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North Carolina Board of Pharmacy News

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Item 2391 – Reminder: Board Member Elections for Northeastern and Central Districts Begin November 1

As reported in the April 2019 and July 2019 issues 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 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 member elections will now occur in conjunction with the annual license renewal period. When pharmacists log in 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.

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

Item 2392 – Board Partners With More Powerful NC Campaign to Confront Opioid Misuse

More Powerful NC, a public-private partnership formed to fight the opioid epidemic, and the Board have partnered to confront prescription opioid misuse. The Board is pleased to provide two more resources for pharmacists and pharmacies in support of the More Powerful NC campaign.

First, the Board has printed prescription vial auxiliary labels that pharmacists are encouraged to place on pain medication prescriptions. These labels encourage patients to protect children by disposing of medications safely and include the *MorePowerfulNC.org* URL. Board inspectors have sheets of the labels for distribution to pharmacies, and any pharmacy that would like to obtain them should email or call Kristin Moore at the Board office. These auxiliary labels are available to pharmacies at no cost, as long as supplies last!

Second, Board member Ashley Duggins worked closely with Attorney General Josh Stein's staff to produce one-sheet "bag stuffer" handouts in several sizes and formats. These bag stuffers provide information to pharmacists and patients on the resources available at *MorePowerfulNC.org.* Board field investigators have copies of these bag stuffers to hand out at pharmacies. The file is also available for any pharmacist, pharmacy, or member of the public to download at *www.ncbop.org/PDF/MorePowerfulNCOpioidBagStufferJuly2019.pdf.*

The Board encourages pharmacists and pharmacies to make these new resources a part of their opioid dispensing process and thanks pharmacists and pharmacies for their unceasing efforts to encourage and ensure proper opioid use, storage, and disposal.

Item 2393 – Expansion of Pharmacist Vaccine Administration Authority

On June 3, 2019, Governor Roy Cooper signed into law Session Law 2019-21, which increases pharmacists' authority to administer vaccines. Here is what you need to know:

1. **Will pharmacists be able to administer more vaccines to patients 18 and older pursuant to protocol?** Yes. This legislation adds serogroup B meningococcal vaccines, human papillomavirus vaccine, and hepatitis A vaccine to the list of vaccines that a pharmacist may administer to persons 18 or older pursuant to protocol.

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NABPF
National Association of Boards of Pharmacy Foundation

USP Postpones Official Dates of USP General Chapters Revisions and Additions

United States Pharmacopeial Convention (USP) has announced that the effective date of the following changes to USP general chapters will be postponed:

- General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations
- General Chapter <797> Pharmaceutical Compounding – Sterile Preparations
- General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

The delay is in accordance with USP's Bylaws, which require the official date of the standard to be postponed while an appeal is pending. In the meantime, conformance with the official versions of Chapters <795> and <797>, including the section "Radiopharmaceuticals as CSPs," will remain official, according to a notice posted to the USP website.

Revisions to USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings are not subject to pending appeals, and will become official on December 1, 2019. During this interim period, Chapter <800> is "informational and not compendially applicable," according to the USP notice. However, the organization encourages utilization of the chapter in the interest of advancing public health. USP also notes that it plays no role in enforcement and that regulators continue to have the authority to make their own determinations regarding enforceability of Chapter <800>.

FDA Issues Statement on Compounded Bulk Drug Substances Ruling

A US district court judge in Washington, DC, recently upheld Food and Drug Administration's (FDA's) interpretation of clinical need regarding bulk substances that may be used by outsourcing facilities in drug compounding. In response to the ruling, FDA has released a statement commending the decision as a "victory for public health in the first such case since the Drug Quality and Security Act (DQSA) was enacted."

In March 2019, FDA announced that vasopressin would not be included as an approved bulk drug substance because there is already an approved product on the market to meet the same medical needs. The ruling was in response to a challenge of that interpretation. In their statement, the agency states that they will continue to evaluate bulk drug substances nominated for use in compounding by outsourcing facilities using the same interpretation of clinical need.

"Our compounding work remains a top priority at the agency. We've long recognized that compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product," the agency states. "But compounded drugs are not approved by the FDA and, therefore, have not been evaluated for safety, efficacy or quality. We've seen first-hand the harm they can cause patients when they're not appropriately compounded."

