

April 2020

News



North Carolina Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Editor's Note: *The content of the North Carolina Board of Pharmacy's Newsletter was finalized prior to the coronavirus disease 2019 (COVID-19) outbreak. Licensees should check the Board's website for the most up-to-date information.*

Item 2400 – Central District Board Member Election Results

North Carolina pharmacists elected Ashley Duggins to serve a five-year term as the Board member from the Central District. As pharmacists in the state know, Dr Duggins has served on the Board since July 2018, when she was selected to fill the remaining two years of Stan Haywood's term.

Dr Duggins owns and operates Prevo Drug in Asheboro, NC. She is a 2002 graduate of the University of North Carolina (UNC) Eshelman School of Pharmacy, where she was a member of Phi Lambda Sigma, the pharmacy leadership society. Dr Duggins precepts students from the UNC Eshelman, Wingate, and Campbell schools/colleges of pharmacy.

Dr Duggins is active in professional associations such as the North Carolina Association of Pharmacists and the National Community Pharmacists Association. She also serves the pharmacy community as a member of the Randolph County Opioid Collaborative Committee and the Randolph County Health Department's Opioid Committee.

Dr Duggins' community service is not limited to pharmacy and health care contexts. She is a member of the Randolph Rotary Club, the Asheboro Randolph Chamber of Commerce, and Journey Church. She serves on the board of directors of the Uwharrie Charter Academy and is a past member of the board of directors for the Randolph County YMCA.

Board members and staff thank Danielle Andreasen, Marshal Carter, Nicole Eastman, Angela Smith, and Tim

Weber for their candidacies. The state's pharmacists had terrific candidates to choose from.

Item 2401 – Northeastern District Board Member Election

At the *Newsletter* press deadline, the results of the Northeastern District Board member election were pending. The top two vote recipients were Wallace Nelson and Cornelius Toliver. No candidate received a "substantial plurality" of the votes in the first round of voting, so this election may go to a runoff. Congratulations to Mr Nelson and Dr Toliver on their campaigns so far.

Board members and staff thank Russell Boratko, Dave Catalano, Ned Clark, Chad Cobus, Tony Mitchum, and Tara Torrence for their candidacies. As was true of the Central District election, the state's pharmacists had great candidates to select from.

The final results of the Northeastern District election will appear on the Board's website at www.ncbop.org and in the July 2020 issue of this *Newsletter*.

Item 2402 – Board Publishes Proposed Amendments to Its Rules Governing Administrative Hearing Procedure

On February 19, 2020, the Board published a proposed thorough revision of its administrative hearing procedural rules in 21 North Carolina Administrative Code (NCAC) Section .2000. The Board has not revised the majority of the rules in a number of years. During that time, both the spirit and the letter of the Administrative Procedure Act (APA) have moved away from the existing rules, and the existing rules contain outdated and extraneous requirements that the Board has not required parties to satisfy in order to decide their claims.

The revisions would:

1. bring the rules into compliance with the letter of the APA;

continued on page 4

National Pharmacy Compliance News

April 2020



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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.

President Trump Signs Legislation Extending Schedule I Status for Fentanyl Analogues

A law to extend the Schedule I status of fentanyl analogues for another 15 months was signed into law by President Donald J. Trump on February 6, 2020. Synthetic fentanyl analogues, often illegally manufactured, are widely believed to be fueling the “third wave” of the opioid crisis, as detailed in the October 2019 issue of *Innovations*[®] (pages 8-11), which can be accessed through the Publications section of the National Association of Boards of Pharmacy[®]'s website.

In February 2018, Drug Enforcement Administration (DEA) issued a temporary order to establish fentanyl-related substances as Schedule I. The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act extends the DEA order, which was set to expire on February 6, 2020. The bill requires the Government Accountability Office to produce a report within 12 months on the public health and safety effects of controlling fentanyl-related substances, according to *Homeland Preparedness News*.

Drug Overdose Deaths Related to Prescription Opioids Declined by 13% in 2018

Fatalities related to the use of prescription opioids declined by 13% in the United States during 2018, according to the 2019 National Drug Threat Assessment released by DEA. Despite this encouraging news, the report makes it clear that the opioid crisis continues at epidemic levels. Specifically, controlled prescription drugs remain a major factor in the record number of overdose deaths since 2017. Benzodiazepines and antidepressants were involved in an increasing number of overdose deaths.

Fentanyl and similar synthetic opioids also remain a major point of concern. Fentanyl maintained high availability through most of the US in 2018. Illegally manufactured versions of the powerful opioid continue to be smuggled into the US, primarily in the form of

counterfeit pills made to look like prescription opioids and powder. Fentanyl remains the “primary driver” of the current opioid crisis, according to the report.

