

OREGON BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

No. 715 2023 Legislative Update

The 2023 regular session of the Oregon Legislature has concluded with the passage of several 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) 2278 Authorizes pharmacists to administer influenza vaccine to persons six months of age or older. Effective September 24, 2023. Operative January 1, 2024.
- HB 2486 Allows certain pharmacy technicians to administer vaccines. Effective immediately. Operative January 1, 2024.
- HB 3258 Requires pharmacy to report dispensing of Schedule II through Schedule V drugs to the Oregon Prescription Drug Monitoring Program when a drug is prescribed and dispensed to an individual for use by the individual or the individual's animal. Removes requirement to report dispensing of naloxone and or a drug containing pseudoephedrine or ephedrine. Effective September 24, 2023. Operative January 1, 2025.
- Senate Bill (SB) 410 Allows state board of pharmacy to adopt rules to issue temporary license to perform duties of pharmacy technician. Effective September 24, 2023.
 Operative January 1, 2024.
- sB 970 Revises
 definitions for
 nonprescription drug
 outlet, adds definition
 of third-party logistics
 provider, and revises
 definition of wholesale
 distributor drug outlet.
 Effective September 24,
 2023. Operative
 November 26, 2023.

National Pharmacy Compliance News

A Service of the National Association of Boards of Pharmacy Foundation (NABPF)

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

Read National News

The effective date of a law is the date on which it becomes law, while the operative date is the date on which it begins to have legal effect. Board staff has begun drafting rules necessary for implementation of 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 stay up to date on proposed rules, receive Board meeting agenda notices, and receive rulemaking notices and adoption of rules notices, sign up here.

No. 716 New CPE Rules Effective July 1, 2023

As of July 1, 2023, new rules for continuing pharmacy education (CPE) in Oregon Administrative Rule (OAR) 855-135 are in effect and OAR 855-021 is repealed. The new rules clarify definitions, incorporate universally acceptable CPE standards, remove outdated language from existing CPE rules, require licensees to register with National Association of Boards of Pharmacy® CPE Monitor®, require CPE credit to be submitted to CPE Monitor or via e-Gov, and streamline the process and requirements for providers and licensees to apply for Board-approved CPE credit.

OAR 855-135-0010 requires that:

- (1) CPE programs must consist of subject matter pertinent to pharmacy including:
 - (a) Socioeconomic aspects of healthcare;
 - (b) Legal aspects of healthcare;
 - (c) Properties and actions of drugs and dosage forms;
 - (d) Etiology, characteristics, therapeutics, and prevention of disease states; or
 - (e) General topics related to pharmacy.

OAR 855-135-0010(2) and (3) outline items that can be or cannot be included in the calculation of CPE credit.

(2) Can Be Included	(3) Cannot Be Included
 (a) A program delivered by an instructor or a panel of instructors; (b) A structured CPE discussion, workshop or demonstration; (c) A structured CPE question and answer session; (d) An ACPE accredited program or board-approved program; 	(a) Welcoming remarks; (b) Meals or social functions; (c) Business sessions (e.g. voting, treasury report, strategic plan); (d) Unstructured discussion, workshops, and demonstrations; (e) Unstructured question and
	answer sessions;

- (e) An ACCME AMA Category 1 accredited program up to the following limits per renewal cycle:
 - (A) 10 hours of CPE for Pharmacists;
 - (B) 6 hours of CPE for Certified Oregon Pharmacy Technicians and Pharmacy Technicians.
- (f) A policy discussion at an Oregon Board of Pharmacy meeting up to a maximum of 2 hours of law CPE per renewal cycle.

- (f) Degree programs;
- (g) Non-ACPE approved certificate programs;
- (h) Licensing or certification examinations;
- (i) Skills training programs;
- (j) Software training programs;
- (k) Learning assessments;
- (I) Program evaluations; and
- (m) Attending CPE programs for which credit was not granted by the provider.

Per OAR 855-135-0030, persons who wish to obtain Board approval for a CPE program must apply a minimum of 45 days **prior** to the date of the program using the form on the Board's website. An application for approval of a CPE program after it occurred or was completed will not be approved.

No. 717 Rulemaking

Licensees are encouraged to review rules added, amended, repealed, and sent to rulemaking during the June and August 2023 Board meetings.

