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

BOARD MEMBER PRESENT

Debra Wilson, D.Ph., President Rissa Pryse, D.Ph., Vice President Adam Rodgers, D.Ph. Melissa McCall, D.Ph. Richard Breeden, D.Ph.

BOARD MEMBER ABSENT Katy Wright, D.Ph. Lisa Tittle, Consumer Member

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The Tennessee Board of Pharmacy convened on Tuesday, November 5, 2019, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 8:01 a.m. Dr. Wilson welcomed the pharmacy students who were in attendance. Dr. Dilliard introduced Brent Culbertson, the new Assistant Commissioner for Health Related Boards.

Minutes

Dr. Rodgers made the motion to accept the minutes from the July 16, 2019 board meeting as amended. Dr. McCall seconded the motion carried.

OGC Report

Mr. Gibbs informed the board that there are currently 50 cases open for discipline within the Office of General Counsel. Of those 50 cases, 3 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.

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

Complaint Summary

1.

Respondent technician admitted to diverting controlled substances.

No prior discipline.

Recommend: Revoke tech registration

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

2.

Respondent technician admitted to diverting controlled substances.

No prior discipline.

Recommend: Revoke tech registration

Dr. Rodgers made the motion to authorize a formal hearing for revocation. Dr. McCall seconded the motion. The motion carried.

3.

Respondent technician admitted diverting controlled substances.

No prior discipline.

Recommend: Revoke tech registration

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

4.

During a periodic inspection, BOP Investigator noted one technician failed to offer counseling on refills for two different patients. Technician admitted to the violation. Technician and the pharmacist on duty were educated by the Investigator. Later during the inspection, another technician was observed releasing three prescriptions without an offer to have the pharmacist counsel. Two of these prescriptions were verified as new but the tech did not notify the pharmacist before releasing them. The new prescriptions were for a minor child.

No prior discipline.

Recommend: For the pharmacy: Costs plus \$5,000 civil penalty with \$4,000 stayed with approved plan of correction.

Dr. Rodgers made the motion to authorize a formal hearing with a \$5000.00 civil penalty with \$4000.00 stayed with a approved plan of correction. Dr. Pryse seconded the motion. The motion carried.

5.

Respondent is the pharmacist on duty for Case 4 above.

No prior discipline.

Recommend: \$ 1,000 civil penalty

Dr. Pryse made the motion to authorize a formal hearing with a \$1000.00 civil penalty. Dr. McCall seconded the motion. The motion carried.

6.

Respondent is the PIC for Case 4 above.

No prior discipline.

Recommend: LOI

Dr. Rodgers made the motion to issue a Letter of Instruction to the pharmacist in charge. Dr. Breeden seconded the motion. The motion carried.

7.

Respondent is the first technician in Case 4 above.

No prior discipline.

Recommend: LOW

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

8.

Respondent is the second technician in Case 4 above.

No prior discipline.

Recommend: LOW

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

9.

Anonymous complainant alleged deceptive and incorrect labeling of compounded drugs by the respondent pharmacy. Specifically, that certain compounded products are being sold as relief for many different ailments and that an excipient is listed as an active ingredient on labels.

BOP Investigator reviewed copies of prescriptions and compound worksheets and found all to be patient specific. The product being compounded is made from a standard formula. The name was rearranged so it would be easier to know the product or prescription being used. Investigator recommended listing the active ingredient first and the pharmacists immediately changed the labeling. Investigator feels education on this subject has remedied the problem.

No prior discipline.

Recommend: Dismiss

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

10.

Respondent technician admitted in writing to diverting controlled substances.

No prior discipline.

Recommend: Revoke technician registration

Dr. Rodgers made the motion to authorize a formal hearing for revocation. Dr. Breeden seconded the motion. The motion carried.

11.

BOP Investigator confirmed the respondent pharmacy operated without a PIC from 4/26/19 until 5/20/19 and neither controlled substance inventory was conducted on the correct date.

