TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Iris Room
Nashville, TN
November 14-15, 2017

BOARD MEMBER PRESENT
Kevin Eidson, D.Ph., President
R. Michael Dickenson, D.Ph., Vice President
Debra Wilson, D. Ph.
Katy Wright, D. Ph.
Adam Rodgers, D.Ph.
Lisa Tittle, Consumer Member

STAFF PRESENT
Reginald Dilliard, Executive Director
Matthew Gibbs, Associate General Counsel
Terry Grinder, Pharmacy Investigator
Richard Hadden, Pharmacy Investigator
Scott Denaburg, Pharmacy Investigator
Rebecca Moak, Pharmacy Investigator
Robert Shutt, Pharmacy Investigator
Andrea Miller, Pharmacy Investigator
Albert Hill, Pharmacy Investigator
Tommy Chrisp, Pharmacy Investigator
Sheila Bush, Administrative Director

BOARD MEMBER ABSENT
Rissa Pryse, D.Ph.

The Tennessee Board of Pharmacy convened on Tuesday, November 14, 2017, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:00 a.m.

Minutes

The minutes from the September 12-13, 2017 board meeting were presented. After discussion, Dr. Dickenson made the motion to approve the minutes as amended. Dr. Wright seconded the motion. The motion carried.

Financial Report

Noranda French, Administrative Assistant 5, gave the board the year-end financial report for fiscal year 2017.

OGC Report

Mr. Gibbs informed the board that there are 50 cases in the Office of General Counsel with 15 of those cases being contested. Mr. Gibbs stated that a rulemaking hearing for hormonal contraceptives and drug depository has been scheduled for the January 30, 2018 board meeting. Rules that pertain to 3PL are in external review.

Mr. Gibbs also informed the board that they are in sunset review and the recommendation is to renew the board for 5 years.

Complaint Summary

Case 1.

Respondent allegedly assaulted an elderly man in February for protesting on the sidewalk and displaying racist material. The victim was allegedly forced out into traffic, placing him in danger of death or serious bodily injury. Respondent was charged with assault and civil rights intimidation. BOP was not aware of this incident until a District Attorney contacted the Board office on 6/19/17. The case was finally settled 8/11/17 when respondent pled guilty to misdemeanor assault and civil rights intimidation. On 8/25/17, a companion case was opened for respondent not notifying BOP within 10 days of a conviction. Dr. Dilliard was contacted by respondent on 10/30/17 and provided a copy of court records, a copy of the plea agreement, and a typed letter apologizing for the behavior and failure to report.

Recommend:

Dr. Wilson made the motion to authorize a formal hearing with probation until the criminal probation has been cleared. Dr. Dickenson seconded the motion. The motion carried.

Case 2.

This is the companion case to Case 1 above for failure to notify BOP of a conviction as required in 1140-02-.01 (17). During the investigation, it was also discovered respondent had failed to report a change of address as required in 1140-02-.01 (15) and has not updated the Practitioner Profile Data since 2014.

Recommend:

Dr. Wright made the motion to issue a **Letter of Instruction** for failure to report a change of address as required. Dr. Dickenson seconded the motion. The motion carried.

Case 3.

Complainant (patient's father) alleged difficulty in obtaining medication from respondent (specialty pharmacy) in a timely manner, resulting in a missed dose. It was also alleged that respondent pharmacy did not update the status of when the medication would be shipped.

BOP Investigator obtained a response and timeline from the respondent:

1/4/17, complainant contacted the pharmacy and was told the plan benefit required a prior approval. Complainant indicated the next dose was due 1/8/17.

1/4/17, an approval was given and a verbal prescription was received by the pharmacy. Complainant was on the same call and was told by a pharmacy representative that it would take one to two business days to process the prescription then he would be contacted to set up delivery. The call was escalated and an assistance program to help with copay was set up during the same call.

1/5/17 to 1/10/17, PIC indicated that all calls from the complainant were received and a status was communicated for each call. PIC also indicated that the 1/8/17 deadline could not be met but shipment did take place within 5 days of receiving the prescription.

1/10/17, a 3 month supply was shipped.

1/11/17, the order was delivered.

Refill authorization was received in March and the complainant enrolled in a program that uses enhanced communications such as text messaging.

Investigator sent a request via e-mail to the complainant for further information in April, but never received a response.

Recommend: Dismiss

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

Case 4.

Complaint alleged the respondent specialty pharmacy dispensed only a 15 days' supply "for months" even though the prescription was written for a 30 day supply. According to the complaint, 3 refills were cancelled by the pharmacy forcing the patient to obtain an emergency supply. It also alleged a pharmacy representative told the patient's caregiver the pharmacy system had a "glitch."

