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SC Department of Labor, Licensing, & Regulation – Board of Pharmacy News

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Upcoming Board Vacancy

Do you live in the Fourth Congressional District? Are you interested in running for the Board? Here is your opportunity!

If you live in the Fourth Congressional District and are interested in serving on the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy, you must meet the following requirements:

- **Reside** in the Fourth Congressional District;
- Be licensed and actively practicing pharmacy in South Carolina; and
- Before December 1, 2019, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists **practicing** in your respective Congressional District.

The term will begin on July 1, 2020, and end on June 30, 2026. After receiving biographies and petitions, the Board administrator will:

- prepare and mail ballots by January 15, 2020, to all pharmacists who have notified the Board that they reside in the Fourth Congressional District; and
- certify as true and valid all ballots postmarked before February 15, 2020, and received by the Board office before February 25, 2020.

Before March 1, 2020, the Board will certify in writing to the governor the names of the three candidates receiving the most votes in the election and the name of the person who the nominee will replace on the Board. The new member, when appointed by the governor, will take office on July 1 of that year. If you are interested in becoming a candidate for this position or have any questions, please contact the Board office at 803/896-4700.

USP Chapter <800>

The Board has received numerous inquiries regarding the implementation of USP Chapter <800>, which is set to become official on December 1, 2019.

As a reminder, the United States Pharmacopeial Convention (USP) is a nonprofit organization that establishes certain standards regarding the operation of pharmacies. These standards are not expressly incorporated into the South Carolina Pharmacy Practice Act. The Board enforces the standards set forth in the Practice Act and permit holders and licensees are expected to comply with specific provisions of USP Chapter <800> outlined in South Carolina Code of Laws Annotated §40-43-88(E). For example, if a standard set forth in the Practice Act is more stringent than a standard set forth in USP Chapter <800>, the entity will be held to the standard contained in the Practice Act.

Please keep in mind that while the Board is not currently adopting USP Chapter <800>, other regulatory and accrediting bodies may be requiring compliance for payment and/or accreditation.

A chart comparing and contrasting USP Chapter <800> with the South Carolina Pharmacy Practice Act can be found under Frequently Asked Questions on the Board website at *https://llr.sc.gov/bop/faq.aspx.*

This is a document intended for use simply as a guide and may not be all encompassing. Thank you to Aubree Justus, University of South Carolina PharmD candidate, for compiling this document.

Epinephrine and Immunization Kits

The EpiPen® and EpiPen Jr® shortage is a serious issue that has been affecting patients and pharmacies all over the US for over a year. Many may wonder what is being done to combat this ongoing issue. In June 2019, Food and Drug Administration, in coordination with Pfizer and Mylan, stated that it was extending expiration dates for 0.3 mg EpiPen auto-injectors by four months. This extension will affect lots with expiration dates between February 2019 and October 2020. If a facility chooses to use the expiration date extension, it is to be noted

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

that documentation needs to be kept with immunization emergency kits.

Another way to combat the national shortage and have the appropriate drug items in your immunization emergency kit is to use EpiPen alternatives. Current alternatives available on the market are Amneal's generic version of Adrenaclick®, Kaléo's AUVI-Q® auto-injector, Sandoz's SYMJEPI™ pre-filled syringe, and Teva's generic version of EpiPen. Epinephrine ampules are also an acceptable alternative to use in immunization emergency kits during the shortage.

Even with the national EpiPen shortage, it is important for pharmacies to be able to safely provide patients with vaccines. With the use of these alternatives, every pharmacy should be able to stock their immunization emergency kits appropriately. As a reminder, with flu season approaching, a fully stocked kit must be accessible anywhere vaccines are given. If a pharmacy is offering to give vaccines in an off-site clinic (eg, flu clinic) an immunization emergency kit should be available for both the facility and the off-site location. If a fully stocked kit is not available, no vaccines should be given.

Also, as a reminder, if any drug item is missing or expired from the immunization emergency kit, a fine of $500 per drug item will be charged to the pharmacist-in-charge (PIC) according to Regulation 99-45 of the Board's Resolution Guidelines for Citations.

State-Certified Technicians

The Board has noticed an increase in pharmacy technicians who have renewed their South Carolina registration as a state-certified technician yet neglected to renew their national certification. This is resulting in numerous technicians across the state practicing as state-certified technicians when in actuality, they do not currently meet the criteria. A technician working out of scope can result in disciplinary action not just for the licensee, but for the PIC as well.

