11/30/2020	T-0023570	Kinney, Elizabeth	Not Granted	7/13/2018	12/31/2020	Not eligible due to 2 year rule		Eugene
11/6/2020	T-0024333	Hyatt, Kaitlyn	11/9/2020	4/22/2019	4/22/2021	Exenuating Circumstances	Managed Healthcare Pharmacy	Eugene
11/23/2020	T-0024206	Guenther, Debra	11/23/2020	2/29/2019	2/27/2021	Exenuating Circumstances	Vetsource	Portland
11/25/2020	T-0024381	Robinson, Crystal	11/25/2020	5/15/2019	5/15/2021		Gold Hill Pharmacy	Gold Hill
11/30/2020	T-0024427	Kendell, Tammy	12/1/2020	5/30/2019	5/30/2021		Vetsource	Portland
11/30/2020	T-0024446	Avery, Arminda	12/2/2020	6/14/2019	6/14/2021		Fred Meyer	
12/5/2020	T-0024249	Strand, Kacy	12/7/2020	3/18/2019	3/18/2021	Exenuating Circumstances	Walgreens	Cornelius
12/8/2020	T-0024428	Cole, Kayla	12/8/2020	5/31/2019	5/31/2020		Asante Three Rivers	Medford
12/17/2020	T-0023709	Jensen, Cindy	Not Granted	8/31/2018	12/31/2020	Not eligible due to 2 year rule	Vetsource	Portland
12/16/2020	T-0024392	Waggener, Cynthia	12/18/2020	5/20/2019	5/20/2021	Extenuating Circumstances	Sky Lakes Inpatient Pharmacy	Klamath Falls
12/22/2020	T-0023695	Dedlow, Mandy	Not Granted	8/28/2018	12/31/2020	Not eligible due to 2 year rule	Rite Aid	Roseburg
12/22/2020	T-0024217	Luczon, Rachel	12/23/2020	3/1/2019	3/1/2021	Extenuating Circumstances	Community Compounding Pharmacy	Lake Oswego
12/22/2020	T-0024313	Stafford, Alexis	12/23/2020	4/11/2019	4/11/2021		Walgreens	Lincoln City
12/22/2020	T-0024197	Chhom, Soponna	12/23/2020	2/25/2019	2/25/2021			
12/25/2020	T-0024414	Hudak, Ginger	12/29/2020	5/28/2019			Caring for the Coast	Astoria
12/24/2020	T-0023800	Kaletina, Tatyana	Not Granted	10/3/2018	12/31/2020	Not eligible due to 2 year rule		
12/30/2020	T-0024373	Steele, Jeremy	12/31/2020	5/9/2019	5/6/2020		Vetsource	Portland
12/31/2020	T-0024311	Garcia, Xavier	1/5/2021	4/11/2019	4/11/2021		Safeway	Philomath

2020 TOTALS

14 Extensions Granted

2 Extension Not Granted

8 Extension Not Granted due to 2 year rule / not eligible for extension Per OAR 855-025-0010(1)

Total Extensions Requested July 6, 2020 - December 31, 2020

PLEASE NOTE: THE DECEMBER 2020 BOARD MEETING MINUTES ARE CONSIDERED DRAFT UNTIL APPROVED BY THE BOARD AT THE FEBRUARY 2021 BOARD MEETING.

Oregon Board of Pharmacy BOARD MEETING MINUTES

Meeting Location: Conference Call December 16-17,2020

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, December 16, 2020

OPEN SESSION

President Shannon Beaman called the meeting to order at 8:34 AM.

Roll Call

Board Members	Here	Absent
Board President Shannon Beaman	X	
Board Vice President Wassim Ayoub	Х	
Board Member Rachael DeBarmore	Х	
Board Member Ian Doyle	Х	
Board Member Mishele Dufour	X	
Board Member Tim Logan	X	
Board Member Michelle Murray	X	
Board Member Cyndi Vipperman	X	
Board Member Nichole Watson		Х

Staff Members	Here	Absent
Chief Compliance Officer Joe Ball	X	
Consultant Pharmacist Jennifer Davis	X	
Compliance Director Brianne Efremoff	X	
Compliance Officer Cheryl Fox	Х	
Licensing Manager Chrisy Hennigan	Х	
Compliance Secretary Elizabeth Hughes	Х	
Compliance Officer Jane Lee		Χ
Administrative Director Karen MacLean	X	
Operations Policy Analyst Rachel Melvin	Х	
Compliance Officer Brian Murch	X	
Compliance Coordinator Kim Oster	X	
Executive Director Joe Schnabel	Х	
Sr. AAG Board Counsel Joanna Tucker Davis	X	

Board Member Nichole Watson was absent. President Shannon Beaman briefly reviewed board meeting procedures with the Board and public.

