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News

Oregon State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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No. 649 Drug Outlet Working Conditions

The Oregon State Board of Pharmacy office has been receiving an increasing number of reports describing potentially unsafe workload and inadequate staffing to ensure that public health and safety is maintained in retail drug outlets. Allegations include that already busy pharmacies are adding coronavirus disease 2019 (COVID-19) vaccine and other services without providing adequate staffing to accommodate them.

Drug outlets are reminded to review Oregon Administrative Rule (OAR) 855-041-1170 and to ensure:

- Sufficient personnel to prevent fatigue, distraction, or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety;
- appropriate opportunities for uninterrupted rest periods and meal breaks;
- adequate time for a pharmacist to complete professional duties and responsibilities including, but not limited to:
  - drug utilization review;
  - immunization;
  - counseling;
  - verification of the accuracy of a prescription; and
  - all other duties and responsibilities of a pharmacist, including that pharmacy technicians are working under the supervision, direction, and control of a pharmacist.

Pharmacists are reminded to review Oregon Revised Statute (ORS) 689.025 and OAR 855-019-0200; ensure that they are fulfilling their duty to use the degree of care, skill, diligence, and professional judgment that is exercised by an ordinarily careful pharmacist in the same or similar circumstances; and ensure that the pharmacy complies with all state and federal laws and rules governing the practice of pharmacy.

No. 650 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
- One pharmacist member position will be available for appointment or reappointment, effective July 1, 2021

Each position is appointed by the governor, and each Board member serves at the pleasure of the governor. The Board encourages all interested and qualified individuals to apply sooner rather than later, as the governor's office may close the applicant pool without notice. For more information, including qualifications and how to apply, please see ORS 689.115 and visit the Board's website.

No. 651 Board Member News

The Board wishes to recognize the service of public member **Tim Logan.** Tim has served on the Board for four years, and the Board is grateful for his work. His professional background in criminal justice and social services brought a thoughtful and valuable perspective to the Board. Significant accomplishments and activities during Tim's tenure with the Board include addressing the COVID-19 public health emergency; implementing legislative directives for pharmacist prescriptive authority, including hormonal contraceptives, naloxone, and the formulary of drugs and devices and statewide protocols from the Public Health and Pharmacy Formulary Advisory Committee; and health equity, including limited-English proficiency labeling, prescription readers and continuing education (CE) in providing culturally appropriate care. He was indispensable in contributing to the Board's policy and strategic discussions over the past four years. He has been an unwavering advocate for patient safety and the public's perspective on policy and compliance issues. Tim was always guided by the Board's mission and had a deep appreciation that the Board's decisions directly impact people's lives. Tim will be missed, and the Board wishes him all the best as he pursues new adventures.

No. 652 Rulemaking

In February 2021, the Board adopted the following temporary rule:

- Division 110 – related to licensee late fee and expiration dates

The Division 110 temporary rule was made possible by the Board's database upgrade and implementation of the online eGov system. These changes have eliminated many of the manual processes required for each license/registration renewal.

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

Guidelines, Materials Available to Health Care Providers for Safely Administering COVID-19 Vaccines

Guidelines and materials are available to support health care providers with safely administering the coronavirus disease 2019 (COVID-19) vaccine, including safe practice recommendations from the Institute for Safe Medication Practices (ISMP) and a United States Pharmacopeia (USP) toolkit.

After numerous reports of errors or hazards associated with the administration of COVID-19 vaccines, ISMP is sharing safe practice recommendations.

A new USP toolkit is also available to facilitate operational efficiencies that can help accelerate delivery and support safe handling of COVID-19 vaccines while maintaining quality and ultimately the public's trust. Download the USP toolkit.

FDA Issues Guidance to Protect Consumers From Methanol Poisoning

Food and Drug Administration (FDA) has issued guidance for industry, *Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID-19).* The guidance is intended to help pharmaceutical manufacturers and pharmacists who engage in drug compounding to avoid using pharmaceutical alcohol contaminated with or substituted with methanol in drug products. FDA noted that methanol is not an acceptable ingredient for any drug product and should not be used. The guidance is available on the FDA website.