Rules Adopted in June 2023

- Divisions 006/041/043/045/080/139/141 related to standards adopted by reference, *effective June 13, 2023. Updates incorporated standards adopted by reference (eg, United States Code, Code of Federal Regulations (CFR), US Pharmacopeia).
- Divisions 019/020 related to pharmacist prescriptive authority, *effective June 13, 2023. Repeals coronavirus disease 2019 (COVID-19) monoclonal antibody and antiviral protocols; repeals emergency insulin rule and amends protocol compendium.
 - Continuation of Therapy Including Emergency Refills of Insulin v. 6/2023
 - Travel Medications v. 6/2023
 - HIV Post-exposure Prophylaxis (PEP) v. 6/2023
 - HIV Pre-exposure Prophylaxis (PrEP) v. 6/2023
 - Contraception v. 6/2023

 Divisions 019/041/043/045/080/139/141/143 – related to annual self-inspection form (SIF) completion date, *effective August 1, 2023. Amends the annual self-inspection due date from "February 1" to "July 1" each year, starting with July 1, 2024.

Rules Adopted in August 2023

- Division 102 related to Board administration, effective March 1, 2024.
- Division 104 related to universal rules, effective March 1, 2024.
- Division 115 related to pharmacists, effective March 1, 2024.
- Division 120 related to interns and preceptors, effective March 1, 2024.
- Division 125 related to pharmacy technicians, effective March 1, 2024.

The Board will publish dedicated articles about how these rule changes affect licensees in the November 2023 and February 2024 editions of this *Newsletter*.

- Proposed Permanent Rules Sent to Rulemaking in August for September 27, 2023
 Rulemaking Hearing. The following rules are open for public comment via rulemaking and will be considered by the Board for potential adoption at its October 2023 Board meeting.
 - Division 007 related to compliance with OHA COVID-19 rules
 - Divisions 019/041/043/044/139 related to short-acting opioid antagonists
 - Division 045 related to USP <795> and USP <797> standards adopted by reference
 - Division 115 related to short-acting opioid antagonists
 - Divisions 115/125 related to pharmacists: applicability, definitions, and counseling; certified Oregon pharmacy technicians/pharmacy technicians: prohibited practices

No. 718 Compliance: Updated SIFs, Electronic Formatting of PHPFAC Protocols, and DEA Guidance on COVID-19-Related Flexibilities

Updated Self-Inspection Forms (SIFs) Available

Updated versions of the pharmacist-in-charge (PIC) annual SIFs are now available on the Board's website, which include updates due to rule changes enacted since the forms were last published in December 2022. Per OAR 855-019-0300(4)(b), a new PIC must complete an inspection on the PIC annual SIF within 15 days of becoming the PIC. New PICs should use the most recent version of the PIC SIF that is available on the Board website to complete this self-inspection.

Effective August 1, 2023, OAR 855-019-0300(5)(c) states that PICs must conduct an annual self-inspection of the pharmacy using the PIC annual SIF provided by the Board by **July 1** each year. This means that if the PIC completed the 2023 SIF by February 1, 2023, the next SIF is not due until July 1, 2024. Updated SIFs will be posted to the Board website in May 2024 to allow PICs time to complete the form by the next deadline on July 1, 2024.

Use of PHPFAC Protocols in an Electronic Format

There is nothing in Oregon Revised Statute (ORS) 689 or OAR 855 to prohibit Pharmacists from collecting and documenting information required in the Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) protocols electronically. The information collected must be the same in its entirety, including wording and order. Demographics listed on the protocols must be collected but do not have to be collected in the same order.

DEA Guidance on COVID-19-Related Flexibilities

During the COVID-19 public health emergency (PHE), Drug Enforcement Administration (DEA) responded to the needs of registrants for increased flexibilities by exercising its authority under 21 CFR §1307.03 to issue temporary exceptions to DEA regulations and by indicating the circumstances in which it would exercise its discretion in enforcing certain statutory requirements. Following the expiration of the COVID-19 PHE on May 11, 2023, DEA issued a *COVID-19 Flexibility Updates* guidance document with updates about the status of COVID-19-related flexibilities.

This guidance document lists the flexibilities that DEA has determined should remain in place under the ongoing opioid PHE to help respond to the opioid crisis after the COVID-19 PHE expired, which flexibilities were terminated on May 11, 2023, and which flexibilities remain in effect until the expiration of the opioid PHE, unless first modified or withdrawn by DEA. The guidance document does not describe the status of telemedicine prescribing flexibilities or medications for opioid use disorder prescribed by telephone, as DEA and the Substance Abuse and Mental Health Services Administration addressed them in the temporary rule titled "Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications."

More information may be found on the DEA Opioid PHE Information web page. Additional questions may be directed to the DEA Diversion Control Division Policy Section by email at odlp@dea.gov or by phone at 571/362-3260.

No. 719 Licensing: Oregon Business Registry Requirement for Facilities

Oregon Business Registry information and registered agent information is required to be provided upon initial registration and renewal of any facility. Additional information can be found on the Oregon

Business Registry and Frequently Asked Questions web pages. The Oregon Business Registry lookup can be found here.