PLEASE NOTE: THE DECEMBER 2020 BOARD MEETING MINUTES ARE CONSIDERED DRAFT UNTIL APPROVED BY
THE BOARD AT THE FEBRUARY 2021 BOARD MEETING.

Staff Member Schnabel introduced new staff positions, Pharmacist Consultant, Jennifer Davis and Office Manager, Devin Peters.

The Board recognized Board Member Dufour for her public service with the Board.

Agenda Review and Approval

MOTION

Motion to approve the agenda was made and unanimously carried (Motion by Beaman, second by Ayoub).

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

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

MOTION

Motion to enter Executive Session at 8:43 AM was made and unanimously carried (Motion by Beaman, second by Ayoub).

Contested Case Deliberation pursuant to ORS 192.690(1) - Not open to the public

MOTION

Motion to resume Open Session at 4:59 PM was made and unanimously carried (Motion by Beaman, second by Ayoub).

Adjourn

MOTION

Motion to adjourn at 5:01 PM was made and unanimously carried (Motion by Beaman, second by Ayoub).

THURSDAY, December 17, 2020

OPEN SESSION

President Shannon Beaman called the meeting to order at 8:34 AM.

Roll Call

Board Members	Here	Absent
Board President Shannon Beaman	Х	
Board Vice President Wassim Ayoub	Х	

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Board Member Rachael DeBarmore	Х	
Board Member Ian Doyle	Χ	
Board Member Mishele Dufour	Х	
Board Member Tim Logan	Х	
Board Member Michelle Murray	Х	
Board Member Cyndi Vipperman	Х	
Board Member Nichole Watson		Х

Staff Members	Here	Absent
Chief Compliance Officer Joe Ball	Х	
Pharmacist Consultant Jennifer Davis	X	
Compliance Director Brianne Efremoff	X	
Compliance Officer Cheryl Fox	Х	
Licensing Manager Chrisy Hennigan	Х	
Compliance Secretary Elizabeth Hughes	Х	
Compliance Officer Jane Lee		X
Administrative Director Karen MacLean	X	
Operations Policy Analyst Rachel Melvin	X	
Compliance Officer Brian Murch	X	
Compliance Coordinator Kim Oster	X	
Office Manger Devin Peters	X	
Executive Director Joe Schnabel	Х	
Sr. AAG Board Counsel Joanna Tucker Davis	Х	

Board Member Nichole Watson was absent. President Shannon Beaman briefly reviewed board meeting procedures with the Board and public and addressed the process to make public comment at the end of the meeting.

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

Deliberation on Disciplinary Cases and Investigations

MOTION

Motion to enter Executive Session at 8:37 AM was made and unanimously carried (Motion by Beaman, second by Ayoub).

Contested Case Deliberation pursuant to ORS 192.690(1) – Not open to the public

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Motion to resume Open Session at 10:35 AM was made and unanimously carried (Motion by Beaman, second by Ayoub).

OPEN SESSION

President Shannon Beaman briefly reviewed board meeting procedures with the Board and public and addressed the process to make public comment at the end of the meeting.

Staff Member Schnabel introduced new staff positions, Pharmacist Consultant, Jennifer Davis and Office Manager, Devin Peters.

The Board recognized Board member Dufour for her public service with the Board.

GENERAL ADMINISTRATION

Motions related to Disciplinary Actions

Board Member Dufour was absent and did not vote in the first seven votes listed below.

Case 2020-0560 Motion to grant waiver of FPGEC requirement.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2018-0462 Motion to modify probation to allow licensee to work at two Board approved locations and reduce testing frequency requirements to 12 UAs per year.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2019-0270 Motion to withdraw Final Order by Default.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0006 Motion to withdraw the previous vote and motion to impose a \$10,000 civil penalty per violation for 1 violation and a \$2,500 civil penalty per violation for 119 violations.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2017-0473 Motion to modify probation to allow licensee to be employed as a pharmacist-in-charge, pharmacy manager or consultant pharmacist.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2018-0289 Motion to accept proposed consent order with \$7,500 of \$10,000 civil penalty stayed and 2019-0045, and five years probation;

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and in

Case 2017-0528 Motion to accept proposed consent order with \$35,000 of \$40,000 civil penalty stayed 2018-0209, and five years probation.

and 2018-0454

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2019-0191 Motion to accept proposed Consent Order.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Board Member Dufour was present and voted in the remaining votes.

