January 2020

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

The Oklahoma State Board of Pharmacy hopes everyone had a great holiday season and you are all off to a great start in the New Year!

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20.01 Former Board Executive Director Passes Away November 22, 2019

Bryan H. Potter, DPh, passed away November 22, 2019. He earned his bachelor of science degree in pharmacy in 1957 from Southwestern Oklahoma State University, College of Pharmacy. He served on the Oklahoma State Board of Pharmacy from 1971-1988; during that time, he was appointed as director of pharmacy, a role that lasted for three years. From 1989 - 1993, he served as the Board's executive secretary and had a title change where he then served as the Board's executive director until 2009. In 2013, Bryan was honored by having the Bryan H. Potter Oklahoma State Board of Pharmacy Building named after him. He is survived by his wife, Katy. Memorials can be made to SWOSU College of Pharmacy Scholarship programs, Meals on Wheels, or Lincoln Teen Center in care of Martin-Dugger Funeral Home, PO Box 707, Elk City, OK 73648. The Board will miss this dedicated public servant and friend whose leadership, integrity, keen intellect, and sharp wit were greatly appreciated.

20.02 2019 Continuing Education Audit

After random selection of 20% of Oklahoma-licensed pharmacists, the Board conducted a continuing education (CE) audit to verify CE reported within the 2018/2019 pharmacist renewal period. As of the date this *Newsletter* was prepared, the Board does not have official results, but during the audit, there were several questions and issues that continued to come up. Please make sure you understand the CE reporting process to avoid any problems. Here are a few tips for clarification:

1. While the renewal period is based on a pharmacist's birth month, the CE reporting period is based on **calendar year (January-December).**

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National Pharmacy Compliance News

January 2020

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.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

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

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

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 a legitimate investigation or legal action is always 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.

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2. CE required with an annual renewal should be for the prior calendar year of renewal. For example, if your pharmacist license expires February 2020, you will submit a minimum of 15 hours taken between January 1, 2019, and December 31, 2019 (the calendar year prior to the date you are renewing).
3. Board policy is that a pharmacist who does not complete his or her CE during the previous calendar year must complete two hours of CE for each hour of CE they failed to complete. **This policy is only valid when the shortage is caught at renewal and the Board office is notified – this policy is not valid if the shortage is caught during a CE audit.** You may find more information regarding this policy on the Board's website.
4. Any non-Accreditation Council for Pharmacy Education-accredited courses must be evaluated by the CE Committee to be approved for credit.
5. Any forms, along with valuable information regarding CE, can be found on the Board website at *https://www.ok.gov/pharmacy/Licensees_&_Applicants/Continuing_Education/index.html.*

20.03 From the Inspector's Desk

E-Prescribing: The Board sent out a blast email in December 2019 that included the e-prescribing statutes. If you did not receive the email, or would like a copy, please send an email to *pharmacy@pharmacy.ok.gov.*

Accurate Reporting to the Prescription Monitoring Program (PMP): Oklahoma Bureau of Narcotics and Dangerous Drugs has reported that IDs for controlled substances have not been getting reported correctly into the PMP. Pursuant to Title 63 Oklahoma Statutes §2-309C:

A. A dispenser of a Schedule II, III, IV or V controlled dangerous substance dispensed pursuant to a valid prescription shall transmit to a central repository designated by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control using the American Society for Automation in Pharmacy's (ASAP) Telecommunications Format for Controlled Substances version designated in rules by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, the following information for each dispensation:

1. Recipient's and recipient's agent's name;
2. Recipient's and recipient's agent's address;
3. Recipient's and recipient's agent's date of birth;
4. Recipient's and recipient's agent's identification number;
5. National Drug Code number of the substance dispensed;
6. Date of the dispensation;
7. Quantity of the substance dispensed;
8. Prescriber's United States Drug Enforcement Agency registration number;
9. Dispenser's registration number; and
10. Other information as required by administrative rule.

If an agent is picking up for a patient, that PMP submission should include the information of both the patient and the agent in regard to the above required information.

Temperature Log Records: Several pharmacies use electronic temperature logs to assist with temperature monitoring of a refrigerator or freezer where prescription-only drugs are kept. Keep in mind that these records must be readily retrievable upon inspection. Pharmacists must be able to log in and access such temperature logs within the pharmacy's system.

20.04 Disciplinary Actions

October 16, 2019

Auro Pharmacies, Inc, dba Central Drugs, #99-1389 – Case 1571: License placed on probation to run concurrent with California sanction. After termination of California sanction, respondent must submit proof from the California State Board of Pharmacy that the license is in good standing. At that time, the Oklahoma license will be placed in good standing. Respondent admits guilt on two counts, including violating the nonresident pharmacy licensing requirements and not maintaining in good standing a pharmacy license in its resident state. Fined $3,000.

Your Rx Pharmacy, Inc #99-6439 – Case 1557: Respondent's canceled Oklahoma license was approved to renew.

Impaired DPh #13204 – Case 1030: Probation was removed and license was placed in good standing. Respondent must continue to follow the terms of the respondent's 10-year contract with Oklahoma Pharmacists Helping Pharmacists (OPHP).

November 20, 2019

Eddie Allen, DPh #8872 – Case No. 1563: Respondent may request suspension be lifted after December 1, 2024, once he has obtained a "fit for duty" and if required, has a new 10-year contract with OPHP. Respondent is fined $15,300 due upon reinstatement of license. Respondent neither admits nor denies guilt on nine counts, including

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violation of health and safety of patient which shall be the registrant's first consideration. **Indefinite suspension.**

Michael Decker, DPh #11839 – Case No. 1570: Respondent shall attend an eight-hour law seminar in addition to the required 15 hours of CE during the calendar year of 2020. All CE hours for 2020 must be live. Respondent must complete *Improving Medication Safety in Community Pharmacy: Assessing Risk and Opportunities for Change* on March 20, 2020. Respondent admits guilt on two counts, including failing to establish and maintain effective controls to prevent prescription errors or misfills. **$2,000 fine.**

Lilly Koutcho, DPh #17198 – Case No. 1569: Respondent's ability to perform sterile compounding duties in Oklahoma is permanently suspended. The executive director may execute an order to stay the suspension if the respondent provides documentation of requirements as stated in the agreed order. The director may reinstate the suspension if the respondent fails to follow the requirements or if the resumed practice would put the public at risk. Respondent is fined $11,000. Payments to begin once the suspension has been lifted. Respondent admits to guilt on 11 counts, including violation of health and safety of patient which shall be the registrant's first consideration. **Indefinite suspension.**

Calendar Notes

- **Upcoming Holidays:** The Board office will be closed on January 20, 2020, for Martin Luther King, Jr Day and February 17, 2020, for Presidents' Day.
- **Upcoming Board Meetings:** The Board is scheduled to meet on January 15, 2020, February 26, 2020, and March 25, 2020. 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 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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