TENNESSEE BOARD OF PHARMACY 665 Mainstream Drive, Iris Room Nashville, TN July 12, 2017

BOARD MEMBER PRESENT

R. Michael Dickenson, D.Ph., Vice President Debra Wilson, D.Ph. Rissa Pryse, D.Ph. Katy Wright, D. Ph. Will Bunch, 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

BOARD MEMBER ABSENT

Kevin Eidson, D.Ph., President

STAFF ABSENT

Tommy Chrisp, Pharmacy Investigator

The Tennessee Board of Pharmacy convened on Tuesday, July 12 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. Dr. Dickenson, Vice president, chaired the meeting.

Minutes

The minutes from the June 13, 2017 board meeting were presented. After discussion, Dr. Wilson made the motion to accept the minutes as presented. Ms. Tittle seconded the motion. The motion carried.

Presentation

Wesley Geminn, Chief Pharmacist for the Department of Health, Mental Health & Substance Abuse Services, appeared before the board to update the board on the new rules for buprenorphine use in a treatment facility.

OGC Report

Mr. Gibbs informed the board that there are 56 open cases for discipline at the Office of General Counsel and 18 of those cases are eligible for contested cases. Mr. Gibbs stated that the rules for hormonal contraceptives are still in review and the rules for charitable drug repository are in process.

Mr. Gibbs also informed the board that the winner of the RFP will be announced on July 17, 2017.

Complaint Summary

Case 1:

Complainant alleged unprofessional conduct when respondent pharmacist refused to fill complainant's prescription because the pharmacist did not feel comfortable filling a prescription written by a doctor that is not in the same town. Complainant also alleged the store manager escorted complainant out of the store for saying a "foul word."

BOP Investigator made a site visit. Respondent was familiar with the complainant and stated the prescription was refused on the following grounds of professional judgment:

Complainant had never used this pharmacy before;

Complainant had never used any pharmacy in this same chain before;

Prescriber's office was in a different city than the pharmacy or the patient;

CSMD report showed controlled substances filled at other pharmacies;

CSMD showed patient had MME of 480;

The prescription was too early to fill;

Complainant became aggressive, slammed fists on the counter, threatened to file a complaint with BOP and used profanity about the pharmacy and the pharmacist.

Respondent notified management who asked the complainant to leave. Respondent feared complainant because of the behavior exhibited and asked security to walk her to her car after work.

Recommend: Dismiss

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

Case 2:

Complainant alleged unprofessional conduct when respondent pharmacist refused to fill complainant's prescription. Complainant also alleged violation of HIPAA, "numerous other medical laws," and violation of doctor/patient confidentiality because respondent pharmacist asked questions about patient's medical history and wanted to know the reason the patient was being prescribed these medications.

BOP Investigator obtained a signed statement from the respondent pharmacist who stated that the prescriptions (Norco and Methadone) were from an out-of-state prescriber. One of the prescriptions (Methadone) was 5 days early. The prescriber was contacted but the pharmacist was not comfortable filling the prescription early. The patient was told he could get that prescription filled when it was time.

Recommend: Dismiss

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

Case 3.

Respondent is the pharmacy for Case 2 above.

Recommend: Dismiss

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

Case 4.

Respondent technician admitted to management and provided a voluntary statement to BOP Investigator that she had been taking Fentanyl for personal use. According to DEA 106 form, 1,350 ml of Fentanyl 100 mcg/2ml were missing. Respondent offered a voluntary surrender of her technician registration. Respondent self-admitted to a rehab facility.

Recommend: Accept voluntary surrender

Dr. Wilson made the motion to accept the pharmacy technician's voluntary surrendered of their pharmacy technician registration. Dr. Pryse seconded the motion. The motion carried.

Case 5.

Complaint from pharmacy management alleged respondent pharmacist stole food and assorted merchandise over a 6 to 12 month period. A copy of a voluntary statement was provided to BOP Investigator. In the statement, respondent admitted taking food and drink items for about a year without paying. Respondent also admitted taking cell phone chargers under the pretense that they were being used as supplies in the pharmacy. An internal investigation and audit did not show any drug losses.

Respondent pharmacist provided BOP Investigator with a signed statement admitting theft of food items off the shelf. When interviewed by Investigator, respondent denied ever stealing drugs and denied any drug or alcohol addiction.

Recommend:

Dr. Wilson made the motion to authorize a formal hearing for a 2 year probation to the pharmacist for unprofessional conduct. Dr. Wright seconded the motion. The motion carried.

Case 6.

