October 2020

North Carolina Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Item 2410 – Southeastern District Board Member Election

The North Carolina Board of Pharmacy will hold an election to fill the Southeastern District seat beginning November 1, 2020, and running through March 1, 2021. The seat is presently held by J. Andrew Bowman, who will complete his first five-year term on April 30, 2021, and is eligible to run for a second term.

The Southeastern District comprises Beaufort, Bladen, Brunswick, Carteret, Columbus, Craven, Cumberland, Duplin, Greene, Harnett, Hoke, Johnston, Jones, Lenoir, New Hanover, Onslow, Pamlico, Pender, Pitt, Robeson, Sampson, Scotland, and Wayne Counties.

When this edition of the *Newsletter* is published, the candidates will likely be set as the deadline for candidates to file the requisite notice and petition support is October 1, 2020.

All pharmacists actively licensed by the Board and living in North Carolina at the time the election begins will be eligible to vote. As in recent elections, beginning November 1, 2020, pharmacists will simply log in to the Board's Licensure Gateway to read about the candidates and cast a vote. Voting and license renewal may be done at the same time, or may be done at different times during separate login sessions.

Board staff will provide more information on the Board's website and through periodic listserv emails to pharmacists. Please exercise your franchise!

Item 2411 – COVID-19 Response

As a reminder, because of the coronavirus disease 2019 (COVID-19) pandemic, the Board office remains closed to the public. Board services to licensees, permittees, registrants, and the public continue without interruption, however. Board meetings continue to be held by teleconference. Interested members of the public and the profession should continue to monitor the Board's website, where instructions for logging in to and participating in Board meetings are posted.

Board members and staff continue to provide updates, links, waivers, and other services to pharmacists and the public. The environment is fast- and ever-changing. Updates appear on the front page of the Board's website. Staff also consolidate and index these materials on the COVID-19 Updates and Resources page at *www.ncbop.org/COVID19.html.*

The COVID-19 Updates and Resources page includes information on:

- Emergency declarations
- Temporary pharmacy closures and relocations
- Emergency rules
- Board waivers and guidance documents
- North Carolina Department of Health and Human Services resources, licensure/registration/volunteer resources, federal guidance, and guidance from other state and local agencies

Pharmacists and the public are encouraged to consult the resources on the COVID-19 Updates and Resources page frequently. As always, Board staff are grateful for feedback and content suggestions.

Item 2412 – HHS Declaration Authorizing Pharmacists to Order and Administer Pediatric Vaccines

On August 19, 2020, the United States Department of Health and Human Services (HHS) issued a declaration authorizing pharmacists "to order and administer," and a "supervised pharmacy intern" "to administer," certain vaccines to patients ages three to 18 during the federally declared COVID-19 public health emergency.

The purpose of this declaration is to mitigate a potential "decrease in rates of routine childhood vaccinations . . . due to changes in healthcare access, social distancing, and other COVID-19 mitigation strategies."

Board members and staff have prepared a guidance document that describes the conditions under which pharmacists may exercise that authority. The guidance document also describes when and how these conditions differ from existing North Carolina law.

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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 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

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."

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Some pharmacists have asked, when ordering and administering vaccines under this grant of authority, who the documented prescriber should be. The answer is the pharmacist exercising this authority. Again, HHS authorized pharmacists to order and administer these vaccines, notwithstanding any state law to the contrary.

Item 2413 – Pharmacists and Pharmacy Personnel Should Be Mindful of Scam Communications Purporting to Be From Board of Pharmacy Staff

In January 2020, Board staff received information about a handful of instances in which someone pretending to be a Board investigator has called a pharmacist. It is happening again.

Board staff were notified in August 2020 that someone impersonating a Board investigator called a pharmacist and gave a fake name (Mike Moore) and a fake Board badge number (347219792) as "proof" of identity. The scammer is using a phone number spoofer so that the Board's main line – 919/246-1050 – appears on caller ID.

The scammer asserted that he was working with Drug Enforcement Administration and Food and Drug Administration on a case involving "suspicious" and "unauthorized activities" involving "illegal drug trafficking" by the pharmacist. The scammer claimed to need various personal information to "verify" he was speaking with the pharmacist. The scammer made various vague threats against recording the call or speaking to anyone about the investigation. He demanded a "personal cell phone" number so he could discuss the case "securely." Background noise clearly indicates the scammer was working from a call center.

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) they should contact the Board immediately. To be sure, Board staff frequently contact 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 them to that fact and providing as much information about the call and caller as you can – including a recording if you are able to make one.

Item 2414 – Notice Concerning Transfer of Ownership Applications

Per Board Rule 21 North Carolina Administrative Code (NCAC) 46.1603 – When New Permit Required:

> A new pharmacy, device, or medical equipment permit is required for a new location, [if there is] a change to a different or successor business entity, or a change resulting in a different person or entity owning more than 50 percent interest in the permit holder or any entity in the chain of ownership above the permit holder, except as provided in 21 NCAC 46 .1604 of this Section. A new permit is required if there is a change in the authority to control or designate a majority of the members or board of directors of a nonprofit corporation holding a pharmacy permit or any nonprofit corporation in the chain of ownership above the permit holder.

This means, if a change of ownership requiring a new permit occurs – and the pharmacy has not obtained the new permit by the effective date of the transfer of ownership – the previous permit becomes void (ie, no longer active) as of the effective date of the transfer of ownership.

Any permit subsequently acquired would not operate retroactively. It will operate from the date of issue forward. This means that an untimely transfer of ownership would result in a pharmacy operating without a permit for a period of time, which could result in Board action for unlicensed practice of pharmacy and other collateral consequences.

Transfer of ownership permit applicants must note that a new owner of a pharmacy may not operate using an old permit under a "power of attorney" or similar order.

To facilitate an orderly transfer, permit applications must be filed well in advance (six to eight weeks) of the planned transaction and, of course, permit applications proceed most quickly when they are complete, correct, and the applicant pharmacist-manager responds quickly to requests for information from Board staff. The applicant pharmacist-manager needs to monitor the permit application status and keep Board staff apprised of any changes to the transaction date. Failure to do these things can lead to significant delays in permit review and as noted above, transferring ownership prior to a new permit's issuance voids the existing permit.

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