October 2018

Oklahoma State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

2920 N Lincoln Blvd, Suite A • Oklahoma City, OK 73105-3488

Board Members and Staff

18.25 Dorothy Gourley, DPh, Appointed as Interim Executive Director

Dorothy Gourley, of Ardmore, OK, was appointed as the interim executive director at the August 8, 2018 Oklahoma State Board of Pharmacy meeting. Gourley previously worked in independent and chain pharmacies in addition to serving as a consultant pharmacist to rural hospitals. She has served as a member of the Board; first appointed in 2005 by Governor Brad Henry, she was reappointed in 2010. Gourley has previously volunteered to serve the state on other committees including: the Drug Utilization Review Board for the Oklahoma Healthcare Authority, the Formulary Advisory Council for Advanced Practice Registered Nurses, and the Certified Registered Nurse Anesthetists Formulary Advisory Council. She is a past president and executive council member of the Oklahoma Pharmacists Association and a member of the Southwestern Pharmacy Alumni Foundation board of directors. Gourley received her bachelor of science degree in pharmacy from Southwestern Oklahoma State University in Weatherford, OK.

Gourley will assist the Board in putting together a search committee for the Board's next full-time, permanent executive director.

From the Inspector's Desk

- **18.26 Oklahoma House Bill (HB) 2931:** Effective January 1, 2020, practitioners are required to utilize electronic prescribing for Schedules II, III, IV, and V. Please read the entire bill and exceptions.
- **18.27 Oklahoma Senate Bill 1446:** Requires doctors and chronic pain patients to enter into a treatment agreement. This bill requires a patient to be staged through a limited initial prescription, a limited second prescription, and then formally advised that continued opioid use can result in addiction.
- **18.28 Oklahoma HB 1948: Release of Information to Patients:** The prescription monitoring program (PMP) history cannot be given to the patient by the pharmacy or any pharmacist, whether the patient is the pharmacist's or not. Registrants (pharmacists) shall have access to the central repository for the purposes of patient treatment and screening. The patient's history may be disclosed to the patient for the purposes of treatment of information at the discretion of the physician and by the physician only. Pharmacists, please review the guidelines at *http://pmp.obn.ok.gov/resource/security-rules*.
- **18.29:** The following rules will go into effect in the very near future. Please note that in the packaging requirement rule below, these medications are not eligible for donation from a long-term care facility or an approved assisted living center in the unused prescription drug program for Oklahoma's medically indigent.
  - **535:15-18: Customized Adherence Medication Package (CAMP):** Established to include packaging for dispensed drugs that is comprised of units containing two or more medications and designed to assist the user in administering or self-administering the drugs in accordance with directions for use.
  - **535:15-18-3: Packaging Requirements:** Five medications that have been dispensed in a CAMP may not be returned to stock or dispensed to another patient when returned to the pharmacy for any reason. If a prescription for any drug contained in a CAMP is changed, then a new appropriately labeled CAMP may be prepared for the patient. Medications that have been dispensed in a CAMP are not eligible for drug donation under the Utilization of Unused Prescription Medication Act.

National Pharmacy Compliance News

October 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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

18.30 Annual CDS Inventory

An annual inventory of all controlled dangerous substances (CDS) must be taken between May 1 and July 1 of each year. A copy of this inventory will be included with the pharmacy renewal application and kept on file at the pharmacy for Board inspections. When changing the owner or pharmacist-in-charge (PIC), a CDS inventory must be taken and sent to the Board within 10 days. A CDS inventory conducted due to a PIC change on dates that are not between May 1 and July 1 does not preclude a pharmacy from the annual CDS inventory requirement. Additionally, one copy of the CDS inventory maintained at the pharmacy needs to be marked as the Drug Enforcement Administration copy.

All return-to-stock containers must be labeled with proper drug expiration dates. These dates should be one year or less from the date of packaging.

18.31 Pharmacy Renewal Application – The Importance of Accurate Information

Section 535:15-5-7.6(c) of the Oklahoma Pharmacy Law Book states that, "A pharmacy technician must be employed in a licensed pharmacy located in Oklahoma to be eligible to renew their pharmacy technician permit."

