

Tennessee Board of Pharmacy  
Board Meeting  
November 14-15, 2023

TENNESSEE BOARD OF PHARMACY  
665 Mainstream Dr, Iris Room  
Nashville, TN 37243

**BOARD MEMBER PRESENT**

Melissa McCall, D.Ph., President  
Shanae McKinney, D.Ph.  
Marlin Blane, D.Ph.  
Robert Harshbarger, III, D.Ph.  
Kyle Phillips, D.Ph.  
Rebecca Leinart, D.Ph.  
Nichole Foster, RT  
Jake Bynum, Consumer Member

**STAFF PRESENT**

Lucy A. Shell, Executive Director  
David Silvus, General Counsel  
Albert Hill, Pharmacist Investigator  
Andrea Miller, Pharmacist Investigator  
Rebecca Moak, Pharmacist Investigator  
Rita Golden, Pharmacist Investigator  
Richard Hadden, Pharmacist Investigator  
Shannon Kelly, Pharmacist Investigator  
Derek Johnston, Pharmacist Investigator  
Scott Denaburg, Pharmacist Investigator  
Patricia Beckham, Pharmacist Investigator

**BOARD MEMBER ABSENT**

Richard Breeden, D.Ph. Vice President

**STAFF ABSENT**

Terry Grinder, Pharmacist Investigator

The Tennessee Board of Pharmacy convened on Tuesday, November 14, 2023, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:01 a.m. with Dr. McCall presiding.

**Minutes**

Dr. McKinney made the motion to accept the minutes from the July 18-19, 2023, and August 3, 2023, board meeting as presented. Dr. Blane seconded the motion. The motion carried.

**Financial Report**

Ms. Emily Godwin, Fiscal Director presented the financial report.

**Waivers**

**Board rule 1140-03-.14(12)**

Dr. McKinney made the motion to approve the request for **Donald DeHart, D.Ph.** to be the PIC at Harris Family Pharmacy and Dunlop Pharmacy for six months (May 2024). Dr. Leinart seconded the motion. The motion carried. Mr. Bynum was recused.

Lindsey Adams, Pharm.D., Director of Compliance at Vanderbilt Hospital, appeared before the board to ask for standardization of their waivers concerning their automated dispensing machines at **Vanderbilt Oral Surgery Pharmacy, Vanderbilt Surgery Center Pharmacy and Vanderbilts Childrens' Surgery and Clinics**. After discussion, Dr. Blane made the motion to authorize Vanderbilt Oral Surgery Pharmacy, Vanderbilt Surgery Center Pharmacy and Vanderbilt Children Surgery and Clinics automated dispensing machines for the PIC to visit monthly, no quarterly reports but they must report errors, cameras for non-surgery center with some type of technician supervision. Dr. McKinney seconded the motion. The motion carried.

**Board rule 1140-01-13(h) and 1140-03-.14 (12)**

**Erlanger Behavioral Health**

Mr. Bynum made the motion to grant Erlanger Behavioral Health Hospital automated dispensing machine waiver request to for the square footage, report errors and the PIC must visit monthly. Dr. McKinney seconded the motion. The motion carried.

**Board rule 1140-03-.14 (12); 1140-01-.13 (3)(d) and 1140-4-.13 (2)(b)**

Mr. Bynum made the motion to grant **Lebanon Surgery Center's** request for Jennie Allen, Pharm.D. to be PIC at Tri Star Mt. Juliet ER, 100 Summit Blvd., Mt. Juliet, Tn and Lebanon Surgery Center, 125 Willard Hagan Dr., Lebanon, TN. Dr. Blane seconded the motion. The motion carried. Mr. Bynum made the motion to grant **Lebanon Surgery Center** request to waive the space requirement and refrigeration. The space at Lebanon Surgery Center will be 84 square feet. Dr. Blane seconded the motion. The motion carried.

Ms. Foster made the motion to grant Vanderbilt Children's Hospital request to expand the use of Script Center kiosk machines for employee use. Dr. Bynum seconded the motion. The motion carried.

**Board rule 1140-01-13 (3) (d), (e) and 1140-03-.14 (13)**

Mr. Bynum made the motion to grant **Vanderbilt Wilson County Hospital Surgery Center** pharmacy request a waiver for hot and cold running water, square footage and for the PIC to be present at least 50% of the time that the pharmacy is open. Vanderbilt Wilson County Hospital Surgery Center has 6 automated dispensing machines. Dr. Harshbarger seconded the motion. The motion carried.