All technicians who renewed this year as a state-certified technician and have not submitted updated information have been contacted via letter requesting the recent documents. Failure to provide those documents will result in the technician being converted to a registered technician. This will decrease the scope of practice for that individual as well as impact the pharmacist to technician ratio.

Please ensure that your state-certified technicians are in compliance.

Pharmacists Beware

The following article is republished, in part, from the August 2019 Alabama State Board of Pharmacy Newsletter *with permission from the Alabama State Board of Pharmacy.*

The Board has seen an increasing number of fraud cases in pharmacies. There are a couple common scenarios that pharmacists should be aware of and avoid.

One scenario involves non-pharmacist owners and/or companies buying independent pharmacies and asking the independent owner to stay on to "aid in the transition" or continue his or her employment with the new owner. In almost every case, the pharmacist owner states that the offer accepted was "too good to pass up." In these situations, the new owner gradually infuses the business with faxed or electronic prescriptions from a location outside of the state. These prescriptions are being generated from call centers that are unethically obtaining patient information and manipulating patients into accepting prescriptions that are not needed, and all co-pays are waived. These prescriptions are refilled every month, regardless of whether the patient requests them or not. In many cases, the patients have asked for the prescriptions to be stopped, but the call center continues to transmit the prescriptions to the pharmacy.

In other cases, the prescriptions are processed and reimbursement is received, but the prescription is never physically filled or delivered. Some prescriptions are filled and mailed to the patient, at which time the patient will ship the prescription back due to the patient's lack of need for the prescription. However, the prescription is never reversed from the insurance, and the non-pharmacist owner and/or company retains the insurance reimbursement. To be valid, prescriptions must be the outcome of a patient-physician relationship. In this scenario, that relationship is questionable. **This is not to say that every non-pharmacist drugstore owner is unethical or committing fraud.** However, as the old saying goes, if it is too good to be true, it probably is. Pharmacists should be inquisitive of any new processes or changes that do not seem right, or if the new owner cannot answer questions to the pharmacist's satisfaction.

A second scenario that is becoming increasingly common is the use of "menu" prescriptions, which allow pharmacists to choose which medications to dispense. These prescriptions are sourced through a sales force employed by the pharmacy owner, which works with a physician's office to identify patients. The prescriptions are faxed or

continued on page 5

continued from page 4

electronically submitted from the physician's office with a statement similar to the following one.

> I authorize the pharmacist-in-charge to substitute the prescribed product that I prescribed with an alternate formula or product if the patient does not have insurance, has a high deductible or co-pay, or has an insurance policy that does not cover the particular product or compound I have prescribed.

Prescriptions bearing this type of statement are invalid, as this blanket statement is not compliant with the South Carolina Pharmacy Practice Act. In addition, the prescription will have a "menu" of product options from which to choose. Again, the South Carolina Pharmacy Practice Act does not allow "menu" prescriptions. The interesting part is that every option has an extremely high reimbursement rate. In some cases, the items on the "menu" are injectable antibiotics with instructions for topical use. These particular items provide very lucrative reimbursement with **no** value to the patient. In most cases, using the injectable medication as a topical medication could have detrimental effects and/or lead to resistance to the antibiotic, rendering it useless when needed. In a few cases, the pharmacist questioned the owners as to the validity of the therapy. The owner produced articles as to the veracity of the therapy. However, if proper examination of the articles was done, the pharmacist would quickly realize that the therapy was not proper, and that dispensing the product would not only be unprofessional, but would be unethical at best and fraudulent at worst. Options on the "menu" may also contain ointments that are to be added to water for a "soak." Ointments do not dissolve and therefore would be useless in a soak. Pharmacists must use their professional judgment in ascertaining whether a prescription product is effective in the manner prescribed by the physician.

Pharmacists often speak of "corresponding responsibility" regarding the dispensing of controlled substances. It is important to note that **all** filled prescriptions require the pharmacist to ensure that the prescriptions are compliant with all federal and state laws and are for the health care benefit of the patient. If, at any time, a pharmacist is concerned that actions at his or her place of employment may be questionable, he or she should contact the Board. Investigators will aid in determining whether there is an issue and will work with the informing pharmacist to identify the next steps.

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