OREGON BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

No. 736 2024 Legislative Update

The 2024 regular session of the Oregon Legislature has concluded with the passage of a few bills that will affect licensees and registrants. The following are brief summaries of selected bills that may require Oregon Board of Pharmacy rulemaking.

- House Bill (HB) 4002 (Sections 6-9) Allows pharmacists to prescribe and dispense early refills of medication for opioid use disorder under specified conditions. Allows pharmacies to have on-site prescription drug lockers without obtaining a license or registration from the Board. Effective April 1, 2024.
- HB 4010 (Sections 1-2) Specifies that flavoring of a prescription drug is not compounding. Effective June 6, 2024.
- Senate Bill 1506 Allows a pharmacist to test and prescribe, dispense, and administer treatment for SARS-CoV-2. Effective June 6, 2024. Operative October 1, 2024. Sunset June 30, 2026.

No. 737 Can a Pharmacist 'Diagnose'?

On September 25, 2023, the Oregon State Pharmacy Association submitted a petition under Oregon Administrative Rule (OAR) 137-001-0070, which allows interested parties to request changes to Board rules. As a result of the petition, the Board received public comments on OAR 855-115-0150 from October 23, 2023, to November 15, 2023. Based on the petition and the public

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comments received, the Board motioned to initiate rulemaking during its December 2023 Board meeting. At the February 2024 Board meeting, the Board amended the rule to remove "diagnose" from the list of prohibited practices in OAR 855-115-0150. It is important to note that while the rule is now silent regarding diagnosis, the Board wishes to explicitly clarify that pharmacists are **not** authorized to diagnose medical conditions, as that is not currently within the statutory scope of the practice of pharmacy as defined in Oregon Revised Statutes (ORS), Chapter 689. Diagnosis remains the exclusive domain of licensed health care professionals within their respective scopes of practice. This clarification is intended to avoid any misinterpretation or confusion as to the limitations of a pharmacist's scope of practice.

No. 738 Does Your Pharmacy Stock Medications Prescribed for HIV PEP?

HIV post-exposure prophylaxis (PEP) therapy is time-sensitive and must be started within 72 hours of a patient's possible exposure to HIV, ideally within the first 24 hours. Unfortunately, many pharmacies do not routinely stock medications prescribed for HIV PEP and the process of finding one in a timely manner can present unforeseen barriers to adherence. To make HIV PEP easier to find, the Oregon AIDS Education and Training Center hosts a directory of pharmacies that stock medications commonly prescribed for PEP at *www.oraetc.org/findpep*. This directory is used by PrEP/ PEP navigators across the state and patients seeking to fill a prescription for HIV PEP. To add your pharmacy to the directory – contact aallison@orpca.org.

The Oregon Legislature passed HB 2574 (2023 Oregon Law, Chapter 411) into law during the 2023 session. The law went into effect on January 1, 2024, and requires hospitals to dispense at least a five-day supply of HIV PEP following a patient's possible exposure to HIV. A complete PEP regimen is 28 days, which may require patients to rely on pharmacies to obtain the rest of their prescriptions. Learn more below:

- Factsheet for Non-Hospital Partners
- PEP Resources for Patients (English)
- PEP Resources for Patients (Spanish)

No. 739 Harm Reduction: Short-Acting Opioid Antagonists and Buprenorphine

As Oregon grapples with rising overdose rates, new laws and policies aim to expand access to shortacting opioid antagonists (eg, naloxone, nalmefene) and buprenorphine.

Oregon Health Authority (OHA) Standing Order

Effective January 1, 2024, and pursuant to ORS 689.808, OHA has issued a statewide standing order that permits Oregon-licensed pharmacists practicing in the state of Oregon to dispense naloxone nasal spray/naloxone injection and necessary supplies to the following people:

- Anyone at risk of overdosing on an opioid.
- Those who might come across someone overdosing on an opioid.
- Owners or any staff members of a building or facility with public access where overdoses from opioids may occur.

Pharmacists can use the OHA standing order (like a pre-written prescription) to dispense naloxone without needing an individual prescription. You can find the standing order on the Board's website. When using the standing order, use the public health officer (eg, physician who signed the order) who authorized the order as the "prescriber."

Pharmacists may still prescribe short-acting opioid antagonists and the necessary medical supplies to administer a short-acting opioid antagonist for opiate overdose pursuant to ORS 689.802 and OAR 855-115-0350.

Labeling Exemption for Short-Acting Opioid Antagonist Nasal Sprays

Effective January 1, 2024, and pursuant to ORS 689.813, a pharmacist who **prescribes** <u>and</u> <u>dispenses</u> from the pharmacy a short-acting opioid antagonist in the form of a nasal spray is exempt from the standard labeling requirements in OAR 855-041-1130. Pharmacists who dispense a short-acting opioid antagonist pursuant to a prescription from another health care practitioner (including via the standing order) must label the short-acting opioid antagonist as required by OAR 855-041-1130.