While attempting to conduct a periodic inspection, BOP Investigator walked into an open pharmacy that did not have a pharmacist on duty and observed a fourth year pharmacy student sell Claritin D. The pharmacy had been opened by a technician and the pharmacist arrived shortly after the Investigator. Investigator noted the following:

Technician had keys to the front door and access code to the pharmacy and had opened the pharmacy;

Intern and technician were working unsupervised;

Staff members were not wearing name tags;

Will-call bin is located outside the pharmacy;

No law book;

Controlled substance invoices were not signed and dated;

Biennial inventory was not separated by schedule or marked as required;

Non patient-specific compounded medication from another pharmacy was found on the premises;

Compounded medication from another pharmacy was found that had the PIC's name on the label but was being used in an adjoining clinic for office use.

A follow up visit by Investigator found all deficiencies have been corrected. Compounding issues have been forwarded to FDA.

Recommend: Reprimand and costs for violations.

Dr. Wilson made the motion to authorize a formal hearing to reprimand the pharmacy and cost for violations. Dr. Wright seconded the motion. The motion carried. Dr. Pryse voted no.

Case 7.

Respondent is PIC and owner for Case 6 above.

Recommend: Reprimand and \$100 civil penalty for key violation

Dr. Wright made the motion to authorize a formal hearing to reprimand to the PIC and accessed a \$100.00 per day civil penalty for the key violation with the cap being \$1000.00. Dr. Bunch seconded he motion. The motion carried.

Case 8.

Complainant PIC notified BOP Investigator of controlled substance losses and an internal investigation resulting in termination of respondent technician's employment. DEA 106 form indicated a loss of 365 Oxycodone 30 mg tablets. PIC reviewed video showing that on two different occasions in the same day, respondent was seen taking a cassette of the tablets and placing the tablets in her ungloved hand, counting the tablets and appeared to put the tablets in her pocket before leaving the pharmacy, which was not a normal workflow function. A third event occurred after the respondent had finished her shift and was viewed placing the tablets in what appeared to be a white ointment jar before leaving the pharmacy. When confronted on the next working day, the respondent did not admit to the diversion. When asked to empty her pockets and purse, it was noted that a "big wad of cash" was located. Respondent's employment was terminated and a police report was filed.

Recommend: Revoke

Dr. Bunch made the motion to authorize a formal hearing for revocation. Dr. Wilson seconded the motion. The motion carried.

Case 9.

Complainant patient alleged a privacy breach by respondent pharmacy by allowing another patient to overhear staff telling complainant about her medication and it needing a prior approval. The other patient allegedly then started asking complainant what the medicine was; what it was for; if she really needed it; and why did it have to be pre-authorized. Then the other patient allegedly started talking about God and paying for the complainant's medication. As the complainant was checking out, the other patient stood beside her to be able to see her cell phone number as she typed in her rewards number; he could see her address on the prescription bag; he followed her around the store until she reached her car; that all of this could be confirmed on video; then complainant believes he stalked her by driving beside her then getting behind her and following her, then she received a text message requesting that she "walkie-talkie" the person sending the text. Complainant feels the respondent pharmacy put her life at risk and did not care about her safety.

PIC reviewed video and told BOP Investigator she saw a man step up beside the complainant then step back into line. PIC assumed that was when the man offered to pay for complainant's medication. PIC stated the man was still in the store at least 3 more minutes after the complainant left and felt it was unlikely to be the same person the complainant felt was following her. The store manager, 2 techs that were on duty, the pharmacist that was on duty, and the pharmacist that took a call from the complainant the following day all gave very similar statements. The store manager and the pharmacist both told the complainant to call the police and complainant responded that the police would not do anything. Since the medication was for anxiety, the pharmacist called the prescribing physician to let him know about the situation. The store manager checked the phone number from the mysterious text and said it was not the same number as the man that talked to the complainant.

BOP Investigator requested a copy of the video, but was told that the footage was not saved. Investigator could not confirm the allegations although it does appear that the video did show someone stepped up beside the complainant as she was paying.

Recommend: LOI to pharmacy to keep patient conversations private

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

Case 10.

Respondent is PIC for Case 9 above. Respondent was on vacation when the incident occurred but did conduct some of the follow-up.

Recommend: Dismiss

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

Case 11.

In a written statement given to BOP Investigator, respondent technician admitted adding unauthorized refills to Tramadol prescriptions for personal use.

Recommend: Revoke

Ms. Tittle made the motion to authorize a formal hearing for 2 year probation to the technician and that the technician not be allowed to work in a pharmacy that dispenses controlled substances. The technician is also required to remain in a treatment program. Dr. Pryse seconded the motion. The motion carried.