Case 2018-0253 Motion to accept proposed Consent Order.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0338 Motion to impose a \$250 civil penalty per violation for 18 violations;

and in

Case 2020-0577 Motion to impose a \$100 civil penalty per violation for 18 violations;

and in

Case 2020-0578 Motion to close with Board direction;

and in

Case 2020-0580 Motion to close with Board direction;

and in

Case 2020-0581 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0579 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0384 Motion to close with Board direction;

and in

Case 2020-0616 Motion to close with Board direction;

and in

Case 2020-0573 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

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Case 2020-0341 Motion to close with Board direction;

and in

Case 2020-0574 Motion to close with Board direction;

and in

Case 2020-0575 Motion to close with Board direction;

and in

Case 2020-0576 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0340 Motion to close with Board direction;

and in

Case 2020-0615 Motion to close with Board direction;

and in

Case 2020-0621 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0339 Motion to close with Board direction;

and in

Case 2020-0614 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0336 Motion to close with Board direction;

and in

Case 2020-0610 Motion to close with Board direction;

and in

Case 2020-0611 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0335 Motion to close with Board direction;

and in

Case 2020-0609 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0403 Motion to close with Board direction;

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and in

Case 2020-0572 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2019-0439 Motion to suspend pharmacist license for 15 days, impose a 3-year probation, and impose a \$1,000 civil penalty per violation for 4 violations and a \$200 civil penalty per violation for 3 violations.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0194 Motion to revoke pharmacist license and impose a \$1,000 civil penalty per violation for 2 violations.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion carried with Ian Doyle and Tim Logan opposed.

Case 2020-0460 Motion to close with Board direction;

and in

Case 2020-0554 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0242 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0449 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2018-0611 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2019-0592 Motion to close with Board direction;

and in

Case 2020-0599 Motion to close with Board direction;

and in

Case 2020-0601 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0484 Motion to close with Board direction;

and in

Case 2020-0401 Motion to impose \$1,000 civil penalty per violation for 1 violation.

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Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0073 Motion to close with Board direction;

and in

Case 2020-0545 Motion to impose a \$1,000 civil penalty per violation for 4 violations;

and in

Case 2020-0546 Motion to impose a \$1,000 civil penalty per violation for 3 violations.

Motion by: Rachael DeBarmore; Second by: Ian Doyle; Motion carried with Shannon Beaman and Wassim Ayoub recused.

Case 2020-0434 Motion to close with Board direction;

and in

Case 2020-0435 Motion to suspend intern license for failure to cooperate until licensee cooperates and for an additional 3 months after he starts to cooperate.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0588 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0495 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0556 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0605 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0608 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0529 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0531 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

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Case 2020-0496 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0451 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0557 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0607 Motion to grant technician license and impose \$1,000 civil penalty per violation for one violation.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0606 Motion to grant technician license and impose a \$1,000 civil penalty per violation for 1 violation.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0618 Motion to grant technician license and impose \$1,000 civil penalty per violation for 1 violation.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0530 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0590 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Cases 2019-0563, 2018-0730, 2018-0539, and 2020-0651 Motion to impose a \$10,000 civil penalty per violation for 30 violations.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0497 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0290 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0180 Motion to close with Board direction.

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Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0540 Motion to deny application.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0439 Motion to impose \$1,000 civil penalty per violation for 2 violations.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0454 Motion to impose a \$1,000 civil penalty per violation for 2 violations.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0456 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion carried with Michelle Murray recused.

Case 2020-0220 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0547 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0026 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0027 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Case 2020-0444 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Ian Doyle; Motion carried with Wassim Ayoub recused.

Case 2020-0414 Motion to close with Board direction.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Motion to accept the items on the consent agenda.

Motion by: Shannon Beaman; Second by: Wassim Ayoub; Motion unanimously carried.

Cases closed with Board direction:

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2020-0372, 2020-0594, 2020-0458, 2020-0405, 2020-0455, 2020-0473, 2020-0474, 2020-0475, 2020-0476, 2020-0478, 2020-0406, 2020-0442, 2019-0322, 2020-0028, 2020-0241, 2020-0325, 2020-0416, 2020-0424, 2020-0504, 2020-0511, 2020-0561, 2020-0564, 2020-0593, 2018-0256, 2019-0705, 2019-0711, 2019-0738, 2020-0036, 2020-0055, 2020-0171, 2020-0177, 2020-0186, 2020-0214, 2020-0255, 2020-0291, 2020-0327, 2020-0342, 2020-0368, 2020-0409, 2020-0410, 2020-0413, 2020-0418, 2020-0419, 2020-0420, 2020-0445, 2020-0447, 2020-0450, 2020-0461, 2020-0464, 2020-0465, 2020-0468, 2020-0487, 2020-0490, 2020-0493, 2020-0499, 2020-0500, 2020-0501, 2020-0502, 2020-0509, 2020-0517, 2020-0521, 2020-0522, 2020-0526, 2020-0532, 2020-0534, 2020-0552, 2020-0553, 2020-05602, 2020-0603, and 2020-0046

Rules

Annual 5 Year Legislative Rule Report Review 2015

Staff Member Melvin provided an overview of the 5-year Legislative Rule Report. Pursuant to ORS 183.405 state agencies must review new rules 5 years after adoption with exceptions. This report must be submitted to the Secretary of State by the end of the year, and no action is required in response to the findings. Staff Member Melvin listed the rules under review, including: Contraceptive Prescribing (OAR 855-019-0400, 0405,0415, 0425, 0430 & 0435), Drug Storage (OAR 855-041-1036), and Manufacturers (OAR 855-060-0002). Board staff was requested to provide responses to the questions that must be answered in the report; their answers were included in the presentation. Responses to questions on each rule group were discussed by the Board.