• Board Statement on Access to Buprenorphine

At the October 2023 Board meeting, the Board adopted a Statement on Access to Buprenorphine for Patients Requiring Medication-Assisted Treatment for Opioid Use Disorder. The Board supports minimizing barriers to accessing buprenorphine and other essential medications for those seeking treatment for opioid use disorder. For additional information, please see the full statement.

No. 740 Rulemaking

Licensees are encouraged to review rules adopted, amended, repealed, and noticed for rulemaking during the April 2024 Board meeting.

- Rules Sent to Rulemaking in April 2024 Rulemaking Hearing May 22, 2024
 - Division 115 Pharmacists PIC Qualifications and Limitations *Repeal
 - Division 115 Pharmacists Services: Prescribing Formulary and Protocol Compendium
 - Each proposed protocol amendment may be viewed here
 - Division 115 Pharmacists Services: Prescribing Practices Short-acting Opioid Antagonists

- Division 120 Interns and Preceptors Prohibited Practices
- Division 020 Pharmacist Prescriptive Authority Protocol Compendium *Repeal
- Division 006/041/043/045/080/115/120/135/139/141 Standards Adopted by Reference
- Division 115 Pharmacists Responsibilities: Outlet Delegation of Final Verification

No. 741 Compliance – 2024 Self-Inspection Forms

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As announced in article #694 of the November 2022 *Newsletter*, the 2024 self-inspection forms (SIFs) are now available on the Board's website. Per OAR 855-115-0210, the pharmacist-in-charge (PIC) of a Drug Outlet Pharmacy must complete an annual self-inspection of the pharmacy using the SIF provided by the Board by July 1 each year and within 15 days of becoming the PIC. The completed SIFs must be signed and dated by the PIC and retained for three years from the date of completion.

No. 742 Compliance – Accessible Pharmacy Services

Oregon pharmacies must provide accessible services for all individuals, regardless of language spoken, vision, or hearing ability. This article outlines key regulations and resources to ensure that patients receive proper communication assistance and medication information.

- Interpretation Pharmacists must work with a health care interpreter from the registry when communicating with a patient who prefers to communicate in a language other than English or communicates in a signed language.
 - ORS 413.550 Definitions for ORS 413.550 to 413.559
 - ORS 413.559 Requirement for provider to work with health care interpreter from registry; exceptions; rules
 - OAR 855-041-1133 Dispensing: Interpretation
 - OAR 950-050-0160 Health Care Provider Requirements
 - OAR 950-050-0170 Interpreting Service Companies
- **Dual Language Labeling** Pharmacies must make prescription labels available in English and 14 languages.
 - ORS 689.564 Language requirements for prescription drug labels; exceptions; interpretation and translation services; rules
 - OAR 855-041-1132 Limited English Proficiency and Accessibility
- **Prescription Readers** Pharmacies must make prescription readers available to persons who are visually impaired, print disabled, or blind.

- ORS 689.561 Prescription readers; compatible labels; exception; rules
- OAR 855-041-1131 Prescription Reader Accessibility
- Federal Laws and Rules related to nondiscrimination
 - 42 United States Code (USC) 18116 Nondiscrimination
 - 42 Code of Federal Regulations 92 Nondiscrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities receiving federal financial assistance and programs or activities administered by the Department of Health and Human Services under Title I of the Patient Protection and Affordable Care Act or by entities established under such title
 - 29 USC 794 Nondiscrimination under Federal grants and programs
- Federal Laws and Rules related to disabilities
 - 42 USC 126 Equal opportunity for individuals with disabilities

Please note that under the Americans with Disabilities Act, your pharmacy must provide effective communication with people who have communication disabilities (vision, hearing, or speech disabilities).

- Title II (public entities state and local government entities): "When choosing an aid or service, title II entities are required to give primary consideration to the choice of aid or service requested by the person who has a communication disability. The state or local government must honor the person's choice, unless it can demonstrate that another equally effective means of communication is available . . . "
- Title III (public accommodations business, commerce, nonprofit, etc): "[E]ntities are encouraged to consult with the person with a disability to discuss what aid or service is appropriate. The goal is to provide an aid or service that will be effective, given the nature of what is being communicated and the person's method of communicating."
- "[All] covered entities may require reasonable advance notice from people requesting aids or services, based on the length of time needed to acquire the aid or service, but may not impose excessive advance notice requirements. 'Walk-in' requests for aids and services must also be honored to the extent possible."

