NOVEMBER 2022

OREGON BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

No. 693 Temporary, Emergency, and Permanent Pharmacy Closures – Requirements to Communicate With the Public and Report to the Board

In April 2022, the Oregon Board of Pharmacy adopted permanent rules requiring Retail Drug Outlet pharmacies to notify the public of temporary, emergency, and permanent pharmacy closures. The Board continues to receive an unprecedented number of complaints from the public concerning the failure of pharmacies to communicate closures – especially temporary closures. If Board notification is required in the rule below, the pharmacy must report the closure to the Board using one of the pharmacy closure notification forms on the website. There are separate forms for a temporary/ emergency closure, permanent closure, and nonresident permanent closure.

Oregon Administrative Rule (OAR) 855-041-1092

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Retail Drug Outlet Pharmacy Closures: Temporary, Permanent, or Emergency

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

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

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

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

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

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

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

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

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

(2) **Permanent Closing.** [Please see the rule for complete language.]

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

(4) **Non-resident Retail Drug Outlet.** [Please see the rule for complete language.]

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

No. 694 Changes to Frequency of Inspections and Self-Inspection Form Deadlines

In 2021, the Board announced that it would begin conducting pharmacy inspections on a biennial basis starting July 1, 2021 and will move the annual self-inspection form (SIF) deadline to July 1, **starting in 2024.** The rationale for this change is to ensure that Board processes are focused on achieving its mission to ensure public safety and to align the inspection cycle with the state's fiscal calendar. Biennial inspections will allow for more intentionality and strategic focus toward high-risk locations and will result in better patient safety outcomes. Because of the increasing complexity and changes in pharmacy practice, licensees and registrants can expect pharmacy inspections to take a minimum of three to five hours to complete. The next biennial inspection cycle will be from July 1, 2023–June 30, 2025. Regarding SIFs, an anticipated timeline for these changes is listed below:

- December 2022 – Board will post updated SIFs to the Board's website
- February 1, 2023 – Pharmacist-in-charge (PIC) deadline to complete SIF
- April 2023 – Board staff will propose to amend rules requiring a PIC to complete the SIF by February 1 annually to July 1 annually. Board may send proposed rules to rulemaking.
- May 2023 – Rulemaking hearing
- June 2023 – Board may adopt proposed rules effective July 1, 2023

If the Board adopts the rule change in June 2023:

- May 2024 – Board will post updated SIF to website
- July 1, 2024 – PIC deadline to complete SIF

No. 695 Rulemaking – Temporary Rules Adopted: Expiration Date Labeling and COVID-19 Antiviral Protocol

On October 17, 2022, the Board adopted two temporary rules: OAR 855-041-1130(10), which allows expiration dating applied to products dispensed in their manufacturer's containers to be the same as that of the manufacturer, and OAR 855-020-0300(2)(e), which adds a coronavirus disease 2019 (COVID-19) antiviral protocol (v. 10/2022) for prescribing Paxlovid™ to the statewide protocol compendium.

Expiration dates had been limited to one year from dispensing or the manufacturer's expiration date, whichever was earlier. This rule amendment allows products dispensed in the original manufacturer's container to be labeled with expiration dates up to the manufacturer's expiration date even if that date is beyond one year. This change may reduce wastage of products such as naloxone, glucagon, or other medications that may not be used within one year from dispensing.

Paxlovid is an antiviral agent that can reduce the risk of hospitalization and death for patients with mild-to-moderate COVID-19 at high risk of disease progression if started within five days of symptom onset. The statewide protocol is based on the Food and Drug Administration (FDA) emergency use authorization (EUA) for Paxlovid, which was amended on July 6, 2022, to include pharmacist prescribing based on specific conditions that can be determined using the Patient Intake Form and Standardized Assessment and Treatment Care Pathway. Pharmacists may choose to use the statewide protocol or prescribe under the terms of the FDA EUA for Paxlovid.

No. 696 Rulemaking – Proposed Permanent Rules Sent to Rulemaking in October for November 22 Rulemaking Hearing

In October 2022, the Board sent the following rules to rulemaking to seek public comment and for potential adoption at its December 2022 Board meeting. Please check the Board's rulemaking

page for the most up-to-date information concerning the proposed rules, information on how to provide comments on the proposed rules, and how to sign up for rulemaking notices.

