



OREGON STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

No. 657 Legislative Update

The 2021 regular session of the Oregon Legislature has concluded with the passage of several bills that will affect pharmacists, pharmacy technicians, interns, and drug outlets. The following are brief summaries of selected bills that will impact licensees and require Oregon State Board of Pharmacy rulemaking. These bills are all effective January 1, 2022.

- **House Bill (HB) 2074:** Increases prescription monitoring program fees from \$25 to \$35.
- **HB 2648:** Allows a pharmacist or pharmacy technician to transfer drugs containing pseudoephedrine or ephedrine without a prescription to a person who is at least 18 years of age and presents the person's valid government-issued photo identification in accordance with Board rules.
- **HB 2958:** Allows a pharmacist to prescribe, dispense, and administer pre-exposure prophylactic antiretroviral therapies and post-exposure prophylactic antiretroviral therapies in accordance with Board rules.
- **Senate Bill 629:** Allows a pharmacist to use telepharmacy to deliver pharmacy services to a patient at a remote location in accordance with Board rules.

Board staff have begun drafting rules for these and other new statutes. Rulemaking procedures require public notice of proposed rulemaking, a public rulemaking hearing, other stakeholder input, and final adoption by the Board. To keep up to date on proposed rules, subscribe to receive Board meeting agenda notices [here](#) and subscribe to receive rulemaking notices and adoption of rules notices [here](#).

No. 658 Rulemaking

In June 2021, the Board adopted the following permanent rules:

- **Division 001/041 – Procedural Rules/Operations of Pharmacies:** Amends rules pertaining to inspections and record retention to provide clarity, transparency, and promote patient safety.
- **Division 006/050 – Definitions:** Repeals Division 050 (Restriction on Retail Sales) and moved the definition of “prescription drug” from Division 050 to Division 006 (Definitions).
- **Division 007 – Public Health Emergency (Intern ratio):** For immunization clinics, an immunizing pharmacist may supervise as many Oregon-licensed immunizing interns as that pharmacist determines, in their own professional judgment, will maintain public health and safety.
- **Division 019/021/025/031 – Cultural Competency CE:** Incorporates cultural competency continuing education (CE) requirement directives set forth in 2019 HB 2011 into rules for pharmacists, certified Oregon pharmacy technicians, and interns.
- **Division 041 – Epinephrine:** Removes limitation on epinephrine dispensed to an entity.
- **Division 041 – Drug Take-Back Programs:** Amends rules related to returned drugs and devices and secure and responsible drug disposal to align with the directives of 2019 HB 3273.
- **Division 020 – Pharmacist Prescriptive Authority – Protocols:** Incorporates recent Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) recommendations into rule and protocol compendia. Clarifies prohibited practices.
- **Division 080 – Controlled Substances:** Adopts United States Code and Code of Federal Regulations standards by reference.
- **Division 110 – Fees:** Implements amended late fee dates for licensees and registrants and matches late fee dates to the license or registration expiration date.

No. 659 Compliance Updates

Pharmacist-in-Charge: Gaps in PIC and ‘Interim’ PIC

Compliance staff has noted an increase in the number of cases in which a pharmacy has operated without a pharmacist-in-charge (PIC). Under Oregon Administrative Rule (OAR) 855-019-0300(4)(a), when a change of PIC occurs, both outgoing and incoming PICs must report

the change to the Board within 15 days of the occurrence on a form provided by the Board. Fifteen days is the time window for reporting the change, not for making the change. For resident pharmacies, no provision exists for a time gap between the outgoing and incoming PIC. The PIC requirement is very important for patient safety and ensuring continuity, accountability, and security within the pharmacy. Each day a pharmacy operates without a designated PIC is a violation of [OAR 855-041-1010\(1\)](#), and the pharmacy could be subject to disciplinary action by the Board.

The term “interim PIC” is sometimes used by employers and pharmacists. Board rules do not recognize an interim PIC. If you are called an interim PIC, you are the PIC of record for the pharmacy and are responsible for compliance with Board statutes and rules.

FIRST® Kits: Unit-of-use Prescription Compounding Kits

Pharmacies utilizing FIRST® Kits manufactured by Azurity Pharmaceuticals are engaged in the act of nonsterile compounding. Per the manufacturer’s [website](#), FIRST® Kits “help facilitate your obligations under 503A and USP <795> to make compounding convenient, and consistent.” Since FIRST® Kits contain bulk ingredients for prescription compounding, they are exempt from Food and Drug Administration approval and do not have manufacturer-approved labeling. Thus, following the compounding kit’s instructions is not considered reconstituting per the manufacturer label.

Under [OAR 855 Division 45](#), a pharmacy engaged in nonsterile compounding must comply with documentation, equipment, and training standards established in US Pharmacopeia (USP) Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations. USP <795> can be viewed online at [www.usp.org](#). A pharmacy is required to complete a compounding record when compounding a drug product using a compounding kit such as the FIRST® Kits.

