October 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

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20.25 Change Notifications

The Oklahoma State Board of Pharmacy greatly appreciates the amount of registrants who sent in verification of employment and contact information after the last *Newsletter.* When submitting any correspondence to the Board office, **it is imperative that you provide license/permit numbers not only for yourself, but also for any employers being reported.** Any correspondence the Board receives without the appropriate license numbers may not be processed.

20.26 License/Permit Display Requirements

A printout from the Board's verification site does **not** meet the license posting requirements listed in Oklahoma rules and statutes. Oklahoma pharmacy technicians must have a permit signed by the supervising pharmacist displayed in the pharmacy at all times. Online renewals allow both pharmacists and technicians to log in and print a license copy at any time for no additional cost. If a technician needs a duplicate copy and has not yet processed his or her first online renewal, a duplicate may be requested through the Board office for a $10 fee.

20.27 Ownership Changes

Pursuant to Oklahoma Administrative Code (OAC) 535:25-3-7, a change of ownership occurs when either 20% or more of the ownership of the entity owning the license, permit, or certificate changes or if a change of ownership form occurs (eg, changing from an LLC to a corporation). Situations where only the percentage of ownership changes will also constitute a change of ownership if the amount of ownership as a whole is changed by 20% or greater. If you have any questions about whether an ownership change application has taken place, you are encouraged to contact the Board office. Because licenses are not transferrable, if a pharmacy has a secondary pharmacy permit (eg, drug supplier, training area, sterile compounding), the new owner must also apply for these permits and pay the associated fee when applying for a new license.

20.28 50-Year License Certificates

Each year, the Board hosts a reception to formally recognize pharmacists who have maintained an Oklahoma license for 50 years. Unfortunately, the coronavirus disease 2019 has forced the Board to cancel the 2020 reception; therefore, the Board is using this *Newsletter* as a way of saying **thank you** for the amount of dedication to the profession of pharmacy that it takes for this type of achievement. **A big congratulations to the following pharmacists licensed in 1970!**

H. Boyd Stephens II #8035	Robert Hilton #8041
Frank Johnson, Jr #8042	Arthur Just #8043
Virgil Kroeker #8044	Charles Randall #8046
Ernie Scott #8048	Murray Wynne #8052
Gary London #8062	Harvey Hollingsworth #8065
Lynette Mikesh #8066	Mary Neparko #8068
Mary Porter #8069	Linda Lynch #8070
Gary Worcester #8072	Gary Tigert #8073
Jacques Ball #8093	Philip Biddy #8094
Larry Carey #8097	Philip Corder #8098

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National Pharmacy Compliance News

October 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.

FDA Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids, OUD Treatment

Recognizing the importance of discussing naloxone with patients receiving opioids or medications to treat opioid use disorder (OUD), Food and Drug Administration (FDA) recommends that health care providers include such discussions as a routine part of prescribing these medications. Further, the agency is requiring label changes to these medications to include this recommendation. The revised labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

"Even during this global pandemic, we have continued to prioritize addressing the opioid crisis," said FDA Commissioner Stephen M. Hahn, MD, in a press release. "Today's action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family."

The complete list of changes is available through an July 2020 Drug Safety Communication.

Proposed Rule to Require Electronic Submission of DEA Form 106

A proposed rule requiring accurate electronic submission of DEA Form 106 was published by Drug Enforcement Administration (DEA) in the *Federal Register* on July 29, 2020. The form, used by DEA registrants to report thefts or significant losses of controlled substances (CS), would also need to be submitted within a 15-day time period under the proposed rule. DEA registrants who experience theft or loss of CS would still be required to notify the DEA Field Division Office in their area, in writing, within one business day of discovery. According to the announcement published in the *Federal Register,* this requirement will impact the remaining 0.5% of DEA Form 106 responses that are reported by paper.

Inappropriate FentaNYL Patch Prescriptions at Discharge for Opioid-Naïve, Elderly Patients

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk-reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at* www.ismp.org.