Standardize Concentrations for Oral Liquid Preparations

ISMP Institute for Safe Medication Practices An ECRI Affiliate

This column was prepared by ISMP, an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert! newsletters at* www.ismp.org.

Few would disagree that standardizing the concentrations of drugs has enormous potential for increasing safety, especially in pediatric care. Standardization limits the risk of variation, especially when patients are transitioned from hospital to home or have prescriptions filled at different pharmacies. However, ISMP has learned of multiple instances in which unrecognized differences or changes in drug concentrations led to confusion and dosing errors.

In one example, a patient was prescribed hydroxyurea, an antineoplastic agent. The community pharmacy compounded a 50 mg/mL suspension for the patient with instructions to take 13 mL (650 mg) for each dose. When the patient was later admitted to the hospital, the inpatient pharmacy prepared their standard concentration of 100 mg/mL, but the same dose volume of 13 mL was ordered. As a result, the patient received doses of 1,300 mg for several days before the error was recognized. It is unclear why the community pharmacy prepared a 50 mg/mL concentration. Perhaps the prescriber ordered that concentration or that was the concentration with which the pharmacist was most familiar.

Similar concentration mix-ups have been reported in literature. In one case, the oral class 1c antiarrhythmic medication flecainide was involved. The parents of a nine-month-old infant were told to increase the child's dose volume of flecainide to 4 mL, assuming the concentration was 5 mg/mL as in the original prescription.[1] However, the parents refilled the prescription at a different pharmacy and received the drug in a 20 mg/mL concentration. The patient received 80 mg/4 mL, a fourfold overdose, resulting in wide complex tachycardia and QRS prolongation.

There have been efforts, including those by a collaborative led by the University of Michigan[2]and the American Society of Health-System Pharmacists (ASHP)[3], to publish lists of consensuses and literature-based standard concentrations. In fact, for the medications involved in the cases above, both the University of Michigan and ASHP standard recommendations are in alignment – hydroxyurea 100 mg/mL and flecainide 20 mg/mL. However, the outreach and communication of these standardization efforts do not appear to be reaching prescribers and pharmacists. Both inpatient and outpatient practitioners need to get on the same set of standard concentrations for compounded oral liquids. It is imperative that both medical and pharmacy professional organizations develop and implement effective strategies to reach and influence practitioners to use the published standard concentrations. ISMP urges prescribers and pharmacists to review the University of Michigan and

ASHP lists and consider adopting the proposed standard concentrations. Your efforts can help reduce the risk of medication errors.

It is also important for pharmacists to provide patients or caregivers with appropriately sized metric-only dosing devices (eg, oral syringes) to measure and administer doses. Label directions for patients and caregivers should include the dose in terms of mL (not teaspoonfuls), matching the dosing device. The community pharmacy label should also include the concentration next to the drug name. To be sure patients or caregivers are able to use the dosing device and measure the proper dose, use the teach-back method to demonstrate how to measure and administer prescribed amounts. This also gives pharmacists, patients, and caregivers an opportunity to catch an error.

References

1. Wang GS, Tham E, Maes J, et al. Flecainide toxicity in a pediatric patient due to differences in pharmacy compounding. Int J Cardiol. 2012;161(3):178-9.
2. *www.mipedscompounds.org/*
3. *www.ashp.org/-/media/assets/pharmacy-practice/s4s/docs/Compound-Oral-Liquid.ashx*

Opioid Use Disorder Educational Programs, Resources Available for Pharmacists

Through its Opioid Use Disorder (OUD) Education Program, the College of Psychiatric and Neurologic Pharmacists (CPNP) provides educational programs and resources that can help pharmacists during the ongoing opioid epidemic. These educational opportunities include Accreditation Council for Pharmacy Education-approved, on-demand programs covering subjects such as pharmacotherapy for OUD, comorbid disorders, and chronic pain and OUD. Toolkits and guides are available to assist pharmacists in the areas of intervention, medication management, and naloxone access.