BOP Investigator obtained a response from the PIC of respondent pharmacy. According to the PIC, the patient's insurance plan changed in October, 2016. The following timeline was provided:

10/7/16: Patient's mother and the prescriber were notified that the new plan required a P/A. The prescriber was contacted 5 times between 10/10/16 and 10/31/16.

10/18/16: The insurance company was called and a 15 day supply was approved until the prescriber could complete the P/A.

10/19/16: The 15 day supply was delivered.

11/3/16: P/A was approved for 10/18/16 to 10/18/17 for 15 days per fill.

12/14/16: Patient's mother requested a 30 day supply instead of 15. Pharmacy submitted a claim for 30 day supply which was denied because the plan pays for 15 days' supply. The order was placed on hold pending approval from the plan.

12/21/16: Pharmacy contacted the plan for an update on the approval and referred the mother to a manufacturer's assistance program to obtain medication until the P/A for 30 days could be approved.

1/17/17: Pharmacy delivered a 30 day supply.

PIC denied a "glitch" in their system but felt it was the plan requirement of only allowing 15 days per fill.

No violations were found during the investigation.

Recommend: Dismiss

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

Case 5.

Complaint alleged respondent pharmacy is likely engaged in unlawful compounding which may put patients at risk. The complaint references an FDA Warning letter "noting significant violations," and also references observations of unsanitary conditions and failure to have valid prescriptions for individually-

identified patients for the drugs produced. Furthermore, the complaint alleged the respondent pharmacy is compounding a copy of a commercially available drug product (testosterone pellets.)

BOP Investigators conducted an intensive and time-consuming investigation in order to thoroughly research potential violations and threats to public health and safety. Investigators compiled a large amount of documentation, conducted several interviews, and obtained sworn statements.

Investigators compiled the following summary of findings:

An FDA inspection occurred in May, 2015 and resulted in a Form 483 being issued with 13 observations. The pharmacy responded appropriately and made the necessary changes to meet USP 797 requirements in 2015.

Respondent pharmacy did fill a total of 3 prescriptions for testosterone 75mg plus methyl cobalamin 1mg pellets for 2 different patients where the physician prescribed and expected the product to be a generic for *Testopel*, testosterone pellets. The medications were described as being prescribed because the cost was lower, not because of any documented medical reason. Pharmacy staff statements that prescribers knew what the pharmacy's products contained and therefore the pharmacy did not need to document it were found to be false. This falls under TCA 53-1-109 (9) (B), being sold as an imitation of another drug. The prescriptions were misfilled by substituting the combination product for the plain testosterone pellets.

(Per correspondence on June 26, 2017, respondent pharmacy will no longer fill testosterone 75mg plus methyl cobalamin 1mg pellets for male patients.)

Respondent pharmacy also compounds a testosterone 80 mg pellet and a testosterone 87.5 mg pellet. None were dispensed for male patients.

Investigators discovered the respondent pharmacy was scanning prescriptions then shredding the hard copies, except C3 through C5 prescriptions filled for Alabama patients. That issue was corrected March 8, 2017 upon recommendation by Investigators.

A review of compounding logs found that pharmacy staff failed to notate the following on the Logged Formula Worksheet:

1. Has each container been labeled (including auxiliary label)

2. If a vial has or has not been reserved for sterile batch sample.

Staff should complete all documentation properly.

A faxed prescription for a controlled substance was found that was electronically signed but not physically signed by the prescriber. There was no note that it had been verbally confirmed as DEA regulations require.

Recommend: Costs and reprimand for misfilling/misbranding 3 prescriptions (53-1-109); improper recordkeeping (1140-03-.03 (2)); incomplete documentation for USP 797 requirements (1140-07-.02).

Dr. Dickenson made the motion to **authorize a formal hearing** for consent order reprimand and case cost for misfiling/misbranding 3 prescriptions, improper recordkeeping and incomplete documentation for USP 797 requirements. . Dr. Wright second the motion. The motion carried

Case 6.

Respondent pharmacist is PIC and owner for Case 5 above.

Recommend: Mirror above reprimand, not including costs.

Dr. Wright made the motion to **authorize a formal hearing** for consent order reprimanded for misfiling/misbranding 3 prescriptions, improper recordkeeping, and incomplete documentation for USP 797 requirements. . Dr. Wilson second the motion. The motion carried

Case 7.

Complaint was generated from a joint inspection with BOP and FDA where some conditions were observed which, if not corrected, could lead to contamination and potentially put patients at risk. Observations include the following:

> Beta-lactam and hazardous drugs were produced without adequate containment or cleaning to prevent cross-contamination.
>
> The ceiling had stains directly above the work bench.
>
> Floor of the compounding room had stains.