Mr. Bynum made the motion to grant **BKW Holdings** pharmacy request for waiver of the 180 square footage and hot & cold running water. Dr. McKinney seconded the motion. The motion carried.

Dr. McKinney made the motion to grant **Vanderbilt Outpatient Surgery Center** waiver request for hot and cold running water, square footage and the PIC to be present at least 50% of the time that the pharmacy is open. Mr. Bynum seconded the motion. The motion carried.

Dr. McKinney made the motion to grant **Baptist Memorial Hospital Carroll County Outpatient Surgery** pharmacy request for waiver of the 180 square footage and hot & cold running water. Ms. Foster seconded the motion. The motion carried.

**Board rule 1140-01-.07 (3)( c) 3 & 5**

Dr. McKinney made the motion to grant **Lena Congtang D.Ph.** request to waive the three hundred and twenty (320) pharmaceutical internship hours and the NAPLEX. Dr. Harshbarger seconded the motion. The motion carried.

## Appearance

### Michael Mitchell, RT

Mr. Mitchell answered “yes” to the question that asked “Have you ever been convicted (including nolo contendere plea or guilty plea) of a felony or misdemeanor (other than a minor traffic offense) whether or not sentenced was imposed or suspended. Documentation submitted indicates the Mr. Mitchell pled guilty to DUI 1st offense on 2/7/2020 and he was arrested on 3/12/2023 for DUI 2nd offense. After discussion, Mr. Bynum made the motion to deny Mr. Mitchell’s pharmacy technician application. Dr. McKinney seconded the motion. The motion carried.

### Pilot Program

StellarRx appeared before the board for review and approval of their pilot program, TennCare Voluntary Long-Acting Reversible Contraceptives. After discussion, Mr. Bynum made the motion to approve the TennCare Voluntary Long-Acting Reversible Contraceptives Pilot Program. Dr. McKinney seconded the motion. The Board approved the pilot program for 3 years or until rules are in place, quarterly reports and inspect 10% of the automated dispensing machines. The motion carried. Dr. Phillips voted no.

### Consent Orders

Mr. Bynum made the motion to approve **Collis Campbell, Pharm D.** consent order for revocation. Dr. Campbell violated T.C.A §63-10-309 (2) Ms. Foster seconded the motion. The motion carried.

Mr. Bynum made the motion to approve **Crestwyn Health Group** consent order as amended with a \$800.00 civil penalty. Crestwyn Health Group violated board rule 1140-04-.15. Dr. Phillips seconded the motion. The motion carried.

Dr. Blane made the motion to approve **Cynthia Hudson, RT** consent order for her pharmacy technician registration to be on probation for one year with quarterly monitoring and cost for the quarterly monitoring. Ms. Hudson violated T.C.A. §63-10-309 (3). Mr. Bynum seconded the motion. The motion carried.

Mr. Bynum made the motion to approve **Catherine Pruett, RT** consent order. Ms. Pruett’s pharmacy technician registration to be on probation for one year. Ms. Pruett violated T.C.A. § 63-10-309 (5). Dr. McKinney seconded the motion. The motion carried. Dr. Blane voted no.

Mr. Bynum made the motion to approve **Robin Qualls, RT** consent order for revocation. Ms. Qualls violated board rule T. C. A §63-10-309 (1). Ms. Foster seconded the motion. The motion carried.

Mr. Bynum made the motion to approve **James Sain, D.Ph.** consent order with a licensed reprimand with a \$1000.00 civil penalty. Dr. Sain violated T.C.A. §63-10-309 (1). Dr. McKinney seconded the motion. The motion carried.

Mr. Bynum made the motion to approve **Kevin Hubbard, D.Ph.** consent order with a license reprimand with a \$1000.00 civil penalty. Dr. Hubbard violated T.C.A. §63-10-309 (3). Dr. McKinney seconded the motion. The motion carried.

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Mr. Bynum made the motion to approve **Ingles Pharmacy #85** consent order with a \$200.00 civil penalty for failure to report the change in PIC and a \$100.00 civil penalty for failure to conduct a proper controlled substance inventory during the change of PIC for a total of \$300.00. Ingles Pharmacy #85 violated T.C.A. §63-10-309 (7). Dr. Harshbarger seconded the motion. The motion carried.