“Illicit drugs, and the criminal organizations that traffic them, continue to represent significant threats to public health, law enforcement, and national security in the United States,” a DEA press release states. “As the National Drug Threat Assessment describes, the opioid threat continues at epidemic levels, affecting large portions of the United States.”

Drug-Resistant Infections Are Increasing

A new report on antibiotic infections released by the Centers for Disease Control and Prevention (CDC) estimates more than 2.8 million antibiotic-resistant infections occur each year, and more than 35,000 Americans are dying annually as a result. While the report notes that prevention and infection control efforts in the US are working to reduce the number of infections and deaths caused by antibiotic-resistant germs, the number of people facing antibiotic resistance is still too high. “More action is needed to fully protect people,” the report states.

The report lists 18 antibiotic-resistant bacteria and fungi and places them into three categories (urgent, serious, and concerning) based on clinical impact, economic impact, incidence, 10-year projection of incidence, transmissibility, availability of effective antibiotics, and barriers to prevention. It also highlights estimated infections and deaths since the last CDC report in 2013, aggressive actions taken, and gaps that are slowing progress.

The full report is available on the [CDC website](#).

NASEM Report Recommends Framework for Opioid Prescribing Guidelines for Acute Pain

Contracted by Food and Drug Administration (FDA), a December 2019 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) seeks to develop evidence-based clinical practice guidelines for prescribing opioids for acute pain. The report, *Framing Opioid Prescribing Guidelines for Acute Pain*:

Developing the Evidence, also develops a framework to evaluate existing guidelines, and recommends indications for which new evidence-based guidelines should be recommended.

As part of its work, NASEM examined existing opioid analgesic prescribing guidelines, identified where there were gaps in evidence, and outlined the type of research that will be needed to fill these gaps. NASEM also held a series of meetings and public workshops to engage a broad range of stakeholders who contributed expert knowledge on existing guidelines, and provided emerging evidence or identified specific policy issues related to the development and availability of opioid analgesic prescribing guidelines based on their specialties.

“We recognize the critical role that health care providers play in addressing the opioid crisis – both in reducing the rate of new addiction by decreasing unnecessary or inappropriate exposure to opioid analgesics, while still providing appropriate pain treatment to patients who have medical needs for these medicines,” said Janet Woodcock, MD, director of FDA’s Center for Drug Evaluation and Research in a statement. “However, there are still too many prescriptions written for opioid analgesics for durations of use longer than are appropriate for the medical need being addressed. The FDA’s efforts to address the opioid crisis must focus on encouraging ‘right size’ prescribing of opioid pain medication as well as reducing the number of people unnecessarily exposed to opioids, while ensuring appropriate access to address the medical needs of patients experiencing pain severe enough to warrant treatment with opioids.”

FDA will next consider the recommendations included in the report as part of the agency’s efforts to implement the SUPPORT Act provision requiring the development of evidence-based opioid analgesic prescribing guidelines.

The report can be downloaded for free on the [NASEM website](#).

New Research Shows Pharmacists Positively Impact Hospital Care Transitions

Patients who received focused attention from pharmacists during hospital stays expressed higher satisfaction, according to research presented at the American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition. The study centered on the effect of pharmacists educating patients about medications as they transitioned out of hospital care. During the study, pharmacists reconciled patients’ medications before discharge, talked with patients about the medications they were taking, and contacted them by phone after discharge to discuss their care.

Of the 1,728 patients included in the study, 414 received the full transition-of-care education protocol, including a follow-up pharmacist phone call. Those patients showed a 14.7% increase in the overall average mean score, as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems survey, which assesses patients’ perceptions of their care after discharge. A post hoc analysis also showed that 30-day readmission rates dropped from 17.3% to 12.4% when a post-discharge phone call was made to patients as a part of the study.

“Pharmacists play a multitude of vital roles for patients during a hospital stay, including comprehensive medication management and ensuring medication safety. Now, they can feel increasingly confident about their role in helping patients when transitioning from different levels of care. Our findings add to growing literature demonstrating that pharmacist involvement in hospital discharge improves outcomes and safety,” said Katherine L. March, PharmD, BCPS, clinical pharmacy specialist at Methodist University Hospital in Memphis, TN, in a press release.

continued from page 1

2. remove rules that attempt to restate substantive law, provisions of the APA, and other Board rules;
3. bring the rules into compliance with the Board's practices;
4. provide clarity on procedural steps not previously covered (or covered adequately) in the rules for the guidance of all parties;
5. notify the parties of certain provisions that are currently covered in Board orders, so that parties can be aware of those provisions from the outset; and
6. generally make the hearing process as efficient as it can be, consistent with the APA.