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fenta**NYL** patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fenta**NYL** patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. One of the more common underlying causes appears to be a knowledge deficit about the dangers of prescribing this opioid analgesic to opioid-naïve patients. Several of the events began in a hospital, with opioid-naïve patients receiving prescriptions for fenta**NYL** patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fenta**NYL** patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

In one event, an 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge

from the ED, the resident was prescribed a fenta**NYL** patch, 25 mcg/hour, every 72 hours. At the LTC facility, a consultant pharmacist reviewed the medication orders and the resident's medication history. The pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the fenta**NYL** patch. The ED physician reported that the resident had received "three small IV push doses" of fenta**NYL** in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fenta**NYL** patch because the resident had a documented allergy to codeine. The ED physician mistakenly believed the fenta**NYL** patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and an upset stomach while taking **HYDRO**codone and acetaminophen when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident's analgesic to oral oxy**CODONE** 5 mg as needed every four to six hours.

Reliance on product labeling and practitioner education alone will not prevent life-threatening errors with fenta**NYL** patches. Yes, health care practitioners should be educated about safe prescribing, and their competency should be verified as a prerequisite to prescribing. But there will always be those who are unaware of the risks they take prescribing fenta**NYL** patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm.

Fenta**NYL** patches should only be prescribed for patients who are opioid-tolerant with persistent, moderate-to-severe chronic pain that requires around-the-clock, long-term opioid administration. In 2018, ISMP called for the elimination of prescribing fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain in our *Targeted Medication Safety Best Practices for Hospitals*. In 2020, this best practice was incorporated into a new best practice (No.15) to verify and document the patient's opioid status and type of pain before prescribing and dispensing extended-release opioids.

When entering discharge and transfer orders, interactive alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria. Consider creating a daily list of discharge prescriptions and transfer orders for fenta**NYL** patches generated from the order entry system, and requiring a hospital pharmacist to review them to verify that the patient is opioid-tolerant and has chronic pain.

Engage patients. Educate all patients prescribed a fenta**NYL** patch and their caregivers about how to use the patch safely.

SAMHSA Health Privacy Rule Revised to Better Integrate, Coordinate Care for Patients With SUD

A revised Substance Abuse and Mental Health Services Administration (SAMHSA) rule will make it easier for people diagnosed with substance use disorders (SUDs) to receive integrated and coordinated care. The revisions to the agency's Confidentiality of Substance Use Disorder Patient Records regulation, 42 CFR Part 2, advances the integration of health care for individuals with SUDs while maintaining critical privacy and confidentiality protections.

According to a US Department of Health and Human Services (HHS) press release, under Part 2, a federally assisted SUD program may only disclose patient identifying information with the individual's written consent, as part of a court order, or under a few limited exceptions. In addition, health care providers, with patients' consent, will be able to more easily conduct quality improvement, claims management, patient safety, training, and program integrity efforts.

The revised rule modifies several major sections of Part 2, including provisions related to records, consent requirements, and research, among others. For a list of changes in the final rule, visit the HHS Fact Sheet.

HHS Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD, the head of SAMHSA, further stated, "Modernizing 42 CFR Part 2 will strengthen the nation's efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders. The rule will make it easier for primary care clinicians to treat individuals with substance use disorders."

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Kenneth Dollar #8099	Vicki Jones #8101
Toni Gibson #8104	Dick Gilkey #8105
Newton Guthrie #8106	Joseph Harmison #8107
Thomas Keeley #8112	Larry Kissick #8114
Denny Lansford #8115	Amos Malone, Jr #8116
Jerry Mayes #8119	John Norman #8125
Sharon Peters #8127	Jack Razook #8129
Charles Reece #8130	Janice Shell #8134
J. Willard Smith #8135	David Woods #8137
Elmer Frech #8138	

20.29 From the Inspector's Desk

Preceptors/Interns/Training Areas

Interns are **only** authorized to work in licensed training areas under the supervision of a licensed preceptor. The training area designation **must** appear on the current pharmacy license and the preceptor designation **must** appear on the pharmacist's current registration, both of which are required to be posted in the pharmacy. Interns are required to have an original license either posted in the pharmacy or on their person as well. Photocopies of these licenses are **not** permitted. Duplicate copies issued by the Board are available with a written request and $10 payment per copy.