Dr. Blane made the motion to reject **Rende Bechtel, D.Ph.** consent order with a licensed reprimand. Dr. Bechtel violated T.C.A. §63-10-309 (5). Dr. McKinney seconded the motion. The motion carried.

Mr. Bynum made the motion to approve **Madison Pharmacy** consent order with a \$8400.00 civil penalty for 84 expired products and \$1000.00 for failing to ensure that pharmacy records are available and retrievable when requested by the Board of Pharmacy Pharmacist Investigator. Madison Pharmacy violated T.C.A. §63-10-309 (5). Dr. Leinart seconded the motion. The motion carried.

Dr. McKinney made the motion to approve **Walter Spence, D.Ph.** consent order for suspension of license. The suspension is stayed, and license placed on 5-year probation with terms and conditions upon receipt of Tennessee Pharmacist Recovery Network contract. Dr. Spence violated T.C.A. §63-10-309 (3). Mr. Bynum seconded the motion. The motion carried.

### **Board Business**

#### **Remote Work Policy:**

Dr. Lucy Shell has asked that the Board interpret the tasks that may be performed outside of the physical pharmacy, as well as other aspects of the remote work policy. The Board can appoint a member in the place of Dr. Rodgers to take this to a committee if they are not ready to move forward with it yet. Dr. Richard Breeden volunteers to work on the remote work policy and bring the discussion back up at the January meeting. Mrs. Nichole Foster motions to appoint Dr. Richard Breeden to work with Dr. Shell and staff. Dr. Rebecca Leinart seconds the motion. All Board members were in favor of the motion, with none opposed. The motion carries.

Dr. McKinney made the motion to adjourn at 5:00 p.m. Mr. Bynum seconded the motion. The motion carried.

### **November 15, 2023**

The Tennessee Board of Pharmacy convened on Wednesday, November 15, 2023, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:01 a.m. with Dr. McCall presiding. Dr. Richard Breeden was present.

### **Contested Case**

#### **Christine Kozlowski, RT**

Ms. Kozlowski was present but not represented by legal counsel. Mr. Peters represented the State. Ms. Elizabeth Cameron was the Administrative Law Judge. Mr. Peters passed out the Notice of Charges. Ms. Kozlowski is charged with violating T. C. A. § T.C.A. §63-10-309 (4) and (6). After discussion, Dr. Breeden made the motion to revoke Ms. Kozlowski's registration and to assess case cost. Ms. Foster seconded the motion. The motion carried. Dr. Blane and Dr. Leinart voided no. Dr. Breeden made the

motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Mr. Bynum seconded the motion. The motion carried.

### **Board Business**

#### **Pellet Sterilization**

Dr. Lucy Shell brought the topic of pellet sterilization to the Board. The issue at hand with pellet sterilization is deciding whether or not compounding pharmacies are considered sterile compounders. The pharmacies prepare the product, then outsource to have the product sterilized through electric beam radiation companies. The product is then sent back to the pharmacies where it is then dispensed to patients. Dr. Marty Blane makes the interpretation that pharmacies who are outsourcing products for sterilization should hold a sterile modifier license. The investigators will work on reviewing what items they would be reviewing during these pharmacy inspections.

#### **Investigator's Report:**

Dr. Lucy Shell discussed that the Investigators will be utilizing the report differently in the future for a way that the Board will be informed of current trends in the field that will be reported to her from the Investigators.

#### **Open Discussion**

Dr. Shanea McKinney asked for a moment to recognize and acknowledge Investigator Derek Johnston for his swift action to a call that she received from a member of the community the week prior. Dr. Derek Johnston was responsive to resolve the situation in a matter of a couple hours. The actions of Investigator Johnston speak to all the Investigators and the Board would like to extend a thank you to all of the work of the Investigators.

#### **Board of Pharmacy Rules:**

Dr. Lucy Shell proposed that the Board make some decisions regarding technician rules. After much discussion, the Board had a motion by Dr. Rebecca Leinart to move forward with the technician rules regarding immunizations and point of care testing as presented. Dr. Marty Blane seconds the motion. All Board members were in favor of the motion, with none opposed. The motion carries.

