December 2020

Tennessee Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

665 Mainstream Drive • Nashville, TN 37243
https://www.tn.gov/health/health-program-areas/health-professional-boards/pharmacy-board.html

Board Office Plans to Post COVID-19 Vaccine Guidance on Website

Visit the Tennessee Board of Pharmacy website for requirements regarding coronavirus disease 2019 (COVID-19) vaccinations for pharmacists and staff **when made available.** Click here for current guidance from the United States Department of Health and Human Services.

NABP and Board Executive Director Warn Licensees of Scammers Impersonating Board Inspectors

Licensees in multiple states are receiving scam phone calls from individuals impersonating state board of pharmacy inspectors, according to communication received from the National Association of Boards of Pharmacy® (NABP®). Licensees should verify the source is legitimate before giving confidential or payment information over the phone.

Scammers are claiming that facilities or individual licenses are under investigation for suspicious activity or drug trafficking. Some "investigators" say they work for Food and Drug Administration (FDA) or Drug Enforcement Administration (DEA). They indicate that licensees will face disciplinary action, a revoked license, and/or arrest if they do not immediately pay a fine over the phone. To appear authentic, many scammers even employ "spoofing"–disguising the caller's phone number to mimic a legitimate source. They may also use a fake name and fraudulent inspector identification number.

If the call sounds suspicious, hang up and call the state board of pharmacy number listed on its website for more information. Licensees should immediately report fraudulent calls to their state boards of pharmacy, the Federal Communications Commission's consumer complaint program, FDA, and/or DEA if they are being impersonated. The Board Executive Director Reginald "Reggie" Dilliard, DPh, has received notifications of such calls and reminds registrants not to give any information to anyone calling in this manner, and to always contact the Board immediately. "Since they are using the Board phone line by spoofing it, registrants are welcome to call the office directly to confirm," explained Dr Dilliard. The best way to contact Dr Dilliard is by email at Reginald.Dilliard@tn.gov.

Schedule II Prescriptions Are No Longer Required to Be on Separate Prescription Forms

The requirement for a Schedule II prescription to be placed on one prescription form (to help pharmacists with record keeping) was repealed in Public Chapter (PC) 883 in 2018. Review the PC here to see the deleted sections at the bottom of the document.

Office of General Council Relays Legislative Update – 2020

Public Chapter 573

This act amends the Tennessee Together statutes. It expands the definition of "alternative treatments" by adding "non-opioid medicinal drugs or drug products, occupational therapy, and interventional procedures or treatments." This is primarily relevant to the treatments that must be disclosed and explained by a health care practitioner to a patient or the patient's legal representative as a prerequisite to obtaining informed consent to treatment with an opioid.

This act took effect on March 19, 2020.

Public Chapter 594

This act was the Tennessee Department of Health's Licensure Accountability Act. The bill allows all health-related boards to take action against a licensee who has been disciplined by another state for any acts or omissions that would constitute grounds for discipline in Tennessee. The law also expands available emergency actions, allowing actions beyond simply a summary suspension. Finally, the act establishes that the notification of law changes to health practitioners can be satisfied by the respective boards posting law changes online. Notice must be maintained online for at least two years following the change.

This act took effect on March 20, 2020.

continued on page 4

National Pharmacy Compliance News

December 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

Public Chapter 761

This act allows certain mid-level practitioners to prescribe buprenorphine when employed in a community mental health center or a federally qualified health center. To be eligible under this law, the practitioner must be licensed and practice as a family, adult, or psychiatric nurse practitioner or physician assistant. He or she must also have a Drug Addiction Treatment Act of 2000 (DATA 2000) waiver issued by Substance Abuse and Mental Health Services Administration/ DEA. There can be no limitations or conditions imposed on the provider's license within the previous three years. Prescriptions by the practitioner must not exceed a 16 mg daily equivalent. The practitioner also must not prescribe a mono product or buprenorphine without naloxone. The provider may only prescribe buprenorphine products to patients treated through the organization that employs the provider. Prescriptions can only be dispensed by a licensed pharmacy to ensure entry into the Controlled Substance Monitoring Database. The provider has a cap of 50 patients at any given time. The law also requires the provider to initiate and lead a discussion regarding patient readiness to taper off medications in their treatment at any time upon the patient's request, but no later than one year after initiating treatment, and then every six months thereafter.

