April 2019

# North Carolina Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

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## *Item 2384 – Board Member Elections for Northeastern and Central Districts to Happen This Fall*

The next North Carolina Board of Pharmacy elections are scheduled to begin November 1, 2019. Pharmacists may remember that the Board amended its rule on elections in 2017 to shift the election period to coincide with the pharmacist license renewal period.

Two district seats will be up for election this year:

- the **Central District,** which consists of Anson, Cabarrus, Chatham, Davidson, Davie, Iredell, Lee, Mecklenburg, Montgomery, Moore, Randolph, Richmond, Rowan, Stanly, and Union counties; and
- 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.

Gene Minton, RPh, is the current Board member from the Northeastern District. Mr Minton is serving his second term. By operation of state law, Mr Minton cannot run for a third consecutive term.

Ashley Duggins, PharmD, RPh, is the current Board member from the Central District. Dr Duggins is eligible to run for another term.

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. Beginning November 1, 2019, pharmacists will simply log in to the Board's Gateway, the same portal used to renew pharmacist licenses, and select from the list of candidates for each district. More information about the online voting method will follow in the fall.

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.**

**Again, 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.

Board staff will host two question-and-answer sessions in late summer – one in Asheboro, NC (Central District) and one in Raleigh, NC (Northeastern District). Anyone interested in learning more about Board service and the election process should plan to attend one of these sessions. More information about nominations and the two information sessions will be posted on the Board's website, *www.ncbop.org,* and emailed to North Carolina pharmacists in the coming months.

Questions about the election should be directed to Jack W. "Jay" Campbell IV, JD, RPh, the Board's executive director.

## *Item 2385 – FDA and NCDA&CS Emphasize That Supplements Containing CBD Are Unlawful Under the Federal and North Carolina FD&C Acts*

On December 20, 2018, former Food and Drug Administration (FDA) Commissioner Scott Gottlieb, MD, issued a statement explaining that while the Farm Bill of 2018 removed hemp from the federal Controlled Substances Act, "Congress explicitly preserved the [FDA's] current authority to regulate products containing cannabis or cannabis-derived compounds under the

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# National Pharmacy Compliance News

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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 Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach*

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

## *FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements*

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

## *Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse*

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP $AWAR_XE$® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the $AWAR_XE$ program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

## New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

## FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

## FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

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Federal Food, Drug, and Cosmetic Act (FD&C Act)." Hence, FDA "treat[s] products containing cannabis or cannabis-derived compounds as [it does] any other FDA-regulated products." Importantly, FDA reminded the regulated community that it is:

> . . . unlawful under the FD&C Act . . . to market CBD [cannabidiol] or THC [tetrahydrocannabinol] products as, or in, dietary supplements, regardless of whether the substances are hemp-derived. This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as . . . dietary supplements.

The full text of Gottlieb's statement may be found at *www.ncbop.org/pdf/fdacannabisstatement122018.pdf.*

In late February, the North Carolina Department of Agriculture & Consumer Services (NCDA&CS), which directly regulates industrial hemp products in North Carolina, began sending letters to businesses that manufacture or sell products containing CBD, emphasizing that:

> North Carolina has routinely adopted by reference the [F]ederal Food, Drug & Cosmetic Act and implementing regulations. The violation of these federal laws and regulations would equally be a violation of state laws and regulations.

The NCDA&CS letter, like former FDA Commissioner Gottlieb's statement, emphasizes that "CBD is the active ingredient in the approved drug product Epidiolex" and that "Since CBD is the active ingredient in the approved drug product Epidiolex, it is currently excluded from being a dietary supplement under section 201(ff)(3)(B)(i) and (ii) of the FD&C Act."

NCDA&CS further emphasized that "CBD products marketed with claims to prevent, mitigate, diagnose, treat or cure serious diseases" make those products "drugs under the FD&C Act." Accordingly, "CBD in products other than the approved drug Epidiolex and which make health claims would be a new drug that cannot legally be introduced into interstate commerce."

For the full text of the NCDA&CS letter, visit *www.ncbop.org/pdf/cbdletterncdeptagriculture.pdf.*

## *Item 2386 – Two New Board Rules Effective March 1, 2019*

The January 2019 *North Carolina Board of Pharmacy Newsletter* discussed in Item 2379 two proposed amendments to rules governing registered nurse dispensing at health departments and pharmacist-manager responsibilities. Those amendments went into effect on March 1, 2019.

First, an amendment to Rule 21 North Carolina Administrative Code (NCAC) 46.2403 adds over-the-counter nicotine replacement therapies to the formulary of drugs and devices that registered nurses in local health department clinics may dispense.

Second, an amendment to Rule 21 NCAC 46.2502 adds a new exception to the general rule that a pharmacist may only serve as pharmacist-manager at one pharmacy. A pharmacist may serve simultaneously as pharmacist-manager at two full-service pharmacies if one of the two is a newly permitted pharmacy that has not yet begun providing pharmacy services to patients. The pharmacist-manager may serve in this dual capacity until the newly permitted pharmacy begins providing pharmacy services to patients or six months from the issuance of the new pharmacy permit, whichever comes first. At that point, the pharmacist must relinquish the earlier pharmacist-manager position and may only serve as pharmacist-manager at the newly permitted pharmacy.

Visit *www.ncbop.org/rulemakings.htm* for details on any rulemakings underway at the Board.

## *Item 2387 – Board Requirements for Submitting Drug Disaster and Loss Reports, Incident Reports, and Drug Disposal Forms*

In August 2017, as part of an ongoing effort to increase efficiency and to provide the most secure platform possible, the Board transitioned to a new online licensing/enforcement system, the Licensure Gateway. It grants access to printable documents, and has a change of address function, online applications, and many more features. Those features include drug disaster and loss reports, incident reports, and drug disposal forms.

Drug disaster and loss reports, incident reports, and drug disposal forms must be submitted by the pharmacist-manager or designated permit personnel through the Licensure Gateway. Board staff no longer accept faxed, emailed, or mailed notifications of potential medication loss, Drug Enforcement Administration Form 106, and drug disaster and loss reports, incident reports, or drug disposal forms.

A reminder to all pharmacist-managers/pharmacists-in-charge on statutes and rules pertaining to these reports:

1. **Drug Disaster and Loss Reports** – North Carolina General Statutes §90-85.25(b) states:

   > The pharmacist in charge of a pharmacy shall report within 10 days to the Board any disaster, accident, theft, or emergency which may affect

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the strength, purity, or labeling of drugs and devices in the pharmacy.

2. **Incident Reports** – Rule 21 NCAC 46.2502(l) states:

   The pharmacist-manager shall report to the Board of Pharmacy information that reasonably suggests that there is a probability that a prescription drug or device dispensed from a location holding a permit has caused or contributed to the death of a patient or customer. This report shall be filed in writing on a form provided by the Board within 14 days of the owner representative or pharmacist-manager's becoming aware of the event. The pharmacist-manager shall retain all documents, labels, vials, supplies, substances and internal investigative reports relating to the event. All such items shall be made available to the Board upon request.

3. **Drug Disposal Forms** – Rule 21 NCAC 46.3001(a) states:

   All registrants under G.S. 90-85.21 shall develop and implement policies and procedures to insure that all out-dated, improperly labeled, adulterated, damaged or unwanted drugs or drug containers with worn, illegible or missing labels are destroyed or disposed of so as to render them unusable.



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