

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

BOARD MEMBER PRESENT

R. Michael Dickenson, D.Ph., President
Debra Wilson, D.Ph., Vice President
Katy Wright, D. Ph.
Adam Rodgers, D.Ph.
Rissa Pryse, D.Ph.
Melissa McCall, D.Ph.
Lisa Tittle, Consumer Member

STAFF PRESENT

Reginald Dilliard, Executive Director
Matthew Gibbs, Associate General Counsel
Richard Hadden, Pharmacy Investigator
Rebecca Moak, Pharmacy Investigator
Robert Shutt, Pharmacy Investigator
Terry Grinder, 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

STAFF ABSENT

Albert Hill, Pharmacy Investigator

The Tennessee Board of Pharmacy convened on Tuesday, January 8, 2019, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 8:02 a.m.

Elections

Dr. Dickenson thanked the Board and the Board staff for the cooperation and help during his leadership as president. Dr. Pryse made the motion to nominate Dr. Wilson as president. Ms. Tittle seconded the motion. The motion carried. Dr. Wright made the motion to nominate Dr. Pryse as vice president. Dr. Rodgers seconded the motion. The motion carried.

Minutes

Dr. Dickenson made the motion to accept the minutes from the December 3, 2018 board meeting as presented. Dr. Pryse seconded the motion carried.

Office of General Counsel Report

Mr. Gibbs stated that there are currently 56 cases open for discipline within the Office of General Counsel. Of those 56 cases, 4 are eligible for a contested 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.

Complaint Summary

1.

A joint DEA/BOP inspection and audit revealed controlled substance discrepancies. Results and educational suggestions were given and a follow-up audit was conducted, however the follow-up audit also showed discrepancies and most of the suggestions had not been followed. The pharmacy's DEA certificate was surrendered and the pharmacy has voluntarily closed.

Recommend: Accept voluntary retirement of pharmacy license

Dr. Dickenson made the motion **to accept counsel's recommendation**. Dr. Rodgers seconded the motion. The motion carried.

2.

BOP Investigator verified allegations that the respondent pharmacy did not have a PIC between 7/1/18 and 7/15/18 and that the required CS inventory was not taken until 7/31/18.

Recommend: Civil penalty

Dr. Dickenson made the motion to **authorize a formal hearing** with a \$1000.00 civil penalty stayed with a \$250.00 civil penalty and an acceptable plane of correction. A Letter of Instruction issued concerning the controlled substance inventory. Dr. Rodgers seconded the motion. The motion carried.

3.

During a periodic inspection 9/26/18, BOP Investigator discovered respondent Oxygen supplier's license had expired 1/31/18. Respondent was instructed to renew. An application was received on 10/5/18.

Recommend: Civil penalty \$900 for operating on an expired license.

Dr. Rodgers made the motion to **authorize a formal hearing** with a \$900.00 civil penalty for operating on an expired license. Dr. Dickenson seconded the motion. The motion carried.

4.

Complaint alleged a misfill resulted in an adverse reaction. BOP Investigator interviewed pharmacy staff and reviewed dispensing records. Investigator discovered that the patient had previously been dispensed one company's generic but it had become unavailable. Another company's generic was dispensed which the patient did not tolerate, so a third company's generic was ordered and the patient has been able to tolerate it. A misfill could not be substantiated. It appears to have been a reaction to a particular company's generic.

Recommend: Dismiss

Dr. Dickenson made the motion to **accept counsel's recommendation**. Ms. Tittle seconded the motion. The motion carried.

5.

Physician complained that respondent pharmacist refused to fill a patient's medication early even though the prescriber authorized an early refill because the patient was "going out of town." Complainant also alleged the respondent is antagonistic and has a bias against patients receiving addiction treatment services.

