



North Carolina Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Item 2396 – Reminder: Board Member Elections for Northeastern and Central Districts Continue Through March 1

Elections for the North Carolina Board of Pharmacy member positions for the Northeastern and Central Districts began November 1, 2019. Pharmacists are reminded that the election continues through March 1, 2019.

Please log in through the Board's Licensure Gateway at <https://portal.ncbop.org>, to read about the candidates and cast your votes. Remember to vote for one candidate from each of the two districts. Voting and license renewal may be done at different times, during separate login sessions.

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

Item 2397 – Board Publishes Proposed Rule Amendments Concerning the DME Subcommittee

The Board has published notice of the proposed repeal of Rule 21 North Carolina Administrative Code (NCAC) 46.2109, amendments to Rules 21 NCAC 46.2102 and 46.2104, and the creation of new Rule 21 NCAC 46.1207. The Board proposes to change the method of selection for its Device and Medical Equipment (DME) Subcommittee from election to appointment. This will bring the selection method for that committee into line with all other Board committees and will further:

1. eliminate wasteful use of Board and candidate resources to hold elections with extremely low voter turnout;
2. potentially increase the interest in serving on the DME Subcommittee, since interested persons would no longer have to run for election; and
3. eliminate term limits for committee members, allowing experienced and contributing members to continue to serve.

A public hearing will be held on February 18, 2020, at 10 AM at the Board office, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517.

Any person may object to the proposed amendments by attending the public hearing on February 18, 2020, and/or by submitting a written objection by 10 AM on February 18, 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.

If an objection is not resolved prior to the adoption of the rules, a person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with North Carolina General Statutes (NCGS) §50B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in NCGS §150B-21.3(b1). The Commission will receive written objections until 5 PM on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919/431-3000.

More information, including the text of the proposed changes, can be found at www.ncbop.org/LawsRules/ProposedRuleAdoptionAmendmentRepeal1207_2102_2104_2109PublicHearing021820.pdf.

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.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at <https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals>.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions*, which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- ◆ creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- ◆ developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- ◆ promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organiza-

nizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management*, which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at <https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages>.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient,” said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. “This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction.”

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA’s efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA’s approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

“Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field,” FDA said in a statement announcing the document’s release. “By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public.”

The full draft document can be accessed at <https://www.fda.gov/media/130216/download>.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA’s approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, *Conditions Under which Homeopathic Drugs May be Marketed*, is being withdrawn due to inconsistency with the agency’s risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

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

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

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 a legitimate investigation or legal action is always 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.

Item 2398 – Pharmacist-Manager Responsibilities for Pharmacy Interns

As pharmacists know, under North Carolina law, a student who is enrolled in a school of pharmacy is not required to register as a pharmacy technician. See NCGS §90-85.15A(e). A student enrolled in a school of pharmacy is considered a “pharmacy intern” and is authorized to “perform all acts constituting the practice of pharmacy” while “working under a pharmacist preceptor or supervising pharmacist.” Rule 21 NCAC 46.1317(29).

In recent months, Board staff became aware of two instances in which a person working in a pharmacy as a pharmacy intern was not (and never had been) a student enrolled in a school of pharmacy. In both cases, investigations continue.

In the meantime, pharmacist-managers are reminded that, as the person who “accepts responsibility for the operation of a pharmacy in conformance with all statutes and rules pertinent to the practice of pharmacy” ((21 NCAC 46.1317(27))), your duties include vetting employees working as pharmacy interns to ensure that they are actually enrolled in a school of pharmacy. The risk to the public of an unqualified person “performing all acts constituting the practice of pharmacy” is obvious. A “pharmacy intern” who is not enrolled in a school of pharmacy is engaged in the unlicensed practice of pharmacy (which is a criminal offense) and the Pharmacy Practice Act specifically authorizes action on a pharmacist’s license or a pharmacy’s permit where either have “aided and abetted an individual to engage in the practice of pharmacy without a license.” NCGS §90-85.38(a)(9).