Contraceptive Prescribing (OAR 855-019-0400, 0405,0415, 0425, 0430 & 0435):

The Board voiced concerns on public awareness of these rules being low. The Board recognized that COVID-19 has created a barrier for these rules to be utilized.

Drug Storage (OAR 855-041-1036):

The Board commended Board staff on the enforcement of this rule and discussed how this rule will help with the distribution of the COVID-19 vaccine. The Board inquired if staff responses involving the clarity of this rule will be addressed. Staff Member Schnabel stated that these responses will be used to evaluate if language updates are needed.

Manufacturers (OAR 855-060-0002):

The Board had no comments in relation to this rule.

The Board voiced support for OAR 855-019-0264, another rule implemented in 2015, being repealed due to outdated language.

Review Rulemaking Hearing Report & Comments

Staff Member Melvin provided a rulemaking hearing report:

- Held rulemaking hearing on 11/24/2020 with Staff Member Melvin as hearing officer
 - o Proposed rules in Division 001,007, 020, 041, 043, and 044
 - o 7 oral comments and 30 written comments received
 - Staff Member Melvin summarized oral comments and included all written comments

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- o Requested if Board members have any comments on report
 - The Board had no comments.

Motion to approve the to accept the 11/24/2020 Rulemaking Hearing Report was made and unanimously carried (Motion by Beaman, second by Ayoub).

Consideration Adoption of Rules

Review rules and potentially send to rules hearing

Division 001 Procedural Rules

Staff Member Melvin provided the following rule background:

- During the October 2020 Board meeting, the Board reviewed Division 001 revisions in alignment with the Board's 2020-2024 Strategic Plan to proactively review & update rules to ensure clarity, transparency and promote patient safety.
- The Board acknowledged that the revisions were based on the most current version of the 7/2019 Attorney General Model Rules, Oregon Revised Statute (ORS) 689, ORS 183 and ORS 676.
- During rule review, the Board discussed the following topics:
 - o Inspections: The Board addressed the need for an inspection to occur at a reasonable time for both the Board staff and drug outlets.
 - Documents available at the time of inspection: The Board highlighted new clarity in rule related to documents required to be available at the time of inspection.

President Beaman led a Board discussion:

- The Board discussed comments provided during the Rules Hearing.
- The Board discussed the difficulties of drug outlets being able to produce 2-3 year old records stored off site for Compliance Officers to review at the time of inspection. The Board also discussed how the language of OAR 855-001-0040 may need to be altered to clearly allow a 72 hour time frame to produce 2-3 year old records. Records less than one year old would be required for review at the time of inspection. Based on discussion with legal counsel, the Board chose to remove OAR 855-001-0040 from the motion to allow further edits to be made.

MOTION

Motion to approve the to adopt proposed rules OAR 855-001-0000, 855-001-0005, 855-001-0010, 855-001-0012, 855-001-0015, 855-001-0016, 855-001-0017, and 855-001-0035, was made and unanimously carried (Motion by Beaman, second by DeBarmore).

Division 007- Executive Order Compliance

Staff Member Melvin provided the following rule background:

- During the October 2020 Board meeting, the board reviewed the current temporary rule which expires 1/11/21 and discussed permanent adoption of this rule.
- The Board discussed and communicated the need for licensees and registrants to comply with Executive Orders.

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- The Board discussed the specificity of this rule and concerns related to long term applicability of this rule for future declared public health emergencies.
 - Staff Member Schnabel addressed the Board's comments and highlighted that not all sections of Division 007 are applicable at any given time and the use of rules within this division would depend upon the specific circumstances of the public health emergency.

The Board had no comments on this rule.

MOTION

Motion to adopt proposed rule OAR 855-007-0086 was made and unanimously carried (Motion by Beaman, second by Ayoub).