Per USP <795>, the following maximum beyond-use dates (BUDs) are recommended for nonsterile compounded drug preparations **“in the absence of stability information that is applicable to a specific drug and preparation.”** The BUD shall not be later than the expiration date on the container of any component. (emphasis added)

- For nonaqueous formulations: The BUD is not later than the time remaining until the earliest expiration date of any active pharmaceutical ingredient or six months, whichever is earlier.
- For water-containing oral formulations: The BUD is not later than 14 days when stored at controlled cold temperatures.
- For water-containing topical/dermal and mucosal liquid and semisolid formulations: The BUD is not later than 30 days.

Pharmacies utilizing FIRST® compounding kits must have a copy of the stability information on file if assigning a different BUD than indicated in the USP <795> standard.

Prescription Readers

As a result of a patient being unable to access a prescription reader, a registrant has been noticed for proposed disciplinary action by the Board to impose a civil penalty in the amount of \$5,000 per violation.

Oregon Revised Statute (ORS) 689.561 states:

- (1) As used in this section:
 - (a) 'Person who is blind' means a person who is:
 - (A) Visually impaired;
 - (B) Print disabled; or
 - (C) A person who is blind as that term is defined in ORS 346.510.
 - (b) 'Prescription reader' means a device that is designed to audibly convey the information contained on the label of a prescription drug.
- (2) Except as provided in subsection (4) of this section, a pharmacy shall notify each person to whom a prescription drug is dispensed that a prescription reader is available to the person upon request. **If a person informs the pharmacy that the person identifies as a person who is blind, the pharmacy shall provide to the person a prescription reader** that is:
 - (a) Available to the person for at least the duration of the prescription; and
 - (b) Appropriate to address the person's visual impairment.
- (3) A pharmacy that provides a prescription reader under subsection (2) of this section shall ensure that the prescription label is compatible with the prescription reader.
- (4) The requirements of this section do not apply to prescription drugs dispensed by an institutional drug outlet.
- (5) The State Board of Pharmacy shall adopt rules to carry out this section.
(emphasis added)

Board rules for prescription readers may be found in [OAR 855-041-1131](#).

No. 660 Become a Drug Take-Back Collection Site

Pharmacies interested in becoming an authorized collector and hosting a drug take-back receptacle can now do so at no cost to the pharmacy. [HB 3273](#), passed during the 2019 legislative session, directs manufacturers of prescription drugs sold in Oregon to develop and implement a drug take-back program for the purpose of collecting prescription drugs from individuals and nonbusiness entities for disposal. It directs the Department of Environmental

Quality (DEQ) and the Environmental Quality Commission to administer the program. The drug take-back program became operational on July 1, 2021. All costs of the program are covered by manufacturer fees.

As an authorized collector under the DEQ program, your pharmacy would host a collection receptacle for disposal of prescription and nonprescription drugs. The program operator will service the receptacles, transport the pharmaceutical waste, and ensure its proper disposal. The cost of collection and disposal will be covered by drug manufacturer fees. If you have questions or would like to enroll as an authorized collector, visit the [DEQ Drug Take-Back Program page](#). Please be sure to modify your Drug Enforcement Administration registration and review [Board rules](#) prior to installing a take-back receptacle.

No. 661 Board Member Opportunities

There are periodic opportunities for interested persons to serve on the Board. The Board has the following member opportunities available:

- Two public member positions

Each position is appointed by Governor Kate Brown and each Board member serves at the pleasure of the governor. For more information, including qualifications and how to apply, please see [ORS 689.115](#) and visit the Board's [website](#).

No. 662 Public Health and Pharmacy Formulary Advisory Committee Opportunities

There are periodic opportunities for interested persons to serve on the PHPFAC. This multidisciplinary committee was convened in 2018 pursuant to [ORS 689.645](#) and [ORS 689.649](#). The Board has the following committee member opportunities available:

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

If you are interested in applying to serve on the PHPFAC, please see the governor's Boards and Commissions [website](#).

No. 663 Board Staff News

The Board welcomes **Erin Richmond, MS, PharmD, RPh**, to the role of compliance officer. Erin earned her doctor of pharmacy degree from the Massachusetts College of Pharmacy and Health Sciences University in 2015. Additionally, she was recognized for her passion of pharmacy practice as the sole recipient of the Student Achievement Award for her graduating class. Erin has gained over a decade of experience in community pharmacy practice, serving

as a pharmacy technician, intern, manager, PIC, and everything in between! Most recently, she graduated from Northeastern University with a master of science degree in regulatory affairs of drugs, biologics, and medical devices.

The Board also welcomes **Alicia Fatka** to the role of licensing representative. Alicia recently relocated to the Northwest and brings many years of customer service experience to the position. She is excited to use her experience to support licensees and applicants of the Board.

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*Joe Schnabel, PharmD, RPh, BCPS - State News Editor
Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor
Amy Sanchez - Publications and Editorial Manager*

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