

TENNESSEE BOARD OF PHARMACY  
WEBEX MEETING  
665 Mainstream Dr.  
Nashville, TN 37243

**BOARD MEMBER PRESENT**

Rissa Pryse, D. Ph President  
Katy Wright, D.Ph., Vice President  
Adam Rodgers, D.Ph.  
Melissa McCall, D.Ph.  
Richard Breeden, D.Ph.  
Dr. Shanae McKinney, D.Ph.  
Jake Bynum, Consumer Member

**STAFF PRESENT**

Reginald Dilliard, Executive Director  
Matthew Gibbs, Associate General Counsel  
Larry Hill, Pharmacy Investigator  
Rebecca Moak, Pharmacy Investigator  
Robert Shutt, Pharmacy Investigator  
Terry Grinder, Pharmacy Investigator  
Richard Hadden, Pharmacy Investigator  
Andrea Miller, Pharmacy Investigator  
Derek Johnston, Pharmacy Investigator  
Scott Denaburg, Pharmacy Investigator  
Rita Golden, Pharmacy Investigator  
Patricia Beckham, Pharmacy Investigator  
Sheila Bush, Administrator Director

The Tennessee Board of Pharmacy convened on Tuesday December 1, 2020, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present by WebEx, the meeting was called to order at 8:10 a.m. with Dr. Pryse presiding. Dr. Dilliard asked that public comments be sent via email.

Dr. Dilliard welcomed the new board members Dr. Shanae McKinney and Jake Bynum, consumer member.

**Minutes**

Dr. McCall made the motion to accept the minutes as presented. Dr. Breeden seconded the motion. A roll call vote was taken. The motion carried.

**Office of General Counsel Report**

Mr. Gibbs stated that there are currently 46 cases open for discipline within the Office of General Counsel. Of those 46 cases 9 are eligible for a contested case hearing.

Mr. Gibbs informed the board that the Tennessee Board of Pharmacy along with the Tennessee Department of Health has been named as two of the defendants contained in the master docket for the National Prescription Opiate Litigation. The Office of the Attorney General is aware of this litigation.

Mr. Gibbs informed the Board's pharmacy intern and pharmacy technician rules are currently in internal review.

### Consent Orders

Dr. McCall made the motion to accept **Daniel M. France, D.Ph.** consent order for license reprimand. Dr. France violated board rule 1140-03-.01 (1)(a). Dr. Breeden seconded the motion. A roll call vote was taken. The motion carried.

Dr. Breeden made the motion to accept **Sabrina Gilliam, R.T.** consent order. Ms. Gilliam violated §T.C.A. 63-10-305 (6) and voluntarily surrendered (same as revocation) her pharmacy technician registration. Dr. McCall seconded the motion. A roll call vote was taken. The motion carried.

Dr. Pryse made the motion to accept **Christopher Reed Helms, D.Ph.** consent order for license reprimand and case cost. Dr. Helms violated board rule 1140-01-.13 (1). Dr. Breeden seconded the motion. A roll call vote was taken. The motion carried.

Dr. McCall made the motion to accept **Kenneth L Horner, D.Ph.** consent order for license reprimand. Dr. Horner violated T.C.A § 53-11-402 (1)(3). Dr. Breeden seconded the motion. A roll call vote was taken. The motion carried.

Dr. Breeden made the motion to accept **Jessica Phipps, D.Ph.** consent order with a \$1000.00 civil penalty. Dr. Phipps violated board rule 1140-03-.01 (1)(a) & (f). Dr. McKinney seconded the motion. The roll call vote was taken. The motion carried.

Dr. Breeden made the motion to accept **Phillip R. Reed, D. Ph.** and Reed's Pharmacy, Inc. consent order for license reprimand and case cost. Dr. Reed and Reed's Pharmacy, Inc violated T.C.A § 63-10-305 (4). Dr. McCall seconded the motion. A roll call vote was taken. The motion carried.

Dr. Breeden made the motion to accept **Cindy Ann Riggs, R.T.** consent order. Ms. Riggs registration will be suspended for ninety (90) day. Upon ratification of this consent order, the suspension will be "STAYED" and Ms. Riggs license will be placed on probation for ninety (90) days. Dr. McCall seconded the motion. A roll call vote was taken. The motion carried.

Dr. McCall made the motion to accept **VGM Group, Inc., lic #5783** consent order with a \$1200.00 civil penalty. VGM Group, Inc. violated T.C.A. §63-10-305 (8). Dr. Pryse seconded the motion. A roll call vote was taken. The motion carried.

Dr. McCall made the motion to accept **Walgreens #4313, lic #3284** consent order with a \$900.00 civil penalty. Walgreens #4313, lic #3284 violated T.C.A. §63-10-305 (8). Dr. Breeden seconded the motion. A roll call vote was taken. The motion carried.