Unable to determine if prior discipline exists.

Recommend: \$50 civil penalty for lack of PIC. \$50 for failure to conduct CS inventory on 4/25/19 and \$50 for failure to conduct CS inventory on 5/20/19.

Dr. Rodgers made the motion to authorize a formal hearing with a \$50.00 civil penalty for lack of PIC, \$50.00 civil penalty for failure to conduct CS inventory on 4/25/19 and a \$50.00 civil penalty for failure to conduct CS inventory on 5/20/19. Dr. Breeden seconded the motion. The motion carried.

12.

Complaint alleged a misfill by respondent pharmacy when an incorrect prescriber and incorrect number of refills were used on a new prescription for Suboxone 8mg/2mg.

BOP Investigator found that when the new prescription was entered, the computer software automatically defaults to the previous prescriber name. This error was not noticed prior to dispensing. The new prescription was written for a seven day supply with no refills but was incorrectly entered with two refills.

No prior discipline.

Recommend: LOW for misfill and recommend all CSMD entries be reviewed and corrected.

Dr. Pryse made the motion to issue a Letter of Warning for the misfill and a recommendation that all CSMD entries be reviewed and corrected. Dr. Rodgers seconded the motion. The motion carried.

13.

Complaint alleged a misfill and possible HIPAA violation after the complainant (who lives in another state) received a text message that a prescription for a child, with a similar first name to her child, was ready to be picked up at the respondent pharmacy located in Tennessee. Complainant contacted her local pharmacy who was able to tell her the prescription was from a prescriber in Tennessee. Complainant called the respondent pharmacy and discovered a TN prescriber had authorized Amoxicillin for a child with the same last name and birthdate and a similar first name. The respondent pharmacy filled the prescription, but did not dispense it, not noticing the name used did not live in Tennessee. After the phone call, the respondent pharmacy corrected the prescription before it was ever dispensed. PIC has flagged the profile so this does not happen again and has directed all pharmacy staff to be reassigned computer based training on data entry/profile selection and follow-up meetings with each employee will be conducted to ensure proper procedures are followed.

The breach of information occurred because of a computer program that automatically notifies patients that a prescription is ready. In this instance, the program committed the breach, not the pharmacist or pharmacy staff.

No prior discipline.

Recommend: LOW for confidentiality

Dr. Pryse made the motion to issue a Letter of Instruction concerning confidentiality. Dr. Breeden seconded the motion. The motion carried.

14.

Respondent technician admitted in writing to diversion of controlled substances and other drugs.

No prior discipline.

Recommend: Revoke technician registration

Dr. McCall made the motion to authorize a formal hearing for revocation. Dr. Rodgers seconded the motion. The motion carried.

15.

Physician complainant alleged respondent pharmacy ignores explicit instructions to void old prescriptions when new prescriptions are ordered. It is also alleged that the pharmacy changes 30 days supply with refills into a 90 days supply without any communication to the prescriber. It is also alleged that a prescription for Clonazepam was refilled 12/18/18 and 1/17/19 even though a prescription issued on 11/13/18 stated to void any previously issued prescriptions for psychotropic drugs.

BOP Investigators confirmed that the prescriber issues multiple prescriptions with refills. Patients can request refills via online or a phone app. So the refilled prescriptions are sometimes picked up before the patient brings the new prescription. The pharmacist admitted not voiding the Clonazepam prescription because she did not consider it to be a psychotropic drug.

PIC agreed to educate staff how to void previous prescriptions as requested and even though refills may be requested up to 6 days early, all efforts will be made to stop any refills from being dispensed before 30 days have elapsed. Additionally, all of the complainant's patients will be flagged in the computer system to help catch any fills before 30 days.

