

newsletter to promote pharmacy and drug law compliance

2023 Legislative Session: Updates and Board Changes

The 2023 legislative session came to an end on April 21, 2023. This year, several bills were passed that directly or indirectly impacted the Tennessee Board of Pharmacy. Notably, two additional seats were added to the Board: an additional pharmacist and a pharmacy technician. The term for serving on the Board also changed from six years to seven years. A summary of all legislation related to the Board for the year can be found on the Board's website.

Harshbarger Joins the Board as Wright Leaves

The Board welcomes newly appointed Member Robert Harshbarger III, PharmD, FACA. Dr Harshbarger is the pharmacy operations manager for Premier Pharmacy in Kingsport, TN. In this role, he coordinates and oversees pharmacy operations including budgeting, workflow design and implementation, policy development, training programs, supply chain logistics, technology implementation, regulatory compliance, and compounding activities. An active member in his community and his profession, he currently serves on the City of Kingsport Economic Development Board of Directors and is a pharmacist full fellow in the American College of Apothecaries.

Dr Harshbarger's term will expire in June 2028.

Dr Katy Wright leaves the Board after completing her term. Welcomed at the November 2016 Board meeting, Wright served her six-year term and stayed on until Dr Harshbarger was appointed. During her years on the Board, Dr Wright routinely volunteered to serve as the Board's representative at meetings, and served as the

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Board's representative to help work on the hormonal contraceptive rules and draft the newest compounding rules. The Board thanks Dr Wright for her service and dedication to the pharmacy profession and the citizens of Tennessee.

Leinart Appointed to New Board Seat

The Board welcomes newly appointed Member Rebecca Leinart, PharmD. Dr Leinart is a district leader for CVS Health. In this role, she oversees CVS Health pharmacies inside Targets across the state of Tennessee. At CVS, Dr Leinart has served in a variety of positions from staff pharmacist to pharmacy manager, to her current position as district leader. As district leader, she can reach the leaders in stores across the state who make a direct patient impact and has become a resource for those leaders. Dr Leinart is an alumna of East Tennessee State University Bill Gatton College of Pharmacy. Dr Leinart's term is set to expire in June 2030.

Foster Appointed to New Board Seat as First Pharmacy Technician

The Board welcomes newly appointed Member Nichole Foster, MBA, MEd, CPhT-Adv. Mrs Foster is the manager of pharmacy technician and client education at CEimpact. In this role, Mrs Foster has the opportunity to expand technician education, as well as support their growth and development in pharmacy practice. Mrs Foster has been working in the pharmacy profession for over two decades with a goal of highlighting the many capabilities of pharmacy technicians. Mrs Foster previously worked at Vanderbilt University Medical Center where she held several roles, including certified pharmacy technician, senior program manager, program director of the Pharmacy Technician Training Program, and co-chair of the Pharmacy Technician Advancement Review Board. Mrs Foster earned her master's degree in education and bachelor's degree in biology from Cumberland University and her master's in business administration from Trevecca Nazarene University. Mrs Foster's appointment establishes her as the first pharmacy technician to serve on the Board. Her term is set to end in March 2030.

Phillips Joins the Board and Replaces Adam Rodgers

The Board welcomes newly appointed Member Matthew Kyle Phillips, PharmD, BCPS. Dr Phillips replaced Adam Rodgers, whose term concluded at the end of July. Dr Phillips is the chief of pharmacy at the VA Tennessee Valley Healthcare System (TVHS) where he oversees and leads pharmacy service for the health care system. In this role, Dr Phillips supervises more than 200 team members at the two main campuses of Nashville and Murfreesboro, as well as the 19 outlying community-based outpatient clinics, which encompass tertiary care, long-term care, and psychiatric care with budget preparations of over \$200 million. Dr Phillips has served the TVHS in several different roles since his pharmacy career began 13 years ago, including clinical pharmacist, inpatient and outpatient pharmacy supervisor, associate chief of pharmacy, and, currently, chief of pharmacy service. Dr Phillips earned his bachelor of science degree in biochemistry from Freed-Hardeman University, followed by his

doctor of pharmacy with honors from the University of Tennessee. Dr Phillip's term is set to expire in July 2030.