Division 020 – Protocol Compendium (PrEP)

Staff Member Melvin provided the following rule background:

- At the October 2020 Board meeting, the Board reviewed the proposed amendment to add a Pre-Exposure Prophylaxis (PrEP) protocol to OAR 855-020-0300.
 - This protocol was recommended by the Public Health and Pharmacy Formulary Advisory Committee at their 9/2020 meeting.
- Staff Member Schnabel provided a <u>PowerPoint</u> presentation on lab tests and highlighted that nothing in this protocol specifies where or how lab tests are performed. Staff Member Schnabel stated that pharmacists and pharmacies will have to comply with state and federal laboratory regulations.
- Staff Member Davis led review of the PrEP protocol package. She presented the following documents for Board review and was directed to make minor clarifying edits.
 - The standardized PrEP Patient Intake Form
 - The standardized PrEP Assessment and Treatment Care Pathway
 - The standardized PrEP Provider Fax
- Since the Board reviewed the PrEP protocol package in October 2020, PrEP therapy (Truvada) is now available in a generic form.
- The Board reviewed the proposed rules in coordination with the required PrEP protocol package and pharmacist comprehensive training program and moved to send the rule to the upcoming rulemaking hearing.

The Board had no comments on this rule.

MOTION

Motion to adopt proposed rule OAR 855-020-0300 was made and unanimously carried (Motion by Beaman, second by Ayoub).

Division 041, 043 & 044 – Limited English Proficiency (LEP)

Staff Member Melvin provided the following rule background:

 At the October 2020 Board meeting, the Board took their second look at the proposed rule language for Divisions 041, 043 and 044 to address the directives of 2019 SB 698, which require accessibility services for Limited English Proficiency (LEP) patients, effective January 1, 2021.

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- These rules are intended for all prescription drugs dispensed directly to patients, and requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies.
- During rule review, the Board discussed the following topics:
 - The need to ensure that all impacted stakeholders, who are required to provide this service are aware of the new statute and rule directives.
 - The need to clarify the list of languages required to be translated.
 - The Board reviewed the list of fourteen languages recommended by the Oregon Health Authority
 Office of Equity and Inclusion and noted that Ukrainian and Dari were not included, so
 recommended deleting them from the rule.
 - The benefits to patient safety and health equity.
 - The current implementation challenges posed including those related to technology, cost, workflow, and the impacts of the ongoing COVID-19 pandemic.
 - The Board encouraged all drug outlets to operationalize these labeling capabilities as soon as possible.
 - The Board may exercise enforcement and Compliance cases related to these rules will be addressed individually per usual Board processes.
 - Enforcement discretion does not establish a delay in the January 1, 2021 operative date of statute and rules, which the Board does not have authority to change.

Staff Member Schnabel provided info:

- It is clear from review of the legislative history of SB 698 that the bill was not intended to require
 translated patient information leaflets, such as REMS Medication Guides or other informational materials
 not generally included as part of a prescription label. It appears that the intent was to allow information
 leaflets in specific situations, such as when directions for use were lengthy and could not fit on the
 container label.
- Staff will bring back proposed language for the Board's consideration in February 2021 to add an
 informational insert definition in rules to provide clarity and meet law's intent.

President Beaman led a Board discussion:

 The Board asked for clarification on why lines pertaining to exceptions for minimum equipment requirements (lines 75-76) had been removed. Board Staff explained that it was no longer felt that the need for an exception was required.

MOTION

Motion to adopt proposed rules OAR 855-041-1132, 855-041-1035, 855-041-1040, 855-043-0005, 855-043-0436, 855-043-0541, 855-043-0736,855-044-0060 and 855-044-0061 was made and unanimously carried (Motion by Beaman, second by Ayoub).

Consider Adoption of Temporary Rules – none

Rulemaking Policy Discussion Items

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Division 080 - Controlled Substances

Staff member Davis provided a background:

- This is the Board's first look at the proposed updates to Division 080. The revisions are proposed in alignment with the Board's 2020-2024 Strategic Plan to proactively review & update rules to ensure clarity, transparency and promote patient safety.
- This update appropriately references and reflects current federal controlled substance regulations, amends and repeals outdated regulations.
- The Board will be reviewing Division 080 today, but with the understanding that since we are so close to the annual CFR update which will occur in April 2021, the Board will have a second look at these proposed updates in April 2021 for approval to send to May rulemaking hearing to be considered for adoption at the June board meeting.
- Each year at the April Board Meeting, the Board will need to review updated CFRs and USCs for Division 080 for approval to send to May rulemaking hearing to be considered for adoption at the June board meeting.

President Beaman led a Board discussion:

The Board inquired if there are other divisions that speak to the disposal of drugs since the language
pertaining to drug disposal has been removed from this division. Board Staff stated that there are other
divisions that address this.