Converting multiple 30 days supply prescriptions into a 90 days supply is an internal metrics "push" whenever there is a sufficient quantity remaining on the prescription. Pharmacists are held accountable to meet a quota of 80% of Medicare or insurance prescriptions to be filled for 90 days supply. Staff agreed to make a diligent effort not to exceed a 30 days supply for the complainant's patients. The computer system can be marked "no" but will ask again at a later date. PIC will educate staff to intervene and reduce fills to 30 days quantities, supplemented with notes in the computer system, frequent verbal and written reminders and discussion of the new steps with all of the complainant's patients.

No prior discipline.

Recommend: LOI for strict conformity

Dr. Rodgers made the motion to dismiss the complaint and refer to the Board of Medical Examiners. Dr. McCall seconded the motion. The motion carried.

16.

Complaint alleged respondent pharmacy had periods of time without a PIC.

BOP Investigator interviewed the current PIC who produced copies of PIC changes that covered all the time gaps. No PIC violation occurred.

No prior discipline.

Recommend: Dismiss

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

17.

Complainant patient alleges the respondent pharmacist failed to counsel on a new prescription for Tramadol. Then, during the same encounter, the complainant claims to have spoken to the respondent about taking the Tramadol with acetaminophen and that the respondent replied in the affirmative. Complainant alleges side effects occurred after one dose of Tramadol and that when she spoke to the respondent again, the respondent stated that Tramadol is not an opioid, but is "opioid like." Complainant did not elaborate on the side effects and did not provide a contact number.

BOP Investigator interviewed the respondent pharmacist who stated that he did counsel the patient and fears that he may have given too much information (including that Tramadol works on serotonin reuptake which could affect her mood) thus causing unnecessary concern by the patient. Respondent stated the patient returned to the pharmacy a few days later, stated she was not counseled and demanded a refund. Respondent stated that he reminded the patient of their previous conversation and refused to issue a refund. Respondent was adamant to the Investigator that counseling occurred and provided sworn written statements detailing his encounters with the patient.

No prior discipline.

Recommend: Dismiss

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

18.

Respondent is the pharmacy for Case 17 above.

No prior discipline.

Recommend: Dismiss

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

19.

Complainant is a pharmacist alleging he was pressured by a nurse and a supervisor into dispensing a buprenorphine prescription from a prescriber that did not have the data waiver DEA number. The complainant alleges he was later offered a chance to resign or be terminated.

BOP Investigator discovered a prescriber with the proper waiver had sent an electronic prescription but it was not received at the pharmacy due to a computer "glitch." Staff members told the Investigator that the patient was present at the clinic and was experiencing symptoms of withdrawal. Complainant did eventually dispense the prescription for the patient.

Respondent for the pharmacy indicated he was unaware of any pressure placed on the pharmacist to fill the prescription. Respondent did state that the pharmacist was not following company direction for the care of patients on the MAT program. Respondent also stated the offer to allow the pharmacist to resign or be terminated was for other issues and not because of this incident.

No prior discipline.

Recommend: LOW to the pharmacy

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

20. (same as 21)

21. (same as 20)

Both complaints have identical or very similar allegations against the same respondent.

Complainant alleged receiving a shipment of diabetic supplies and prescription creams unexpectedly. Complainant took the box to her local pharmacy for assistance. (Note: the local pharmacy that assisted the patient is not the respondent pharmacy.) Complainant alleged the mail-order pharmacy refused to cooperate with her local pharmacy, and that a different phone number than that on the shipment was given to reach a respondent pharmacist.

Complainant stated she does remember speaking to someone on the phone asking if she wanted help for her pain and they would contact her doctor. The caller already had information on the patient's doctor and asked for the patient's last 4 digits of her social security number. According to the complainant, the caller was rude and pushy.

BOP Investigators found that mail order counseling requirements were not met since the phone number on the prescription label goes to a customer service department located in another state. Investigators were also told that the respondent's call center initially refused to give copies.

Finally the patient was instructed to return the prescriptions to the pharmacy. The pharmacist at the respondent pharmacy would not deny re-dispensing products that were returned.

The pharmacy located in Tennessee has since closed.

No prior discipline.