Dr. Breeden made the motion to accept **Walgreens #6256, lic #3756** consent order with a \$1000.00 civil penalty with a corrective action plan. Walgreens #6256, lic #3756 violated board rule 1140-03-.01(1)(a) & (f). Dr. Pryse seconded the motion. A roll call vote was taken. The motion carried.

Dr. McCall made the motion to accept **Wesscare Home Medical, LLC** consent order with a \$800.00 civil penalty. Wesscare Home Medical, LLC violated T.C.A § 63-10-305 (8). Dr. Breeden seconded the motion. A roll call vote was taken. The motion carried.

Dr. Breeden made the motion to accept **Daija A'Yanna Woods, R.T.** consent order. Ms. Woods violated T.C.A. § 53-10-105 (a) and voluntarily surrendered (same as revocation) her pharmacy technician registration. Dr. McCall seconded the motion. The motion carried.

Dr. Pryse made the motion to accept **Robert B Clevenger, D.Ph.** consent order with a \$4500.00 civil penalty. Dr. Clevenger violated T.C.A § 63-10-306 (a). Dr. Breeden seconded the motion. A roll call vote was taken. The motion carried.

Dr. Breeden made the motion to accept **Marley Drug, Inc** consent order. Marley Drug, Inc. violated board rule 1140-01-.08 (3)(a)(1) with a \$75,500.00 civil penalty, the license suspended for one month, the suspension “STAYED” upon ratification of this consent order and placed on probation for 2 years. Dr. McCall seconded the motion. A roll call vote was taken. The motion carried.

Dr. McCall made the motion to accept **Alexis Hall, RT** consent order. Ms. Hall violated T.C.A § 53-10-104(a) and voluntary surrender (same as revocation) her pharmacy technician registration. Dr. Breeden seconded the motion. A roll call vote was taken. The motion carried.

### **Rules**

Mr. Gibbs presented the following draft rule pertaining to medical devices. After discussion, Dr. Breeden made the motion to accept the draft rules for medical devices as presented. Dr. McCall seconded the motion. A roll call vote was taken. The motion carried.

### **Inspections of medical device manufacturers**

1. Manufacturers and distributors of a medical device shall submit either:

- (a) A Form 482 issued by the United States Food and Drug Administration (“FDA”) as evidence of a facility inspection, and, if applicable, a response letter, as documented on a Form 483, from the FDA indicating the firm’s responses to the most recent inspection findings appear to be acceptable and no further action is warranted by the firm or FDA; or
- (b) Documented evidence, such as International Organization for Standardization (ISO) 13485 certification number, date of visit and expiration date of certificate, from a Notified Body that the firm is in good standing and their ISO 13485 certification is valid. Response may include dates of Phase 1 and Phase 2 assessments from a Notified Body/Registrar in the certification process; or
- (c) Evidence of successful Medical Device Single Audit Program certification. Alternatively, a report including corrective action plans for Medical Device Single Audit Program certification and approval.

between December 1 and December 31 of each calendar year. Submission of a documents referenced in 1(a) – (c), which demonstrates immediate and continuous compliance with any and all federal laws and regulations, shall serve in lieu of a physical, on-site inspection conducted by the Board, subject to paragraph 3, below.

2. Failure to submit documents referenced in 1(a) – (c) or submission of a self-audit which does not demonstrate immediate and continuous federal compliance may result in a request from the Board for the production of any and all corresponding documents related to any mandatory reporting or compliance requirements directed by the federal government or its agencies or the International Standards Organization.

3. Notwithstanding any rule provision to the contrary, the Board retains authority to conduct any inspection or investigation when, in the Board’s sole determination, public health, safety, and welfare necessitates such an inspection or investigation.

## **Financial Report**

Alicia Grise, Fiscal Director, presented the year end the financial report to the board.

Dr. Wright left the meeting.

## **Waivers**

### **Board rule 1140-01-.07(3)**

Dr. Breeden made the motion to approve the request from Joel Daniel, Pharm. D., to waive the one hundred and sixty (160) internship hours but he must successfully take and pass the MPJE. Dr. McCall seconded the motion. A roll call vote was taken. The motion carried

### **Board rule 1140-05-.01**

Dr. Breeden made the motion to approve the request from Candice Burtner, Pharm. D., to accept continuing education hours from Institute of Functional Medicine for the continuing education audit. Mr. Bynum seconded the motion. A roll call vote was taken. Dr. McKinney voted no. The motion carried.

Dr. Rodgers logged into the meeting and Dr. Wright returned at 9:40 a.m.