Division 019, 021, 025, 031- Cultural Competency CE

Staff member Davis provided background:

- The Board initially discussed Cultural Competency CE (CCCE) at the December 2019 meeting and the following items were considered:
 - o Fiona Karbowicz, Pharmacist Consultant, provided a presentation that explained:
 - 2019 HB 2011 amended ORS 676.850 to state that the "board shall adopt rules to require
 a person authorized to practice the profession regulated by the board to complete
 cultural competency continuing education."
 - The effective date/operative date of this legislation is 7/1/2021.
 - The statute requires "a person authorized" (i.e. RPh, CPT and possibly interns) to complete CCCE every other renewal and has a number of carve-outs (i.e. retired, not practicing).
 - The Board has options to re-articulate the statute in rule and determine the frequency and number of hours required for CCCE.
 - The Board contemplated the following:
 - Requiring a certain number of CCCE hours every cycle rather than every other cycle.
 Discussion included that annual CCCE requirements would help licensees track completion and with compliance/audits.
 - Incorporating or adding on hours for CCCE. The Board consensus at the time to require 2 hours every renewal cycle and incorporate into current CE requirements rather than adding additional hour requirements.
 - Licensees could discern if based on the title of the program if it would apply for CCCE.

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- The Board's first look at proposed rule language concerning Cultural Competency CE was completed in February 2020. At the time, the only revision to Division 21 was adding an entirely new chapter called Cultural Competency Continuing Education specific to pharmacist CE that required 2 hours of CCCE every renewal cycle as part of the 30 required hours and adding one line of rule to Division 25 that required 2 hours of CCCE every renewal cycle as part of the 20 required hours. The Board engaged in discussion about going through rules and cleaning them up and Board staff provided education on how the clean-up process would work.
- This is the Board's second look at the proposed rule language for Divisions 019, 021, 025, 031 to address
 the directives of 2019 HB 2011 (ORS 676.850) which requires specified health professional regulatory
 boards to require people authorized to practice the profession regulated by the Board to complete
 cultural competency continuing education as a condition of renewal of the authorization to practice.
 HB2011 makes these continuing education requirements operative on July 1, 2021. HB 2011 also requires
 continuing competency every other renewal.
 - o The Board, under its authority in ORS 689.285 and ORS 689.486, is requiring continuing competency CE every renewal, which will also satisfy the requirements of 2019 HB 2011.
 - The additional revisions to Division 021 are in alignment with the Board's 2020-2024 Strategic Plan to proactively review & update rules to ensure clarity, transparency and promote patient safety.
 - O Structurally, Division 019 has traditionally referred RPHs to Division 021 (Continuing Pharmacy Education) for details on CPE requirements; however, Division 025 (PT and CPT) has traditionally kept the CPE requirements in the Division. To provide consistency throughout Chapter 855 the CPE requirements for all license types have been moved into Division 021 (CPE). In Divisions 019, 025, 031 there is now language referring licensees to Division 021 for CPE requirements.

President Beaman led a Board discussion over a series of inquiries presented by Staff Member Davis:

- Policy Discussion: Does the Board agree with incorporating the newly required cultural competency CE into the existing 30-hour CE requirement for pharmacists?
 - The Board voiced support for this. However, the Board presented concerns on the phrasing of "cultural competency" and the implications of the word "competency." Based on discussion with legal counsel, the Board understands that this phrasing will be used in the rule since it is used in the statute.
- Policy Discussion: Does the Board want to continue to not require recent pharmacy graduates to complete pain management CE during their first license renewal period? This rule was initially implemented when renewals were annual rather than biannual.
 - The Board weighed the benefits and limitations of requiring pain management CE to be completed during the first renewal period. The Board requested that Board staff reevaluate the statute pertaining to this rule and bring back more information of possible adjustments for future discussion. Concerns included length of first renewal period and workload of recently licensed pharmacists.
- Policy Discussion: Does the Board want to continue allowing recent pharmacy graduates to not complete
 any CE for their first renewal period? This rule was initially implemented when renewals were annual
 rather than biannual.

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- The Board voiced support for changing the rule to require CE to be completed during the first renewal period. They requested that Board staff reevaluate the statute pertaining to this rule and bring back more information of possible adjustments for future discussion.
- Policy Discussion: Does the Board want to continue allowing pharmacists licensed by reciprocity to not complete any CE for their first renewal period?
 - The Board requested that Board staff reevaluate the statute pertaining to this rule and bring back more information of possible adjustments for future discussion.
- Policy Discussion: Does the Board agree with incorporating the newly required cultural competency CE into the existing 20-hour CE requirement for CPTs?
 - o The Board voiced support for this.
- Policy Discussion: Does the Board want to continue allowing recently licensed CPTs to not complete any CE for their first renewal period? This rule was initially implemented when renewals were annual rather than biannual.
 - The Board requested that Board staff reevaluate the statute pertaining to this rule and bring back more information of possible adjustments for future discussion.
- Policy Discussion: Does the Board was to accept all ACPE approved CE?
 - o The Board voiced support for this.
- Policy Discussion: Does the Board want to allow CPTs to earn CE through graduate or professional degrees and through preparing and presenting CE programs?
 - The Board voiced support for including CPTs in this allowance.
- Policy Discussion: Does the Board want to continue to allow onsite training to be considered CE?
 - The Board discussed the differences between site specific training and CE programs offered by employers. The Board voiced support for removing onsite training to be considered CE. The Board discussed the avenues through which employers can have their training programs approved as CE.
- Policy Discussion: Does the Board approve the addition of OAR 855-021-0050(3) allowing Board staff to utilize NABP's CPE Monitor service for CE audits?
 - The Board clarified that proof of completion outside of the CPE Monitor will still be accepted and voiced their support.
- Staff Member Davis asked for Board comment on the remaining updates that have been made to the rules.
 - The Board discussed the lengthening of the time period that licensees must keep records of completed CE from 3 years to 6 years.