Recommend: Close and refer to interested agencies.

Dr. McCall made the motion to accept counsel's recommendation. Dr. Breeden seconded the motion. The motion carried. Dr. Pryse was recused.

22. (same as 23)

23. (same as 24)

Respondent is the PIC for the Tennessee location in Case 20 and 21 above.

No prior discipline.

Recommend: LOW for re-dispensing, refusal to give copies, improper counseling on mailed items.

Dr. Rodgers made the motion to accept counsel's recommendation. Dr. McCall seconded the motion. The motion carried. Dr. Pryse was recused.

24.

Complainant is an insurance company that alleges the respondent pharmacy contacted Medicare members and shipped unwanted topical medications and diabetic testing supplies that were not requested by the patients. Specific names were not released.

Complainant reports that the respondent pharmacy has stopped shipping to complainant's patients.

The pharmacy located in Tennessee has now closed.

No prior discipline.

Recommend: Close and refer to interested agencies.

Dr. McCall made the motion to accept counsel's recommendation. Dr. Breeden seconded the motion. The motion carried. Dr. Pryse was recused.

25.

BOP Investigator found a wholesale/distributor with a license that expired 2/28/19. Investigator also found there was no temperature/humidity device present and no log was being kept, the alarm system was not working, proper records were not being kept, and the manager on site

could not produce required policies and procedures. As of 10/7/19, no renewal application has been received.

Recommend: Civil penalty \$800.00 if renewed before November and include warning language about violations.

Dr. Pryse made the motion to authorize a formal hearing with a \$800.00 civil penalty if the license is renewed before November 1, 2019. Dr. McCall seconded the motion. The motion carried.

26.

Respondent's technician registration expired. A new application was started but Respondent did not respond to a deficiency letter from the Board office. Respondent never completed the application process. Respondent had criminal charges bound over to grand jury and later an arrest warrant was issued for missing a court date.

The application time period has expired.

No prior discipline.

Recommend: Flag to prevent re-application until legal issues are resolved.

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

27.

Anonymous complaint alleged the respondent pharmacy is understaffed and putting pressure on the PIC to perform various duties including filling a high volume of prescriptions, counseling patients, answering phone calls, and sometimes working the cash register. The complaint also alleged that ownership is trying to replace older pharmacists with younger pharmacists willing to accept lower rates of pay.

BOP Investigator met with the PIC who declined to discuss or give a statement out of fear of jeopardizing the job. Investigator will periodically visit and assess the situation.

Unable to determine if prior discipline exists.

Recommend: Dismiss/reopen if PIC changes mind.

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

28.

Complaint alleged a misfill occurred. Patient alleged an albuterol inhaler copay was too expensive so the patient found a coupon and the prescriber authorized a change. However, that one was too expensive so the patient asked to bill insurance. The patient got home and noticed

the inhaler was the original inhaler and not the ProAir HFA inhaler that the prescriber had ordered trying to save the patient money. Patient admitted to being very upset, threatening to files complaints and asking for the name of the responsible pharmacist.

BOP Investigator conducted a thorough investigation. There was no indication of a misfill, just confusion on brands, discount cards, and prices.

No prior discipline.

Recommend: Dismiss

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

29.

Complaint from a prescriber alleged that, on 6/28/19, the respondent pharmacy incorrectly submitted the prescriber's name on a controlled substance prescription when reporting to CSMD. Prescriber began contacting the pharmacy to request the CSMD record be changed but it has not been changed yet.

BOP Investigator confirmed a misfill resulted in the incorrect submission. A compounded drug that was supposed to contain cyclobenzaprine was misfilled using gabapentin. When the prescriber originally contacted the pharmacy, the misfill was corrected. Prescriber has made multiple calls and has sent letters but the CSMD information was still incorrect as of 10/8/19.

Investigator also noted that pre-printed compounded prescription orders may violate FDA regulations.

No prior discipline.

Recommend: Reprimand for failure to correct CSMD. Refer pre-printed compounded prescription orders to FDA.