### **Board rule 1140-01-.13 (d) & (e)**

Dr. Wright made the motion to approve the request from Vanderbilt Oral Surgery Clinic to waive the requirement for the pharmacy to have hot and cold running water and to be 180 square feet. Dr. McKinney seconded the motion. The motion carried.

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

Dr. McKinney made the motion to approve the request from Joyce Broyles, Pharm.D. to be PIC at Methodist Healthcare-Central, 1265 Union Ave, Memphis, TN and Alliance Health Services, Inc., Methodist Hospice Residence B, 6416 Quince Rd, Memphis, TN 38119 for six (6) months. Dr. McCall seconded the motion. A roll call vote was taken. The motion carried.

## **General Discussion**

Dr. Dilliard presented the Food and Drug Administration (FDA) Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State Board of Pharmacy or Other Appropriate State Agency and the Food and Drug Administration (MOU) to the board. After discussion, the board decided to move this discussion to the January 26-27, 2021 board meeting.

Dr. Dilliard presented the Health and Human Services (HHS) Guidance and Declarations concerning COVID19 and Vaccinations. After discussion, Dr. Wright made the motion to support the guidelines issued by HHS. The Investigators, upon inspections, will check for the certifications completed by pharmacy technician who are administering the vaccines. Dr. McCall seconded the motion. A roll call vote was taken. The motion carried.

Dr. Dilliard presented a request from Dr. Phipps for clarification concerning board rule 1140-14-.08 which states “Discontinued, outdated, defective, or deteriorated drugs, devices, or related materials and containers with worn, illegible, or missing labels shall be returned to the pharmacy practice site for proper disposition. All such drugs, devices or related materials returned to the pharmacy practice site must be destroyed unless in unit does packaging, unopened commercially prepackaged containers and in the professional judgement of the pharmacist in charge or designee, the medications or related materials meet all federal and state board standards for product integrity” and cross contamination. After discussion, Dr. Breeden made the motion that in conjunction with this rule that the board does not considered multidose packaging to meet all the board’s standards and integrity to be returned to the pharmacy. Dr. McCall seconded the motion. A roll call vote was taken. The motion carried.

Dr. Dilliard informed the board that T.C.A. §63-1-160 concerning E-Prescribing of Schedule II, III, IV or V controlled substances goes into effect on January 1, 2021. An application for the waiver of this statute is on the board’s website and will be maintained by the Controlled Substance Monitoring Database.

Dr. Breeden made the motion to adjourn at 11:30 a.m. Dr. McCall seconded the motion. The motion carried.

### **December 2, 2020**

The Tennessee Board of Pharmacy reconvened on Wednesday December 2, 2020, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present by WebEx, the meeting was called to order at 8:00 a.m. with Dr. Pryse presiding.

Dr. McKinney left the meeting at 9:00 a.m.

#### **Contested Cases**

##### **Alex Owen, RT**

Mr. Owen was not present nor represented by legal counsel. Mr. Gibbs represented the State. Ms. Mary Collier was the Administrative Law Judge. Mr. Gibbs asked to proceed in default. After discussion, Dr. Wright made the motion to proceed by default. Dr. McCall seconded the motion. A roll call vote was taken. Mr. Gibbs passed out the Notice of Charges. After discussion, Dr. Rodgers made the motion to revoke Mr. Owens’ registration as a pharmacy technician and assess case cost. Dr. McCall seconded the motion. A roll call vote was taken. The motion carried. Dr. Wright made motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. McCall seconded the motion. A roll call vote was taken. The motion carried.

##### **Brittany Pugh, RT**

Ms. Pugh was not present nor represented by legal counsel. Ms. Mary Collier was the Administrative Law Judge. Mrs. Hughes-Toombs asked to proceed in default. After discussion, Dr. Breeden made the motion to proceed by default. Dr. Wright second the motion. A roll call vote was taken. The motion carried. Mrs. Hughes-Toombs passed out the Notice of Charges. After discussion, Dr. Breeden made the motion to revoke Ms. Pugh's registration as a pharmacy technician and assess case cost. Dr. McCall seconded the motion. A roll call vote was taken. The motion carried. Dr. Rodgers made motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. McCall seconded the motion. A roll call vote was taken. The motion carried.

### **Consent Orders**

Dr. Wright made the motion to accept **Morris Haddox, II, D.Ph.** consent order with a \$250.00 civil penalty. Dr. Haddox violated board rule 1140-01-.07 (3)(a). Dr. Breeden seconded the motion. A roll call vote was taken. The motion carried.

Dr. Rodgers made the motion to adjourn at 10:33 a.m. Dr. Breeden seconded the motion. The motion carried.

**The minutes were approved at the January 26, 2021 board meeting as presented.**