Part of a pharmacy's renewal application is listing all currently employed pharmacists and technicians. Failure to list a technician on the renewal will result in the technician's employment record ending effective on the date the renewal application is processed, which will then prevent the technician from being able to renew until the Board has been notified of employment. When renewing a pharmacy license, please verify **all** employees are listed and all information provided is accurate. Please remember an affidavit is being signed with the renewal attesting all information provided is true and complete!

18.32 Naloxone Prescribing and Dispensing

Pharmacists can dispense naloxone without obtaining an order from a physician or another type of prescriber.

When pharmacists dispense naloxone, they should use their name as the prescriber.

If you need to bill the prescription to insurance and you do not have a National Provider Identifier number, then you may need to contact the physician for authorization to fill the prescription under the physician's name.

Pharmacists should not just assume that it is okay to use the physician's name for third-party billing purposes.

18.33 Important Information Regarding Tribal ID Cards


UNITED STATES
DEPARTMENT OF THE INTERIOR
BUREAU OF INDIAN AFFAIRS
EASTERN OKLAHOMA REGIONAL OFFICE
Certificate of Degree of Indian Blood
This is to certify that Jane Ellen Doe
born 04/01/1954 is 3/4 degree Indian blood
of the Choctaw Tribe
9/5/2017 Date
Acting Officer

On March 20, 2018, the Oklahoma Bureau of Narcotics 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 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. 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.)


Choctaw Veteran
Tribal Membership Card
Choctaw Nation of Oklahoma
P.O. Box 1210
Durant, OK 74702-1210
CHOCTAW NATION
Faith • Family • Culture
Jane Ellen (Doe) Billy
123 Main St
Durant, OK, 74701
Membership #: CN268400
DOB: 04/01/1954
Gender: Female
Date Approved:
Date Expires:
Director, Citizen Membership
Chief, Choctaw Nation

18.34 Disciplinary Actions

Irene Thi Nguyen, DPh #13478 – Case No. 1526: Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of required continuing education (CE) in the calendar years 2018 and 2019 for a total of 23 hours of CE each year. All CE required to renew her license shall be live during the calendar years 2019 and 2020. Respondent admits to guilt on all four counts including as PIC responsible for all aspects of the operation related to the practice of pharmacy, which includes a proper record keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs. **$1,750 fine.**

Impaired DPh, #11099 – Case No. 1519: Respondent's license is suspended for 10 years. The suspension is immediately stayed and placed on probation for 10 years until June 13, 2028. Respondent is to remain compliant with all terms of their 10-year recovery monitoring agreement with Oklahoma Pharmacists Helping Pharmacists (OPHP) and must notify all future employers of their OPHP contract. After June 30, 2023, respondent may petition the Board and request the suspension be stayed and that the probation be lifted. Granting probation may be at the Board's discretion upon the respondent showing compliance with their OPHP contract and that practicing would not put the public at risk. During probation, the Board may add to or modify any conditions of the probation that the Board determines necessary to protect the public. Termination of respondent's contract is cause to immediately suspend respondent's license and to require an appearance before the Board to show evidence that the respondent has entered into and is compliant with all conditions of a recovery monitoring agreement satisfactory to the Board and that the respondent has a fit for duty evaluation from a Board-approved provider. **Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of required CE in the calendar years 2018 and 2019 for a total of 23 hours of CE each year. All CE required to renew their license shall be live during the calendar years 2018 and 2019.** Respondent admits to guilt on all nine counts including the health and safety of patients being the registrant's first consideration.