Dr. Breeden made the motion to authorize a formal hearing for licensure reprimand for failure to correct CSMD. Dr. Rodgers seconded the motion. The motion carried.

30.

Respondent is the dispensing pharmacist for Case 29 above.

No prior discipline.

Recommend: LOW for misfill

Dr. Rodgers made the motion to issue a Letter of Warning for the misfill and submit a root cause analysis within 30 days . Dr. Pryse seconded the motion. The motion carried.

31.

Complainant prescriber alleged being told by a patient that the respondent pharmacy filled a 90 day supply of the patient's haloperidol without authorization from the patient or the prescriber. Complaint stated the prescriber does not issue 90 day supply of psychotropic medications because of risks.

BOP Investigators reviewed pharmacy records and the patient's entire profile back to 2010. Investigators found no medications for that patient had ever been filled for greater than a 30 day supply. Investigators also found that the patient had never had any haloperidol filled at the respondent pharmacy. The allegations could not be substantiated.

No prior discipline.

Recommend: Dismiss

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

32.

Complainant prescriber alleged that the respondent pharmacy and staff ignore instructions on newly written prescriptions to void previous prescriptions.

BOP Investigators reviewed prescription records and determined a Clonazepam prescription was filled on 10/9/18. It had 3 refills. It was refilled on 1/19/19 and again on 2/29/19. Meanwhile a new Clonazepam prescription was received on 2/4/19 and it also had 3 refills. It was put on hold and filled originally on 5/27/19 and was never refilled. This prescription did have a comment section with the following direction: "Pharmacist: Please void any previously issued psychotropic rxs from our office and replace w/ these newly issued rxs."

Investigators noted that no clonazepam prescriptions were filled early and that both prescriptions were the same strength, dosage and directions. However, the allegation made by the prescriber was confirmed. The PIC provided a statement that the complainant's prescribing process causes confusion of whether each new prescription is directing the pharmacy to void all previous psychotropic prescriptions, or just that particular drug. It also states that the pharmacy has a heavy workload, tech hours are being cut, and there is very little time to look back at profiles to void off prescriptions whenever new prescriptions are issued.

Unable to determine if prior discipline exists.

Recommend: LOI for strict conformity

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

33.

Complainant prescriber alleged that the respondent pharmacy and staff ignored a request via phone on 5/27/19 to void a patient's prescription for Alprazolam 0.5mg that was originally placed on hold on 5/2/19. A new verbal prescription for Alprazolam 0.25 was authorized on 5/27/19. It was for a 15 day supply with no refills. The Alprazolam 0.5mg was filled on 6/18/19 at the patient's request.

BOP Investigators obtained a statement from the PIC and reviewed dispensing records. Neither pharmacist recalls being asked to void the 0.5mg prescription. Since the 0.25mg prescription was only for a 15 day supply, neither prescription was filled early. No notes or documentation about the phone call were found. The 0.25mg prescription was a verbal order and it also did not have any notation about the prescriber requesting that the 0.5mg prescription be voided.

Unable to determine if prior discipline exists.

Recommend: Dismiss

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

34.

Complaint alleged a misfill when Clonidine 0.1mg was filled and dispensed with instructions to take 1 tablet every 6 hours as needed for SBP over "75"instead of "175." Two doses were administered and complaint alleged the patient's blood pressure "bottomed out" and the patient felt terrible for the next several days.

BOP Investigators reviewed the prescription. The PIC provided a written statement that the note on file says "don't know if nurse called in wrong-written down wrong or if discharge papers were incorrect." The prescription was filled and dispensed. Investigators could not confirm counseling occurred, but noted that counseling was being performed during their visit at the pharmacy. When the patient's family members contacted the pharmacy, the correct instructions were verified and the label was changed to >175.

No prior discipline.

Recommend: Dismiss against pharmacy

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

35.