HHS, FDA Publish New Action Plan for Importation of Certain Prescription Drugs

The US Department of Health and Human Services (HHS) and FDA have published a Safe Importation Action Plan to allow for the safe importation of certain drugs originally intended for foreign markets. The action plan outlines two possible pathways:

- **Pathway 1** would rely on the authority in the Federal Food, Drug, and Cosmetic Act Section 804 to authorize demonstration projects to allow importation of drugs from Canada. The proposed rules would include conditions to ensure the importation poses no additional risk to consumers and must result in a significant cost reduction.
- **Pathway 2** would allow manufacturers to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the US versions. Manufacturers would use a new National Drug Code for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

The action plan states that the final proposal for these rules may differ from the descriptions "to reflect further consideration of the relevant issues."

"Today's proposal is the result of the hard work by the dedicated staff of the FDA, in close collaboration with HHS and the White House, to identify potential pathways we can pursue to support the safe importation of certain prescription drugs," said Acting FDA Commissioner Ned Sharpless, MD in a press release. "We've been keenly focused on ensuring the importation approaches we've outlined pose no additional risk to the public's health and safety. We know there are many operational challenges to address through each of these pathways, and are actively working through them as we look to formally announce these policies, with opportunity for public comment, in the coming months."

The full action plan can be accessed via the HHS website at *https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf.*

Pain Reliever Misuse Decreased by 11% in 2018, NSDUH Survey Indicates

Prescription drug misuse, including abuse of stimulants and pain relievers, decreased in 2018, according to the recently released 2018 National Survey on Drug Use and Health (NSDUH). The annual survey, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), a division of HHS, is a primary resource for data on mental health and substance use, including abuse of prescription drugs, among Americans.

Key findings of the 2018 NSDUH include:

- Past-year abuse of psycotherapeutics decreased from 6.6 from 6.2%.
- Past-year abuse of pain relievers decreased from 4.1% to 3.6%.
- Past-year abuse of stimulants decreased from 2.1% to 1.9%.
- Past-year abuse of opioids decreased from 4.2% to 3.7%.

"This year's National Survey on Drug Use and Health contains very encouraging news: The number of Americans misusing pain relievers dropped substantially, and fewer young adults are abusing heroin and other substances," said HHS Secretary Alex Azar. "At the same time, many challenges remain, with millions of Americans not receiving treatment they need for substance abuse and mental illness. Connecting Americans to evidence-based treatment, grounded in the best science we have, is and will remain a priority for President Donald Trump, for HHS, and for SAMHSA under Assistant Secretary Elinore McCance-Katz."

A recorded presentation of the data, along with a written summary and the full report are available on the SAMHSA website at *https://www.samhsa.gov/data/nsduh/reports-detailed-tables-2018-NSDUH.*

Additional Efforts Needed to Improve Naloxone Access, CDC Says

A new Vital Signs report published by the Centers for Disease Control and Prevention (CDC) states that naloxone dispensing has grown dramatically since 2012, with rates of naloxone prescriptions dispensed more than doubling from 2017 to 2018 alone. However, the rate of naloxone dispensed per high-dose opioid dispensed remains low, with just one naloxone prescription dispensed for every 69 high-dose opioid prescriptions.

The researchers for the report examined dispensing data from IQVIA, a health care, data science, and technology company that maintains information on prescriptions from 50,400 retail pharmacies, representing 92% of all prescriptions in the US. According to their analysis, dispensing rates were higher for female recipients than for male recipients, and higher for persons aged 60-64 years than for any other age group. The researchers also found that the rate of naloxone prescriptions dispensed varied substantially across US counties, with rural and micropolitan counties more likely to have a low-dispensing rate.

"Comprehensively addressing the opioid overdose epidemic will require efforts to improve naloxone access and distribution in tandem with efforts to prevent initiation of opioid misuse, improve opioid prescribing, implement harm reduction strategies, promote linkage to medications for opioid use disorder treatment, and enhance public health and public safety partnerships," the report states in its conclusion. "Distribution of naloxone is a critical component of the public health response to the opioid overdose epidemic."

The Vital Signs report can be accessed at *www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm.*

Altaire Pharmaceuticals Recalls Multiple OTC Ophthalmic Products

Due to a lack of sterility assurance, Altaire Pharmaceuticals, Inc, is voluntarily recalling over-the-counter (OTC) drug products and lots sold as generic ophthalmic medications at Walgreens, Walmart, CVS, and other retail pharmacies. To date, there have been no reports of adverse events related to the recalled products.

