December 2020

Kentucky Board of Pharmacy News

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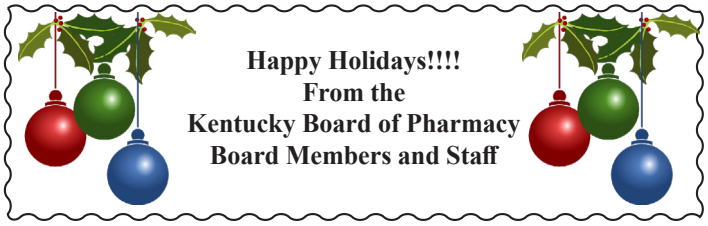

Continuing Education Reminder

A pharmacist shall complete a minimum of one and five-tenths (1.5) CEUs (15 contact hours) annually between January 1 through December 31 pursuant to 201 Kentucky Administrative Regulations (KAR) 2:015 Section 5(1). A pharmacist first licensed by the Board within 12 months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education provisions.

2021 CAPTASA Conference

The 2021 Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse (CAPTASA) Conference has been canceled due to concerns of coronavirus disease 2019.

Recognitions

The Board would like to recognize the following individuals for their service and dedication to the Board.

- Shannon Stiglitz has served a four-year term on the Advisory Council. Her term expires December 31, 2020.
- Kelly Whitaker has served a four-year term on the Advisory Council. Her term expires December 31, 2020.
- Michael Wyant has served a four-year term on the Advisory Council. His term expires December 31, 2020.
- Chris Killmeier has served an eight-year term on the Pharmacy Recovery Network Committee. His term expires December 31, 2020.
- Joel Thornbury has served a four-year term on the Pharmacy Recovery Network Committee. His term expires December 31, 2020.
- Ron Poole has served as president of the Board for 2020. He has served a four-year term on the Board. His term expires December 31, 2020.
- Craig Martin has served a five-year term on the Board. His term expires December 31, 2020.

Eden Davis — General Counsel

The Board is pleased to announce the addition of Eden Davis as general counsel. Ms Davis joined the Board as general counsel on October 16, 2020. Ms Davis comes to the Board from the Cabinet for Health and Family Services (CHFS) where she served as assistant general counsel. Ms Davis is an experienced litigator, having tried over 100 cases. Prior to working for CHFS, Ms Davis worked in private practice in Louisville, KY, and as a public defender in Hopkinsville, KY. Ms Davis began her legal career doing legislative and policy work for the National Oceanic and Atmospheric Administration and the National Wildlife Federation. Ms Davis is a summa cum laude graduate of Murray State University and a graduate of Louisiana State University Paul M. Hebert Law Center. She lives in Lexington, KY, with her husband, a 160-pound dog, a cat, and six chickens.

Pharmacist TB Reporting Requirements

Submitted by Michele Pinkston, PharmD, RPh

Although rates are low, tuberculosis (TB) is diagnosed in patients every year in Kentucky, and it is vital that our health departments be informed of all active cases. The regulation governing TB and other infectious disease reporting, 902 KAR 2:020 – Reportable Disease Surveillance, gives pharmacists a key role in TB surveillance in the commonwealth. This regulation has been in effect since February 2015, and requires that pharmacists give notice to the local health department or the Kentucky Department for Public Health (KDPH) when two or more medications (see list below) used for the initial treatment of active TB are

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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."

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dispensed to a patient. The requirement to report extends to inpatients in a health care facility or to ambulatory patients in a health care facility or pharmacy:

Section 15. Tuberculosis.

(1) A pharmacist shall give notice if two (2) or more of the following medications used for the initial treatment of active tuberculosis are dispensed to an inpatient in a health facility or to an ambulatory patient in a health facility or a pharmacy:
  (a) Rifampin or rifabutin;
  (b) Isoniazid;
  (c) Pyrazinamide; and
  (d) Ethambutol.

(2) A report of tuberculosis shall be considered priority and shall be reported to the local health department serving the county in which the patient resides.

(3) If the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health.

(4) The report shall include:
  (a) Information required in Section 4(16) of this administrative regulation; and
  (b) Names of the medications dispensed.

