May 2021

State of Ohio Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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From the Director's Desk

Dear Ohio Pharmacist,

As the state continues its coronavirus disease 2019 (COVID-19) vaccination efforts, the State of Ohio Board of Pharmacy has released a COVID-19 vaccine inspection guide. The inspection guide will help to ensure compliance with COVID-19 vaccine storage and handling requirements. The guide can be accessed by visiting *www.pharmacy.ohio.gov/VACinspect.*

The Board has received several requests to reissue pharmacist pocket cards to demonstrate vaccine eligibility. Please be advised that the Board no longer issues pocket cards. Instead, the Board recommends using the license verification look-up feature on eLicense Ohio by visiting *https://elicense.ohio.gov/oh_verifylicense.*

Finally, terminal distributor of dangerous drugs (TDDDs) renewal opened on January 30. In response to the COVID-19 outbreak, the Ohio General Assembly passed House Bill 404, which required all licenses/registrations set to expire on or before April 1, 2021, to be extended until July 1, 2021. All TDDDs were extended from March 31, 2021, to July 1, 2021. Any license renewed after the expiration date of July 1, 2021, will be assessed a late fee. More information about renewal can be found on the Board's website.

As a reminder, Board staff continues to work remotely during the COVID-19 pandemic. If you have any questions, please do not hesitate to contact the Board via contact@pharmacy.ohio.gov or 614/466-4143. For the latest information on the Board's COVID-19 updates, visit *www.pharmacy.ohio.gov/COVID.*

On behalf of the Board, thank you for all that you do to help keep Ohioans safe and healthy.

Sincerely,

Steven W. Schierholt, Esq
Executive Director
State of Ohio Board of Pharmacy

Reminder: Outpatient Inspection Guide Continuing Education Opportunity

To assist with the implementation of the new outpatient pharmacy rules, the Board has developed a one-hour jurisprudence quiz. This quiz is intended to test a participant's knowledge of the new outpatient pharmacy rules and provides one contact hour (0.1 CEU) of Board-approved jurisprudence for pharmacists and registered pharmacy technicians.

For more information on the quiz, visit *www.pharmacy.ohio.gov/OPquiz.*

Prescriber Compounding Rules – Effective March 31, 2021

On March 31, 2021, new rules for prescriber compounding (Chapter 4729:7-3 of the Ohio Administrative Code (OAC)) went into effect.

To assist licensees in complying with the new rule chapter, the Board recently published a prescriber compounding inspection guide, which may be accessed by visiting *www.pharmacy.ohio.gov/PrescriberComp.*

The inspection guide aligns with internal guidance used by Board inspectors and allows licensees to conduct self-inspections to ensure compliance. The guide also includes links to the new rules, important

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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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definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

Reminder for Pharmacists: The prescriber compounding rules do not impact pharmacy compounding. Please be advised that pharmacy compounding rules are in the process of being updated. Click here for more information pending pharmacy compounding rules.

COVID-19 Response Efforts

The Board is committed to protecting the health and safety of Ohioans during the COVID-19 pandemic. The Board posted a document on its website that provides COVID-19 guidance and response efforts, including the issuance of waivers to assist licensees in addressing operational needs. **Waivers can be found starting on page 5 of the following document:** *www.pharmacy.ohio.gov/COVID.*

For more information on the state's efforts to address COVID-19, visit *www.coronavirus.ohio.gov,* or call 1-833/4-ASK-ODH.

PREP Act Expanded to Include Recently Inactive Pharmacists and New Flexibility for Health Care Students

Pursuant to the Public Readiness and Preparedness Act (PREP Act), the United States Department of Health and Human Services has expanded its guidance to include recently inactive (within the last five years) pharmacists and pharmacy interns in the list of clinicians who can administer COVID-19 vaccines. The amendment also allows health care students to administer COVID-19 vaccines under the supervision of any health care professional.

For more information on these updates and the requirements to qualify, visit the following links:

- PREP Act Fact Sheet – Expanding the COVID-19 Vaccination Workforce
- Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

2021 Virtual Law Reviews and Responsible Person Roundtables

Join the Board for a presentation to learn about the latest developments in pharmacy law and rules.

Law Review topics will include:

- New requirements for terminal distributors of dangerous drugs
- New outpatient pharmacy rules and inspection guide
- Board COVID-19 response efforts
- Pharmacy compounding rules and implementation plan

Responsible Person Roundtable topics will include:

- Duties of a responsible person
- General provisions applicable to a terminal distributor of dangerous drugs
- Duty to report requirements
- Additional compliance resources

Who should attend?

- Pharmacists, pharmacy interns, registered or certified pharmacy technicians, and pharmacy compliance staff employed in outpatient/community-based pharmacies.

For more information and registration information, visit *www.pharmacy.ohio.gov/2021Review.*

OARRS Updates

OARRS and Prescriber DEA Numbers

Per rule 4729:8-3-02 of the OAC, pharmacies and medical marijuana dispensaries are required to report the prescriber's Drug Enforcement Administration (DEA) registration number or another mutually acceptable identifier. If a prescriber has a personal DEA number or uses a hospital DEA number plus identifying suffix, the pharmacy shall use that number for all prescriptions reported to Ohio Automated Rx Reporting System (OARRS). Controlled substances (CS) should always have the prescriber's true DEA number/hospital DEA number plus suffix on the submission.

A pharmacy should only report the default DEA number of OH1111119 if the prescriber does not have a DEA registration. Thus, the default DEA registration number can only be reported for non-CS (eg, gabapentin or naltrexone).

OARRS audits are showing pharmacies reporting the default DEA number on dispenses of CS. Failure to submit correct information may result in administrative discipline against the reporting pharmacy's license. Therefore, you are strongly encouraged to

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check your prescriber database for accurate prescriber DEA numbers.

OARRS Account Update and Delegate Reverification Workflow

As a reminder, since September 30, 2020, OARRS users are prompted to update or confirm their PMP AWARxE profile information on a biannual basis. The purpose of this verification requirement is to ensure that all OARRS profile information is up to date and accurate.

Additionally, OARRS will also be requiring semi-annual confirmation of all linked delegates to protect the security of the patient data in the system. Account holders will receive emails indicating that they have 45 days to complete this verification process.

OARRS account holders are strongly encouraged to log in to their accounts to verify the required information. Failure to confirm account details and delegates may disrupt user access, including delegate access. The website to verify this information is *https://ohio.pmpaware.net.*

Important: This provision will not impact integrated systems where OARRS information is directly accessed via an electronic medical record or pharmacy dispensing system.

For more information on these processes, the Board has developed the following guidance documents:

- Delegate Reverification Workflow: *www.pharmacy.ohio.gov/workflow*
- OARRS Account Update: *www.pharmacy.ohio.gov/accountupdate*

Account holders should review these documents for any questions. For additional questions, account holders should contact the Board's OARRS Department via email at support@pharmacy.ohio.gov.

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