FDA chose not to take further action and referred the matter back to BOP to ensure appropriate corrective actions were taken. BOP Investigator verified the pharmacy stopped compounding beta-lactams and NIOSH Class 1 hazardous chemicals. It was also verified the pharmacy improved the compounding area to meet recommended standards.

Recommend: LOI to recommend following applicable USP standards.

Dr. Wilson made the motion to issue a **Letter of Instruction** to recommend following applicable USP standards. Ms. Tittle seconded the motion. The motion carried.

Case 8.

Complaint against respondent pharmacist alleged inaccurate entries in the patient's medical record and assessment plan. It also alleged the respondent is not properly trained to perform the duties being performed for the complainant patient.

BOP Investigator reviewed patient chart information and respondent pharmacist's training. Patient notes are accurate for the information provided to the respondent at the time of patient assessment. Respondent does have specialized training and more than twenty years of experience. Investigator found no violations.

Recommend: Dismiss

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

Case 9.

Respondent technician pled guilty to manufacturing, distributing and possession of anabolic steroids.

Recommend: Revoke technician registration

Dr. Wilson made the motion to **authorize a formal hearing** for revocation to the pharmacy technician. Dr. Rodgers seconded the motion. The motion carried.

Case 10.

BOP and DEA conducted a joint inspection and audit of respondent pharmacy. The pharmacy was located in a physician's office building and also has a pain clinic next door. No major issues were noted and the audit found no major discrepancies. BOP Investigator returned later to address the high dispensing volume of opioids for pain. Five patient names were selected to review for high quantities, early refills, high MME, and potential red flag violations. No red flag were found that could not be explained. The investigator found documentation of obtaining approval from prescribers before filling prescriptions early. The pharmacy also had documentation of denied early fills. There was also proof that the pharmacy consults with prescribers and patients regarding decreasing opioid use and MME's. The pharmacy provided proof that a previous prescriber of high quantities of opioids had died and many of those patients now go elsewhere. Since the BOP visit, the pharmacy has now moved out of that office building and is now located several blocks away. No violations were found and investigator noted that education during previous visits appears to have been beneficial.

Recommend: Dismiss

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

Case 11.

Complaint alleged that a request to fill only 30 day supply of a 90 day prescription on two medications was ignored and the pharmacist filled the prescriptions with a 90 day supply. When confronted about the situation, the pharmacist responded that the prescription was filled correctly and the medication could not be returned after it had left the pharmacy.

BOP Investigator obtained responses from both the pharmacist and technician on duty when the incident occurred, and the PIC. Investigator could not find a violation even if the allegations were true.

Recommend: Dismiss

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

Case 12.

Respondent is the dispensing pharmacist for Case 11 above.

Recommend: Dismiss

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

Case 13.

Respondent is the PIC for Case 11 above.

Recommend: Dismiss

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

Case 14.

BOP Investigator discovered respondent LTC pharmacy had been without a PIC for 66 days. Investigator also discovered that medications were being delivered to nursing homes' automated dispensing machines by pharmacy technicians. At the pharmacy, the medications were loaded into a plastic box and locked with a zip-tie. The tech would open the zip locked box and load the ADM at the alternate site without a pharmacist present.

The PIC issue was addressed while the Investigator was on-site. Investigator instructed pharmacy management to only deliver and load ADM's in compliance with BOP requirements.

Recommend: $50 per month X 3 months (66 days) civil penalty for lack of PIC.

LOW for ADM violation

Dr. Dickenson made the motion to **authorize a formal hearing** with a civil penalty $150.00 ($50.00 per month) for not having a PIC for 3 months and a Letter of Warning for the automated dispensing machine violations. Dr. Wright seconded the motion. The motion carried.

Case 15.

Respondent technician admitted in writing to theft of one Gabapentin because he had left his medication at home. Respondent did have a valid prescription but was terminated.

Recommend: Probation

Dr. Dickenson made the motion to **authorize a formal hearing** with 1 year probation. Ms. Tittle seconded the motion. The motion carried.

Case 16.

BOP Investigator conducted an inspection of respondent pharmacy and found high volumes of opioids and buprenorphine were being dispensed. Investigator audited the pharmacy to verify dispensing complies with standards. Explanations and documentation were obtained.

Controlled substances total 19.2% of the pharmacy's prescriptions.

Cash sales of controlled substances total 3%. 97% are filed on insurance.

Pharmacy is open 24 hours and averages 455 prescriptions daily. It is staffed with 6 full time pharmacists and utilizes 300 technician hours per week. The pharmacy is next to a 400+ bed hospital and has 4 urgent care centers in the area.