- Division 019 – related to 2022 House Bill (HB) 4034 duties of a pharmacist
- Division 139 – related to 2022 HB 4034 prohibited practices
- Division 019 – related to 2022 HB 4096 out-of-state volunteer pharmacist
- Division 062 – related to drug distribution agent
- Divisions 010/019/020 – related to pharmacist prescriptive authority
    - COVID-19 antiviral (Paxlovid)
    - Travel medications
    - Post-exposure prophylaxis (PEP)
    - Pre-exposure prophylaxis (PrEP)
    - Contraception
- Divisions 021/135 – related to continuing pharmacy education
- Divisions 019/141 – related to pharmacy prescription kiosk
- Divisions 006/019/031 – related to definitions
- Division 041 – related to prescription labeling expiration date

The following rules will be sent to rulemaking to seek public comment, and the Board does not anticipate adopting in December 2022:

- Divisions 001/102 – related to procedural and universal rules
- Divisions 025/125 – related to pharmacy technicians
- Divisions 019/020/031/041/115 – related to pharmacists

No. 697 Compliance

The following collection of recent compliance issues includes information concerning fraudulent prescriptions, recent inspection observations, mask mandate enforcement, prescription transfer requirements, prescribing and dispensing naloxone to entities, and age-related vaccine reminders.

- **Fraudulent Prescriptions – Promethazine With Codeine**
  Compliance officers are fielding an uptick in phone calls from licensees who have received fraudulent prescriptions, specifically for promethazine with codeine. Further, pharmacists are expressing concerns that fraudsters are starting to call them in and cite an indication for COVID-19 cough, which may add urgency to the fill and an increase in the chance of inappropriate filling.
  Applicable state and federal laws include:

OAR 855-019-0210 Duties of the Pharmacist Receiving a Prescription

(2) A pharmacist receiving a prescription is responsible for:

(a) Using professional judgment in dispensing only pursuant to a valid prescription. A pharmacist shall not dispense a prescription if the pharmacist, in their professional judgment, believes that the prescription was issued without a valid patient-practitioner relationship. In this rule, the term practitioner shall include a clinical associate of the practitioner or any other practitioner acting in the practitioner's absence. The prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice and issued pursuant to a valid patient-practitioner relationship; and

(b) Ensuring that the prescription contains all the information specified in Division 41 of this chapter of rules including the legible name and contact phone number of the prescribing practitioner for verification purposes.

Code of Federal Regulations §1306.04 Purpose of issue of prescription

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but **a corresponding responsibility rests with the pharmacist who fills the prescription.** (emphasis added)

- **Inspection Observations**

  During recent inspections, compliance officers have observed the following regarding limited English proficiency and prescription reader accessibility:

  - Pharmacies that have not posted a sign with all 14 languages as required under OAR 855-041-1035(1)(g)(B);
  - employees who are unable to work the software for dual language labeling in all 14 languages;
  - labeling that only contains the patient's preferred language and not **both** English **and** the patient's preferred language as required by OAR 855-041-1132; and
  - pharmacies that have not posted a sign or are not providing notification to all patients concerning access to a prescription reader as required by OAR 855-041-1131.

Each PIC is encouraged to review all of examples above with pharmacy staff and confirm that the proper programs and policies are in place for compliance with the law.

- **Mask Mandate Enforcement**
  Compliance officers continue to receive inquiries from licensees and registrants concerning mask requirements at a pharmacy and complaints from patients alleging pharmacies are not complying with state regulations. Applicable rules regarding masks in a health care setting are as follows:
  - OAR 333-019-1011: Masking Requirements to Control COVID-19 in Health Care Settings
    - Oregon Health Authority (OHA) rules requiring masking in health care settings – including pharmacies.
  - OAR 855-007-0088: Compliance with OHA's COVID-19 Requirements
    - Board rules requiring compliance with OHA rules.

- **Prescription Transfers**
  In June 2022, the Board adopted amended rules that permit a pharmacy to transfer a prescription for the purpose of an initial fill and **require** pharmacies to respond to transfer requests by another pharmacy on behalf of the patient or patient's agent in a timely manner. The Board office continues to receive complaints of noncompliance with OAR 855-041-2115(4).