BOP Investigator interviewed the respondent and reviewed dispensing records and documentation. According to a sworn statement, when the respondent asked the prescriber for a reason for authorizing the early fill, the respondent stated the prescriber indicated she thought the patient was going out of town. When asked if the prescriber knew where, the prescriber became irate and said it should not matter. When the patient arrived, the pharmacist asked and the patient said the trip was to a state park approximately 20 miles away. After explaining to the patient that the medication could be picked up at a pharmacy closer to the state park, the patient opted to return to the respondent's pharmacy two days later.

Recommend: Dismiss

Dr. Dickenson made the motion to **accept counsel's recommendation**. Dr. Rodgers seconded the motion. The motion carried.

6.

Complaint was referred to BOP from a BME case alleging a patient received an incorrect medication due to a prescription generated and sent to the pharmacy by an office manager of the prescriber. The referral (from BIV) asks whether a pharmacist should have questioned the prescription rather than dispensing the prescription as written.

BOP Investigator conducted a thorough investigation and also reviewed the case file provided by BIV. Although the prescriber charted Clomiphene, the electronic prescription received by the pharmacy was clearly for Clomipramine. The prescription does list an associated diagnosis of azoospermia for the male patient. The pharmacist did not question the prescription for Clomipramine since it can be used to help with conditions such as PE in males. The incorrect medication order was sent to the pharmacy electronically and was dispensed as written. There does not appear to be a violation on the part of the pharmacy.

Recommend: Dismiss

Dr. Dickenson made the motion to **accept counsel's recommendation**. Dr. Wright seconded the motion. The motion carried.

7.

Complaint alleged the respondent pharmacist refused to transfer prescriptions for two patients because the patients owed the respondent money.

BOP Investigator interviewed the respondent and his pharmacy staff. Investigator was told the patients do owe money to the pharmacy but there is no policy to hold a transfer due to money being owed. Staff told the Investigator that one patient only wanted to transfer because of a preferred generic medication but cancelled the request when the respondent's pharmacy received the brand wanted. The patient confirmed that. Investigator was told the other patient never wanted to transfer, but a family member had made the request. That patient has moved out of the family member's home and preferred to stay with the respondent pharmacy.

Recommend:

Dr. Pryse made the motion to **dismiss** the complaint. Dr. Rodgers seconded the motion. The motion carried.

8.

BOP office was notified that the respondent technician was terminated for drinking an alcoholic beverage on lunch break, which violated company policy.

BOP Investigator obtained documentation and sworn statements. The allegation was proven. The respondent stated she was not on duty in the pharmacy that day, but was attending a training class in the back of the store building. Respondent stated she was unsure about company policy and admitted she made a poor choice. She stated she only had one bottle of beer with lunch but did post a picture on Snapchat showing the beer.

Recommend: LOW

Dr. Wright made the motion to issue a **Letter of Warning** to the pharmacy technician. Ms. Tittle seconded the motion. The motion carried.

9.

BOP office was notified that the respondent technician was terminated for drinking an alcoholic beverage on lunch break, which violated company policy.

BOP Investigator obtained documentation and sworn statements. The allegation was proven. The respondent stated he was not on duty in the pharmacy that day, but was attending a training class in the back of the store building. Respondent stated he is willing to take any consequence and admitted he made a big mistake.

Recommend: LOW

Dr. Wright made the motion to issue a **Letter of Warning** to the pharmacy technician. Ms. Tittle seconded the motion. The motion carried.

10.

Complainant (a Nurse Anesthetist) alleged the respondent pharmacist refused to fill a self-prescribed, non-controlled maintenance medication (Duloxetine) the complainant had written because he was going out of town and did not have enough time to visit the doctor for a new prescription. The respondent allegedly called the complainant's office to verify the prescription, which ultimately caused complainant's employer to question the prescription. Complainant also alleges the Respondent counseled the complainant in front of other patrons that it was illegal to self-prescribe.

BOP Investigator interviewed the respondent pharmacist who admitted the fill was denied; a call was made to verify the prescriber and the patient were the same person; no mention of the drug name or drug schedule was mentioned during the call by the pharmacist; the prescription was written for 5 refills; and the denial to fill discussion was held at the counseling window away from customers. No violation by the pharmacist could be found.