DUR decisions are documented in the computer.

PIC estimates 3 or 4 prescriptions are refused each week. Refusals are documented by scanning a copy of the prescription and making notes on the copy. They can also make a note in the patient profile.

The pharmacy monitors some patients by keeping copies of pain contracts. Patients to monitor are selected by professional judgment.

The pharmacy had a policy of refilling 2 days early. Investigator educated staff that early refills should only be done on a case-by-case basis by using professional judgment.

Decisions of whether to fill prescriptions are made by pharmacists using professional judgment. CSMD is regularly used by pharmacists and interns. Technicians are not currently allowed to access CSMD. Pharmacists provided the Investigator with adequate explanations of Morphine equivalents.

Investigator did not find any unexplained red flags. Education was provided advising staff to not have an early refill policy, and to make those decisions on individual cases.

Recommend: Dismiss with education from Investigator

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

Case 17.

BOP Investigator conducted an inspection of respondent pharmacy and found high volumes of opioids and buprenorphine were being dispensed. Investigator audited the pharmacy to verify dispensing complies with standards.

Controlled substances total 20% of the pharmacy's prescriptions.

Cash sales of controlled substances total 3%. 97% are filed on insurance.

Pharmacy is open 24 hours and averages 650 prescriptions per day.

216 pharmacist hours and 413 technician hours are allotted each week.

Staff members review patient history and CSMD for Tennessee and surrounding states.

Early refills are not allowed except on very rare occasions.

All C2's and buprenorphine products are double counted.

Investigator was shown documentation on pharmacists making decisions on a case-by-case basis. Decisions are documented in the computer.

They also keep a folder of prescriptions they have declined. PIC estimates the pharmacy averages 10 refusals per day. The most common reason to decline is distance. They refuse buprenorphine prescriptions unless the criteria for monotherapy are met. Doctor shoppers and pharmacy shoppers are declined. Clonazepam is not filled for patients that are pregnant of breast feeding.

Pharmacists demonstrated adequate knowledge of morphine equivalents.

Patient records were reviewed for several patients with high ME. Investigator saw good notes and supportive diagnosis codes for those patients.

In summary, Investigator did not find any violations.

Recommend: Dismiss

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

Case 18.

Complaint was opened after BOP Investigator was given information by a source that wishes to remain anonymous. The information alleged the respondent pharmacy is compounding with an unapproved product, Ipamorelin. Ipamorelin is classified as a small molecule oligopeptide hormone with a mechanism of action of growth hormone releasing factor agonist. It was once in phase IIb trials for treatment of postoperative ileus in the U.S. but was discontinued due to lack of efficacy. It has not been approved for human use in the U.S. Investigator found that Ipamorelin was being used in combination with Sermorelin, GHRP-2 and GHRP-6("GHRP" stands for Growth Hormone Releasing Peptides). Sermorelin is FDA approved as a diagnostic tool for measuring growth hormone in the body and was used to treat GH deficiency in children. The manufacturer discontinued production of the brand because there was a better treatment for children by using recombinant DNA Growth Hormone. However, the chemical is still available for purchase from chemical suppliers. GHRP-2 and GHRP-6 are in the same class and there are conflicting interpretations of whether FDA allows use of these chemicals (and whether FDA can enforce their interpretation.) Most of the prescriptions found for these products were from prescribers that have performance, weight-loss, or anti-aging clinics.

Another complaint was combined with this one after Board Investigators discovered a sterile product from respondent pharmacy at a clinic located inside another pharmacy. That product appears to have been used as "office use" since it was not labeled with a patient's name and is believed to have been used to promote weight loss. The clinic had been closed prior to Investigators' visit but the vial of medication had been left behind. Investigators believe FDA will view this as manufacturing rather than pharmacy compounding.

Recommend: Forward to FDA

This complaint has been tabled.

Case 19.

Respondent is owner and pharmacist for Case 18 above.

Recommend:

This complaint has been placed on hold.

Case 20.

Complaint alleged respondent pharmacy refused to transfer a prescription.

BOP Investigator received a response from the PIC of respondent pharmacy. The response indicated that company policy adheres to a strict interpretation of federal code 1306.25 and since the prescription was a controlled substance that was "on-hold," it cannot be transferred.

Recommend: Dismiss

This complaint has been place on hold.

Case 21.

Complaint was opened after respondent pharmacist self-reported two misfills that occurred within three months of each other. In both misfills, respondent pharmacist miscalculated the dosage used in two separate compounded products dispensed to two separate patients.