Dr Adam Rodgers leaves the Board after completing his term. Welcomed to the Board in September 2017, he completed a six-year term. Dr Rodgers represented the Board in a variety of ways, including serving on the Controlled Substance Monitoring Database (CSMD) Committee, appearing before the General Assembly's Joint Operations Committee on numerous occasions, and acting as the Board's delegate on the interview committee for the executive director. The Board thanks Dr Rodgers for his service and dedication to the pharmacy profession and the citizens of Tennessee.

Board Holds Rulemaking Hearing

On Monday, May 8, 2023, during a public rulemaking hearing, the Board heard from interested licensees and stakeholders on several rules affecting pharmacy practice in Tennessee. In two different rulemaking hearing notices filed, the Board discussed and voted on rules involving acceptable inspections for out-of-state sites, pharmacy technician-to-pharmacist ratio changes, compounding regulations, fee decreases for initial pharmacy technician applications, accessible prescription label requirements, and collaborative pharmacy practice agreements related to ivermectin. The archived rulemaking hearings are located here and here. The language included in the hearing notices was amended during the rulemaking hearing based on feedback, which can be found in the minutes of that meeting. The final language and effective date of the changes will be posted on the Tennessee Secretary of State website, when available. The Board intends that all aspects of the rulemaking hearing will be enforceable on the effective date. As of December 1, 2023, no effective date has been named, but a 90-day period will be in place from when an effective date becomes available and the named date.

USP and Rule Changes

While many aspects of United States Pharmacopeia (USP) apply to the compounding of products, all pharmacies that handle hazardous drugs, such as testosterone, should be familiar with USP <800> requirements. Licensees may wish to obtain the updated regulations that are applicable to their pharmacy practice. If receiving, storing, and dispensing hazardous drugs, a copy of the most current NIOSH List is also recommended.

For the handling of hazardous drugs as it relates to USP <800>, all pharmacies need to be aware of the requirement to obtain an assessment of risk. The requirements may be found in USP <800> under the heading "List of Hazardous Drugs" and include at least the type of hazardous drug, dosage form, risk of exposure, packaging, and manipulation. USP <800> also outlines the receipt and storage of hazardous drugs, which will need to be addressed in the pharmacy's policies and procedures.

USP <795> for nonsterile compounding will also be enforceable as part of the rule changes. While the new chapter became official on November 1, 2023, the Board rules will be effective at a later date, likely in the first quarter of 2024. The Board encourages those doing nonsterile compounding to

review the Board's pending rules, which can be found in the May minutes, to know how the changes will affect their practice – specifically the proposed "Nonsterile Simple Compounding Preparations" section of the new rules. This will help determine whether all sections of USP <795> apply, or only if those sections apart from the "Compounding Facilities" will apply.

When the rules become effective, the current chapters of USP <795>, <797>, <800>, and <825> will be memorialized in rule and will be enforced.

For additional information regarding USP, Frequently Asked Questions are available here.

Public Guidance Regarding the Removal of DATA-Waiver in Dispensing Buprenorphine

The Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) has released public guidance regarding the prescribing of buprenorphine. Please view the document and video on the TDMHSAS website. For questions, please contact Dr Wes Geminn, chief pharmacist and state opioid treatment authority for TDMHSAS at sota.office@tn.gov.

CSMD Updates and Reminders

Make sure to update your Tennessee Data Collection Submitter Account information. The CSMD team will contact you with any questions or issues related to submissions utilizing this contact information. Additionally, every day a report is sent to the email address on file with the subject line "File Processed Successfully Notification." This report contains information related to the submission, including errors that must be corrected. If you need help correcting errors, please contact the CSMD team at CSMD.admin@tn.gov or 615/253-1305.

