April 2018

Oklahoma State Board of Pharmacy News

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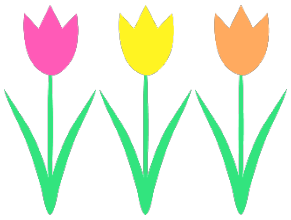

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From the Inspector's Desk

- **18.12 Temperature Logs:** It is recommended that every pharmacy maintain a temperature log for any refrigerator or freezer where prescription only drugs are kept. For those also storing immunizations, the Centers for Disease Control and Prevention requires that temperatures are checked and logged twice daily. There is currently no rule for temperature logs, but there is potential for it to become a rule next year.
- **18.13 Drug Abuse Treatment Act-Waived Physicians:** According to Drug Enforcement Administration (DEA) regulations, a prescription for buprenorphine-containing products must contain the prescribing practitioner's federal DEA number and the practitioner's "X" DEA number, which denotes prescribing authority for these types of drugs. If either DEA number is missing, a pharmacy cannot fill the prescription until it is added. A pharmacist can add the DEA or "X" DEA number with or without confirming the prescription with the practitioner.
- **18.14 CDS Files:** If a pharmacy has entered a controlled dangerous substance (CDS) prescription into the computer and changes the information because there was something wrong on the original back tag, then the pharmacy must place a new back tag with the correct information that corresponds to that prescription. The same process applies to a CDS prescription that has been placed on hold. Once the prescription is filled and dispensed, the original hard copy must be pulled, and the new back tag indicating the date of filling and the pharmacist's initials must be placed on the prescription. Even if the pharmacy reports the correct information to insurance and the prescription monitoring program, the hard copy still serves as the primary record and should reflect the correct information.
- **18.15 Addition of Information to CDS Hard Copies:** A pharmacist, without confirmation from the prescribing practitioner, may add the patient's address or age, the prescribing practitioner's federal DEA number, or the generic drug name (if used). After confirming with the prescribing practitioner, the pharmacist may add information indicating the strength, whether the prescription is tablet or capsule form, and whether it is compounded if such additions would not materially alter the prescription. The directions (Sig) or the quantity may also be added by the pharmacist after

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National Pharmacy Compliance News

April 2018

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.*

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA.* To access the *2017 NDTA,* visit *www.dea.gov/divisions/hq/2017/hq102317.shtml.*

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.*

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at *www.nccmerp.org/sites/default/files/nan-20171012.pdf.*

FDA Advises on Opioid Addiction Medications and Benzodiazepines

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs,* is located on the GAO website at *www.gao.gov/products/GAO-18-25.*

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at *https://doi.org/10.15288/jsad.2017.78.805.*

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of *www.ptcb.org.*

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confirming with the prescribing practitioner. Information added after confirming with the prescribing practitioner should be noted on the back of the prescription.

- **18.16 Immunizing Pharmacists:** A pharmacist must have completed an approved training course **and** received registration for immunizations with the Oklahoma State Board of Pharmacy **prior** to administering immunizations. Immunization certificates from the Board should be displayed in the pharmacy along with a copy of current CPR certification. If you are floating to different pharmacies that provide immunizations or covering a shift at a different pharmacy that provides immunizations, you need to make sure that you have proper licensing credentials with you. You need to have a current copy of your license renewal, a copy of your immunization certificate, and a current copy of your CPR certification.
- **18.17 Oklahoma Technician Exam and Training:** The Board's technician examination required for all pharmacy technicians licensed April 2012 or later is available on the Board's website. The exam is attached to the new application for pharmacy technicians. This exam must be maintained and readily retrievable in the pharmacy for inspection. Please do not send the completed exam to the Board. Also, do not forget that technician training is required to be updated on an annual basis for all technicians. In addition, if a technician works at a different location or pharmacy, a copy of the technician exam along with yearly training should be kept there as well. Documentation of annual training must also be maintained and readily available in the pharmacy. If training is completed via computer, then print transcripts regularly and keep them in the pharmacy to expedite inspections. It is time-consuming for pharmacists and compliance officers to obtain records off the computer, and many staff pharmacists do not know how to access those records. Records may not be maintained in another department, such as human resources.

18.18 Staff Changes at the Board

The Board office looks a little different these days! Cindy Fain, chief compliance officer, resigned in March after being with the Board 19 years. Susan Dozal, administrative programs officer, retired in February after being with the Board 28 years. Both Cindy and Susan were greatly appreciated and will be missed. The Board office would also like to introduce two of its newest inspectors.

Keevie Ridener, PharmD, DPh, of Bixby, OK, began employment with the Board as a compliance officer on September 29, 2017. Keevie graduated from the University of Oklahoma College of Pharmacy in 2007. She was previously employed as a pharmacy manager for a chain pharmacy in Tulsa, OK. Her territory includes much of Tulsa, Creek, and Oklahoma counties. She receives email at kridener@pharmacy.ok.gov.

Jeremy Davis, PharmD, DPh, of Glencoe, OK, began employment with the Board as a compliance officer on September 22, 2017. Jeremy graduated from Southwestern Oklahoma State University College of Pharmacy in 2001. He was previously employed as a hospital pharmacy director in Tulsa. His territory includes central and northwest Oklahoma. He receives email at jdavis@pharmacy.ok.gov.

Disciplinary Actions

For more information, you may view hearing minutes at *http://ok.gov/pharmacy/Board/Minutes/index.html.*

18.19. January 17, 2018 Board Hearing

Kendra Wright, DPh #14143 – Case No. 1497: Respondent neither admits nor denies guilt on all four counts including incorrectly filling or misfilling a prescription, failing to establish and maintain effective controls against prescription errors or misfills, failing to prepare and review all compounding records to ensure that no errors have occurred in the compounding process, and failure of pharmacist or pharmacy manager (pharmacist-in-charge) to fulfill the responsibilities as set out in Oklahoma Administrative Code 535:15. **$4,000 fine. Respondent's license is placed on probation for one year until January 17, 2019.**

Brittney Anduze, Technician #10478 – Case No. 1493: Found guilty on two counts including committing theft while working as a registrant. **Revoked.**

Shayla Howard, Technician #22789 – Case No. 1494: Found guilty on two counts including committing theft while working as a registrant. **Revoked.**

Terrie Kriley, Technician #13115 – Case No. 1495: Found guilty on three counts including committing theft while working as a registrant and possessing a CDS without a valid prescription. **Revoked.**

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Robert R. Murdock, Technician #22924 – Case No. 1496: Found guilty on three counts including committing theft while working as a registrant and possessing a CDS without a valid prescription. **Revoked.**

Absolute Veterinary Compounding Pharmacy, #99-7495 – Case No. 1498: Neither admits nor denies guilt on four counts including incorrectly filling or misfilling a prescription or drug order; failing to obtain a new license after change of name, ownership, and/or location; and failing to report to the Board all changes in any information required for licensure. **$4,000 fine. Respondent's license is placed on probation for one year until January 17, 2019.**

Victoria Moore, Technician #23454 – Case No. 1499: Found guilty on three counts including committing theft while working as a registrant. **Revoked.**

Calendar Notes

The Board will meet on **April 18** and **June 13, 2018.** The Board office will be closed **Monday, May 28** for Memorial Day and **Wednesday, July 4** for Independence Day. Future Board dates will be available at *www.pharmacy.ok.gov* and will be noted in the July *Newsletter.*

Change of Address or Employment?

Please be diligent in keeping your information up to date and if possible, remind your coworkers and employees. This continues to be an ongoing problem, and 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 also accepted as official notification.

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."

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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