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North Carolina Board of Pharmacy News

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Item 2388 – Update on Board Member Elections for Northeastern and Central Districts This Fall

As reported in the April 2019 issue of this *Newsletter,* the next North Carolina Board of Pharmacy elections are scheduled to begin November 1, 2019.

Two district seats will be up for election this year:

1. the **Central District,** which consists of Anson, Cabarrus, Chatham, Davidson, Davie, Iredell, Lee, Mecklenburg, Montgomery, Moore, Randolph, Richmond, Rowan, Stanly, and Union Counties; and
2. the **Northeastern District,** which consists of Bertie, Camden, Chowan, Currituck, Dare, Durham, Edgecombe, Franklin, Gates, Granville, Halifax, Hertford, Hyde, Martin, Nash, Northampton, Pasquotank, Perquimans, Tyrell, Vance, Wake, Warren, Washington, and Wilson Counties.

The winners of this election will begin their terms on May 1, 2020.

All pharmacists actively licensed by the Board and living in North Carolina at the time of the election will be eligible to vote for these two seats.

To be eligible to run for one of the two seats, the candidate must be a licensed pharmacist residing in one of the counties that comprise the district at the time of the election. Candidates who wish to stand for election will be required to submit a petition signed by 10 pharmacists residing in the relevant district to the Board office by **October 1, 2019.**

Board staff are hosting two informational sessions for pharmacists interested in running for the Board. The first is Tuesday, September 10, 2019, at 7 PM, at the McKimmon Conference and Training Center at North Carolina State University. The second is Tuesday, September 24, 2019, at 7 PM, at the Hampton Inn Asheboro at 117 East Dixie Drive, Asheboro, NC. These locations are within the Northeastern and Central Districts, respectively. However, any pharmacist interested in running for the Board from either district, or just interested in finding out more about Board service, is welcome to attend either session.

As a reminder, all actively licensed pharmacists living in North Carolina at the time of the election are eligible to vote, regardless of the district in which they reside. It is only the candidate and the pharmacists signing the candidate's petition who are district-limited.

You may recall that the Board amended its election processes last year. Board member elections will now occur in conjunction with the annual license renewal period. When pharmacists log on to their profile through the Board portal during the renewal period, they will be presented with a link to candidate information and an electronic ballot. To familiarize pharmacists with the portal-based voting system, Board staff plan to run a mock election in late summer. Thomas, the dog of Board Executive Director Jack W. "Jay" Campbell IV, JD, RPh, asks for your vote as the cutest dog on the planet during that mock election.

Questions about the election should be directed to Board Executive Director Jay Campbell.

Item 2389 – Pharmacist-Manager Responsibilities When a Pharmacy Is Closing Permanently

As pharmacists know, the pharmacist-manager is the person who accepts responsibility for the legal operation of a pharmacy. A pharmacist-manager's responsibility extends to ensuring that when a pharmacy closes existing patients are not blindsided by that closure, have adequate opportunity to select a new pharmacy of their choice, and do not experience a disruption in care.

21 North Carolina Administrative Code (NCAC) 46 .2502(h) specifies that when "a pharmacy is to be closed

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National Pharmacy Compliance News

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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.*

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permanently," the pharmacist-manager must "if possible" provide:

> notice of the closing . . . to the public by posted notice at the pharmacy at least 30 days prior to the closing date and 15 days after the closing date. Such notice shall notify the public that prescription files may be transferred to a pharmacy of the patient's or customer's choice during the 30-day period prior to the closing date. During the 30-day period prior to the closing date, the pharmacist-manager and the pharmacy's owner (if the owner is other than the pharmacist-manager), shall transfer prescription files to another pharmacy chosen by the patient or customer, upon request.

In recent months, Board staff have received complaints from patients who were blindsided by pharmacy closures, given no pre-closure opportunity to transfer prescriptions to a new pharmacy of their choice, and, in some cases, faced days or weeks in delay obtaining a transfer of their prescriptions. This is unacceptable. And it is unlawful.

Pharmacist-managers are expected to comply with 21 NCAC 46 .2502(h). Failure to do so will result in Board staff opening a disciplinary case and, if the facts dictate, seeking disciplinary action. From time to time, pharmacist-managers have pointed to the "if possible" language in 21 NCAC 46 .2502(h) to try and excuse noncompliance. The "if possible" language is included to deal with situations in which a pharmacy closes because of sudden, unforeseeable events. Inconvenience, desires of another pharmacy purchasing the closing pharmacy's files, and the like do not trump the patient protection requirements of 21 NCAC 46 .2502(h).

Item 2390 – Board Director of Inspections Krystal Stefanyk Receives NABP's John F. Atkinson Service Award

Board Director of Inspections Krystal Stefanyk received the National Association of Boards of Pharmacy® (NABP®) John F. Atkinson Service Award at NABP's Annual Meeting in Minneapolis, MN, this past May 2019. Krystal received the John F. Atkinson Service Award for her dedication to protecting the public health and her work in pharmacy and facility inspections.

Krystal has served the people of North Carolina as a Board inspector for 13 years and has served as director of inspections since 2014. Krystal is recognized nationally as an expert in inspection processes and in United States Pharmacopeia (USP) standards governing compounded drug product preparation. She revamped the Board's inspection forms, training programs, and processes to ensure public health and safety are well protected. Her efforts led to North Carolina's participation in NABP's Multistate Pharmacy Inspection Blueprint Program, which provides the highest level of public safety protection. Becoming a Blueprint state assures other state boards of pharmacy that North Carolina sterile compounding pharmacies licensed in those states are operating lawfully and safely. Krystal has been actively involved in NABP and has served as an NABP accreditation surveyor for 11 years.

Krystal is a sought-after speaker on inspection and compliance topics at the local, state, regional, and national levels. She has organized multistate workshops on inspecting nonsterile compounding facilities with speakers from USP and fellow state boards.

Board staff and members congratulate Krystal on this well-earned and well-deserved honor.

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