November 2020

News

SC Department of Labor, Licensing, & Regulation – Board of Pharmacy

Published to promote compliance of pharmacy and drug law

Kingstree Bldg, 110 Centerview Dr • PO Box 11927 • Columbia, SC 29211-1927
https://www.llr.sc.gov/bop • 803/896-4700

Upcoming Board Vacancy

Do you live in the Second Congressional District? Are you interested in serving on the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy? Here is your opportunity!

If you are interested in serving, you must meet the following requirements:

- **Reside** in the Second Congressional District;
- Be licensed and actively practicing pharmacy in South Carolina; and
- Before December 1, 2020, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists **practicing** in your respective Congressional District.

The term will begin on July 1, 2021, and end on June 30, 2027. After receiving biographies and petitions, the Board administrator will:

- Prepare and mail ballots by January 15, 2021, to all pharmacists who have notified the Board that they reside in the Second Congressional District, and
- Certify as true and valid all ballots postmarked before February 15, 2021, and received by the Board office before February 25, 2021.

Before March 1, 2021, the Board will certify in writing to the governor the names of the three candidates receiving the most votes in the election and the name of the person who the nominee will replace on the Board. The new member, when appointed by the governor, will take office on July 1 of that year. If you are interested in becoming a candidate for this position and have questions, please contact the Board office at 803/896-4700.

Congratulations to New Board Members

On September 23, 2020, the South Carolina Senate confirmed two new members of the Board.

Artie McKnight, RPh, was appointed to the Seventh Congressional District. A graduate of the Medical University of South Carolina, he is the director of pharmacy for McLeod Regional Medical Center. Mr McKnight brings more than 20 years of experience in a wide variety of pharmacy settings, including clinical and health-systems administration. In addition, he has been active in state and national organizations throughout his career.

Michael Bedenbaugh, MS, MBA, PharmD, RPh, was appointed to the Fourth Congressional District. Dr Bedenbaugh finished his professional education at the South Carolina College of Pharmacy, where he also completed a master of business administration at the Moore School of Business. Following his professional studies, he completed a two-year postgraduate residency and master of science degree at the University of Virginia in pharmacy administration. Dr Bedenbaugh has extensive experience in home infusions and is currently the director of pharmacy services for Intramed Plus.

The Board would like to thank Spencer Morris, PharmD, RPh, and Eric Strauss, PharmD, RPh, who tirelessly served the Board and the citizens of South Carolina.

Legislative Updates

Amendments to electronic prescribing exemptions, H4938

In 2019, the General Assembly enacted Act 65 to mandate practitioners electronically prescribe controlled substances, with exceptions, by January 1, 2021. This 2020 act amends the 2019 law to add exemptions from electronic prescribing for hospice care programs, home infusion pharmacies, a patient who is receiving services from a facility established pursuant to Section 44-11-10, and a practitioner who issues an oral authorization in the case of an emergency.

Effective date: January 1, 2021.

Pharmacist-administered flu vaccine to persons under 12 years old, H4663

The act amends state law requirements to allow pharmacists to administer flu vaccines to persons under 12 pursuant to a protocol issued by the South Carolina Board of Medical Examiners. The Joint Pharmacist Administered Vaccines Committee must submit recommendations to the Board of Medical Examiners no later than three months after the effective date of the act.

Effective date: September 28, 2020.

The Joint Vaccines Committee will be meeting in the near future to update the current South Carolina protocol.

Pharmacists are encouraged to confirm that their individual liability policy covers immunizations for children.

Please see the next article for information on the Public Readiness and Emergency Preparedness Act (PREP Act) Amendment.

National Pharmacy Compliance News

November 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

ISMP Institute for Safe Medication Practices An ECRI Affiliate

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."