Recommend: Dismiss

Dr. Wright made the motion to **accept counsel's recommendation** and to refer to the Board of Nursing. Ms. Tittle seconded the motion. The motion carried.

11.

Respondent pharmacist received two DUI's within a short time in 2016 due to emotional upheaval that occurred during divorce. The last case was not resolved until April 30, 2018. An explanation of the delay was requested by BOP staff. A complaint was opened and BOP Investigator assigned to research and obtain statements. Respondent completed court required classes, jail time and probation with no problems. Respondent has no reported problems at work and stated he only drank after work. Respondent has sought and obtained help from professional counselors for his health.

Recommend:

Dr. Wright made the motion to dismiss the complaint. Dr. Dickenson seconded the motion. After discussion, Dr. Wright withdrew her motion. Dr. Dickenson made the motion to issue a **Letter of Instruction** to the pharmacist. Dr. Rodgers seconded the motion. The motion carried.

12.

Complaint alleged the respondent pharmacy did not perform a proper DUR and possibly did not check CSMD before filling pain prescriptions for a patient. BOP Investigator reviewed records and interviewed staff. The patient was an employee of a dental clinic with access to the prescription printing process and appears to have created prescriptions for oxycodone 30mg.

Four prescriptions were presented to this pharmacy by the patient during the months of May and June of 2018. Each prescription appeared to meet all legal criteria including the use of tamper-resistant paper. The first two prescriptions were dispensed as written. The CSMD of TN and other states was utilized in determining whether to fill any of the four prescriptions.

The third prescription caused the dispensing pharmacist to write patient notes into the pharmacy's computer software (e.g. early fill request; high strength; high quantity for a dentist's office; need for verification). A female, claiming to be employed by the dentist's office, called the pharmacy and requested for the medication to be filled.

The fourth prescription was denied.

Recommend:

Dr. Dickenson made the motion to issue a **Letter of Warning** to the pharmacy. Dr. Wright seconded the motion. The motion carried.

13.

Two prescriptions were presented to this pharmacy by the same patient, referenced above, in June and July of 2018. The pharmacist at this location has the ability to see patient notes entered by the pharmacist from case 12.

On June 29, 2018, the pharmacist filled a prescription for oxycodone 30mg #180. The TN CSMD was checked; however, it does not appear the patient notes were referenced. After speaking with the patient the pharmacist decided to fill the prescription. The prescription was presented between 2 A.M. and 3 A.M.

About 30 days later, the same patient presented another prescription for oxycodone to the same pharmacist at the same pharmacy around the same time of day. This time the pharmacist utilized both the TN and VA CSMD and attempted to verify the telephone number on the prescription. The pharmacist discovered the phone number listed on the prescription was not the same as the phone number listed on the website for the prescriber's office. The pharmacist denied this prescription.

Recommend:

Dr. McCall made the motion to issue a **Letter of Warning** to the pharmacy. Dr. Pryse seconded the motion. The motion carried.

14.

BOP Investigator accompanied FDA on an inspection at a pharmacy that performs non-sterile compounding. Investigator discovered 198 expired Active Pharmaceutical Ingredients (API's) co-mingled with in-date product. At least five instances were found where expired product had been used to prepare compounds that were then dispensed. Two instances of compounding hazardous drugs without containment, segregation, cleaning of work areas or protection of personnel were found. One instance of compounding and dispensing a non-approved drug was found. The pharmacy was not placing an expiration date on the dispensing labels of compounded products. There were no formula worksheets, batch records or SOP.

Pharmacy owners provided a letter that all non-sterile compounding would stop immediately. Proof was provided that all chemicals have been returned to a reverse distributor.

Recommend: Reprimand, civil penalty \$1,980, plus costs.

Dr. Dickenson made the motion to **authorize a formal hearing** with a \$1980.00 civil penalty, a license reprimand and case cost to the pharmacy. Dr. Pryse seconded the motion. The motion carried.

15.