For patient #1, a new formula was used by the pharmacist when calculating Clindamycin for a sterile preparation to be injected into the patient's eye. The prescription called for 1.5mg/ml but was miscalculated and the patient received 15mg/ml. The patient lost vision in that eye. Although it is not clear that the misfill caused the loss of vision in that eye, a settlement was reached.

Patient #2 was disabled from a 2012 automobile accident and used an intrathecal pump to help with chronic pain and muscle spasms. Respondent pharmacist compounded a mixture of Baclofen and Morphine calling for 1.8mg/ml of morphine. It was miscalculated and the patient received a morphine

concentration of 18mg/ml. The patient died about a week later. Although it is not clear that the misfill caused the patient's death, a settlement was reached.

Respondent pharmacist took full responsibility for the misfills and stated they are "inexcusable." Contributing factors offered were a hostile work environment, an uncertain future of the practice site, and the use of new formulas that were not double checked.

Corrections that are now in place include a new SOP requiring double checks by a second person, a procedure for compounding with a new formula in the compounding record, and a new procedure for compounding and dispensing intrathecal preparations.

Recommend:

Dr. Wilson made the motion to **authorize a formal hearing** with a civil penalty of $1000.00 per misfil , 2 inspections with a 6 month time frame with cost to the pharmacist, submit a root analysis to the board and an acceptable plan of correction. Dr. Rodgers seconded the motion. After discussion, Dr. Wilson amend the motion that all but $1000.00 of the civil penalty will be stayed with the submission of an acceptable plan of correction. Dr. Dickenson seconded the motion. The amended the motion carried.

Case 22.

Complaint alleged a misfill of a compounded medication resulted in a pediatric patient being airlifted on two consecutive days due to symptoms that could not be explained. A hospital pharmacist began to suspect the medication and called the dispensing pharmacy. It was then discovered that the clonidine medication had been incorrectly compounded to a strength of 2mg/ml instead of 0.02mg/ml.

Respondent pharmacist admitted the mistake occurred because clonidine powder was used instead of clonidine tablets or a clonidine aliquot.

Corrections that are now in place: an internal peer review was conducted; P&P updated to require pediatric compounds of clonidine be prepared by using tablets; and all calculations involved in pediatric compounds must be checked by two pharmacists.

Recommend:

Dr. Dickenson made the motion to issue a **Letter of Warning** to the dispensing pharmacist. Ms. Tittle seconded the motion. The motion carried.

Case 23:

Complaint alleged respondent pharmacy caused the patient to go without Losartan/HCTZ 100/25 for 2 ½ months.

BOP Investigator obtained prescription copies and the patient's medication printout. The following facts are known:

90 day supply was filled 2/15/17 and picked up 2/16/17;

At 1:07pm on 5/10/17, 7 other prescriptions were picked up;

At 2:54pm on 5/10/17, pharmacy received an e-script for the Losartan/HCTZ;

Nobody picked up the prescription;

On 5/23/17, pharmacy received another e-script for the Losartan/HCTZ;

Nobody picked up the prescription and it was returned to stock 10 days later;

Respondent pharmacy uses automated phone calls and text messages to let patients know a prescription is ready, however, the patient is not enrolled to receive automated phone calls;

Pharmacy staff members were not aware of any complaints filed either at store level, or corporately and did not know where communication broke down.

Recommend: Dismiss

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

Reinstatements

Thomas J. O'Donnell, D.Ph.

Dr. O'Donnell requested to have his licensed reinstated. Dr. O'Donnell's license was revoked on 04/19/2017. After discussion, Dr. Dickenson made the motion to reinstate Dr. O'Donnell's license. Dr. O'Donnell's license will be on five (5) year probation once he has completed all the necessary requirements for reinstatement with the following conditions. Dr. Rodgers seconded the motion. The motion carried

(a) The Respondent shall completely abstain from the consumption of alcohol or any other drugs, except as specified in (b);

(b) The Respondent shall be able to consume legend drugs or controlled substances prescribed by the Respondent's primary physician, except in the case of an emergency or upon proper referral from the Respondent's primary physician. Upon ratification of this order, the Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary care physician. The Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary physician each time the Respondent changes primary physicians;

(c) The Respondent shall not obtain or attempt to obtain any prescriptions in the Respondent's name for any legend drugs, controlled substances or devices containing same from a physician other than the Respondent's primary physician or from any other health care provider, such as a nurse practitioner, physician's assistant or psychiatrist;

(d) The Respondent shall destroy any unused controlled substances prescribed under the provisions of subsection (b) no later than thirty (30) days following the completion of the prescribed course of treatment;

