August 2019

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

Published to promote compliance of pharmacy and drug law

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https://www.llr.sc.gov/bop • 803/896-4700

New Board Officers

At its June 2019 meeting, the South Carolina Department of Labor, Licensing, & Regulation (LLR) – Board of Pharmacy elected new officers for the upcoming year.

Eric Strauss, PharmD, RPh, will serve as Board chairperson. Dr Strauss represents the Fourth Congressional District.

J. Addison Livingston, PharmD, RPh, of Swansea, SC, representing the Second Congressional District, will serve as vice chairperson.

Each will serve a one-year term in their position from July 1, 2019, until June 30, 2020.

The Board would like to take this opportunity to thank Spencer Morris, PharmD, RPh, for his time and dedication while serving as chair for the previous year.

Congratulations to Board Appointee

The Board would like to congratulate Heather Harris, PharmD, RPh, of Pomaria, SC, on her recent appointment to the Board representing the Fifth Congressional District. Dr Harris' term began on July 1, 2019. She replaced Marvin Hyatt, RPh, and her six-year term expires on June 30, 2025. Dr Harris' practice site is at Dominion Energy. Having practiced in both independent and corporate settings, the Board looks forward to the valuable expertise Dr Harris will provide.

In addition, Board members and staff extend their sincere appreciation to Mr Hyatt for his dedication and service to the citizens of South Carolina. Mr Hyatt has selflessly served on the Board for many years, and the Board wishes him all the best.

Legislative Updates

On May 13, 2019, Governor Henry McMaster signed S.463 into law, which became effective immediately upon signature.

This bill provides that:

> Unless a prescriber has specified on a prescription that dispensing the prescription for a maintenance medication in an initial amount followed by periodic refills is medically necessary, a pharmacist may exercise his professional judgment, in consultation with the patient, to dispense up to a ninety-day supply of medication per refill up to the total number of dosage units as authorized by the prescriber on the original prescription.

This law does not apply to scheduled medications, psychotherapeutic drugs, or medications that are required to be reported to the prescription monitoring program.

In consulting with the patient, the pharmacist must use readily available, existing mechanisms, such as online claim adjudication, and inform the patient of any cost changes of the proposed dispensing change.

Additionally, if the pharmacist is presenting the patient with an option to not use an available benefit plan, then the pharmacist must inform the patient that any amounts paid would potentially not apply to the deductibles or other out-of-pocket calculations of his or her benefit plan.

This section shall not be construed to supersede or invalidate any third-party payer agreement, in whole or in part, between a third-party payer and a retail pharmacy.

At its June 2019 meeting, the Board interpreted "psychotherapeutic drugs" to be antipsychotic medications.

New LLR/Board of Pharmacy Website

Beginning in July 2019, the LLR launched a new website and updated logo. A lot of work has been done to make the website more user-friendly. You will find that the number of clicks necessary to access information has been reduced and that information is more readily available. As with any new system or rollout, there will be enhancements that need to be made, and the Board welcomes your feedback.

National Pharmacy Compliance News

August 2019

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 Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a Drug Safety Communication, provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

"Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse," the agency said in the communication. "Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances."

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the News and Events section of the FDA website.

DEA Warns of Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a DEA press release, this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of legitimate investigation or legal action is made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- maintaining quality manufacturing compliance,
- strengthening and refining regulations on compounding from bulk drug substances,
- finalizing the agency's memorandum of understanding with the states, and
- issuing revised draft guidance for compounding by hospital and health systems.

"We've worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs," then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a statement published on the FDA website. "We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . ."

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a press release from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

"Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis," Senate Minority Leader Chuck Schumer said in the press release. "We must hold China accountable for their role in the fentanyl trade. China's new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers."

In a December meeting with President Donald Trump, China's President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be "the largest source of illicit fentanyl and fentanyl-like substances" in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a press release posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy® (NABP®) Drug Disposal Locator Tool, available in the AWAR$_X$E® Prescription Drug Safety section of the NABP website, *www.nabp.pharmacy/initiatives/AWARxE.* With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at *https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine.*

Compliance Tips: Prescription Transfers

One of the most common issues discovered upon routine inspections involves the transfer of prescriptions. Specifically, the time of transfer and the National Drug Code/manufacturer are the most common missing items. Section 40-43-86(G)(4) of the South Carolina Pharmacy Practice Act outlines the requirements for receiving a transferred prescription **(emphasis added).**

(4) The pharmacist receiving the transferred prescription information shall record in writing or electronically the following:
  (a) the word "transfer" on the face of the transferred prescription;
  (b) any information required to be on a prescription, including:
    (i) the date of issuance of the original prescription;
    (ii) the date and **time** of transfer;
    (iii) the pharmacy's name, address, and original prescription number from which the prescription information was transferred;
  (c) the name of the transferring pharmacist;
  (d) **the manufacturer or brand name of drug dispensed;** and
  (e) documentation that the receiving pharmacist shall dispense refills based on the transferring pharmacist's certification under subsection (G)(3).

Board Notification

According to the South Carolina Pharmacy Practice Act, the following items should be reported to the Board within a timely manner. Forms for the necessary notifications can be found on the Board website, *https://www.llr.sc.gov/bop.*

Report to the Board within 10 days:

- Change of name
- Change of address
- Change of employment
- Change of pharmacist-in-charge (PIC) status
- Permanent closing
- Change of ownership, management, location, consultant pharmacist, or PIC of a pharmacy
- Change of employment of technicians or pharmacists
- Disasters, accidents, destruction, or loss of records

Report to the Board within 30 days:

- Theft or loss of drug
- Conviction of any employee of state or federal drug laws
- Return permit for permanently closed facility

Repackaging of VA and Other Medications

Often, pharmacies that service long-term care facilities are asked to repackage medications that a resident may have received at an outside entity, such as prescriptions filled by the Department of Veterans Affairs (VA) (ie, federal) pharmacies. Previously, the Board determined that this practice was not acceptable. At the request of a number of pharmacies in South Carolina, the Board was asked to give an updated opinion on whether or not this practice may be allowed. The Board upheld its previous interpretation. The repackaging of previously dispensed medications by another pharmacy is not allowed under the South Carolina Pharmacy Practice Act.

Contact Information

As the Board relies more and more on technology to communicate with and educate the Board's licensees, it becomes more necessary for the Board to have the correct information on file. Please make sure to update your email address any time there is a change. Also, you can follow the Board on Facebook.

Connect with LLR by visiting:

- Twitter: @SCDLLR
- Facebook: @SCLLR
- Website: *www.llr.sc.gov*

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