April 2021

Oklahoma State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Board Members and Staff

20.35 Fraudulent Agent Scam

Please be mindful of a current scam involving the Oklahoma State Board of Pharmacy and other regulatory agencies, including Drug Enforcement Administration (DEA), which involves "fake" agents contacting licensees regarding an investigation. These agents are threatening suspension of licensing, etc, unless fines are paid to them. They are using forms on letterhead that appear to represent the Board and other regulatory agencies, including the correct phone number, fax number, and email address. This is not, nor has it ever been, the way the Board conducts investigations. If you are contacted in this manner, please reach out to your compliance officer and/or the Board's main office to verify.

20.36 Best Practice Recommendations

During the coronavirus disease 2019 pandemic, it seems that more and more citizens are noticing the practice/work habits of pharmacy personnel and staff.

The Board has received complaints of pharmacy personnel not wearing masks and not wearing gloves when handling medication by hand for the purpose of bubble packing/carding/unit dosing.

While the Board does not have any laws and rules regarding wearing masks or wearing gloves when handling medication, the Board does recommend both as "Best Practice."

20.37 CDS Prescription Refill Transfers

The transfer of prescription information for the purpose of refilling a controlled dangerous substance (CDS) prescription must be communicated directly between two licensed pharmacists. According to DEA Title 21 Code of Federal Regulations, Part 1306, Section 1306.25, CDS prescription transfers must be communicated directly between two licensed pharmacists and cannot be done by interns or any other pharmacy personnel.

20.38 Compounding Commercially Available Products and/or Alternate Product and Alternate Dosage Forms

Compounding a drug product that is commercially available is generally prohibited. In special circumstances, a pharmacist may compound an appropriate quantity of a drug that is different from a Food and Drug Administration-approved drug that is commercially available based on **documentation provided by the prescribing physician of a patient's specific medical need.**

This documentation must be available when requested by the Board or its compliance officers.

20.39 Information for Pediatric Psychotropic Medication

Below are links to the Oklahoma State University (OSU) Department of Psychiatry and Behavioral Sciences and the Oklahoma Pediatric Psychotropic Medication Resource Guide.

The Board has been asked to make this information available to pharmacists and pharmacies.

- OSU Department of Psychiatry and Behavioral Sciences: *https://medicine.okstate.edu/academics/psychiatry*
- Resource guide: *https://medicine.okstate.edu/academics/psychiatry/documents/psychotropic-medication-guidelines-pages-final.pdf*

National Pharmacy Compliance News

April 2021

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.

20.40 Obituaries: Ed McFall and Lonny Wilson

Former Board Member Charles Edward "Ed" McFall, DPh, passed away on October 30, 2020. He served on the Board from 1989 to 1993. Ed was the director of pharmacy at Memorial Hospital and Physicians Group in Frederick, OK, and consultant to Memorial Nursing Center. He also practiced in Shawnee, OK, at the Medical Center and at Comanche County Hospital in Lawton, OK. He also dedicated his time to being a member of the Board of Trustees of Memorial Hospital in Frederick, president of Region Six, Oklahoma Pharmacists Association, and chair of the Rural Health Planning Committee. He served on the Utah Pharmaceutical Association Board as president.

Ed was recognized in 2000 by the University of Oklahoma Health Sciences Center College of Pharmacy Alumni Association and presented with the Distinguished Alumni Award for outstanding accomplishments, leadership, and service in the profession. He was presented the nationally sponsored Bowl of Hygeia Award in 2001 for his advocacy of pharmacy and outstanding community service. On May 25, 2017, Ed was named Rural Health Advocate of the Year by the Rural Health Association of Oklahoma. For the full obituary, click here.