A public hearing on the proposed amendments will be held on May 26, 2020, at 10 AM at the Board office, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517.

Any person may comment on the proposed amendments by attending the May 26 public hearing, and/or by submitting a written objection by 10 AM on May 26, 2020, to Jay Campbell, executive director, North Carolina Board of Pharmacy, at 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517, via fax at 919/246-1056, or via email at jcampbell@ncbop.org.

The Board is interested in all comments pertaining to the proposed rules and rule changes. All persons interested and potentially affected by the proposals are strongly encouraged to read this entire notice and make comments on the proposed rules.

More information on these proposed amendments can be found at <http://www.ncbop.org/rulemakings.htm>.

Item 2403 – Board Statement Concerning Supervising Physician Information on Prescriptions Issued by PAs and NPs

The North Carolina Medical Board's rules governing physician assistants (PAs) and nurse practitioners (NPs) state that prescriptions issued by these practitioners must contain the name of the practitioner's supervising physician (PAs and NPs) and the phone number of the supervising physician (PA only). See 21 NCAC 32S.0212(5)(c) and 21 NCAC 32M.0109(5)(A). In recent months, a number of pharmacists have inquired whether a prescription from a PA or NP lacking this information is "illegal," "invalid," or otherwise ineligible for dispensing by a pharmacist.

The answer is **no**. The Medical Board's requirements are imposed on a PA or NP for purposes of the Medical Board's supervision of those practitioners. The absence of a supervising physician's name and telephone number does not render a PA- or NP-issued prescription "invalid,"

"illegal," or otherwise ineligible for dispensing under the North Carolina Food, Drug, and Cosmetic Act or the North Carolina Pharmacy Practice Act. These statutes set forth requirements for a valid prescription under North Carolina law – and neither requires supervising physician information to be included on PA- or NP-issued prescriptions.

Accordingly, if the Medical Board wished to take action against a practitioner that it regulates for failure to include this information on a prescription, that is the Medical Board's prerogative. But, again, that information's presence or absence does not affect a PA- or NP-issued prescription's eligibility for dispensing by a pharmacist. If a pharmacist has concerns about a PA- or NP-issued prescription that the pharmacist cannot resolve after discussion with the prescriber, the Medical Board maintains an online database that readily identifies each and every PA's supervising physician(s) located [here](#). Likewise, the North Carolina Board of Nursing maintains an online database that readily identifies each and every NP's supervising physician(s) located [here](#).

Item 2404 – CPhT Applicants May Now Establish Eligibility With NHA's ExCPT Certification

Effective February 12, 2020, certified pharmacy technician (CPhT) applicants may establish eligibility with National Healthcareer Association's (NHA's) Exam for the Certification of Pharmacy Technicians (ExCPT) certification. Applicants may also continue to establish eligibility with Pharmacy Technician Certification Board certification. When completing the online technician registration application, applicants will be asked to specify which certification they hold. Further instructions are found in the application itself.

Item 2405 – Pharmacists and Pharmacy Personnel Should Be Mindful of Scam Communications Purporting to Be From Board Staff

In January 2020, Board staff received information about a handful of instances in which someone was pretending to be a Board investigator calling a pharmacist.

Board staff was notified that someone impersonating a Board investigator has called several pharmacists and given a fake name and fake Board badge number as "proof" of identity. The telephone number that the impersonator is using appears on caller ID as the Board main line: 919/246-1050.

continued on page 5

continued from page 4

The impersonator has told pharmacists that there is a problem with their license, pending litigation, and that their license had been revoked. The impersonator tells the pharmacists that they need to stop what they are doing and work with the impersonator to resolve the issue. These calls appear to be an attempt to get the recipient to disclose personal information. Board staff is aware of similar scam calls involving someone who claims to be a Drug Enforcement Administration (DEA) agent and, in addition to seeking personal information, demands money to resolve a problem with DEA registration.

Board staff reminds pharmacists and pharmacy staff that the names of all the Board's investigators are listed on the Board's website, and if they are unsure or suspicious when contacted by someone claiming to be a Board staff member (whether by phone, email, or other communication) that they should contact the Board

immediately. Board staff frequently contacts pharmacists and pharmacy staff on all manner of issues. Again, if you are suspicious about the true identity of the caller, please reach out to the Board office directly.

Also, if you are the recipient of what appears to be a scam call, Board staff would appreciate you alerting the Board and providing as much information about the call as possible.

Page 5 – April 2020

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