These educational materials and resources can be accessed through the CPNP website.

National Diabetes Prevention Program – How Pharmacists Can Get Involved

Pharmacists can play a key role in preventing type 2 diabetes by helping to expand the reach of the National Diabetes Prevention Program (National DPP) – a program led by the Centers for Disease Control and Prevention (CDC) that makes it easier for patients with prediabetes or who are at risk for type 2 diabetes to participate in evidence-based lifestyle changing programs to reduce their risk and improve overall health. CDC offers an action guide for community pharmacists that outlines ways pharmacies can raise awareness of prediabetes. The National DPP is a partnership among private and public organizations to screen and test for prediabetes and refer people with prediabetes to a CDC-recognized lifestyle change program participating in the National DPP, and deliver the National DPP lifestyle change program. More information about how pharmacists can participate is available on the CDC website.

Surgery Patients Receive More Opioids in the US Than in Other Countries

Patients in the US are prescribed a disproportionally higher number of opioids after surgeries compared to surgery patients in other countries, according to a new study. The study, published in the *Journal of the American College of Surgeons,* reviewed data from 2,024 surgery patients and found that 83% of US patients without pain were prescribed opioids, compared with 8.7% of non-US patients without pain. The authors concluded that US patients are prescribed more amounts of opioids at higher rates regardless of the severeness of their post-surgical pain. The authors recommend that more efforts are made toward ensuring that opioid prescriptions are tailored to patients' needs.

The full text of the study can be accessed by visting *www.journalacs.org/article/S1072-7515(20)32336-X/fulltext.*

Study Finds 94% Drop in Symptomatic COVID-19 Cases With Pfizer's Vaccine

A study by Israel's largest health care provider, health maintenance organization Clalit, reported that there is a 94% drop in symptomatic COVID-19 cases with the Pfizer vaccine. The study represents 600,000 people who received two doses of the Pfizer COVID-19 vaccine in Israel. Clalit, which covers more than half of all Israelis, noted the same group who received the COVID-19 vaccine doses was also 92% less likely to develop serious illness from the virus. The study compared the vaccine recipient group to another group of the same size and medical history who had not received the vaccines. Read the full study here.

NABP Executive Director/Secretary Addresses Pharmacists' Involvement in COVID-19 Vaccination During FIP Webinar

NABP Executive Director/Secretary Lemrey "Al" Carter, PharmD, MS, RPh, presented during the International Pharmaceutical Federation's (FIP's) Regulators' Forum on pharmacists' involvement with COVID-19 vaccination on February 4, 2021. The webinar addressed a new regulatory vaccination preparedness self-assessment tool and risk assessment, the expanded roles for pharmacists, and data FIP has collected on vaccinations by pharmacists. View the webinar here.

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The positive impact and efficiencies of these new systems allow for the alignment of the late fee with the expiration date of the license/registration. It is still recommended that licensees submit renewal applications early enough to allow for processing and mailing of the license/registration. Any renewal received after the expiration of the license/registration will be assessed the late fee.

No. 653 Licensing Updates

Reminder – Pharmacist License Renewals

During the period from July 1 through June 30 of each biennial license renewal cycle, each pharmacist must have satisfactorily completed 30 hours of CE **prior to submission** of the license renewal. A minimum of at least two hours of CE credit must be earned in the area of pharmacy and drug law. A minimum of two hours of CE credit must be earned in the area of patient safety or medication error prevention.

In accordance with OAR 855-021-0005(2), pharmacists applying for the first renewal of their license have to complete CE if they have been licensed by the Board for at least one year prior to July 1 of the renewal period. However, a pharmacist reciprocating into Oregon will not be required to submit proof of continuing pharmacy education during the initial license cycle, per OAR 855-021-0025.

- Pharmacists initially licensed between July 1, 2019, and June 30, 2020, must complete the CE requirements for the 2021 renewal. (Note: this does not apply to initial licensure by reciprocity.)
- Pharmacists initially licensed between July 1, 2020, and June 30, 2021, do not have to complete the CE requirements for the 2021 renewal.