Respondent is the dispensing pharmacist for Case 34 above. Although counseling could not be confirmed, Investigators believe proper counseling and/or proper DUR would have caught this error before it was dispensed.

No prior discipline.

Recommend: Reprimand for violation of 1140-03-.01 (3) (a)(5)

Dr. Rodgers made the motion to authorize a formal hearing with a license reprimand for violating board rule 1140-03-.01(3)(a)(5). Dr. Breeden seconded the motion. The motion carried.

36.

Complaint by a prescriber alleged the respondent pharmacy did not notify the prescriber that a patient was not filling Clozapine regularly and that the pharmacy dispensed the patient's Clozapine without proper bloodwork. The prescriber received a "Final Overdue Lab Alert" and the prescriber felt that the pharmacy should have known and should have informed the prescriber.

BOP Investigators interviewed the pharmacy's PIC and reviewed pharmacy records. It was found that the pharmacy software will not allow Clozapine to be filled without current and appropriate lab values entered at the time of fill. The system does not allow an override. Lab values are sent to the pharmacy with the e-script from the prescriber. Clozapine was dispensed on June 17, July 20, August 22, and September 17, each for a 30 day supply. The pharmacy had no reason to contact the prescriber since the prescriptions were not being rejected. No violation could be found.

No prior discipline.

Recommend: Dismiss

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

37.

Respondent pharmacist entered a "best interest" guilty plea July 28, 2017 for theft greater than \$10,000. It was not reported to BOP as required in 1140-02-.01 (17). Also noted, the respondent renewed BOP license May 29, 2018 and did not disclose the conviction.

BOP Investigator received a response stating that the "best interest plea" had no charges of guilt and charges would be completely removed/expunged after July, 2020. Respondent also made restitution of \$ 21,000.00.

Recommend: \$1,000 civil penalty for failing to report.

Dr. Rodgers made the motion to authorize a formal hearing with a \$1000.00 civil penalty for failure to report. Dr. Pryse seconded the motion. The motion carried.

38.

Multiple allegations of unprofessional conduct were received at the BOP office from sources that wish to remain anonymous. BOP Investigators found that respondent has accessed CSMD records of patients and non-patients of the employing pharmacy and also accessed the records of at least one pharmacist co-worker. Investigators found a total of 39 times the CSMD was inappropriately accessed, including 4 times that the respondent's estranged wife's records were accessed without a reason or permission. It is also alleged the respondent made threats and left vulgar notes on an acquaintance's car.

Respondent is currently on probation with BOP. Respondent's employment was terminated on September 25th. Respondent was arrested for harassment, verbal threats and intimidation on October 14th.

November 11, 2011 – License suspended indefinitely for addiction to alcohol, narcotics or other drugs.

February 7, 2017 – License placed on probation for five years.

Recommend: Revoke pharmacist license. Refer case to OCR for HIPAA violations.

Dr. Rodgers made the motion to authorize a formal hearing for revocation of the pharmacist license and to refer the case to OCR for HIPPA violations. Dr. Pryse seconded the motion. The motion carried.

39.

Anonymous complaint was forwarded from another department. The complaint alleges misconduct at the respondent pharmacy involving a pharmacist compounding and dispensing prescriptions without authorization and pharmacy staff using misappropriated funds from customers to satisfy staff's deductibles.

BOP Investigators reviewed records and interviewed staff. A collaborative pharmacy practice agreement was on file at the pharmacy, listing the pharmacy but not the individual pharmacists. The CPPA allows pharmacists to manage hormone therapy for patients of the collaborating physician. The pharmacist showed investigators some examples of patient case files. The pharmacist stated other prescribers sometime call in verbal requests for the pharmacist to manage their patients' hormone therapy. Investigators educated that the CPPA needs to be updated to be more specific about which pharmacists are covered and that verbal requests from prescribers to manage their patients need to be documented and, if applicable, CPPA agreements should be signed, or patient-specific orders should be generated.