(e) The Respondent shall report to the Board, in writing, the ingestion of any and all legend drugs or controlled substances (a copy of the prescription will satisfy the requirement);

(f) The Respondent shall submit to random sampling of urine, blood or bodily tissues for the presence of drugs and alcohol, at the Respondent's own expense, by agents of the Board, such as the Tennessee Pharmacist Recovery Network for as long as the Respondent has an active license. In the event that the sampling indicates the presence of drugs for which the Respondent does not have a valid prescription or the sampling indicates the presence of alcohol, then formal disciplinary charges may be brought against the Respondent which could result in the revocation of the Respondent's remaining term of probation or the suspension or revocation of the Respondent's license to engage in the practice of pharmacy. Prior to such disciplinary charges being heard by the Board, the Respondent's license may be summarily suspended;

(g) The Respondent shall comply with all of the terms and conditions of the extended aftercare contract he entered into with the Tennessee Pharmacist Recovery Network. Respondent shall return a copy of said contract with this consent order to the Board Office.

(h) The Respondent shall not serve as pharmacist-in-charge for a period of three (3) years from the start date of probation; however, after a period of two (2) years' probation the respondent may petition the Board for a modification of this Consent Order to remove the restrictions upon show of good causes. The Respondent shall not work as a "floater" for a period of three (3) years, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without permission of the Board;

(i) Respondent shall complete all provisions required for the reinstatement of his license listed in Board Rule 1140-01-.07 (3) (b):

1. Provide written notice to the board requesting an active license;
2. Satisfy all past due continuing pharmaceutical education as required by the board;
3. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked;

Corey Bradley, D.Ph.

Dr. Bradley requested to have his licensed reinstated. Dr. Bradley's license was revoked on 04/12/2017. After discussion, Dr. Wright made the motion to reinstate Dr. Bradley's license. Dr. Bradley's license will be on five (5) year probation once he has completed all the necessary requirements for reinstatement with the following conditions. Dr. Dickenson seconded the motion. The motion carried

(a) The Respondent shall completely abstain from the consumption of alcohol or any other drugs, except as specified in (b);

(b) The Respondent shall be able to consume legend drugs or controlled substances prescribed by the Respondent's primary physician, except in the case of an emergency or upon proper referral from the Respondent's primary physician. Upon ratification of this order, the Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary care physician. The Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary physician each time the Respondent changes primary physicians;

(c) The Respondent shall not obtain or attempt to obtain any prescriptions in the Respondent's name for any legend drugs, controlled substances or devices containing same from a physician other than the Respondent's primary physician or from any other health care provider, such as a nurse practitioner, physician's assistant or psychiatrist;

(d) The Respondent shall destroy any unused controlled substances prescribed under the provisions of subsection (b) no later than thirty (30) days following the completion of the prescribed course of treatment;

(e) The Respondent shall report to the Board, in writing, the ingestion of any and all legend drugs or controlled substances (a copy of the prescription will satisfy the requirement);

(f) The Respondent shall submit to random sampling of urine, blood or bodily tissues for the presence of drugs and alcohol, at the Respondent's own expense, by agents of the Board, such as the Tennessee Pharmacist Recovery Network for as long as the Respondent has an active license. In the event that the sampling indicates the presence of drugs for which the Respondent does not have a valid prescription or the sampling indicates the presence of alcohol, then formal disciplinary charges may be brought against the Respondent which could result in the revocation of the Respondent's remaining term of probation or the suspension or revocation of the Respondent's license to engage in the practice of pharmacy. Prior to such disciplinary charges being heard by the Board, the Respondent's license may be summarily suspended;

(g) The Respondent shall comply with all of the terms and conditions of the extended aftercare contract he entered into with the Tennessee Pharmacist Recovery Network. Respondent shall return a copy of said contract with this consent order to the Board Office.

(h) The Respondent shall not serve as pharmacist-in-charge for a period of three (3) years from the start date of probation; however, after a period of two (2) years' probation the respondent may petition the Board for a modification of this Consent Order to remove the restrictions upon show of good causes. The Respondent shall not work as a "floater" for a period of three (3) years, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without permission of the Board;

(i) Respondent shall complete all provisions required for the reinstatement of his license listed in Board Rule 1140-01-.07 (3) (b):

1. Provide written notice to the board requesting an active license;
2. Satisfy all past due continuing pharmaceutical education as required by the board;
3. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked;

Dustin Hoffman, D.Ph.