In addition, all covered entities must pay for the auxiliary aid or service unless they can demonstrate that it would be an undue financial burden. In that case, the entity must provide a different auxiliary aid or service to provide effective communication.

Excerpts above are from https://www.ada.gov/resources/effective-communication/.

When a compliance officer is inspecting your pharmacy, expect them to ask you practical questions related to these accessibility tools. These questions may include:

- Interpretation:
 - How do you identify patients who would benefit from interpretation services?
 - How do you document interpretation services provided?
 - How do you provide interpretation to a patient requiring signed language?
- Dual Language Labeling:
 - How do you identify patients who would benefit from dual language labels?
 - How do you ensure that prescriptions for which dual language labels have been requested have dual language labels applied prior to release to the patient?
 - Show me how you would create a label for this prescription in Arabic?
- Prescription Readers:
 - Do you know how to obtain a prescription reader and related supplies?
 - Do you know what type of prescription reader your patient uses?
 - Do you know how to set and use the prescription reader?

No. 743 Compliance- Expired Products from COVID-19 Ancillary Supply and Mixing Kits

In 2021 and 2022, the Strategic National Stockpile (SNS) rapidly distributed ancillary supply and mixing kits, with essential items for administering COVID-19 vaccines. These kits included several products with a limited shelf life, or expiration date. For example:

- Alcohol Pads
- Needles / Syringes
- Diluent for mixing

As a reminder, please routinely check the expiration date of these ancillary products (including those received from other suppliers) to ensure all outdated product is quarantined from general stock and appropriately disposed of in accordance with state and local requirements. Any drug product must be disposed of according to OAR 855-041-1025.

No. 744 Licensing – Certified Oregon Pharmacy Technician and Pharmacy Technician License Renewals

All technicians will need to renew their license in the coming weeks. Here are a few reminders:

During the period from July 1 through June 30 of each biennial license renewal cycle, each technician must have satisfactorily completed 20 hours of continuing pharmacy education (CPE) to qualify for license renewal. CPE required for the 2024 renewal includes a minimum of at least:

- two hours of CPE in pharmacy law;
- two hours of CPE in patient safety or medication error prevention; and
- two hours of CPE in cultural competency either approved by OHA under ORS 413.450 or any cultural competency CPE.

If technicians applying for the first renewal of their license have not been licensed by the Board for at least one year prior to July 1, 2024, they only need to complete two hours of CPE in cultural competency, in accordance with OAR 855-135-0070(2). All technicians initially licensed between July 1, 2022, and June 30, 2023, must complete all the continuing education requirements for the 2024 renewal.

Also, don't forget that OAR 855-135-0070(4) and (5) require technicians to ensure that all Accreditation Council for Pharmacy Education-accredited CPE is recorded in CPE Monitor[®] and that all Boardapproved or Accreditation Council for Continuing Medical Education credit is uploaded to the licensee's e-Gov record with the Board **prior** to submission of their license renewal.

No. 745 Board Member and Board Staff News

The Board and its staff extend their heartfelt thanks to **Cyndi Vipperman**, a Board member, and **Kim Oster**, compliance coordinator, for their exceptional service to the Board and the citizens of Oregon.

Board Member News

Cyndi served as a distinguished Board member for eight years, from February 2016 to February 2024, and one year as Board president during the 2019-2020 term. During her tenure, Cyndi played a pivotal role in several key accomplishments:

- · Implementing biennial licensure for pharmacists and pharmacy technicians
- Establishing innovative registration types to better serve the evolving pharmacy landscape
- Revising licensee rules to adapt to industry changes and ensure patient safety
- Participating in strategic planning and implementing initiatives for continuous improvement
- Navigating the COVID-19 public health emergency to ensure safe and uninterrupted pharmacy services
- Implementing legislative directives and rules to improve equity and access to pharmacy services through various means, including dual-language labeling and interpreters
- Participating in rule revisions, Rules Advisory Committees, and work groups
- Welcoming new Board members with diverse perspectives and strong leadership

Cyndi's unwavering advocacy for patient safety, her insightful contributions to Board decisions and rulemaking, and her extensive experience as a pharmacy technician have been invaluable assets to the Board. Her dedication has undoubtedly advanced public health, safety, and welfare in Oregon.

Board Staff News

Kim Oster served as Compliance Coordinator for 14 years. Her unwavering commitment to supporting the compliance team, the Board, and licensees has been greatly appreciated. Her willingness to assist the team with a positive attitude will be sincerely missed. The Board extends its best wishes to Kim as she embarks on her new role as the Principal Executive of the Oregon Board of Maritime Pilots, where she will continue to serve the state of Oregon.

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Jamal T. Fox, MPA - State News Editor Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor Megan Pellegrini - Publications and Editorial Manager

800 NE Oregon St, Suite 150 | Portland, OR 97232