Investigators found that staff and their family members pay for their medications and the pharmacist witnesses. They do use payment options such as flex cards, checks, cash and credit cards. Investigators reviewed records of card payments. No violations were found in this investigation other than the CPPA and requests by other prescribers for the pharmacist to manage patients needed better and more specific documentation.

No prior discipline.

Recommend: LOI

Dr. Breeden made the motion to issue Letter of Instruction. Dr. Rodgers seconded the motion. The motion carried.

40.

Respondent is the pharmacist for Case 39 above.

No prior discipline.

Recommend: LOI

Dr. Rodgers made the motion to issue Letter of Instruction. Dr. McCall seconded the motion. The motion carried.

41.

Respondent is the technician specifically named in Case 39 above.

No prior discipline.

Recommend: Dismiss

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

42.

Complaint originally initiated from a prescriber noticing some controlled substance prescriptions were wrongfully entered into CSMD. As the complaint was being investigated by different agencies, suspicions mounted that forgeries by a pharmacist might be involved.

BOP Investigator obtained statements from prescribers denying authorizing at least thirteen different prescriptions with refills. All the denied prescriptions were for the same patient, who is a pharmacist working at the respondent pharmacy.

No prior discipline.

Recommend: Pharmacy management to review and correct prescriber names associated with the complaint.

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

43.

An investigation uncovered at least thirteen different prescriptions with refills had been reduced to writing by the respondent pharmacist for himself and family members. Of the five practitioners listed as the prescribers, four denied authorizing any of the prescriptions. The fifth prescriber had died but the clinic was able to verify those prescriptions were not authorized. Controlled substances on the prescriptions included Diphenoxylate/Atropine, compounded testosterone topical, and Carisoprodol.

Respondent pharmacist stated he was told by all the prescribers that they would authorize anything he or his family needed, except Schedule 2 narcotics, provided that he create the prescription or contact them. Respondent did not have any proof of such an agreement and the prescribers denied having an agreement.

No prior discipline.

Recommend: Reprimand with probation.

Dr. Pryse made the motion to authorize a formal hearing with licensure reprimand and 1 year probation. The pharmacist cannot fill prescriptions for himself or family members. Dr. McCall seconded the motion. The motion carried.

44.

Complainant is a medical clinic director. The complaint alleges that a physician's assistant employed at the clinic was listed as the prescriber for the respondent's Alprazolam prescription. The physician's assistant denied authorizing this drug for the respondent. The verbal order prescription listed was for 60 Alprazolam 0.5mg to take ½ to 1 tablet at bedtime as needed for anxiety. It showed that the original and five refills were authorized. All were filled and dispensed within a six month timeframe.

Respondent admitted to BOP Investigator that he was not seen personally by the prescriber but the prescriber had prescribed for him and family members in the past. Respondent claimed he was involved in divorce proceedings when the prescription was phoned in and that the prescriber is best friends with his ex-wife. According to the respondent, the prescriber even suggested he should see a counselor.

Prescriber denied authorizing the prescription and claims to only give refills if a patient is going on a trip. Prescriber also stated she normally prescribes Clonazepam instead of Alprazolam. Prescriber did admit to being friends with the respondent's ex-wife.

August 29, 2013 – Assessed \$1,400 civil penalty for failing to have a technician registered between May 6, 2011 and October 5, 2012.

Recommend: Reprimand with probation

Dr. Pryse made the motion to authorize a formal hearing with licensure reprimand and 1 year probation. The pharmacist cannot fill prescriptions for himself or family members. Dr. Breeden seconded the motion. The motion carried.

45.

Respondent pharmacist admitted to diversion of controlled substances and was terminated from employment.

No prior discipline.

Recommend: Revoke

Dr. Breeden made the motion to authorize a formal hearing for revocation. Dr McCall seconded the motion. The motion carried.

46.

Respondent pharmacist served as PIC when an investigation into another pharmacist diverting drugs revealed large shortages of controlled substances. Although the respondent was not considered to be involved in diversion, his employment was terminated for negligence when management felt he should have known or noticed drugs were being diverted.