Complaint alleged the respondent pharmacy employees were rude; they were working unsupervised without a pharmacist; prescriptions were not ready when promised; and that the pharmacy was "a disaster waiting to happen" by being extremely busy and understaffed.

BOP Investigator interviewed staff and reviewed prescriptions and staffing reports. Pharmacy staff disputed the allegations. The prescriptions involved were ready as promised even though the prescriber had to be called for legibility issues. The prescriptions were not picked up until about two hours later. Staffing reports showed a pharmacist was on duty and a second pharmacist arrived shortly afterward. Investigator observed workflow and employee workload and did not see any workload issues. When asked, the pharmacist stated the opinion that there were no workload issues at this location. None of the allegations could be substantiated.

Recommend: Dismiss

Dr. Dickenson made the motion to **dismiss the complaint**. Dr. Pryse seconded the motion. The motion carried.

16.

Complaint alleged a misfill.

BOP Investigator confirmed the misfill. A 90 day supply of maintenance medication was dispensed in three separate manufacturer's bottles of 30 tablets each. A dispensing label was placed over the manufacturer label on each bottle. It was confirmed that one of the bottles was actually a different drug. When the pharmacist was made aware of the misfill, the correct medication was dispensed, the prescriber was contacted, a gift card and apology were given by pharmacy staff and a plan of correction was issued indicating a renewed emphasis on scan and visual verification to the pharmacy staff. Investigator could not determine if workload issues may have contributed to the misfill.

Recommend:

Dr. Pryse made the motion to issue a **Letter of Warning** to the pharmacy concerning putting labels on each bottle 90 day prescription. Dr. Wright seconded the motion. The motion carried.

17.

Respondent is the dispensing pharmacist and the PIC for Case 16 above.

Recommend: LOW for misfill

Dr. Pryse made the motion to issue a **Letter of Warning** for the misfill. Ms. Tittle seconded the motion. The motion carried.

18.

Respondent is currently PIC for Case 16 above but was not PIC at the time of the incident.

Recommend: Dismiss

Dr. Dickenson made the motion to **accept counsel's recommendation**. Dr. Wright seconded the motion. The motion carried.

19.

An unsatisfactory inspection report with numerous notations was issued to the respondent pharmacy. Those issues included: CS invoices not always signed and dated as required; several C2 invoices were not separate from other invoices; C2 orders not correctly entered as received and closed; verbal orders not initialed; change of PIC CS inventory not in compliance with DEA requirements; large overstocks of non-controlled inventory. BOP Investigators attempted to conduct an audit of random CS, however it could not be completed because of the invalid starting inventory and unreliable computer reports from the pharmacy's system. Investigators questioned if counseling was being performed correctly and educated staff about requirements. Investigators also educated PIC on all the above violations and told PIC that a follow-up inspection, including another audit attempt, would be performed in 30 to 60 days to see if deficiencies had been corrected.

When Investigators returned for the follow-up, very little had changed and Investigators perceived a lack of a sense of urgency by the PIC. Investigators were told by PIC that she had decided to wait because their annual inventory of the store would occur later in the year and thought it would be easier to do a CS inventory at that time instead of the time period Investigators had requested.

Recommend: LOW to the pharmacy with follow-up inspection and audit by BOP Investigators in 30 days.

Dr. Dickenson made the motion to **authorize a formal hearing** to Reprimand the license. Ms. Tittle seconded the motion. After discussion, Dr. Dickenson amended the motion to assess case cost. Ms. Tittle seconded the amended motion. The motion carried.

20.

Respondent is PIC for Case 19 above.

Recommend: LOW with requested plan of correction; follow-up by BOP within 30 days of POC.

Dr. Dickenson made the motion to **authorize a formal hearing** to Reprimand the license and to assess case cost. Dr. Rodgers seconded the motion. The motion carried.

21.

BOP Investigator discovered the respondent had a conviction that was not reported to BOP. Respondent apologized and stated he received probation and was ordered to attend anger management classes then the case would be expunged.