Federal and State Actions Regarding Pharmacist-Administered Vaccines

As you have likely seen, both the state and federal governments have recently taken action in regard to pharmacist-administered vaccines. South Carolina has enacted Act No. 158, which amends South Carolina Code of Laws Annotated Section 40-43-190(A)(2)(b) by allowing the influenza vaccine to be administered to a person under the age of 12 pursuant to the protocol issued by the Board of Medical Examiners upon recommendation of the Joint Pharmacist Administered Vaccines Committee. Prior to this amendment, the influenza vaccine could only be administered pursuant to the protocol to an individual 12 years or older. The Joint Pharmacist Administered Vaccines Committee and the Board of Medical Examiners hope to issue the new protocol in the coming weeks.

Additionally, the United States Department of Health and Human Services (HHS) Office of the Secretary recently issued its third amendment to the Declaration under the PREP Act for medical countermeasures against the coronavirus disease 2019 (COVID-19). This action significantly changes the circumstances in which certain pharmacists and pharmacy interns may order and/or administer vaccines. The Board would stress that the third amendment to the Declaration is **temporary** in nature and was issued in response to the COVID-19 pandemic.

The Board previously published an overview of the third amendment to the Declaration, which is available here. Licensees and permittees are encouraged to read the Board's overview, as well as the third amendment to the Declaration in full. The third amendment to the Declaration allows for the ordering and administration of any vaccine the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18, according to ACIP's standard immunization schedule. HHS subsequently issued a guidance that would allow state-licensed pharmacists to order and administer, and state-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to administer, **COVID-19 vaccines** to persons ages three or older, subject to certain requirements.

To order and/or administer vaccines pursuant to the third amendment to the Declaration:

- The licensed pharmacist must complete a practical training program of at least **20 hours** that is accredited by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed or registered pharmacy intern must complete a practical training program that is accredited by ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- The licensed pharmacist must complete a minimum of **two** hours of ACPE-accredited, immunization-related continuing pharmacy education during each state licensing period.

Additionally, the pharmacist must comply with South Carolina record keeping and reporting requirements. Again, licensees and permittees should review the Board's overview, as well as the full third amended Declaration, to obtain a comprehensive understanding of this temporary expansion of the ability of pharmacists and interns to order and/or administer vaccines.

Phone Scam

The Board has become aware that licensees in multiple states, including South Carolina, are receiving scam phone calls from individuals impersonating state board of pharmacy inspectors. Licensees should be cautious of giving confidential or payment information over the phone without verifying that the source is legitimate.

Scammers, claiming to be state board of pharmacy inspectors or investigators, are calling pharmacists and saying that their facility or individual license is under investigation. Scammers may also state that they are working with Food and Drug Administration (FDA) or Drug Enforcement Administration (DEA) on a case, and further claim that the licensee is under investigation for suspicious activity or drug trafficking. In either case, the scammers claim that licensees will face disciplinary action, a revoked license, or arrest if they do not immediately pay a fine over the phone.

Additionally, many scammers are "spoofing" the phone number used to call the pharmacist. Spoofing involves disguising the caller's true phone number and making it appear that the phone number is from a legitimate source. Scammers may even give a fake name and a fraudulent inspector identification number as "proof" of identity. If the call sounds suspicious, hang up and call the Board directly at 803/896-4700 or contact the Board at contact.pharmacy@llr.sc.gov. For your reference, the Board inspectors/investigators are as follows:

- Alison Gratton
- Bonnie Wilgus
- Doug Murray
- Martin Chan
- Ray Trotter

If a licensee receives a scam call from someone impersonating a state board inspector or investigator, please report it immediately to Ray Trotter at Ray.Trotter@llr.sc.gov.

If the scammer is impersonating an FDA or DEA inspector, please make a report to the respective agency. In addition, the licensee may also report scam calls to the Federal Communications Commission's consumer complaint program. Please provide as many details about the scam call as possible.

What Does it Mean to Be a PIC?

