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Tennessee Board of Pharmacy News

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Tennessee Governor Bill Lee Appoints New Board Member

On September 30, 2019, Governor Bill Lee announced his appointment of Richard Breeden, PharmD, as the newest member to the Tennessee Board of Pharmacy. Dr Breeden will replace outgoing Board member, Mike Dickenson, DPh, who completed his six-year term at the last Board meeting held July 16-17, 2019.

In a message to Board members, Board Executive Director Reginald "Reggie" Dilliard, DPh, noted that Dr Breeden, a graduate of Mercer University College of Pharmacy in Atlanta, GA, is currently the director of clinical education for South College in Knoxville, TN.

"We look forward to Dr Breeden's participation and contribution to the Board, and thank him for his willingness to serve," Dr Dilliard said.

Public/Consumer Member Lisa Tittle Resigns From Board of Pharmacy

On a somber note, Dr Dillard notified members with the regrettable news that Public/Consumer Member Lisa Tittle has retired, effective November 30, 2019. Dr Dilliard expressed his sadness and understanding of her resignation due to health and family issues.

Mrs Tittle has served on the Board as the public/consumer member since January 24, 2017, after previously working with the Tennessee Department of Health, Bureau of Health Licensure and Regulation as an administrative assistant. Dr Dilliard noted that she brought a wealth of financial knowledge. "Her contribution to the Board has been immense and vital with her past experience," Dr Dilliard said. "She will be missed."

Important Information Concerning USP's Announcement Postponing the Effective Date of Revised Chapters <795> and <797>

The United States Pharmacopeial Convention (USP) announced 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. Click here for more details.

The Board is currently only empowered by statute and rule to enforce applicable USP standards for sterile compounding. While the appeals process continues for these new standards with USP, the current standards for **sterile compounding** will continue to be enforced. The Board encourages all compounders of sterile and nonsterile products to continue to protect their patients' and employees' safety in compounding medications and promotion of safe handling of hazardous drugs.

ADS Diversion

On a diversion investigation in a Tennessee hospital, it was found that an employee used a possible weakness in the security of an Automated Dispensing System (ADS) area to steal narcotics. Generally, an ADS is programmed in partitions or virtual areas (eg, emergency department, floor, operating room). It is advised to run a report of all areas with any transactions to circumvent someone charging to an area under the radar. A reconciliation audit may have caught this diversion sooner, and is strongly encouraged, periodically.

Board Office Staff Delivers 'The Take-Home Message'

Board staff reminds registrants of the following:

- **Oxcarbazepine Suspension's Short Expiration Date:** Oxcarbazepine suspensions are opened, but many times not marked as such, and returned to the pharmacy shelves. With no date of opening or calculated date of expiration, the seven-week expiration is being ignored. Remember that this is a medication indicated for seizure, and potency is a concern.
- **Do not forget to return expired medications, especially controlled substances (CS) before counting the biennial inventory,** otherwise, these medications are required to be counted. Remember Board Rule 1140-03-.11 Outdated and Deteriorated Drugs:

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National Pharmacy Compliance News

December 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.

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The owner or pharmacist in charge of a pharmacy practice site shall immediately return or destroy all outdated, defective, or deteriorated prescription drugs and devices and related materials; except that the destruction of controlled substances listed in any schedule shall be performed by a Board approved agent or vendor.

- **Review Collaborative Care Rules and Regulations:** More Tennessee-registered pharmacists are collaborating with doctors in new areas from diabetes care to antibiotic stewardship. It is advised to review the following definitions/regulations:

  Tennessee Code Annotated §63-10-204

  (4) "Collaborative pharmacy practice" is the practice of pharmacy whereby one (1) or more licensed pharmacists licensed in this state, jointly and voluntarily work with one (1) or more prescribers licensed in this state, under a collaborative pharmacy practice agreement to provide patient care services, to achieve optimal medication use and desired patient outcomes;

  (5) "Collaborative pharmacy practice agreement" is a written and signed agreement entered into voluntarily between one (1) or more licensed pharmacists in this state, and one (1) or more prescribers licensed in this state, each of whom is in active practice in this state providing patient care services in this state, that provides for collaborative pharmacy practice, as defined by law;

  - ◊ Board Rule 1140-03-.17 Collaborative Pharmacy Practice
  - ◊ Board Policy Statement on Preventive Care

New DEA Regulation Requires Pharmacies to Register for Suspicious Order Reporting System

On October 23, 2019, Drug Enforcement Administration (DEA) launched a new Suspicious Orders Report System (SORS). An announcement about the system was sent to registrants by email. According to an email from the Nashville, TN, DEA Office, Supervisory Diversion Investigator James "Jim" Stevens indicated that some registrants did not get a message because no email was listed, an incorrect email was on file, or the message went to a spam folder. Stevens explained that **pharmacies are one of the 12 entities required to register.** SORS is an online, centralized database required by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act **(SUPPORT Act, Pub. L. 115-271).** There have been discussions questioning if pharmacies that do **no** distributions are exempt (ie, pharmacy to pharmacy or pharmacy to prescribing practitioner). Stevens indicated that pharmacies found to distribute CS without registration may be in violation and may be cited. He recommends all pharmacies be registered as it only takes a few minutes to do so. For complete details, navigate to the following link.

