April 2019

Oklahoma State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Board Members and Staff

19.05 New Faces Coming Soon to the Board Office

The deadline to receive applications for the executive director position was January 31, 2019, and the job posting has since closed. A search committee has been established and initiated the process of reviewing the received applications and will begin scheduling interviews in the near future. Interim executive director, Mrs Dorothy Gourley, DPh, has been overseeing the office since August 2018 and has done an incredible job thus far.

After 20 years of doing an outstanding job of serving the northeastern territory of Oklahoma, Senior Compliance Officer Betty Beil, DPh, has officially retired. Her knowledge and value to the Oklahoma State Board of Pharmacy and the community will definitely be missed. The Board is currently working to fill this open position.

19.06 General Housekeeping Reminders

Technician Permit Renewals – As a reminder, Oklahoma pharmacy technicians cannot renew their permits if they do not have a current employment record on file with the Board office. When completing pharmacy renewal applications, please be sure that **all** technicians are listed on the renewal. Failure to do so not only results in a Board hold being placed on the technician permit, it also causes delays in processing the technician renewal and creates an administrative burden on Board office staff to gather the necessary documentation required to release the Board hold. In addition, this sometimes puts a burden on the pharmacy itself when the permit expires and the technician can only perform clerk duties until he or she receives the updated permit.

Continuing Education – Oklahoma-licensed pharmacists are required to obtain 15 hours of continuing education (CE) per calendar year (January through December). Sometimes this can get confusing for those who think the CE time frame runs concurrent with the renewal time frame, which is birth month to birth month. CE must be completed in the calendar year prior to renewal and documented with the renewal application (eg, all renewal applications submitted in 2019 should include 15 hours of CE taken between January 1, 2018, and December 31, 2018). Board guidelines for CE violations are posted on the Board's website at *https://www.ok.gov/pharmacy/Licensees_&_Applicants/Continuing_Education/index.html.* If you determine that you do not have enough CE to renew your license, please refer to the posted guidelines. If you have any questions about CE or the information available through the provided link, please contact the Board office during normal business hours.

Oklahoma State Board of Pharmacy Newsletter* Versus Blast Emails From the Board** – To subscribe to the **Board *Newsletter, visit *https://nabp.pharmacy/boards-of-pharmacy/oklahoma,* click the "Subscribe to the

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National Pharmacy Compliance News

April 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 Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP $AWAR_XE$® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the $AWAR_XE$ program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

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Oklahoma State Board of Pharmacy Newsletter Email Alert" link, and complete the sign-up box. The Board provides specific information in the *Newsletter,* and it is sent out by the National Association of Boards of Pharmacy® to a mailing list generated through the subscription process.

To subscribe to **email alerts from the Board,** please click on one of the envelopes throughout the Board's website. An example of an envelope link image is provided on the left. You will be required to enter your email address and create a password, and then you will be given a list of subscription topics to choose from. Some people prefer to only be notified of certain topics, and some people wish to receive any and all alerts sent out from the Board office. This is completely up to the subscriber and can be changed at any time. Subscriptions are not tied to any licensure information, so you may register with multiple email addresses, if you choose to do so. The Board utilizes this system to send out information regarding rule changes, employment opportunities at the Board, etc. Please note that this system cannot be used for any employment opportunities outside of the Board. If you have questions, please contact the Board office.

19.07 From the Inspector's Desk

Pharmacies that are performing the Clinical Laboratory Improvement Amendments-waived flu or strep test should refrain from making a diagnosis and should simply report the results to the patient's physician for diagnosis and treatment.

Per Oklahoma Statute Title 59, § 353.1.39, "'prescriber' means a person licensed in [Oklahoma] who is authorized to prescribe dangerous drugs within the scope of practice of the person's profession." By law, the **only** drug that Oklahoma pharmacists may prescribe is naloxone.

This type of collaborative practice agreement is prohibited based on the following state statutes:

- **535:10-9-5(c)** "The agreement shall not violate any state or federal law." **(Agreements)**
- **535:10-3-1.1(7) "Practice of medicine.** A pharmacist will refrain from any attempt at diagnosis or treatment that might infringe upon the legally constituted right or obligation of any licensed practitioner or mid-level practitioner." **(Rules of Professional Conduct)**
- **535:15-3-13(d) "Valid patient prescriber relationship.** The pharmacy and pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued without a valid preexisting patient-prescriber relationship." **(Pharmacist's Responsibility in a pharmacy)**

Note: None of the previous information in this article applies to pharmacists with a certificate to administer immunizations.

Things to Keep in Mind When Entering Prescriptions

When entering original prescription information, please make sure all data entry is accurate and current based on the prescription in front of you. Verify the prescriber's address, phone number, fax number, and any other contact information, as well as the written date, refills, etc. The Board office has received several complaints from prescribers who are receiving refill requests, prior authorizations, and other requested information at incorrect or old locations due to the prescriber information not being updated when the prescription is entered.

The Board office has also received complaints of prescriptions being filled under incorrect prescribers with similar names. Please keep in mind that data accuracy is critical to avoid delays in patient care and to ensure that the correct information is transmitted to the prescription monitoring program.

The Centers for Disease Control and Prevention has prescribing guidelines for opioids. If you are interested in reviewing this information, visit *www.cdc.gov/drugoverdose/prescribing/guideline.html.*

19.08 Disciplinary Actions

November 28, 2018

Impaired DPh, #13663 – Case No. 1543: Indefinite suspension. Before suspension will be lifted, respondent must enter into and remain compliant with all terms of a 10-year recovery monitoring agreement with Oklahoma Pharmacists Helping Pharmacists (OPHP). Respondent must appear before the Board to show evidence that respondent has entered into and is compliant with all conditions of a recovery monitoring agreement and the respondent has a fit for duty evaluation from a Board-approved provider.

January 16, 2019

Kimberly Spilman, Technician #9366 – Case No. 1544: Admits guilt on all three counts including theft while working as a registrant. **Revoked.**

Ashley Buford, Technician #23582 – Case No. 1546: Admits guilt on all four counts including theft while working as a registrant. **Revoked.**

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Justin McKillop, Technician #9799 – Case No. 1547: Admits guilt on all four counts, including knowingly or intentionally possessing a controlled dangerous substance, unless such substance was obtained directly or pursuant to a valid prescription or order from a practitioner, and testing positive for marijuana. **Revoked.**

Sara Anderson, DPh #15532 – Case No. 1548: Respondent is required, in addition to the required 15 hours of CE during the calendar year 2019, to complete 28 additional hours of CE, for a total of 43 hours of CE during 2019. Seven hours of the 28 additional hours of CE that the respondent is to attend and report prior to October 1, 2019, shall be live. Respondent is required to submit proof of the additional 28 hours of CE to the Board no later than October 1, 2019. Respondent admits guilt to the violations as set forth in count one. **$700 fine.**

Calendar Notes

- **Upcoming holiday:** The Board office will be closed on May 27, 2019, for Memorial Day.
- The Board may have unexpected closings or delayed openings due to inclement weather.
- **Upcoming Board meeting:** The Board is scheduled to meet on April 17, 2019, 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 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.

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)

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