The Tennessee Department of Health continues to support, at no charge to the licensee, an integration tool, Gateway. This tool allows integration between your pharmacy software or electronic health records and the CSMD, allowing you to quickly access the information needed. If you are interested in integration, more information can be found online.

PIC Changes and CS Inventories

Board Rule 1140-03-.14 outlines various requirements for a pharmacist-in-charge (PIC). A PIC is named at each Tennessee-licensed pharmacy and a successor PIC shall be named and sent to the Board immediately upon a change. According to the rule, "the outgoing pharmacist in charge shall, prior to departure, conduct with the successor pharmacist in charge a joint inventory of all controlled substances. In case of failure of the outgoing pharmacist in charge to comply with this requirement, the successor pharmacist in charge shall conduct such inventory alone."

The controlled substance (CS) inventory should be done in accordance with Title 21 Code of Federal Regulations (CFR) §1304.11 and be a complete and accurate record of all CS on hand at the date of the inventory. The inventory may be taken either as of the opening of business or as of the close

of business on the inventory date and it shall be indicated on the inventory. The inventory shall be maintained in written, typewritten, or printed form at the registered location. For those not completing an inventory because of a PIC change, an inventory of all stocks of CS on hand must occur at least every two years with the same requirements listed above.

Tennessee Pharmacy Recovery Network

The Tennessee Pharmacy Recovery Network (TPRN) was selected by the Board in a competitive bidding process to continue as the peer assistance program for the next three years. If pharmacists, pharmacy students, or pharmacy technicians need help with addiction or know an associate who does, please contact Dr Nancy Hooper, director of TPRN, by phone at 615/256-3023 or by email at nancy@tnpharm.org. An informational link is located on the website.

The Board would like to send a note of gratitude to Dr Baeteena Black, who retired as director of TPRN on April 1, 2023. Dr Black was recognized by the Board at the Tennessee Pharmacists Association Winter Meeting in February by selecting her as this year's recipient of the Kendall Matthew Lynch Tennessee Board of Pharmacy Award for Excellence in Public Health. This award is to recognize those who, like Kendall, late executive director of the Board, put forth great effort to protect the public health and safety of Tennesseans and greatly furthered the goals and objectives of the Board. Individuals who qualify for this award show exemplary service to public health through enforcement, regulation, or other initiatives. In her role as director of TPRN, Dr Black has worked closely with the Board to advocate for those who are ready to reenter practice. The Board members appreciate all her years of service and efforts to protect, and promote, the public health in this state.

Disciplinary Actions

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

Report Theft or Significant Loss of CS

Per Title 21, CFR, Section 1301.76(b), registrants must notify their local Drug Enforcement Administration (DEA) Field Division office, in writing, of the theft or significant loss of CS within one business day of discovery. Tennessee registrants must now satisfy this requirement by submitting all relevant information via email to tntheftorloss@DEA.gov. Registrants must still complete DEA Form 106 and may do so online via the DEA website. You may satisfy the Board regulation to immediately report theft or loss by sending a copy to pharmacy.health@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 9 AM. It is advised to check for schedule changes on the Board website under the Meeting Schedule section. The next Board meeting is currently scheduled for January 30-31, 2024.

Tennessee Board of Pharmacy Members

- Dr Melissa McCall, President and Pharmacist Member
- Dr Richard Breeden, Vice President and Pharmacist Member
- Dr Shanea McKinney, Pharmacist Member
- Dr Marty Blane, Pharmacist Member
- · Dr Robert Harshbarger III, Pharmacist Member
- Dr Rebecca Leinart, Pharmacist Member
- Dr M. Kyle Phillips, Pharmacist Member
- · Mrs Nichole Foster, Pharmacy Technician Member
- Weakley County Mayor Jake Bynum, Consumer Member

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