July 2019

Oklahoma State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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19.09 Personnel Changes at the Board Office!

Interim Executive Director **Dorothy Gourley, DPh,** has officially gone back to enjoying retirement after serving the Oklahoma State Board of Pharmacy since August 2018. Her devotion, dedication, hard work, and endless knowledge have definitely been appreciated during this time. Dorothy will be extremely missed at the office.

Marty Hendrick, PharmD, DPh, is very excited and honored to begin his role as executive director of the Board. After growing up in Alva, OK, Marty graduated from Oklahoma University School of Pharmacy in 2006. Marty's career as a pharmacist has taken him to Nevada, MO; Tulsa, OK; and Wilmington, NC. He previously worked as a compliance officer for the Board from 2015-2017, serving the central territory, before his family moved to the East Coast. Marty is married with an eight-year-old son, a dog, and three cats. In his free time he has spent countless hours renovating a 100-year-old house not far from the beach in North Carolina. Marty is going to miss living on the coast in Wilmington, but he is very excited to rejoin the Board and to be back in his home state of Oklahoma.

Kim Hibbard, DPh, of Broken Arrow, OK, began employment with the Board as a compliance officer on April 30, 2019. Kim graduated from Southwestern Oklahoma State University College of Pharmacy in 1993. She was previously employed as a retail pharmacist for a chain pharmacy in Tulsa. As a compliance officer, her territory includes much of Tulsa and northeast Oklahoma. She receives email at khibbard@pharmacy.ok.gov.

19.10 General Housekeeping Reminders

- Please post all required licenses, certificates, permits, etc, in such a manner that all information is visible to the compliance officer.
- Pictures on pharmacy technician permits should not be covering up expiration dates or any other information on the permit. Please do not cover up portions of one pharmacy technician permit with another pharmacy technician permit.

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National Pharmacy Compliance News

July 2019

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 Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a Drug Safety Communication, provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

"Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse," the agency said in the communication. "Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances."

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the News and Events section of the FDA website.

DEA Warns of Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a DEA press release, this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of legitimate investigation or legal action is made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- maintaining quality manufacturing compliance,
- strengthening and refining regulations on compounding from bulk drug substances,
- finalizing the agency's memorandum of understanding with the states, and
- issuing revised draft guidance for compounding by hospital and health systems.

"We've worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs," then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a statement published on the FDA website. "We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . ."

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a press release from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

"Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis," Senate Minority Leader Chuck Schumer said in the press release. "We must hold China accountable for their role in the fentanyl trade. China's new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers."

In a December meeting with President Donald Trump, China's President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be "the largest source of illicit fentanyl and fentanyl-like substances" in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a press release posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy® (NABP®) Drug Disposal Locator Tool, available in the AWAR$_X$E® Prescription Drug Safety section of the NABP website, *www.nabp.pharmacy/initiatives/AWARxE.* With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at *https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine.*

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- Pharmacy technician permits and intern certificates should not be folded in such a manner that portions of the name or expiration date are not visible without taking it out of a frame.

19.11 From the Inspector's Desk

Important Information Regarding Tribal ID Cards

(Originally published in the October 2018 Newsletter)

On March 20, 2018, the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) informed the Board that it has received the "green light" to add the new Choctaw Nation tribal ID card to the list of acceptable tribal IDs for filling controlled dangerous substance (CDS) prescriptions. The card is already in use (issue date must be January 1, 2018, or later), therefore, some of their citizens already have the newer version of the card. It is estimated that it will take approximately two years to reach all of their citizens. Prescription monitoring program (PMP) administrators should advise callers of this change, effective immediately.

Current List of Accepted Tribal IDs

- Muskogee Creek Nation
- Cherokee Nation
- Choctaw Nation (**Only** if they have the newer version of the card as pictured below.)