No. 720 Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) News

The Board acknowledges the service of **Amy Burns**, **Mark Helm**, and **Helen Turner**, and welcomes three new members to the PHPFAC: **Andrew Gibler**, **Mark Meyers**, and **Katherine Hammond**.

- The Board and staff thank Amy Burns, Mark Helm, and Helen Turner for their dedicated service to the PHPFAC, the Board, and the citizens of Oregon. As inaugural members of the PHPFAC, these committee members were involved in groundbreaking work, which includes development of rules pertaining to pharmacist prescribing via the compendia, recommending 14 protocols, and nine formulary items to the Board for addition to the protocol and formulary compendia.
- New PHPFAC Member Andrew Gibler, PharmD, is the clinical pharmacy policy and programs manager at Oregon Health Authority (OHA). He graduated with a bachelor's degree from Oregon State University (OSU) in 2003 and a doctor of pharmacy degree from OSU/Oregon Health & Science University (OHSU) in 2007 before completing a post-graduate residency program at Legacy Health in Portland, OR. Before coming to OHA, he was the director of pharmacy for Legacy Mount Hood Medical Center in Gresham, OR; Unity Behavioral Health Center in Portland; and the outpatient pharmacy department at Legacy Emanuel in Portland. Previous experiences also include time as the clinical coordinator for the drug use research and management team at the OSU/OHSU College of Pharmacy, and as a drug policy pharmacist at OHSU. His professional interests include drug policy, public health, medical literature evaluation, and mentoring pharmacy residents and students. Andrew served 10 years on the board of directors for the Oregon Society of Health-System Pharmacists, including a term as president of the organization.
- New PHPFAC Member Mark Meyers, MD, is a partner at Springfield Family Physicians in Springfield, OR. Dr Meyers graduated from OHSU and completed a family practice residency at Sioux Falls Family Practice. He has spent the vast majority of his life in Oregon, with a few years spent away during his education. Observing his grandfather's work serving his community as a family physician was a major reason he chose to become one. Throughout his career, he has found ways to be involved in his community, using what he has learned as a family physician to improve the way we provide health care to citizenry, while trying to maintain work-life balance.
- New PHPFAC Member Katherine Hammond, DNP, FNP-C, APRN, CEN, is a family nurse practitioner (FNP) at Providence Medical Group. She received a bachelor of science degree in nursing from the University of Miami and a master of science and doctor of nursing

practice from OSHU. As a nurse practitioner she has worked in public health, school-based health, geriatric home visits, family practice, family planning, and urgent care. She has also taught in two different undergraduate nursing programs and two different FNP programs. Additionally, she serves as the FNP consultant/expert witness for the Oregon Board of Nursing and is the co-chair of a national committee for the Emergency Nurses Association.

No. 721 Board Member News

• The Board wishes to acknowledge the service of Michelle Murray. The Board and staff thank Michelle for her dedicated service to the Board and the citizens of Oregon. She has been a distinguished Board member for the past four years, from July 2019 through June 2023, and served her last year as Board president.

Significant accomplishments and activities during Michelle's tenure with the Board include:

- Participating in the new strategic planning process, then working to develop and implement the plans;
- Navigating the COVID-19 PHE;
- Implementing legislative directives and rules to improve equity and access to pharmacy services, such as the use of:
 - Dual language labeling;
 - Interpretation services;
 - Prescription readers; and
 - Remote Dispensing Site Pharmacies, Pharmacy Prescription Lockers, and Pharmacy Prescription Kiosks.
- Guiding rule updates and participating in rules advisory committees and work groups;
- Continued development of the formulary and protocol compendia;
- Leading the executive director recruitment; and
- Welcoming four new members to the Board.

Her contributions to Board decisions and rulemaking with her vast experience in healthsystem pharmacy has been invaluable and has served to advance public health, safety, and welfare.

- There are periodic opportunities for interested persons to serve on the Board. The Board has:
 - Two pharmacy technician member positions available for reappointment or appointment. Apply by November 5, 2023.

 One public member position available for reappointment or appointment. Apply by November 5, 2023.

Board members are appointed by Governor Tina Kotek and each Board member serves at the pleasure of the governor. If you are interested in applying to serve on the Board, please visit the Board Member Opportunities web page, review ORS 689.115, and apply through the governor's Boards and Commissions website.

No. 722 Board Staff News

The Board extends a warm welcome to one new staff member. **Craig Vesterby** has joined the team as a licensing representative. Craig joins the agency staff with experience as a Washington pharmacy technician. Also, the Board would like to acknowledge the retirement of Management Secretary **Loretta Glenn**, who has retired after a 15-plus year career with the Board. Loretta's commitment and dedication to supporting the agency, Board, and committees has not gone unnoticed, and her willingness to always chip in and help the team with a smile will be missed. The Board wishes her well in her much-deserved retirement.

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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