OAR 855-041-2115

Transfer of Prescription Information Between Pharmacies

(1) Prescriptions may be transferred between pharmacies for the purpose of an **initial** or refill dispensing provided that:

(a) The prescription is invalidated at the sending pharmacy; and

(b) The receiving pharmacy obtains all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability.

(2) Prescriptions for controlled substances can only be transferred one time.

(3) Pharmacies using the same electronic prescription database are not required to transfer prescriptions for dispensing purposes.

(4) An Oregon registered pharmacy **must transfer a prescription:**

(a) To a pharmacy requesting a transfer on behalf of the patient or patient's agent unless the transfer would compromise patient safety or violate state or federal laws or rules; and

(b) **By the end of the next business day of the request.** (emphasis added)

- **Prescribing and Dispensing Naloxone to Entities Is Permitted**
  Pharmacists can prescribe naloxone to individuals and to entities, such as schools, businesses, and organizations. Pharmascists can also dispense naloxone prescriptions from other authorized prescribers for entities. Naloxone prescriptions need not be issued to an individual patient. This flexibility in the rule permitting a pharmacist to prescribe and/or dispense naloxone to entities is intended to make it easier to make this lifesaving medication more accessible in schools, businesses, and communities. Any person having once lawfully obtained naloxone may possess, distribute, or administer it for the purpose of reversing opioid overdose. Opioid-related overdoses and deaths continue to increase, and every community in Oregon has been adversely impacted. We can all play an important role in helping treat individuals suffering from opioid use disorder.

  See OAR 855-019-0460: Naloxone – Delivery of Care and Prescribing

- **Age-Related Vaccine Errors**
  The Board has received multiple complaints concerning age-related vaccine errors. The Institute for Safe Medication Practices (ISMP) released a bulletin on September 22, 2022, drawing attention to age-related vaccination errors. During the pandemic there has been an intense focus on COVID-19 vaccine safety; however, almost half (46%) of non-COVID-19 vaccine errors reported to ISMP between June 2020 and December 2021 were for the wrong age plus the wrong vaccine or dose. ISMP recommends the following to prevent age-related vaccine errors: maximizing technology, streamlining purchasing, storing separately, verifying identity/age/vaccine requested, labeling syringes, engaging the patient, documenting the vaccines, and educating practitioners.

  For more details, please read the entire ISMP bulletin and newsletter.

No. 698 Licensing – Drug Outlet Renewals

Drug outlet renewals are coming soon! Renewal notices will be sent out in mid-January for all drug outlet registrations expiring on March 31, 2023. Online license renewal is required for most registration categories. Online renewal ensures timely processing and allows for each registrant to verify all facility information, update the mailing address and contact information, and order certified copies of the registration. The renewal ID and registration code will be provided on the renewal notification.

No. 699 Public Health and Pharmacy Formulary Advisory Committee – Opportunities

There are opportunities for interested persons to serve on the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC). This multidisciplinary committee was convened in

2018 pursuant to Oregon Revised Statutes (ORS) 689.645 and ORS 689.649. The Board has the following committee member opportunities available:

- One pharmacist member position
- One advanced practice registered nurse member position
- Two physician member positions

If you are interested in applying or know a qualified person who might be interested in applying to serve on the PHPFAC, please visit the governor's Boards and Commissions website.

No. 700 In Memoriam: Gary Schnabel, Former Board Executive Director

Gary Schnabel, executive director of the Oregon Board of Pharmacy from 1999-2014, passed away on November 5, 2022. Gary joined the Oregon Board of Pharmacy as compliance director in 1994 and was selected as executive director in 1999. Under Gary's leadership, the Oregon Board of Pharmacy received the National Association of Boards of Pharmacy's Fred T. Mahaffey Award in 2009 and 2013, which recognizes a board of pharmacy that has substantially contributed to the protection of the public health and welfare through the enforcement of state and federal laws and regulations. After 19 years of service to the Oregon Board of Pharmacy, he retired in 2013. Gary is survived by his wife, Tammy, six siblings, and countless nieces and nephews. His kindness and humor will be missed, and we extend our sympathies to his family, friends, and colleagues.

The Oregon Board of Pharmacy News is published by the Oregon Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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