The facility must employ one or more physicians and have adopted clinical protocols for medication-assisted treatment. The mid-level collaborating physician must hold an active DATA 2000 waiver and be treating patients with buprenorphine at the same facility. The facility must employ providers who accept TennCare and are accepting new TennCare patients. The facility must verify identification of patients. The collaborating physician must review 100% of the charts of patients being prescribed a buprenorphine product and can only collaborate/supervise four nurse practitioners or physician assistants.

This act took effect on July 1, 2020.

Local DEA Offers Guidance When Selling or Closing a Pharmacy

Thinking about selling or closing a pharmacy? According to James "Jim" Stevens, DEA Group Supervisor for the Nashville, TN, office, owners have been contacting DEA after a sale is completed with issues yet to be addressed. "It is a lot easier to attend to it before the close than after, and we do not charge for advice or guidance," said Stevens. To obtain contact information and a mailing address for your local DEA office, click here. The Board also has a guidance document for closing or transfer of pharmacies.

Board Staff Clarifies Record-Keeping Requirements for Electronic Prescriptions

As 2021 approaches, so does the new stipulation for electronic prescriptions. Pharmacists are asking for clarification regarding the record keeping required by the Board and DEA.

Board requirements: all prescription records must be kept for two years. As the ability to keep records electronically increases, the Board allows electronic prescriptions to be kept electronically provided that the records are readily retrievable for inspection. This allowance negates the need to print the prescription and file as a hard copy provided that the computer record meets all other requirements of Board rule 1140-03-.03, including ". . . serially numbered and numerically filed . . . " The Board also allows a verbal and faxed prescription to be kept in a computer file provided it too meets all the other requirements of Board rule 1140-03-.03. For many pharmacies, some of these regulations are forgotten because the computer system "back label" already has these entries incorporated, as do the prescriptions sent through certain electronic prescribing for controlled substances systems. Do not get caught storing files electronically without the required data (pharmacist initials, date/amount dispensed, etc).

DEA requirements: registrants should review the following codes of federal regulation in their entirety as some areas may differ from non-controlled allowances by the Board. The record-keeping requirements include §1304.04 Maintenance of records and inventories, and the section that includes electronic prescriptions can be found in §1311.305 Recordkeeping.

Updates Are Now Available for the Pharmacist's Manual

Click here for the updated version of the DEA Diversion Control Division's *Pharmacist's Manual*. New information is available regarding the Controlled Substance Ordering System and the new single-sheet DEA Form 222.

Disciplinary Actions

For disciplinary actions taken against registrants licensed with the health-related boards, click here.

Tennessee Pharmacists Recovery Network

If impaired, or you suspect a colleague or technician may be, please contact Dr Baeteena Black, Tennessee Pharmacists Recovery Network Board program director, by phone at 615/256-3023, by email at bblack@tnpharm.org, or visit the website.

Board Meeting Schedule

The Board extends an open invitation for all registrants and the general public to attend its public meetings at 665 Mainstream Drive, Nashville, TN 37243. The meetings are currently scheduled to begin at **8 AM.** Pharmacists may receive two hours of live continuing education valid for their Tennessee pharmacist license: on a full meeting day and one hour on a half day.

continued on page 5

continued from page 4

Because of COVID-19, past meetings have been conducted using WebEx on the first day instead of the two days listed. Therefore, it is advised to c**heck for schedule changes** on the Board website under the Meeting Schedule tab.

The **2021** meeting schedule is as follows:

- January 26-27
- March 9-10
- May 4-5
- July 13-14
- September 14-15
- November 16-17

Tennessee Board of Pharmacy Members

- Dr Rissa Pryse – President
- Dr Katy Wright – Vice President
- Dr Adam Rodgers – Board Member
- Dr Melissa McCall – Board Member
- Dr Richard Breeden – Board Member
- Dr Shanea Mckinney- Board Member
- Mr Jake Bynum – Public Member

The *Tennessee Board of Pharmacy News* is published by the Tennessee 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.

Rissa Pryse, DPh - Tennessee Board of Pharmacy President & Newsletter Editor

Reggie Dilliard, DPh - Executive Director & Newsletter Editor

Scott G. Denaburg, PharmD, DPh, CISCI - Contributor & Tennessee Board of Pharmacy Investigator

Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Amy Sanchez - Communications Manager