Customized Adherence Medication Package

As a reminder, a pharmacy must make sure that the packaging used to provide "comingled medication" to patients for patient medication adherence provides and has the proper labeling. The rules regarding this can be found in the Pharmacy Law Book – OAC 535:15-18. Please make sure you are in compliance with these requirements. Labeling requirements are also listed below:

(a) Packaging must bear, at a minimum, the labeling requirements as stated in Title 59, Section 353.20.1(B); and (1) Physical description of medication (i.e. imprint, description) or be separately packaged; (2) Expiration date; (3) Lot number(s), if required; (4) Date and time to be given;

(b) If packaging is detachable into individual units of administration time, each individual unit must bear: (1) The name of patient; (2) The name and strength of the medication(s); and (3) Date and time to be given.

Break-Ins and Robberies

It is extremely important that the Board is notified immediately anytime there is a robbery or break-in at an Oklahoma pharmacy. The Board asks that you contact your compliance officer directly. For contact information, please visit the website at *www.ok.gov/pharmacy/Board/Board_Staff/index.html.*

20.30 Disciplinary Actions

CVS #2324, #2-5549 – Case No. 1568: Respondent is placed on probation for two years until July 15, 2022. Respondent has agreed to take the following actions: **1)** Within 30 days of this Order, a memorandum to all Oklahoma CVS pharmacists describing their rights and responsibilities. This memo shall focus on the circumstances in which a pharmacist is required by Board rule to document the existence of conditions that could cause prescriptions to be filled in an unsafe manner due to inadequate staffing and the form and manner to be used to report these conditions. The memo will also make clear that no pharmacist will ever be retaliated against for compliance with this rule. **2)** Within 60 days of this Order, the Respondent pharmacy will conduct an internal quality assurance (QA) analysis of the medication error involved to determine whether the failure to follow established policies or procedures contributed to the error, determine whether any additional policies or procedures would have prevented the error from occurring, and determine whether any additional training or education of staff at CVS #2324 would prevent other medication errors of this type. CVS will advise all Oklahoma CVS pharmacists of the findings of the QA analysis and will implement any changes warranted by this QA analysis as soon as practicable in all Oklahoma CVS pharmacies. Further, the Board strongly recommends that Respondent pharmacy's corporate management consider implementing the following management recommendations in all Oklahoma CVS pharmacies: **1)** Increase the number of Board-permitted technicians working together during a shift; institute pharmacy staffing policies that require and allow each pharmacist to take at least one 30-minute lunch break during each assigned shift. **2)** Non-Board-permitted support staff in training to become Board-permitted technicians should be trained at pharmacies designated as a "training pharmacy" prior to being placed into a permanent assignment. **3)** A Board-permitted district pharmacy technician leader must be on duty during all training. **4)** All hours worked by a pharmacy technician-in-training should not count toward assigned technician hours allotted to any training pharmacy. **5)** All training pharmacies should be provided additional hours to support training of new hires. This should include both pharmacist and pharmacy technician hours. **6)** A pharmacy technician-in-training should not work at his or her assigned pharmacy until all training is complete. **7)** Pharmacy technician training should not be considered complete until the "training pharmacy" and each permanent assigned pharmacy evaluate the new hire as proficient in performing safely and efficiently all tasks allowed a Board-permitted pharmacy technician. **8)** In determining each pharmacy's staffing needs, all controlled substance (CS) (Schedule II-V) prescriptions should be counted toward the total prescription volume. **9)** In determining each pharmacy's staffing needs, all vaccines should be weighed much more heavily when compared to total prescription volume. **10)** All patient care queue calls should be outsourced to a corporate or independent "call center" so no pharmacist involved in filling prescriptions is required to make such calls during a pharmacy shift. **11)** All "wait time" measurements should be removed from consideration for the purposes of any employee bonuses or compensation decisions. Respondent neither admits nor denies guilt on all counts, including OAC 535:15-3-16(a): "Adequate staffing to safely fill prescriptions is the responsibility of the pharmacy, the pharmacy manager, and the pharmacist. If conditions exist that could cause prescriptions to be filled in an

