November 2019

News

Virginia Board of Pharmacy

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Board Member Appointments and Meeting Dates

Governor Ralph Northam recently appointed the following individuals to the Virginia Board of Pharmacy:

- **James L. Jenkins, Jr, BSN, RN,** of Mechanicsville, VA, Neuroscience Intensive Care Unit, Virginia Commonwealth University Health System. Mr Jenkins was reappointed to serve a four-year term after filling a partial term vacated by a previous citizen Board member.
- **William T. Lee, DPh, MPA, FASCP,** of Radford, VA, senior director of pharmacy innovations, Carilion Clinic. Mr Lee was appointed to serve a four-year term. He replaces Rafael Saenz, whose term on the Board had expired.

Additionally, at its September 25, 2019 meeting, the Board finalized the 2020 dates for full Board meetings. Upcoming full Board meetings will be held on December 9, 2019; March 24, 2020; June 16, 2020; September 9, 2020; and December 10, 2020. The meetings are open to the public. Agendas and minutes are accessible online at *http://www.dhp.virginia.gov/pharmacy/pharmacy_calendar.htm.*

E-Profile ID Now Required – Effective June 26, 2019

Regulation 18 Virginia Administrative Code (VAC) 110-20-22 and amendments to 18VAC110-20-80 and 18VAC110-20-105 require pharmacists, pharmacy interns, and pharmacy technicians to provide the Board with their e-Profile number when applying for or renewing their license or registration. The e-Profile number is available free of charge from the National Association of Boards of Pharmacy® (NABP®) and facilitates the exchange of information between the Board and NABP, which is necessary for licensure processes. To establish an e-Profile ID, please visit the NABP **e-Profile dashboard,** select the "Customers" button, and follow the instructions for setting up a new account.

Paperless Licensing Initiative

The Board is implementing a process to cease mailing on an annual basis the hard copy licenses, registrations, and permits that bear an expiration date. A final hard copy will be issued that contains no expiration date. This final copy should be maintained, carried, or posted in accordance with relevant applicable laws and regulations. As of July 1, 2019, all newly issued, reinstated, or duplicate copies of pharmacy technician registrations began following this new process and thus, do not bear an expiration date. Additional licensure categories will continue to be phased in during the calendar year and during the upcoming renewal cycle. State health regulatory boards, employers, insurance providers, and citizens seeking verification of current licensure status of any license, registration, or permit in the Commonwealth of Virginia may obtain this information via the License Lookup feature at *https://dhp.virginiainteractive.org/Lookup/Index.* Information obtained via License Lookup serves as primary source verification. Individuals may request a replacement or duplicate of a final hard copy license through an individual online account at *http://www.dhp.virginia.gov/mylicense/renewalintro.asp.*

Renewal of Pharmacist Licenses and Pharmacy Technician Registrations

Current pharmacist licenses and pharmacy technician registrations expire at midnight on December 31, 2019. Please note that practicing on a lapsed license or registration is unlawful and constitutes grounds for disciplinary action by the Board. Renewal notifications have been sent to the email addresses on file with the Board and to the official mailing address of record for those persons who have not provided the Board with an email address. Either an established login and password from a previous

continued on page 4

National Pharmacy Compliance News

November 2019

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.

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.

Pharmacists Invited to Participate in NAPLEX Pharmacy Practice Survey

The National Association of Boards of Pharmacy® (NABP®) sent email invitations to randomly-selected pharmacists in all areas of practice encouraging them to participate in the NAPLEX Pharmacy Practice Analysis Survey. Analysis of the survey results is used to evaluate the North American Pharmacist Licensure Examination® (NAPLEX®) competency statements.

The analysis of practice supports the relevance of the NAPLEX competency statements, which define the content for the examination. This analysis helps ensure that competency statements, otherwise known as the examination "blueprint," are in line with pharmacy practice standards and measure the knowledge, skills, and abilities of entry-level pharmacists. In addition, the review supports the NABP mission to protect the public health by providing the state boards of pharmacy with a reliable means of assessing competency that assists them with licensure decisions to support safe and effective practice.

continued from page 1

renewal cycle may be used to gain access, or licensees may use the license number and personal identification number provided in the renewal notification. Licensees are encouraged to renew online. Additionally, please be sure to review for accuracy both the public address and address of record (private) as well as phone numbers and email addresses that the Board has on record.

Fees for renewals received by the Board by December 31, 2019, are as follows:

- pharmacist current active license – $90;
- pharmacist current inactive license – $45; and
- pharmacy technician registration – $25.

To change a pharmacist license status from active to inactive, follow the online instructions for changing the status and submitting the $45 renewal fee for inactive status. An additional late fee of $30 for current active pharmacist licenses, $15 for current inactive pharmacist licenses, and $10 for pharmacy technician registrations must be submitted for renewals received by the Board after December 31, 2019. Renewals are processed the next business day following receipt. However, it may take seven to 10 business days following the Board's receipt of a renewal to receive the updated license or registration by mail. Holidays may further delay processing and receipt by mail. If a license or registration is not received via mail within 14 days of submitting the renewal, please contact the Board by email at pharmbd@dhp.virginia.gov. As a reminder, the updated license or registration will not contain an expiration date and will serve as a final paper copy of the license or registration. Maintain this final copy for the duration of your career in active practice. (For more information, refer to the article in this newsletter on Paperless Licensing Initiative.)