Investigator also discovered the respondent has been administering injectable drugs based upon a standing order to administer vaccines but without a collaborative practice agreement for other drugs.

Recommend:

Dr. Dickenson made the motion to **authorize a formal hearing** with a \$1000.00 civil penalty stayed with a \$500.00 civil penalty with proof of an updated collaborative practice agreement and a Letter of Warning. After discussion, Dr. Dickenson withdrew the motion. After further discussion, Dr. Wright made the motion issue a **Letter of Warning** for reporting convictions in a timely manner. Dr. Rodgers seconded the motion. The motion carried.

Waiver

Board rule 1140-01-.13(3) (d)

Dr. Dickenson made the motion to approve the request from **TopRx** to waive the requirement for the pharmacy to be 180 square feet. TopRx will be 130 square feet. Dr. Pryse seconded the motion. The motion carried.

Board rule 1140-01-.03 (6)

Dr. Dickenson made the motion to approve the request from **Raju Bashar, Pharm. D.** to grant an extension of the 90 days requirement from NABP for score transfer. Dr. Pryse seconded the motion. The motion carried.

Consent Orders

Dr. Wright made the motion to accept the consent orders as presented. Dr. Dickenson seconded the motion. The motion carried.

SUSPENDED

Anna Mackenzie Vanbenschoten, D.Ph.

VIOLATED T.C.A. 63-10-305 (4)

Christopher D. Gilbert, D.Ph.

VOLUNTARILY SURRENDERED (same as revocation)

Kimberly Freeman, RT

Director's Report

Dr. Dilliard asked the board to authorize travel for the Tennessee Pharmacist Association (TPA) Winter Meeting scheduled for February 23-26, 2019 at the Doubletree Hotel, Nashville, TN. Dr. Pryse made the motion to authorize travel for the Tennessee Pharmacist Association Winter Meeting for board members, the executive director and pharmacy investigators. Ms. Tittle seconded the motion. The motion carried.

Dr. Dilliard asked the board to authorize travel for the National Association of Boards of Pharmacy (NABP) Annual Meeting scheduled for May 16-18, 2019 in Minneapolis, MN. Dr. Wright made the motion to authorize travel for the National Association of Boards of Pharmacy Annual Meeting for the executive director and board members. Dr. Pryse seconded the motion. The motion carried. Dr. Dickenson made the motion to nominated Dr. McCall to be the board's delegated. Dr. Rodgers seconded the motion. The motion carried.

Dr. Dilliard informed the board of the pharmacy updates and asked the board to consider attending as well. The pharmacy updates are scheduled for the following dates and locations: January 27, 2019, Franklin, TN; February 9, 2019 Kingsport, TN; March 3, 2019, Memphis, TN; March 16, 2019, Chattanooga, TN; March 30, 2019, Cookeville, TN; April 6, 2019, Murfreesboro, TN and April 13, 2019, Knoxville, TN.

Dr. Dilliard asked the board to authorize travel to attend the NABP multistate pharmacy jurisprudence exam (MPJE) item writing workshop scheduled for March 13-14, 2019. Dr. Wright made the motion to authorize travel to the NABP multistate pharmacy jurisprudence exam (MPJE) item writing workshop. Dr. Pryse seconded the motion.

Dr. Baeteena Black, Director of Tennessee Pharmacist Recovery Network, invited the board to the Tennessee Pharmacist Recovery Network retreat on March 1-3, 2019 in Maryville, TN.

Rules

Dr. Dilliard asked the board to discuss rules changes. After discussion, the board decided to appoint Dr. Dickenson, Dr. Dilliard and Mr. Gibbs to draft the new/amended rules and present to the board.

January 9, 2019

The Tennessee Board of Pharmacy reconvened on Wednesday, January 31, 2018 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members were present, the meeting was called to order at 8:00 a.m., by Dr. Wilson, president.