Additionally, Oregon has a one-time pain management CE requirement, which must be completed within 24 months of your first license renewal. Per OAR 855-021-0016, a pharmacist shall complete seven hours of CE in pain management, which must include the Oregon Pain Management Commission's one-hour, required web-based module, as well as six additional pain management-related programs. This pain management CE can be counted toward the 30-hour total required.

Contraceptive Training Certificate of Completion – Upload to eGov

Per OAR 855-019-0415(2), "A pharmacist must submit a copy of the certificate of completion of training to the Board within 15 days of completion." Pharmacists should upload their completion certificates using eGov, where licensees can maintain their own record and upload documents directly to their profile. Please visit *https://orbop.mylicense.com/EGOV* and register for a new personal account; or if already registered, log in to access your account. Instructions for creating a new account can be found on the Board website. Once you are logged in to your account, click on "Update License Info" in the menu, then navigate to "Attach Documents" to upload your certificate to the selected license account.

No. 654 Compliance Updates

Phone Scam

The Board has become aware that licensees are receiving scam phone calls from individuals impersonating Board staff members. Licensees should be cautious of giving confidential or payment information over the phone without verifying that the source is legitimate. Board staff will never ask for or accept payment for any fees by phone. Scammers, claiming to be Board staff members, are calling pharmacists and saying that their facility or individual license is under investigation. Scammers may also state that they are working with Food and Drug Administration or Drug Enforcement Administration on a case, and further claim that the licensee is under investigation for suspicious activity or drug trafficking. In either case, the scammers claim that licensees will face disciplinary action, a revoked license, or arrest if they do not immediately pay a fine over the phone. Additionally, many scammers are "spoofing" the phone number used to call the pharmacist. Spoofing involves disguising the caller's true phone number and making it appear that the phone number is from a legitimate source. Scammers may even give a fake name and a fraudulent inspector identification number as "proof" of identity. If the call sounds suspicious, hang up and call the Board directly at 971/673-0001, or contact the Board at pharmacy.board@oregon.gov.

Drug Storage

Due to the February snow/ice storm and the temporary/prolonged power outages that occurred throughout the state, pharmacies should review temperature data to see if any excursions occurred during the inclement weather. Pharmacists-in-charge are reminded to review drug storage polices, emergency action plans, and training to determine if they are up to date or need to be modified based on issues encountered during recent inclement weather. Rules pertaining to drug storage are located in OAR 855-007-0120 and OAR 855-041-1036.

Compliance Officer on Duty

Each week, a compliance officer is assigned duty for the week. This individual is responsible for prioritizing and responding to compliance-related inquiries during the assigned week. Please be aware that Board staff may not provide individualized legal advice on how the law applies to practice in the field; however, they may be able to highlight or point out regulations that may apply to an inquiry.

No. 655 Meeting Schedules, Agendas, and Notices

- To view upcoming Board and Rulemaking Hearing meetings for 2021-2022, visit *https://www.oregon.gov/pharmacy/Pages/Board-Minutes.aspx*, scroll to the

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bottom of the page to the "Upcoming Board Meeting & Rulemaking Hearings Schedule" calendar, and advance the calendar by month using the greater than symbol (>) located on the top left-hand side of the calendar.

- To view upcoming Public Health and Pharmacy Formulary Advisory Committee meetings, visit *https://www.oregon.gov/pharmacy/Pages/PFAC .aspx,* and scroll down to the "Meeting Schedule" cal-endar.
- Subscribe to receive Board meeting agenda notices here.
- Subscribe to receive rulemaking notices and adoption of rules notices here.

No. 656 Board Email Domain Change

The Board of Pharmacy email domain is scheduled to change on May 21, 2021. The old domain "@oregon.gov" will change to "@bop.oregon.gov." Please see the Board website for updates.

The *Oregon State Board of Pharmacy News* is published by the Oregon State 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.

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