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unsafe manner, [they] shall take action to correct the problem." **$75,000 fine.**

Impaired DPh #11594 – Case No. 1579: Suspended for 10 years. Respondent has received a "fit for duty" from Oklahoma Pharmacists Helping Pharmacists (OPHP); therefore, the suspension is immediately stayed. Respondent shall attend an eight-hour law seminar in addition to the required 15 hours of continuing education during the calendar years of 2021 and 2022, for a total of 23 hours during each calendar year. All hours during the years of 2021 and 2022 shall be live. Respondent neither admits nor denies guilt regarding counts 1-22, including it being unlawful for any person knowingly or intentionally to possess a controlled dangerous substance unless such substance was obtained directly, or pursuant to a valid prescription or order from a practitioner.

CVS Pharmacy No. 10491, #9-6762 – Case No. 1593: Fined $18,814.29.

CVS Pharmacy No. 06021, #7-5385 – Case No. 1594: Fined $16,236.99. The Board strongly recommends that Respondent pharmacy's corporate management consider implementing the following management recommendations in all Oklahoma CVS pharmacies: **1)** Increase the number of Board-permitted technicians working together during a shift; institute pharmacy staffing policies that require and allow each pharmacist to take at least one 30-minute lunch break during each assigned shift. **2)** Non-Board-permitted support staff in training to become Board-permitted technicians should be trained at pharmacies designated as a "training pharmacy" prior to being placed into a permanent assignment. **3)** A Board-permitted district pharmacy technician leader must be on duty during all training. **4)** All hours worked by a pharmacy technician-in-training should not count toward assigned technician hours allotted to any training pharmacy. **5)** All training pharmacies should be provided additional hours to support training of new hires. This should include both pharmacist and pharmacy technician hours. **6)** A pharmacy technician-in-training should not work at his or her assigned pharmacy until all training is complete. **7)** Pharmacy technician training should not be considered complete until the "training pharmacy" and each permanent assigned pharmacy evaluate the new hire as proficient in performing safely and efficiently all tasks allowed a Board-permitted pharmacy technician. **8)** In determining each pharmacy's staffing needs, all CS (Schedule II-V) prescriptions should be counted toward the total prescription volume. **9)** In determining each pharmacy's staffing needs, all vaccines should be weighed much more heavily when compared to total prescription volume. **10)** All patient care queue calls should be outsourced to a corporate or independent "call center" so no pharmacist involved in filling prescriptions is required to make such calls during a pharmacy shift. **11)** All "wait time" measurements should be removed from consideration for the purposes of any employee bonuses or compensation decisions. Respondent neither admits nor denies guilt on all counts, including OAC 535:15-3-16(a): "Adequate staffing to safely fill prescriptions is the responsibility of the pharmacy, the pharmacy manager, and the pharmacist. If conditions exist that could cause prescriptions to be filled in an unsafe manner, [they] shall take action to correct the problem."

CVS Pharmacy No. 06109, #1-5390 – Case No. 1595: Fined $14,948.34.

Jeffrey Scott Terry, DPh #14550 – Case No. 1596: Guilty on four counts, including submitting fraudulent billing or reports to a third-party payer of prescription drugs. **Revoked.**

Lisa C. Morris, Technician #1355 – Case No. 1597: Guilty on four counts, including theft. **Revoked.**

Calendar Notes

- **Upcoming Holidays:** The Board office will be closed on November 11, 2020, for Veterans Day; November 26-27, 2020, for Thanksgiving; and December 24-25, 2020, for Christmas.
- **Upcoming Board Meeting:** There are no meetings scheduled after the date of this publication. Please visit the Board website for updates.

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 **not** accepted as official notification. Emailed notifications can be sent to pharmacy@pharmacy.ok.gov or faxed to 405/521-3758.

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]

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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