19.12 Announcement From OBNDD Regarding the PMP

On May 15, 2019, a new security feature was released that requires delegates to be reviewed and approved every six months. This is to ensure that access to the confidential personal health information is limited to only authorized persons and eliminate any unauthorized disclosures of confidential personal health information. The review window began May 15 and ended June 30. This allowed over 45 days to either review and approve or reject delegate accounts. If you have any questions or concerns do not hesitate to contact OBNDD. As always, OBNDD appreciates your partnership.

To contact Oklahoma PMP Aware, please call 855/965-4767.

19.13 Disciplinary Actions

March 6, 2019

Impaired Pharmacist, DPh #12582 – Case No. 1537: Respondent must enter into an Oklahoma Pharmacists Helping Pharmacists (OPHP)-approved inpatient evaluation program, which must consist of a minimum of three consecutive inpatient days. Respondent must enter into a recovery monitoring agreement with OPHP. Respondent must obtain a fit-for-duty evaluation. After five years, respondent may petition the Board and request to be reinstated with no limitations.

If respondent terminates the contract with OPHP, it will be cause for immediate suspension and the respondent must appear at the next regularly scheduled Board meeting to show evidence that the respondent has complied with all conditions of the OPHP contract and has submitted a fit-for-duty evaluation. Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of required continuing education (CE) in the calendar years of 2019 and 2020 for a total of 23 hours of CE each year. All CE required to renew the license shall be live during the calendar years of 2019 and 2020. Respondent neither admits nor denies guilt on seven counts including practicing pharmacy without reasonable skill and safety by reason of illness; use and/or abuse of drugs, narcotics, chemicals, or any other type of material; or as a result of any mental or physical condition. **Indefinite suspension.**

Kasey Haggard, Technician #20656 – Case No. 1545: Admits guilt on six counts including theft of CDS. **Revoked.**

Scotty Black, DPh #15142 – Case No. 1549: Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of required CE in the calendar years of 2019 and 2020 for a total of 23 hours of CE each year. All CE required to renew his license shall be live during the calendar years of 2019 and 2020. Two hours of the required 23 hours to renew shall include "pain management and/or opioid abuse." Respondent neither admits nor denies guilt on seven of the nine counts

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including not attempting to resolve a possible prescription error or situation of potential harm to the patient when the risk of harm to the patient was apparent or should have been apparent to the pharmacist. **$3,500 fine.**

Dana Tim Knowles, DPh #10160 – Case No. 1551: Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of required CE in the calendar year 2019 for a total of 23 hours of CE. Three hours of the required 23 hours of 2019 CE must consist of "medication error prevention." All CE required to renew his license shall be live during the calendar years of 2019 and 2020. Respondent neither admits nor denies guilt on all seven counts including failing to follow the rules of professional conduct requiring pharmacists to conduct themselves at all times in a manner that will entitle them to the respect and confidence of the community in which they practice. **$3,500 fine.**

Impaired Pharmacist, DPh #14486 – Case No. 1552: At the time when respondent is ready to rejoin OPHP, respondent shall enter into and abide by a lifetime contract. Respondent may petition the Board and request to be placed on probation upon proof of successfully completing five years of the OPHP contract, obtaining a fit-for-duty evaluation, and receiving a recommendation from OPHP that the license be placed on probation. If respondent is found noncompliant with the contract in any way, the noncompliance restarts the five-year period that must be completed before requesting probation. Respondent admits guilt on three counts including violating a Board Order or an Agreed Order and violating a voluntary or Board-ordered rehabilitation program for the impaired contract. **Indefinite suspension.**

Kylee Stetson, Technician #24245 – Case No. 1553: Guilty on all six counts including theft of CDS. **Revoked.**

Tara Woder, Technician #21505 – Case No. 1554: Guilty on four counts including theft while working as a registrant. **Revoked.**

Calendar Notes

- The Board office will be closed on July 4, 2019, for Independence Day.
- Because of the deadline of this *Newsletter,* there are no scheduled meetings to report. The Board will post meeting dates on the Board website once they have been scheduled.

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 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. 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.

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