Both DEA Numbers Are Required on Prescription Hard Copies When Prescribing "X" Data Waiver Medications for Addiction

DEA Diversion Program Manager Claude "Martin" Redd explained in a recent email that "the individual practitioner must include the identification number (the DEA number) on all records when dispensing and on all prescriptions when prescribing narcotic drugs." In addition, he said, "In §1306.05(b), a prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for **detoxification treatment or maintenance treatment** must include the identification number (DEA X data waiver number) issued by the Administrator under Sec. 1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of Sec. 1301.28(e) of this chapter."

Therefore, both the "X" data waiver number and the regular DEA number must be recorded on the prescription.

DOJ Moves to a New DEA Form 222 Format

According to the following link found on the Department of Justice (DOJ) website, DEA is moving to a new single-sheet format of DEA Form 222. Effective October 30, 2019, the regulation change allows registrants to continue to use the current triplicate version for a two-year period.

Board Office Alerts Registrants to Schedule Time for CSOS Renewals

Board staff was recently alerted that Controlled Substance Ordering System (CSOS) renewals may only be obtained twice (three-year periods) before a new application package must be filled out and sent to DEA. Therefore, it is recommended that all DEA registrants check their CSOS expiration date and review the above link so that privileges are not abruptly revoked/expired. Be advised to keep extra DEA 222 forms available if needed.

Investigators Complete Sterile Compounding Certification

In June and October 2019, respectively, Board Pharmacist Investigators Derek Johnston and Pat Beckham added the Certification in Sterile Compounding for Inspectors (CISCI)

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credentials to their names. The investigators completed the Boot Camp, taught by CriticalPoint, located in Totowa, NJ. They became the fourth and fifth Board investigators to gain certification along with colleagues Rebecca Moak, Andrea Miller, and Scott Denaburg. Rita Golden plans to complete her training next year when scheduling permits. Board Executive Director Reggie Dilliard indicated that more investigators were needed with specific training in USP <797>, USP <800>, and USP <825>. These investigators are required to inspect every 12 months for those sites compounding sterile preparations.

Disciplinary Actions

For disciplinary actions taken against registrants licensed with the Board and other health related boards, click here.

TPRN Provides Assistance to Pharmacy Registrants

If you need help or know an associate (pharmacist or pharmacy technician) who does, please contact Dr Baeteena Black, Tennessee Pharmacy Recovery Network (TPRN) program director, by phone at 615/256-3023 or by email at bblack@tnpharm.org. More information including the reporting form, is located on the TPRN website.

Report Theft or Significant Loss (New Phone Numbers Updated for DEA)

Per Title 21, Code of Federal Regulations, Section 1301.76(b), registrants must notify their local DEA office, in writing, of the theft or significant loss of CS within one business day of discovery. Tennessee registrants may now satisfy this requirement by submitting all relevant information via email to tntheftorloss@usdoj.gov. Registrants must still complete DEA Form 106 and may do so online via the DEA website. Questions? Please contact a diversion investigator at 571/362-7674 or Supervisory Diversion Investigator James N. Stevens at 571/362-7113. You shall also satisfy the Board regulation to immediately report theft or loss and may do so by sending a copy to Dr Terry Grinder at terry.grinder@tn.gov.

Board Meeting Schedule

The Board extends an open invitation for all registrants and the general public to attend its public meetings at 665 Mainstream Drive, Nashville, TN 37243. The meetings are currently scheduled to begin at **8 AM.** Pharmacists may receive up to two hours of live continuing education, valid for their Tennessee pharmacist license on a full meeting day, and one hour on a half day. As always, **check for schedule changes** on the Board website under the Meeting Schedule tab.

The **2020** meeting schedule is as follows:

- January 7-8
- March 10-11
- May 5-6
- July 14-15
- September 15-16
- December 1-2

Tennessee Board of Pharmacy Members

- Dr Debra Wilson – President
- Dr Rissa Pryse – Vice President
- Dr Katy Wright – Board Member
- Dr Adam Rodgers – Board Member
- Dr Melissa McCall – Board Member
- Dr Richard Breeden – Board Member
- To Be Announced – Public Member

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