October 2020

Arizona State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

1616 W Adams St, Suite 120 • Phoenix, AZ 85007 • Website: *https://pharmacy.az.gov*
Email: kgandhi@azpharmacy.gov

Board Members

The Board Is on Facebook

Follow the Arizona State Board of Pharmacy for the latest news and updates at *https://www.facebook.com/Arizona-State-Board-of-Pharmacy-396869467321193.*

Update Your Profile

In an effort to communicate more effectively with its licensees and permittees, the Board noticed that contact information in its system is not always current and up to date. You are required to update your personal contact information and pharmacy employer within 10 days after a change pursuant to Arizona Revised Statutes §32-1926. Please use your online profile to update your contact information.

Welcome New Deputy Director Jennifer Keonavong

Jennifer earned her doctor of pharmacy degree from Midwestern University College of Pharmacy – Glendale, AZ. She completed two years of post-graduate residency training and holds certifications with the Board of Pharmaceutical Specialties and Compliance Certification Board. Jennifer dedicated several years of her career to ambulatory and acute care pharmacy practice. Over the last five years, she discovered her passion for pharmacy regulatory compliance. Currently, Jennifer works as the pharmacy compliance audit program director in Banner Health's corporate ethics and compliance department. She has also served as an adjunct faculty member, student and resident preceptor, freelance medical writer, and contributor to state and national peer-reviewed publications. Jennifer looks forward to joining the team and supporting the mission of the Board.

Time for 2020 License/Permit Renewal

Renewal season is upon us! Renewals will be available from **Tuesday, September 8 through Sunday, November 1.** You can renew online quickly and easily by logging in to your profile and clicking the "Renewal" button near the top of the page.

Once you have submitted your renewal application and payment, your renewed license will be available in your profile upon approval. You will be required to log back in to your profile to save or print your license.

If you do not have a profile yet, click here to register!

For best results, please use a standard desktop or laptop computer running a current version of Google Chrome.

Continuing Education Requirement for 2020 Renewal

Pharmacists:

- Thirty total continuing education (CE) hours required for renewal.
- Three of the 30 hours must be opioid related; topics include substance use or addiction.
- Immunizers: two of the 30 hours must be on immunization-related education.

Technicians:

- Twenty total CE hours required for renewal, plus two additional CE hours if you are a remote dispensing site pharmacy technician.
- Three of the 20 hours must be opioid related; topics include substance use or addiction.

Continued on page 4

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."

Continued from page 1

- Remote dispensing site pharmacy technicians must complete two hours of CE on remote dispensing site pharmacy practices accredited by the Accreditation Council for Pharmacy Education. This CE is in addition to the 20 hours of required CE for all pharmacy technicians.

New Applicants for Licensure

As you or your employee apply for a pharmacy technician or technician trainee license, it is extremely important that you answer all the questions honestly. The number one issue the Board has to deal with is related to the question: Have you been arrested for, charged with, pled guilty or no contest to, or been convicted of two or more felony or misdemeanor offenses? Even if the case was dismissed, set aside, expunged, etc, you **must** disclose and provide all the supportive documentation. The current discipline for failure to disclose is a $250 civil penalty in most cases. There are cases that require further discussion and may result in an application that is denied licensure.

For employers: If an application for pharmacy technician or technician trainee has exceeded four weeks, you may want to discuss with your candidate what may be happening. The Board cannot discuss an application with anyone other than the applicant.

Protecting Yourself From ID Theft and Scams in the Workplace

As working professionals with advanced degrees, we may have a false sense of security when it comes to ID theft and scams. We show up day after day to the safety of our "little corner of the working world," whether it be a 600-square-foot retail pharmacy or the basement of a 700-bed hospital. We talk to physicians, nurses, medical assistants, other pharmacy personnel, and – from time to time – regulatory agents such as law enforcement officers, Drug Enforcement Administration (DEA), Food and Drug Administration, or compliance staff from the Board. Unfortunately, we are not immune to the criminal element that exists among us.

Recently there has been a rash of regulatory imposters. They may pose as DEA or compliance staff. They may call or come to your pharmacy. They may know your name and may even know the name of the regulatory person they are impersonating. These imposters may make threats and demands. They may tell you that your license has been suspended and you need to remedy the situation immediately, demanding payment of some sort. They may ask you to step out of the pharmacy and call back on your personal cell phone. So, how do you protect yourself?

There are a few simple things you can do:

1. Listen to that little voice in the back of your head. If it does not feel right, it probably is not.
2. No regulatory agent, whether DEA/Board compliance or other law enforcement personnel, would ever call and ask you for personal information.
3. If there is a person in front of you claiming to be a compliance officer and you do not recognize him or her, ask for identification. If you are still not sure, look up his or her name on the Board website at pharmacy.az.gov; there should be a picture of the person under staff members. If you cannot tell if it is the person, all compliance staff cell numbers are listed. When you call the number, the phone of the person in front of you should ring.
4. Call a compliance officer you are familiar with, and ask them to speak to the person in front of you.
5. Report any suspected DEA scam activity to your local DEA field office. DEA will never fax or call to demand payment of any kind from an individual.
6. Never give your personal information (Social Security number, account numbers, etc) to someone you do not know, especially over the phone.
7. If you still have doubts, call your direct supervisor for further guidance.

Most importantly, never be afraid to explain that you wish to verify someone's identity prior to letting them into the pharmacy. A regulatory agent will always show identification. Look at it. Does the picture match? Does it have the correct agency name on it? It only takes a few minutes to verify. Sadly, it can take years to correct ID theft.

If you should become a victim of identity theft, report the incident to the Federal Trade Commission at *www.consumer.ftc.gov/features/feature-0014-identity-theft.*

Disciplinary Actions and Updates – Health Boards

Disciplinary actions for the Arizona State Board of Pharmacy, Arizona Medical Board, Arizona Naturopathic Physicians Medical Board, Arizona Board of Osteopathic Examiners, and Arizona Regulatory Board of Physician Assistants can be found at *https://pharmacy.az.gov/resources/disciplinary-actions/quarterly-updates.*

The *Arizona State Board of Pharmacy News* is published by the Arizona 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.

Kamlesh "Kam" Gandhi, PharmD - State News Editor
Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor
Amy Sanchez - Communications Manager