Staff Member Davis provided a presentation on CPE policy items that were bookmarked at the February 2020 Board meeting, including updating rules to align throughout the divisions and language modernization, the difference between and history of ACPE CPE and Non-ACPE CPE, and the process for Non-ACPE CPE approval by Board staff.

Staff Member Davis requested guidance from the Board on if they would like to transition to exclusively accepting ACPE CPE.

The Board voiced support for continuing to accept Non-ACPE CPE on an individually evaluated basis.

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Staff Member Davis requested guidance from the Board on if they want to keep the current Non-ACPE CPE approval process. If so, the Board was requested to provide clearer guidelines, including approved categories and a maximum number of Non-ACPE CPE hours accepted. Additionally, the Board was asked if they would like to contract with a Non-ACPE provider and avoid the individual Board approval process?

The Board voiced support for revising the process of approving Non-ACPE CPE and for Board staff to
research options for contracting with a Non-ACPE CPE provider. The Board gave staff guidance to convene
a RAC to discuss this process.

Staff Member Davis provided statistics from the most recent pharmacist CE audit to show how NABP's CPE Monitor can save resources and time for both Board staff and licensees.

- The Board voiced support for requiring licensees to provide their NABP e-profile ID to streamline the CE audit process. At this time, the Board does not support using NABP's CPE Monitor to outsource the audit process and audit 100% of licensees each renewal, but they requested that Board staff continue to research this option and bring back more information for future discussion.
- The Board voiced support for allowing licensees to keep their records of completed CE in NABP's CPE Monitor.

Public Health and Pharmacy Formulary Advisory Committee

Nothing to report at this time

Staff Member Schnabel left the meeting at 3:55pm to attend a meeting with the Governor's Office.

Discussion Items

COVID-19

Staff Member Schnabel provided and update that was read by Staff Member Davis:

Most of the activity around COVID-19 is the arrival of the Pfizer/BioNTech vaccine and the impending shipment of the Moderna vaccine. The Oregon Health Authority is responsible for vaccine distribution in Oregon and, due to the specialized handling required of the Pfizer vaccine, they have established a spoke and hub model for ultra-cold storage and distribution to administration sites.

Division 007 rules for distribution of vaccines from the federal government establishes storage of vaccine in Receipt, staging, and storage (RSS) centers and points of dispensing. It also requires long-term storage to be in a registered pharmacy or a Drug Room. We have established a COVID-19 Drug Room application for this purpose and have issued two registrations to date.

Since our last board meeting, we have issued two COVID-19 updates to address vaccine storage and distribution, OSHA regulations, face covering guidance, and the board's statement on DHHS Guidance on immunization services.

• Preceptor to Intern ratio for COVID-19 Vaccine Clinics

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- In order to increase vaccination capacity at immunization clinics for COVID-19 vaccination, the OSU/OHSU College of Pharmacy and Oregon Health Authority asked if the 2:1 ratio of pharmacy intern to pharmacist could be increased by the board.
 - The Board discussed the benefits and possible risks to patient safety of increasing the current ratio. After discussion, the Board provided direction for Board staff to implement a temporary rule in Division 007 allowing immunizing pharmacists to oversee as many immunizing interns as they see fit during the public health emergency. The Board wishes for this temporary rule to be effective upon filing and will review a permanent rule adoption next year.

Board Member DeBarmore left the meeting at 4:15pm.

Exemption Request

- Staff member Davis presented a special permit request from QPharma Inc. to distribute medication samples directly to patients due to limitations of patients attending physical appointments in order to receive medication samples from practitioners.
 - Staff requested parameters for approval, rationale, what needs to be met for other entities to have an approved request (ie. COVID, FDA guidance, etc.), special permit process and expiration.
 - o The Board discussed how this special permit could affect patient safety and patient access.
 - The Board provided criteria for their approval of this request. Their approval was based on the current public health emergency, the required involvement of practitioners requesting the samples for patients, and an expiration date of six months from issuance. After six months, a new special permit may be considered.