In the state of South Carolina, being the pharmacist-in-charge (PIC) comes with many responsibilities and duties. To be a PIC, one must be licensed in this state and must accept the responsibilities for the lawful operation of a pharmacy. The

continued on page 5

continued from page 4

PIC is in full and actual charge of the pharmacy and pharmacy personnel. The following is the statute in the South Carolina Pharmacy Practice Act that details the duties of the PIC. These responsibilities should be considered before accepting a PIC position.

Section 40-43-86(B)(4)(a-c)

(B)(1) No person may operate a pharmacy without a pharmacist-in-charge. The pharmacist-in-charge of a pharmacy must be designated in and sign the application for the pharmacy permit, and in each renewal thereof. A pharmacist may not serve as pharmacist-in-charge unless he is physically present in the pharmacy a sufficient amount of time to provide supervision and control. A pharmacist may not serve as pharmacist-in-charge for more than one pharmacy at any one time without written permission from the board.

Subsection (B)(1) does not apply to a college or university athletic department pharmacy.

(2) Each institutional pharmacy shall be directed by a pharmacist, hereinafter referred to as the pharmacist-in-charge who is licensed to engage in the practice of pharmacy in this State.

(3) The pharmacist-in-charge shall have the following responsibilities:

(a) assuring that all pharmacists, technicians, and interns employed at the pharmacy are currently licensed, certified, or registered and that interns and technicians wear proper identification while on duty;

(b) notifying the Board of Pharmacy immediately of any of the following changes:

(i) change of employment or responsibility as the pharmacist-in-charge;

(ii) change of ownership of the pharmacy;

(iii) change of address of the pharmacy; or

(iv) permanent closing of the pharmacy;

(c) making or filing any reports required by state or federal laws and regulations;

(d) responding to the Board of Pharmacy regarding any violations brought to the pharmacist-in-charge's attention.

(4) The pharmacist-in-charge must be assisted by a sufficient number of licensed pharmacists and registered pharmacy technicians as may be required to competently and safely provide pharmacy services.

(a) The pharmacist-in-charge shall maintain and file with the board of pharmacy, on a form provided by the board, a current list of all pharmacy technicians assisting in the provision of pharmacy services.

(b) The pharmacist-in-charge shall develop and implement written policies and procedures to specify the duties to be performed by pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall, at a minimum, specify that pharmacy technicians are to be personally supervised by a licensed pharmacist who has the ability to control and who is responsible for the activities of pharmacy technicians and that pharmacy technicians are not assigned duties that may be performed only by a licensed pharmacist. One pharmacist may not supervise more than a total of four pharmacy technicians at a time, including both state-certified and nonstate-certified technicians. One pharmacist may not supervise more than two nonstate certified technicians at a time. If a pharmacist supervises only one or two pharmacy technicians, these technicians are not required to be state-certified. Pharmacy technicians do not include personnel in the prescription area performing only clerical functions, including data entry up to the point of dispensing, as defined in Section 40-43-30(15).

(c) For the purpose of dispensing by institutional pharmacies to institutional facility in-patients the pharmacist to technician ratio may not exceed a one to three employment ratio. The allowable employment ratio for a site is determined by comparing the number of pharmacists employed at the site to the number of pharmacy technicians employed at the site. The day to day operational pharmacist to technician personal supervision ratio is to be determined by the pharmacist-in-charge.

(5) The pharmacist-in-charge shall develop or implement, or both, a procedure for proper management of drug recalls which may include, where appropriate, contacting patients to whom the recalled drug products have been dispensed.

(6) The pharmacist-in-charge of an institutional pharmacy shall establish or implement, or both, written policies and procedures for provision of drugs to the medical staff and other authorized personnel whenever a licensed pharmacist is not physically present in an institutional facility by use of night cabinets and/or by access to the pharmacy. A licensed pharmacist must be on call at all times.

The *South Carolina Board of Pharmacy News* is published by the South Carolina 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.

Traci Collier, PharmD, Administrator - State News Editor
Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor
Amy Sanchez - Communications Manager