Lonny Dean Wilson, DPh, former president of the National Community Pharmacists Association (NCPA) and prominent pharmacy leader for the state of Oklahoma, passed away on January 25, 2021. Lonny served on the executive committee of NCPA beginning in 2005, and later serving as president during the 2011-2012 year. Lonny found great joy in his work as an independent community pharmacist, owning and operating several pharmacies throughout the state. In 1989, he began his journey with Pharmacy Providers of Oklahoma, where he managed third-party pharmacy programs, a buying group, and a national claims transmission network. As a result of his commitment to the profession, an endowed scholarship in his name was created at Southwestern Oklahoma State University (SWOSU) in 2013, to assist students interested in independent pharmacy pursue their goals. Lonny was a recipient of the NCPA Calvin J. Anthony Lifetime Achievement Award in 2016, the SWOSU College of Pharmacy Dean's Distinguished Service Award in 2012, the American Pharmacists Association Bowl of Hygiea Award for distinguished service in the community in 1994, as well as countless others. For the full obituary, click here.

20.41 From the Inspector's Desk

Whenever a pharmacy adds space or utilizes a new space to store medications, it must notify the Board. There is a possibility that these changes would prompt an inspection, which could result in a special inspection fee. Pharmacies are beginning to store their vaccines in an immunization room to free up more space inside the pharmacy, but the immunization room must be secured in the same way as the pharmacy is secured. This room must be locked and can only be accessed by a pharmacist. Referenced below is the section of the Board law book that addresses this subject. Even though this may not technically be considered a "remodel" in some situations, this would be considered adding additional storage areas. Therefore, pharmacies must notify the Board in advance of their plans to utilize additional space outside of the actual pharmacy.

(h) Remodel. The pharmacy and the PIC are responsible to notify the Board in writing in advance of any remodel in the pharmacy that would result in a change in square footage, plumbing, or additional storage areas. Such pharmacy shall be subject to inspection by the Board and shall be required to pay an inspection fee.

20.42 Break-Ins and Robberies

It is extremely important that the Board is notified immediately any time there is a robbery or break-in at an Oklahoma pharmacy. The Board asks that you contact your compliance officer directly. For contact information, please visit the Board website at *https://www.ok.gov/pharmacy/Board/Board_Staff/index.html.*

20.43 Disciplinary Actions

Jason Robert Revel, DPh #17446 – Case No. 1609: Respondent must attend an eight-hour law seminar in addition to the required 15 hours of continuing education (CE) during the years of 2021 and 2022. All CE for the years 2021 and 2022 must be live and include eight hours of nonsterile compounding. Respondent admits to guilt on counts 1-686, including the pharmacist-in-charge (PIC) having the responsibility to ensure that all compounders meet all requirements for training, testing, and education set forth in the Oklahoma Administrative Code 535:15-10-3 regulations and the regulations set forth in United States Pharmacopeia standards. **Fined $34,300.**

Revan, Inc, dba Revan Rx, #1-8423 – Case No. 1610: Respondent admits to guilt on counts 1-686, including registrant conduct; registrants shall conduct business in conformity with all federal, state, and municipal laws at all times. **Fined $34,300.**

Calendar Notes

- **Upcoming Holidays:** The Board office will be closed on May 31, 2021, for Memorial Day and July 5, 2021, for Independence Day.
- **Upcoming Board Meeting:** The Board is scheduled to meet on May 19, 2021. All meetings begin at 8:30 AM.

Change of Address or Employment?

Please be diligent in keeping your information up to date and, if possible, remind your coworkers and employees. Failure to notify the Board is a violation of Oklahoma pharmacy law. All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or employment. Online updates through the license renewal page are **not** accepted

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as official notification. Emailed notifications can be sent to pharmacy@pharmacy.ok.gov or faxed to 405/521-3758. License/permit numbers must be included to be accepted.

Special Notice About the Newsletter

The *Oklahoma State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. Oklahoma Pharmacists Helping Pharmacists (OPHP) is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574, ext 5773. All calls are confidential.

This publication is issued by the Oklahoma State Board of Pharmacy as authorized by Title 59 O.S. 353.7. Copies have not been printed but are available through the agency website. [74 O.S. §3105 and 65 O.S. §3-114]

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

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