In addition to submitting the renewal fee, each current active pharmacist or pharmacy technician must attest to having successfully obtained all necessary continuing education (CE) hours during the 2019 calendar year. Please note that there is no specific topic required for CE in 2019. Each year, pharmacists are required to obtain 15 contact hours of qualifying CE per calendar year and pharmacy technicians must obtain five contact hours of qualifying CE per calendar year. Individuals who have not obtained the appropriate amount of CE during 2019 may request a one-time extension for no cause shown. Any subsequent extension requests will be granted for good causes only. Such requests must be made in writing and prior to renewing the license. Any individuals who request an extension will have their CE audited the following year. Refer to Guidance Documents 110-4 and 110-42 at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm* for more information related to CE.

New Requirement for Pharmacies to Be Fully Operational Within 90 Days

To address a growing concern for possible fraudulent activity, Regulation 18VAC110-20-140 now requires a pharmacy to be fully operational within 90 days of the pharmacy permit being issued. This requirement went into effect on August 22, 2019. The Board may grant an extension for good cause shown, such as circumstances beyond the control of the permit holder.

Amendments to Naloxone Protocols Adopted

When a person authorized in subsections X and Y of §54.1-3408 of the Drug Control Act dispenses naloxone, the dispenser must comply with a protocol that was adopted by the Board of Pharmacy, in consultation with the Virginia Board of Medicine and the Virginia Department of Health. The Board of Pharmacy had previously adopted two such protocols. Guidance Document 110-44, originally adopted in 2015, addresses pharmacists' dispensing of naloxone pursuant to §54.1-3408(X) and Guidance Document 110-45, originally adopted in 2017, addresses other persons who may dispense naloxone pursuant to §54.1-3408(Y). During the 2019 Virginia General Assembly Session, House Bill (HB) 2158 and HB 2318 were passed to further expand provisions for dispensing naloxone and therefore, amendments to the naloxone protocols were necessary. The Board adopted such amendments at its September 25, 2019 meeting.

To reduce possible confusion and streamline the protocols, the Board voted to combine the two protocols into one document by repealing Guidance Document 110-45, and to further amend the protocol found in Guidance Document 110-44 by including the newly enacted changes in law. Following a 30-day public comment period, the amended protocol in Guidance Document 110-44 will tentatively become effective in early to mid-November 2019. All persons authorized to dispense naloxone are strongly encouraged to review the protocol and dispense accordingly.

Health Commissioner's Standing Order for Naloxone

Pharmacists and pharmacy technicians are reminded that Virginia Health Commissioner M. Norman Oliver, MD, issued a standing order in April 2018 authorizing pharmacists to dispense naloxone to anyone requesting it. Based on recent media reports, it appears that not all pharmacists are aware of the standing order despite ongoing educational efforts on this subject. Please assist the Board in communicating this allowance to both peers and

continued on page 5

continued from page 4

the public. Additionally, please ensure that all pharmacy staff members, including all cashiers, are aware of this allowance in law. The Board is aware of circumstances wherein pharmacy cashiers have turned away customers requesting naloxone because they believed a prescription was necessary for obtaining the drug. Pharmacist questions regarding the use of the commissioner's standing order should be directed to pharmbd@dhp.virginia.gov.

Documentation of Corrective Action Required for Inspection-Related Deficiencies

After an inspection of a pharmacy wherein deficiencies are identified, the inspector provides an inspection summary to the pharmacist on duty. If deficiencies are cited during a routine pharmacy inspection that warrant the imposition of a monetary penalty as recommended by Guidance Document 110-36, the inspector will also provide the pharmacist with a notice and prehearing consent order (PHCO). The pharmacist-in-charge (PIC) is responsible for appropriately responding to the PHCO within the required time frame listed in the document. If the cited violations are not being contested, the PIC may sign the consent order, submit the monetary penalty, and provide documentation of corrective action taken for each of the deficiencies. In instances wherein structural or physical deficiencies are cited, such as defects to a cleanroom, a photo must be submitted as evidence that each deficiency was corrected. Other violations may also require the submission of documentation showing completed testing or certification. Alternatively, if the PIC is contesting the deficiencies cited, he or she must request an informal conference for further consideration by the Board within the specified time frame listed in the PHCO. It is strongly recommended that the PIC also provide a written explanation for why immediate corrective action is unnecessary.

USP Standards Under Appeal

On September 23, 2019, the United States Pharmacopeial Convention (USP) published a *Notice of Intent to Revise*, which stated that Chapters <795>, <797>, and <825> were under appeal and that "USP's Bylaws provide that the official date of a standard under appeal must be postponed while an appeal is pending. Therefore, **USP is postponing the official dates of the revised <795> and <797>, and the new general chapter <825> until further notice.** In the interim, the currently official chapters of <795> (last revised in 2014) and <797> (last revised in 2008) including the section *Radiopharmaceuticals as CSPs* will remain official . . . General Chapter <800> is not subject to any pending appeals and will become official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable." While USP and the Board encourage utilization of USP Chapter <800> in the interest of advancing public health, the Board cannot legally require compliance with requirements in Chapter <800> related to compounding until the appeals of Chapters <795> and <797> are resolved and the revised chapters become effective. Once the revised Chapters <795> and <797> become effective, only those requirements in Chapter <800> related to compounding will be enforced by the Board.

The Board adopted amendments to Guidance Document 110-36 on September 25, 2019. After publication in the Registrar and following a 30-day public comment period, the amended Guidance Document will tentatively become effective in November 2019. Inspectors will continue to inspect for USP Chapter <800> standards for educational purposes only.

The *Virginia Board of Pharmacy News* is published by theVirginia Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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