Wells Pharmacy Network, LLC, #99-6026 – Case No. 1506: Respondent shall not compound a drug product that is commercially available within the marketplace or that is essentially a copy of an available Food and Drug Administration (FDA)-approved drug product for delivery to any Oklahoma residents or entities located in Oklahoma, except pursuant to the provisions of Oklahoma Administrative Code 535: 15-10-8(h)(1) and (2). The Board shall not pursue an administrative complaint or other disciplinary action against respondent for any alleged violations arising out of the actions or conduct set forth in the Agreed Order that predates the date of the approval of the Agreed Order, unless respondent violates the order or commits any other violation of the Oklahoma Pharmacy Act or Board rules. Respondent admits that if this matter went to a hearing before the Board there is sufficient evidence for a find-

Continued on page 5

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ing of guilt on 797 counts; including authorizing any person, firm, or business establishment to act as a "pick-up station" or intermediary for the purpose of having prescriptions filled or delivered whether for profit or gratuitously. **$52,525 fine.**

Empower Pharmacy, #99-7594 – Case No. 1510: Respondent neither admits nor denies guilt on all 372 counts including compounding a drug preparation that is commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug product. **$37,200 fine.**

Souchinda Nanthavongdouangsy, DPh #15854 – Case No. 1509: Respondent neither admits nor denies guilt on all 372 counts including compounding a drug preparation that is commercially available in the marketplace or that is essentially a copy of an available FDA-approved drug product. **$6,045 fine.**

Alicia P. Seifert, Technician #21022 – Case No. 1521: Found guilty on four counts including possession of drug paraphernalia. **Revoked.**

Brianna Clark, Technician #21144 – Case No. 1533: Found guilty on four counts including knowingly or intentionally possessing a CDS unless such substance was obtained directly or pursuant to a valid prescription or order from a practitioner. **Revoked.**

Paula O'Connor, Technician #11882 – Case No. 1534: Found guilty on four counts including committing theft while working as a registrant. **Revoked.**

Parks Drug, #99-8151 – Case No. 1518: Respondent admits guilt on all 11 counts including establishing and maintaining effective controls against diversion of prescription drugs. Respondent's license is on probation for five years until August 7, 2023. **$22,264 fine.**

Impaired DPh, #11415 – Case No. 1523: Respondent neither admits nor denies guilt on all nine counts. Respondent's license is suspended for 10 years. The suspension is immediately stayed and placed on probation for 10 years until August 8, 2028. Respondent is to remain compliant with all terms of their 10-year recovery monitoring agreement with OPHP and must notify all future employers of their OPHP contract. After August 30, 2023, respondent may petition the Board and request the probation be lifted. Granting probation may be at the Board's discretion upon the respondent showing compliance with their OPHP contract and that practicing would not put the public at risk. During probation, the Board may add to or modify any conditions of the probation that the Board determines necessary to protect the public. Termination of respondent's contract is cause for immediate suspension of respondent's license and requires an appearance before the Board to show evidence that respondent has entered into and is compliant with all conditions of a recovery monitoring agreement satisfactory to the Board and that respondent has a fit for duty evaluation from a Board-approved provider. **Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of required CE in the calendar years 2018 and 2019 for a total of 23 hours of CE each year. All CE required to renew their license shall be live during the calendar years 2019 and 2020.**

Impaired DPh, #14288 – Case No. 1536: Respondent neither admits nor denies guilt on all 14 counts. Respondent's license is suspended for 10 years. The suspension is immediately stayed and placed on probation for 10 years until August 8, 2028. Respondent is to remain compliant with all terms of their 10-year recovery monitoring agreement with OPHP and must notify all future employers of their OPHP contract. After August 30, 2023, respondent may petition the Board and request the probation be lifted. Granting probation may be at the Board's discretion upon the respondent showing compliance with their OPHP contract and that practicing would not put the public at risk. During probation, the Board may add to or modify any conditions of the probation that the Board determines necessary to protect the public. The termination of respondent's contract is cause for immediate suspension of respondent's license and requires an appearance before the Board to show evidence that respondent has entered into and is compliant with all conditions of a recovery monitoring agreement satisfactory to the Board and that respondent has a fit for duty evaluation from a Board-approved provider. **Respondent shall attend a one-day (eight-hour) law seminar in addition to 15 hours of required CE in the calendar years 2018 and 2019 for a total of 23 hours of CE each year. All CE required to renew their license shall be live during the calendar years 2019 and 2020.**

Calendar Notes

The Board will meet on November 28, 2018, 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.

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Dorothy Gourley, DPh - Interim Executive Director
Brittany Parrott - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Suhajda - Communications Manager