MOTION

Motion to grant an exemption and issue a special permit to QPharma Inc. under ORS 689.527(7) and unanimously carried (Motion by Beaman, second by Ayoub). Rachael DeBarmore was absent from the vote.

Strategic Planning

2020-2024 Plan Updates:

Staff Member Melvin read notes provided by Staff Member Schnabel with an update on the following strategic goals:

- Technicians
- Technology
- Licensing
- Regulation
- Communication

Last month, meeting was held to update our 2020-2024 strategic plan. Due to the significant disruption of board operations brought about by two public health emergencies, one of which is ongoing, the progress made on the plan is less than anticipated.

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Despite the setbacks, clear direction from the board was expressed regarding pharmacy technicians and technologies to address the increasing role of pharmacists in providing patient care services, such as vaccination, laboratory testing, and protocol prescribing.

In the strategic planning update meeting, the board articulated the following priorities for rulemaking beginning in early 2021, a few of which may require further DOJ review or statutory change:

- Technician assist vaccine administration
- Technician assist in obtaining vaccination history from patient
- Remote technician supervision for data entry
- Remote technician supervision for insurance and prescription management
- Remote technician supervision for prescription filling/verification ("pharmacist-less pharmacy")
- Technicians receiving verbal/transfer prescriptions
- Final verification process ("Tech check Tech", TCVP)
- Intern rules for preceptor authority to allow specific practices prior to end of P-1 year
- Technician access to pharmacy without pharmacist
- Medication history updates for hospitalized patients
- Self-service prescription kiosks

Board staff will begin to work on implementing these priorities as we enter 2021 and will keep you apprised of progress at each board meeting.

Regarding the three goal areas that were not a focus of the update – Licensing, Regulation, and Communication: work continues toward streamlining the licensing process through enhancements of the new licensing platform, MLO; several comprehensive rule reviews have been completed with the goal of one per quarter being met, and; the communication plan continues to be executed and enhanced.

ISSUES AND ACTIVITIES

Reports:

Board Member Ayoub	Reported virtual attendance at ASHP December 6-10.
Board Member Beaman	No report
Board Member DeBarmore	Absent
Board Member Doyle	No report
Board Member Dufour	No report
Board Member Logan	No report
Board Member Murray	No report
Board Member Vipperman	Excused
Board Member Watson	Absent

Financial/Budget Report

Financial Update

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Staff Member MacLean briefly reported on the October Financial Report mailing provided to the Board. She also advised that the Governor's Budget for the agency will be moving to the Legislature. The agency request was largely approved as requested with a few reductions that were made to all agencies such as adjustments for inflation. One policy package will be moving forward, one was pulled. We are still waiting for instructions for the presentation document and when it will occur. It's anticipated to be virtual.

Legislative Updates:

There will be a special legislative session on Monday 12/21 to address COVID-19 and wildfire relief legislation.

Board Meeting Dates:

•	February 10-12, 2021*	Portland	
•	April 7-8, 2021	Portland	
•	June 9-10, 2021	Portland	
•	August 11-13, 2021*	Portland	
•	October 13-14, 2021	Portland	
•	November 3-4, 2021	TBA	(Strategic Planning)
•	December 8-9, 2021	Portland	

Proposed 2022 Board Meeting Dates:

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

Rulemaking Hearing Dates

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

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

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PAST MEETINGS

- OSPA Annual Seminar (virtual) 10/17/2020 Law Update
 - o Staff Members Schnabel and Davis attended and presented an Oregon Pharmacy Law Update.

FUTURE MEETINGS

- NABP Interactive Member Forum (virtual) January 27, 2021
 - o President Beaman and Vice President Ayoub will attend.

Approve Consent Agenda*

*Items listed under the consent agenda are considered 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.

- NAPLEX Scores May 1, 2020 August 31, 2020
- MPJE Scores May 1, 2020 August 31, 2020
- License/Registration Ratification September 30, 2020 December 8, 2020
- Pharmacy Technician Extensions July 6, 2020 December 8, 2020
- Strategic Planning Mtg Minutes –November 18-19, 2020

MOTION

Motion to approve Consent Agenda as revised, was made and unanimously carried (Motion by Beaman, second by Ayoub). Rachael DeBarmore was absent from the vote.

PUBLIC COMMENT

The following people provided public comment:

- Paige Clark, R.Ph. OSU/OHSU College of Pharmacy
- Lis Houchen National Association of Chain Drug Stores (NACDS)
- Kristen Beiers-Jones RN, MN OHSU School of Nursing

Adjourn

MOTION

Motion to adjourn at 5:25 PM was made and unanimously carried (Motion by Beaman, second by Ayoub). Rachael DeBarmore absent.