A full list of the affected products and lot numbers, as well as instructions on how to return the product, are available through the following press releases:

- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall Of Multiple Ophthalmic Products Sold At CVS
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Wal Mart
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Walgreens
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program.

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2. **Will pharmacists be able to administer the flu vaccine by protocol to younger patients?**
   Yes. This legislation authorizes pharmacists to administer the flu vaccine to patients at least 10 years old pursuant to protocol. Pharmacists are authorized to administer the flu vaccine to patients at least six years old pursuant to a prescription order.
3. **Is this new authority effective now?**
   The legislation became effective on October 1, 2019.
4. **What do pharmacies need to do to implement the new authority?**
   First, the North Carolina Academy of Family Physicians, the North Carolina Medical Society, the North Carolina Pediatric Society, the North Carolina Association of Community Pharmacists, the North Carolina Association of Pharmacists, and the North Carolina Retail Merchants Association have produced a new minimum standard screening questionnaire for immunizing pharmacists (as required in the statute). That questionnaire is available for download from the Board's website at *www.ncbop.org.*
   Second, immunizing pharmacists must collaborate with their supervising physicians to revise their vaccination protocols to reflect the new vaccines that may be administered and the new permissible age for flu vaccine administration.

Item 2394 – New Legislation Allows Donation of More Prescription Drugs to Free and Charitable Pharmacies

The General Assembly passed, and Governor Cooper signed into law, an amendment to North Carolina General Statute 90-85.44, which governs the donation of drugs and devices in North Carolina.

Prior to this amendment, North Carolina law required that a donated drug or device have at least six months remaining on its expiration date at the time of donation. As amended, the statute makes a drug eligible for donation if, among other things, the drug has not reached its expiration date at the time of donation.

Board staff updated the frequently asked questions (FAQs) on drug donation to reflect this change. Pharmacists are encouraged to review the FAQs at *www.ncbop.org/faqs/Pharmacist/faq_DonatingRXs.htm* for a refresher on drug donation regulation.

Item 2395 – USP Postpones Effective Date of Revised Chapters <795> and <797>

United States Pharmacopeial Convention (USP) announced on September 23, 2019, that – as required by USP Bylaws – it is postponing the effective date of USP Chapters <795> and <797> while appeals for review of these revised chapters are resolved. These chapters were previously scheduled to go into effect on December 1, 2019. More details can be found at *https://www.uspnf.com/notices/compounding-chapters-postponement.*

How does USP's announcement affect North Carolina-permitted pharmacists and pharmacies?

1. Existing USP Chapters <795> and <797> will continue to be enforced. Board inspections and investigative staff will continue to use the inspection forms and tools mapped to existing USP chapter requirements. As pharmacists know, under both federal law (the Drug Quality and Security Act (DQSA)) and Board Rule 21 North Carolina Administrative Code (NCAC) 46.2801, compounding activities must conform with the standards in these chapters. The revised chapters will be enforced when they go into effect. USP did not set a new effective date in its September 23, 2019 announcement.
2. Board staff will **not** begin inspecting for compliance with USP Chapter <800> standards in compounding activities on December 1, 2019. USP's announcement notes that Chapter <800> is not subject to an appeal and will go into effect on December 1, 2019. Nonetheless, both the DQSA and Board Rule 21 NCAC 46.2801 require compliance with USP Chapters <795> and <797> and other chapters incorporated into them. Existing Chapters <795> and <797> do not incorporate Chapter <800>; however, revised Chapters <795> and <797> do. Accordingly, Board staff will begin inspecting for compliance with Chapter <800> standards at such time as the revised chapters go into effect. Again, USP did not set a new effective date in its September 23, 2019 announcement. Pharmacies that have already implemented changes to comply with Chapter <800> are commended for doing so. And pharmacies working toward Chapter <800> compliance are strongly encouraged to take the time afforded by this delay to finalize those preparations. For a review of prior Board statements concerning USP Chapter <800>, visit *http://www.ncbop.org/PDF/BoardPositionStatementforUSP800UPDATEDMarch2019.pdf* and *http://www.ncbop.org/PDF/NCBOP_USP_800_Statement.pdf.*

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