Pharmacists may utilize the Kentucky Reportable Disease Form (Epid TB-1 Pharmacist Reporting) to report the appropriate information. This form may also be found on the Board website. The form may be faxed to the local health department where the patient resides. A directory for local health departments with fax numbers can be found at *chfs.ky.gov/agencies/dph/dafm/Pages/lhd.aspx*.

If unable to report to the local health department, the information may be faxed to the KDPH TB Prevention and Control Program at 502/564-3772. Pharmacists can also phone the office directly at 502/564-4276.

The full Reportable Disease Surveillance regulation, 902 KAR 2:020, can be found at *apps.legislature.ky.gov/law/kar/902/002/020.pdf*.

Vaccine Tips and Reminders

Storage and Handling

The Centers for Disease Control and Prevention (CDC) published the most recent Vaccine Storage and Handling Toolkit in January 2020. The toolkit includes recommendations and guidance on how to properly manage vaccine supply and prevent errors that may result in poor patient outcomes and wasted vaccines.

Improper vaccine storage and handling can lead to a reduction in vaccine potency and potentially an inadequate immune response in patients. Vaccines overexposed to heat, cold, or light can lose potency. Refrigerated vaccine exposure to freezing temperatures (below 0°C or 32°F) is especially destructive to vaccine potency. CDC recommends against storing vaccines in a dormitory-style combined refrigerator/freezer unit due to the significant risk of exposure to freezing temperatures.

Storing vaccines in pharmaceutical-grade refrigerators is recommended by CDC, but if vaccines are stored in household-grade refrigerators it is best practice to store vaccines in the center of the refrigerator at least two to three inches away from the walls, ceiling, floor, or door. CDC recommends against storing vaccines on doors or in drawers within a household-grade refrigerator due to temperature inconsistencies. A distinct separation between vaccines and other refrigerated medications is also recommended.

Temperature in the refrigerator or freezer used for vaccine storage is to be monitored. CDC recommends a calibrated digital data logger for the most accurate temperature monitoring. The CDC toolkit includes a list of temperature monitoring devices (TMD) that are not recommended (such as alcohol or mercury thermometers). If the TMD displays a daily minimum and maximum temperature, the CDC recommends recording that information daily. If the TMD does not display a minimum and maximum temperature, the pharmacy is to record the temperature twice daily at the beginning and end of the workday.

If vaccines require reconstitution or to be drawn, CDC recommends waiting until just prior to administration. Vaccines should be drawn up in a designated area away from possible contamination and pharmacists should practice proper hand hygiene and use proper drawing technique to avoid contamination. KDPH reported a cluster of adverse vaccination reactions in 2018-2019 linked to poor vaccine handling and administration. Multiple patients in three different states presented with mycobacterium infections, including lesions and abscesses from vaccinations from a single provider.

If vaccines are to be taken off site for administration (such as a flu clinic), CDC recommends a maximum total time of eight hours including transport time away from the primary storage. CDC recommends against transporting vaccines in the manufacturer's original shipping container except as a last resort in emergencies.

The CDC toolkit has several more recommendations and best practices related to training staff and responding

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to temperature excursions and emergencies, including power outages.

Vaccine Information Statement

The National Childhood Vaccine Injury Act (NCVIA) requires pharmacists administering certain vaccines (including influenza) to provide the adult patient or child's parent/legal representative a copy of the Vaccine Information Statement (VIS) prior to administration of the vaccine. VISs for all vaccines are available on the CDC's website. CDC recommends providing VISs for those vaccines not covered under the NCVIA (eg, shingles). The Immunization Action Coalition has translated VISs into approximately 40 different languages.

There are multiple ways the VIS can be provided to patients for review prior to vaccine administration, including:

- ♦ printed paper copies;
- ♦ permanent, laminated pharmacy copies;
- ♦ electronic copies viewed on a computer or video display at the pharmacy;
- ♦ electronic copies viewed on the patient's personal device; and
- ♦ a copy provided at a previous visit or instructions provided in advance on how to access it electronically.

Patients must still be offered a copy of the VIS to take with them following vaccination.

Official Method of Notification

The *Kentucky Board of Pharmacy Newsletter* is considered an official method of notification to pharmacists, pharmacist interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.** Please read carefully. The Board encourages you to store them electronically in a folder or keep them in the back of the *Kentucky Pharmacy Law Book* for future reference.

The *Kentucky Board of Pharmacy News* is published by the Kentucky 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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