Contested Cases

Vanessa Thigpen, RT

Ms. Thigpen was not present nor represented by legal counsel. Mr. Gibbs represented the State. Mr. Shannon Barnhill was the Administrative Law Judge. Mr. Gibbs asked to proceed in default. Dr. Dickenson made the motion to proceed in default. Ms. Tittle seconded the motion. The motion carried. Mr. Gibbs passed out the Notice of Charges. Ms. Thigpen is charged with violating T.C.A. 53-10-104 (a) and (b) and T.C.A. §53-10-105 (a). After discussion, Dr. Dickenson made the motion to revoke Ms. Thigpen registration as a pharmacy technician. Dr. Pryse seconded the motion. After further discussion, Dr. Dickenson amended his motion to add case cost. Dr. McCall seconded the amended motion. The amended motion carried. Ms. Tittle made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Pryse seconded the motion. The motion carried.

Geleeya Callicutt, RT

Ms. Callicutt was not present nor represented by legal counsel. Mr. Gibbs represented the State. Mr. Shannon Barnhill was the Administrative Law Judge. Mr. Gibbs asked to proceed in default. Dr. Dickenson made the motion to proceed in default. Dr. Rodgers seconded the motion. The motion carried. Mr. Gibbs passed out the Notice of Charges. Ms. Callicutt is charged with violating T.C.A. 53-10-104 (a) and (b) and T.C.A. §53-10-105 (a). After discussion, Dr. Pryse made the motion to revoke Ms. Callicutt registration as a pharmacy technician and assess case cost. Dr. Dickenson seconded the motion. The motion carried. Ms. Tittle made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. McCall seconded the motion. The motion carried.

Alice Jane Hernandez, RT

Ms. Hernandez was not present nor represented by legal counsel. Mr. Gibbs represented the State. Mr. Shannon Barnhill was the Administrative Law Judge. Mr. Gibbs asked to proceed in default. Dr. Wright made the motion to proceed in default. Dr. Dickenson seconded the motion. The motion carried. Mr. Gibbs passed out the Notice of Charges. Ms. Hernandez is charged with violating T.C.A. 53-10-104 (a) and (b) and T.C.A. §53-10-105 (a). After discussion, Dr. Wright made the motion to revoke Ms. Hernandez registration as a pharmacy technician and assess case cost. Dr. Dickenson seconded the motion. The motion carried. Dr. Dickenson made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Rogers seconded the motion. The motion carried.

Danyelle Caprecia Luster, RT

Ms. Luster was not present nor represented by legal counsel. Mr. Gibbs represented the State. Mr. Shannon Barnhill was the Administrative Law Judge. Mr. Gibbs asked to proceed in default. Dr. McCall made the motion to proceed in default. Ms. Tittle seconded the motion. The motion carried. Mr. Gibbs passed out the Notice of Charges. Ms. Luster is charged with violating T.C.A. 53-10-104 (a) and (b) and T.C.A. §53-10-105 (a). After discussion, Dr. Dickenson made the motion to revoke Ms. Luster registration as a pharmacy technician and assess case cost. Ms. Tittle seconded the motion. The motion carried. Ms. Tittle made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. McCall seconded the motion. The motion carried.

Evan McKenzie, RT

Mr. McKenzie was not present nor represented by legal counsel. Mr. Gibbs represented the State. Mr. Shannon Barnhill was the Administrative Law Judge. Mr. Gibbs asked to proceed in default. Ms. Tittle made the motion to proceed in default. Dr. Dickenson seconded the motion. The motion carried. Mr. Gibbs passed out the Notice of Charges. Mr. McKenzie is charged with violating T.C.A. 53-11-402 (a) (3) and T.C.A. §63-10-305 (4). After discussion, Dr. Dickenson made the motion to revoke Mr. McKenzie registration as a pharmacy technician and assess case cost. Ms. Tittle seconded the motion. The motion carried. Dr. Pryse made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Wright seconded the motion. The motion carried.

Dr. Dickenson made the motion to adjourn at 11:00 a.m... Dr. Wright seconded the motion. The motion carried.

The minutes were approved and ratified at the March 12, 2019 board meeting.