Dr. Hoffman requested to have his licensed reinstated. Dr. Hoffman's license was revoked on 04/19/2017. After discussion, Dr. Dickenson made the motion to reinstate Dr. Hoffman's license. Dr. Hoffman's license will be on five (5) year probation once he has completed all the necessary requirements for reinstatement with the following conditions. Dr. Wilson seconded the motion. The motion carried

(a) The Respondent shall completely abstain from the consumption of alcohol or any other drugs, except as specified in (b);

(b) The Respondent shall be able to consume legend drugs or controlled substances prescribed by the Respondent's primary physician, except in the case of an emergency or upon proper referral from the Respondent's primary physician. Upon ratification of this order, the Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary care physician. The Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary physician each time the Respondent changes primary physicians;

(c) The Respondent shall not obtain or attempt to obtain any prescriptions in the Respondent's name for any legend drugs, controlled substances or devices containing same from a physician other than the Respondent's primary physician or from any other health care provider, such as a nurse practitioner, physician's assistant or psychiatrist;

(d) The Respondent shall destroy any unused controlled substances prescribed under the provisions of subsection (b) no later than thirty (30) days following the completion of the prescribed course of treatment;

(e) The Respondent shall report to the Board, in writing, the ingestion of any and all legend drugs or controlled substances (a copy of the prescription will satisfy the requirement);

(f) The Respondent shall submit to random sampling of urine, blood or bodily tissues for the presence of drugs and alcohol, at the Respondent's own expense, by agents of the Board, such as the Tennessee Pharmacist Recovery Network for as long as the Respondent has an active license. In the event that the sampling indicates the presence of drugs for which the Respondent does not have a valid prescription or the sampling indicates the presence of alcohol, then formal disciplinary charges may be brought against the Respondent which could result in the revocation of the Respondent's remaining term of probation or the suspension or revocation of the Respondent's license to engage in the practice of pharmacy. Prior to such disciplinary charges being heard by the Board, the Respondent's license may be summarily suspended;

(g) The Respondent shall comply with all of the terms and conditions of the extended aftercare contract he entered into with the Tennessee Pharmacist Recovery Network. Respondent shall return a copy of said contract with this consent order to the Board Office.

(h) The Respondent shall not serve as pharmacist-in-charge for a period of three (3) years from the start date of probation; however, after a period of two (2) years' probation the respondent may petition the Board for a modification of this Consent Order to remove the restrictions upon show of good causes. The Respondent shall not work as a "floater" for a period of three (3) years, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without permission of the Board;

(i) Respondent shall complete all provisions required for the reinstatement of his license listed in Board Rule 1140-01-.07 (3) (b):

1. Provide written notice to the board requesting an active license;
2. Satisfy all past due continuing pharmaceutical education as required by the board;
3. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked;

Robin Terrero, D.Ph.

Dr. Terrero requested to have her license reinstated. Dr. Terrero's license was revoked on January 28, 2015. After discussion, Dr. Wright made the motion for Dr. Terrero to enter an agreement with the Tennessee Pharmacist Recovery Network (TPRN) and to appear before the board when TPRN and its Advocates recommend and support her appearance. Dr. Dickenson seconded the motion. The motion carried.

General Discussion

Dr. Dilliard asked the board if they would allow him to sign consent orders for reinstatements to allow the pharmacist to go to work faster. Signed reinstatement orders have to be approved by the board and requirements met before the license will be eligible to return to work. After discussion, Dr. Wilson made the motion to allow Dr. Dilliard to sign the reinstatement order but the orders will still need to be ratified by the board.

Dr. Dilliard informed the board that he will be meetings with the TPRN to discuss drug testing in colleges. Dr. Rodgers will also participate with in the discussion. Dr. Dilliard will report the findings at the January 30-31, 2018 board meeting.

Dr. Wright will work with the Office of General Counsel to develop a procedure to audit complaints without seeing the actual complaints.

Application Review

Tyree Walker, RT

Mr. Walker is applying for registration as a registered pharmacy technician. He marked "yes" to the question that asked "Have you ever been convicted (including non contendere plea or guilty plea) of a felony or misdemeanor (other than a minor traffic offense) whether or not sentence was imposed or suspended? Documentation submitted that Mr. Walker pled guilty to possession or casual exchange-controlled substance on 09/06/2012 and was sentence to 6 months suspended sentence; 11/7/2014 he was found guilty of DUI sentence to 48 hours in jail; 10/6/2016 guilty of possession or casual exchange-controlled substances. After discussion, Dr. Wilson made the motion to approve Mr. Walker's application for registration as a pharmacy technician with a 1 year probation and contract with TPRN which include random drug screens. Mr. Walker's registration as a pharmacy technician will automatically be revoked with one failed drug screen. Dr. Rodgers seconded the motion. After discussion, Dr. Dickenson amended the motion to state that Mr. Walker's registration would be suspended upon a failed drug screen until he can appear before the board. Dr. Rodgers seconded the motion. The amended motion carried.