Case 12.

BOP Investigator was provided a copy of a signed statement in which respondent tech admitted stealing controlled substances on multiple occasions to sell on the street.

Recommend: Revoke

Dr. Bunch made the motion to authorize a formal hearing for revocation. Dr. Wright seconded the motion. The motion carried.

Case 13.

BOP Investigator was provided a copy of a signed statement in which respondent tech admitted stealing controlled substances on multiple occasions to sell on the street.

Recommend: Revoke

Dr. Wilson made the motion to authorize a formal hearing for revocation. Dr. Pryse seconded the motion. The motion carried.

Case 14.

BOP Investigator was provided a copy of a signed statement in which respondent tech admitted stealing controlled substances for personal use and agreed to restitution.

Recommend: Revoke

Dr. Wright made the motion to authorize a formal hearing for revocation. Ms. Tittle seconded the motion. The motion carried.

Case 15.

BOP Investigator was provided a copy of a signed statement in which respondent tech admitted stealing controlled substances on multiple occasions.

Recommend: Revoke

Dr. Bunch made the motion to authorize a formal hearing for revocation. Dr. Pryse seconded the motion. The motion carried.

Presentation

Antoinette Welch, Director of the Bureau of Investigations for the Department of Health, appeared before the board. Ms. Welch informed the board that effective July 1, 2017 the pain clinics will be required to be licensed and inspected. Each pain clinic will be required to pay \$1500.00 for each inspection which will be unscheduled inspections. Pain Clinics were previously issued certificates only. Ms. Welch also stated that pain clinics can no longer have a pharmacy adjacent to it and the owner of the pain clinic cannot own a pharmacy.

Reinstatement Christopher Pittman

Dr. Pittman requested to have his licensed reinstated. Dr. Pittman's license was revoked on 09/22/2016. After discussion, Dr. Bunch made the motion to reinstate Dr. Pittman's license. Dr. Pittman's license will be on ten (10) year probation once he has completed all the necessary requirements for reinstatement with the following conditions. Dr. Pryse 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, Dr. Harry Burke, Jr, 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 six (6) years from the start date of probation; however, after a period of four (4) 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 six (6) 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;
- 4. Successfully complete the jurisprudence examination
- 5. Complete one hundred and sixty (160) pharmaceutical internship hours within ninety (90) Consecutive days

Waivers

Board rule 1140-01-.07(3) (b) 5(ii) & (iii)

Dr. Wilson made the motion to approve the request from Brandon Howard, Pharm. D., to waive the three hundred and twenty (320) internship hours but he must successfully take and pass the MPJE. Dr. Wright seconded the motion. The motion carried.

Dr. Wilson made the motion to approve the request from Mark Hill, D.Ph., to waive the one hundred and sixty (160) internship hours but he must successfully take and pass the MPJE. Dr. Bunch seconded the motion. The motion carried.

Dr. Bunch made the motion to approve the request from Yihua Song, D.Ph., to waive the three hundred and twenty (320) internship hours but she must successfully take and pass the MPJE. Dr. Wright seconded the motion. The motion carried.

Consent Orders

Dr. Bunch made the motion to approve the following consent orders as presented. Ms. Tittle seconded the motion. The motion carried.

PROBATION Deena Nance, RT

VIOLATED BOARD RULE 1140-01-.09 (1) J. C. Williams, D.Ph.-\$ 1000.00 civil penalty Elaine Lents, D.Ph. - \$1000.00 civil penalty

VOLUNTEER SURRENDER Sarah Morris, RT Amber Riley, D.Ph.

VIOLATED BOARD RULE 1140-02-.02 (1) George E. Miller, D.Ph.-\$300.00 civil penalty Donna C. Miller, RT. - \$50.00 civil penalty

Director's Report

Dr. Dilliard explained to the board that they need to consider rule changes and asked the board to appointment someone to work on the changes with him. Some of the changes will include, pharmacy technician requirements, intern licenses, remote practices, prescription drugs deliveries, kiosks, continuing education requirements, USP 795 enforcement, definitions and repackaging. Dr. Dickenson will work with Dr. Dilliard on the rules changes.

Dr. Dilliard informed the board that the investigators will be using a universal inspection form created by NABP.

Dr. Bunch made the motion to adjourn at 2:25 p.m. Dr. Pryse seconded the motion. The motion carried.

The minutes were approved and ratified as amended at the September 12-13, 2017 board meeting.