The Board has decided to not move forward with the technician rules regarding technician product verification at this time. The Board has moved to take these technician rules to a rules committee. Mrs. Nichole Foster has volunteered to work with OGC for wording of technician product verification rules.

Dr. Lucy Shell also discussed that rules surrounding drug donation repository programs and charitable pharmacies can be deleted in whole from the rules of the Board, as rules will not be needed for these topics anymore due to changes in legislation. The Board agreed that these rules should move forward as being deleted in the next rules packet.

#### **Intern Rules:**

These rules have been appointed to be worked on in the rules committee.

#### **Travel:**

NABP Member Forum

- No members were available to go to the Member Forum.

TPA Winter Meeting

- Mrs. Nichole Foster made a motion that all members of the Board, or Board staff, who would like to attend TPA Winter Meeting are able to, Dr. Richard Breeden seconded the motion. All Board members were in favor of the motion, with none opposed. The motion carries.

Conference

- Dr. Lucy Shell asks for the Board to grant her permission to attend the conference if they see it fit. Dr. Marty Blane motions to allow Dr. Lucy Shell to attend the conference if she chooses to do so, Dr. Richard Breeden seconds the motion. All Board members were in favor of the motion, with none opposed. The motion carries.

**Kendall Matthew Lynch Award Nominee:**

Dr. Marty Blane motions to nominate Shelia Bush to receive the Kendall Matthew Lynch Award for 2024, Dr. Richard Breeden seconds the motion. All Board members were in favor of the motion, with none opposed. The motion carries.

**CSMD Member:**

Dr. Adam Rodgers, previous Board member, served on the CSMD database when he was a member. The committee meets twice each year in Nashville, and the Board needs to appoint a new member to the committee. Mayor Jake Bynum also serves on the committee. Dr. Marty Blane volunteered to serve on the committee. Mrs. Nichole Foster makes a motion for Dr. Marty Blane to be on the CSMD committee, Dr. Richard Breeden seconds. All Board members were in favor of the motion, with none opposed. The motion carries.

**Office of General Counsel Report:**

Mr. Gibbs informed the Board of the compounding rule changes that were proposed and adjusted by the Attorney General's office.

- The word 'board' is now capitalized throughout the rules.
- The January 1<sup>st</sup> implementation date has been deleted from the rules because the rules cannot be made retroactive.
- BUD language has been defined in the rules.
- Addition of "establishment of a quality assurance program" to the rule – likely just a formatting adjustment.
- "Applicable as highlighted" – deletion of the word 'applicable' to the rule
- More detail to be added to one of the rules regarding compounding hazardous drug products.
- Addition of "all of" to one of the rules to clarify what is required.

Mr. Gibbs informed the Board that federal law changed to grant greater portability to service member's spouses. Mr. Gibbs asked for the Board's permission to allow the department to go forward with rulemaking to recognize service members and spouses who are in this state under military orders to allow them to engage in the profession in which they hold a license. Dr. Marty Blane made the motion to move forward with the rule-making hearing, Dr. Richard Breeden seconded the motion. All Board members were in favor of the motion, with none opposed. The motion carries.

Mr. Peters presented the disciplinary report. A total of 65 cases were reviewed between July 18, 2023, and November 14, 2023.

**Dismissed:**

- 1.) Failure to allege a practice act violation - 24
- 2.) Failure to substantiate allegations – 15
- 3.) Duplicate case opened -- 1

**LOI:**

- 1.) Misfill – 1
- 2.) Practice Site Violation-- 1

**LOW:**

- 3.) Misfill – 1
- 4.) Recording Keeping/Unlicensed Activity - 1

**Civil Penalty:**

- 1.) PIC Change/CS Inventory Violation - 3
- 2.) Unregistered Technician -- 2

**Reprimand**

- 1.) Multiple Compounding/ Records Violations – 1

**Probation**

- 1.) Record Keeping/Practice Site Violations – 3

**Suspension**

- 1.) Drug Diversion/Substance Abuse – 2

**Revocation**

- 2.) Drug Diversion – 4
- 3.) Unprofessional Conduct – 1
- 4.) Unprofessional Conduct/Compounding/Records -- 2

**Further Investigation – 3**

Dr. Breedon made the motion to adjourn 12:30 p.m. Ms. Foster seconded the motion. The motion carried.

**The minutes were approved and ratified at the January 30, 2024 board meeting.**

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