Item 2399 – A Few Words About Prescription Transfers

On a semi-regular basis, Board staff members receive calls from pharmacists raising concerns or complaints about prescription transfer practices. Typically, the concern or complaint takes one of the following forms:

1. the pharmacist complains that another pharmacy (or, more frequently, a particular pharmacist) refuses to transfer prescriptions upon request;
2. the pharmacist complains that another pharmacy (or pharmacist) agrees to transfer prescriptions, but takes a long time to do so; or
3. the pharmacist complains that another pharmacy (or pharmacist) is “tricking” or “coercing” patients into transferring prescriptions.

Let’s set the table. Board Rule [21 NCAC 46.1806](#) authorizes the transfer of prescriptions among pharmacies, and it sets forth procedural and record-keeping requirements for doing so. Pharmacists seldom

have questions about these procedural or record-keeping requirements. Instead, most of the focus in these situations is one word in the rule – “permissible.” The introductory language of Rule 46.1806 says that the “transfer of original prescription information for the purpose of refill dispensing is permissible between pharmacies . . . ” Pharmacies or pharmacists who have refused to transfer a prescription typically respond to a complaint by saying that the rule makes transfers “permissible,” and not “mandatory.” What tends to get lost in this blinkered argument is the most important factor – the patient.

Patients have the right to select their pharmacy provider. Patients have many reasons for choosing a particular pharmacy in the first instance or deciding that they wish to change to a different pharmacy. Whatever those reasons are, the patient is the decision maker. A patient’s wishes must be respected, not only because it is the right thing to do, but also to avoid interruption of care that could well prove harmful to the patient. With this background in mind, this is how Board staff approach transfer complaints:

1. Pharmacists are expected to consult with one another professionally and politely to resolve transfer issues. Staff often find that the root of a transfer dispute is a personal or business conflict among pharmacists or pharmacies. These types of disputes are not a reason to involve the Board, nor are they a reason to delay (or deny) a patient’s care.
2. In some cases, a pharmacist alleged to have wrongly refused a transfer will state that he or she simply wants to confirm the request with the patient. That, in and of itself, does not necessarily raise an issue. However, “I’m checking with the patient” must not become a pretext for denying a transfer or delaying one to such a degree that the patient’s continuity of care is jeopardized. Also, pharmacy policies and procedures that incentivize staff pharmacists to delay or deny transfers place those pharmacists, the pharmacist-manager, and the pharmacy permit in potential jeopardy.
3. Board staff treats a transfer complaint from a patient as a higher priority matter than a transfer complaint from a pharmacist. This is because, as noted above, transfer complaints relayed by pharmacists are often rooted in personal or business conflicts. Direct patient complaints are more typically rooted in potential harm resulting from interrupted drug therapy. A patient who alerts the Board that his or her transfer request is not being honored, or is not

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- being honored in a timely fashion, will find a ready ear and a helping hand from Board staff.
4. After a patient complaint, if neither professional consultation among the pharmacists nor informal intervention of Board staff occurs (usually by way of a phone call to both pharmacists with a suggestion that the patient's request be met without further delay), Board staff will open a case and pursue it as a disciplinary matter focusing on potential negligence in a pharmacist's or pharmacy's outright refusal to transfer or a dilatory transfer.
 5. Pharmacies are expected to have adequate staff on hand to fulfill a patient's transfer request in a timely fashion. As noted in Item 2389 of the [July 2019 Newsletter](#), in recent months, some pharmacies have abruptly closed without adequate (and legally required) notice to patients. Predictably, this results in the pharmacy receiving the prescription files getting bombarded with transfer requests. The pharmacist-manager of the receiving pharmacy must staff it sufficiently to accomplish timely transfers. Failure to do so will lead to a Board staff investigation and potential discipline.
 6. If a pharmacy or pharmacist complains to the Board that it believes a patient was "tricked" or "coerced" into transferring prescriptions, Board staff needs, at a minimum, the patient's name and contact information and strongly prefers to receive the complaint from the patient directly. In Board staff's experience, most often the patient explains that he or she did authorize a transfer but was uncomfortable admitting this to his or her now-former pharmacy. However, if a patient directly alleges that he or she experienced a transfer that he or she did not authorize, it is a serious matter that could involve not only the Board, but also law enforcement agencies or the North Carolina Attorney General's Office.

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