Eric Lethenstrom (Quinn Abrams) RT

Mr. Lethenstrom answered "yes" to the question that asked "Have you ever been convicted (including a nolo contendere plea or guilty plea) of a felony or misdemeanor (other than a minor traffic offense) whether or not sentence was imposed of suspended" Documentation submitted indicates that Mr. Lethenstrom pled guilty to unlawful restraint 2nd degree, assault 3rd degree and criminal trespass 1st degree on April 17, 2012. He was sentence to 1 year in jail suspended and conditional discharge 2yrs. After discussion, Dr. Dickenson made the motion to approve Mr. Lethnstrom's application for registration as a pharmacy technician. Dr. Wilson seconded the motion. The motion carried.

Appearance

Express Scripts/Accredo,

Rich Palombo, RPh, D.Ph., Sr. Director of Pharmacy Regulatory Affairs, appeared before the board request a waiver of board rule 1140-01-.13 (3) (a), (b), (c), (d), (e) and (f). After discussion, Dr. Dickenson made the motion approve the request of Express Scripts/Accredo for the pharmacy for the department shall have necessary counters and storage space; (b) The department shall have a representative stock of prescription drugs and devices and related materials sufficient to compound and dispense medical and prescription orders as indicated by experience; (c) The department shall have the apparatus and equipment needed to compound and dispense medical and prescription orders properly. ; (d) The department shall occupy a space of not less than one hundred eighty (180) square feet. ; (e) The department shall have hot and cold running water and immediate area refrigeration. Ms. Tittle seconded the motion. The motion carried.

Waivers
Board rule 1140-02-.02 (7)

Dr. Dickenson approved Trilogy NuScriptRx dba PCA NuScriptRx request to increase the pharmacist to technician ratio from 4:1to 6:1. Dr. Wilson seconded the motion. The motion carried.

Consent Order

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

PROBATION
Benjamin Todd Bradford, D.Ph.

REVOCATON
Dana M. Sokohl, D.Ph.

The meeting adjourned at 4:15 p.m.

November 15, 2017

The Tennessee Board of Pharmacy reconvened on Wednesday, November 15, 2017 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members were present, the meeting was called to order at 9:00 a.m., by Dr. Eidson, president. Dr. Dickenson and Ms. Tittle were not in attendance.

Contested Cases

Ashley D. Henderson, RT

Ms. Henderson was not present nor represented by legal counsel. Mr. Gibbs represented the State. Mr. Tom Stovall was the Administrative Law Judge. Mr. Gibbs asked to proceed in default. Dr. Wilson made the motion to proceed in default. Dr. Wright seconded the motion. The motion carried. Mr. Gibbs passed out the Notice of Charges. Ms. Henderson is charged with violating T. C. A. §53-11-401(a) (1), T.C.A. §63-10-305 (a); T. C. A. § 53-11-308 (a) and T.C. A. §63-10-305 (6). Dr. Wilson made the motion to revoke Ms. Henderson's registration and to assess case cost. Dr. Rodgers seconded the motion. After discussion Dr. Wilson amended the motion to include a civil penalty of $200.00 for each forged prescription for a total of $1000.00. Dr. Rodgers seconded the amended motion. A roll call vote was taken on the amended motion. The motion carried. A roll call vote was taken on the original motion. That motion carried... Dr. Wright made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Wilson seconded the motion. The motion carried.

Director's Report/General Discussion

Dr. Dilliard informed the board that Dr. Denaburg was asked to do a presentation on Nuclear Buprenorphine at MALTAGON. Dr. Denaburg received a favorable response. A roundtable was conducted in Johnson City on buprenorphine.

Dr. Wright asked if the board should consider rules USP 800 which covers sterile and non-sterile compounding. The Board decided that since board rule 1140-07-.02 (1) states "All sterile products shall be prepared in compliance with applicable USP standards for pharmaceutical compounding" that a rule change would not be necessary.

Dr. Eidson asked about the collaborative practice rules and what is defined as preventative medicine. The collaborative care contract does not define preventative care. The board suggested task force to discuss a possible definition. The task force will consist of Dr. Dickenson, Dr. Eidson, Mr. Gibbs, TPA and a representative from a chain and independent pharmacy.

Dr. Dilliard discussed with the board possible rule changes for pharmacy technicians and pharmacy interns.

Dr. Wilson made the motion to adjourn at 11:15 a.m. Dr. Wright seconded the motion. The motion carried.

The minutes were approved and ratified at the January 30-31, 2018 board meeting.