Respondent told BOP Investigator that he was the director of two hospital pharmacies and was kept extremely busy by multiple duties related to formulary changes, ADM system changes, and other duties as requested by management. Respondent stated he was self-taught and was unaware of ways drugs could be diverted in ADM's.

No prior discipline.

Recommend: LOI to learn responsibilities of PIC and become familiar with equipment. Recommend if he ever becomes PIC then he should learn to perform reconciliation audits.

Dr. Rodgers made the motion to issue a Letter of Instruction to the PIC stating that he/she must learn the responsibilities of a PIC, become familiar with equipment and how to perform reconciliation audits. Dr. McCall seconded motion. The motion carried.

47.

BOP was made aware that a pharmacy, compounding sterile product, ceased all compounding, then recalled product as suggested by FDA due to sterility issue concerns.

2009 – Civil penalty issued for failing to properly label prescription drugs.

Recommend: Revocation or suspension with terms.

Dr. Rodgers made the motion to authorize a formal hearing for suspension until all USP 797 standards have been met and the pharmacy re-inspected by a pharmacy investigator. Dr. McCall seconded he motion. The motion carried.

48.

Respondent is PIC for Case 47 above. Since the facility does cGMP, respondent has very little authority for QA.

No prior discipline.

Recommend: LOW

Dr. Pryse made the motion to issue a Letter of Warning. Dr. Breeden seconded the motion. The motion carried.

49.

TBOP was notified that the respondent pharmacy had dispensed and shipped 243 prescriptions into Tennessee without being properly licensed from 12/27/13 until 9/27/16. That included 19 shipped into Tennessee after an application was filed but before a license was granted on 9/28/16. Also alleged was that the PIC knew this was a violation and that the respondent pharmacy did not report to CSMD as required.

No prior discipline.

Recommend: Mimic other states' discipline: Suspend license for one month, all of which is stayed for two years provided no laws, rules or regulations are violated. Additional \$1,000.00 per prescription times 243 = \$243,000.00. Penalty for 54 prescriptions filled, checked and sent to patients in Tennessee by the pharmacist owner that was not licensed in Tennessee. \$1,000.00 per RX times 54 = \$54,000.00. Total \$297,000.00.

Dr. Pryse made the motion to authorize a formal hearing to suspend the pharmacy license for one month with the suspension stayed provided not laws, rules or regulations are violated, assessed a \$243,000.00 civil penalty for shipping 243 prescriptions into Tennessee without being properly licensed from 12/27/2013 until 9/27/2016and a \$54,000.00 civil penalty for 54 prescriptions filled, checked and sent to patients in Tennessee by the pharmacist owner who was not licensed in Tennessee. Dr. McCall seconded the motion. The motion carried.

50.

Respondent pharmacist began working for the pharmacy in Case 49 above on 2/28/16. Respondent admitted checking 16 of the prescriptions sent into Tennessee before the pharmacy was licensed 9/28/16, knowing that the pharmacy was not licensed. Respondent was not licensed as a pharmacist in Tennessee until 8/17/16. Respondent admitted two controlled substances (Testosterone) were sent into Tennessee but were not reported to CSMD. A reporting waiver was obtained in 2019.

No prior discipline.

Recommend: \$1,000.00 per RX violations = \$16,000.00; \$1,000.00 per CSMD violations = \$2,000.00. Total of \$18,000.00

Dr. Pryse made the motion to authorize a formal hearing with a \$16,000.00 civil penalty for checking 16 of the prescription sent into Tennessee before the pharmacy was licensed and a \$2000.00 civil penalty for not reporting to the CSMD. The pharmacist was not licensed in Tennessee until 9/28/2016. Dr. Breeden seconded the motion. The motion carried.

51.

BOP Investigator was able to determine the respondent 3PL had operated unlicensed in Tennessee for a period of twelve months. They are now licensed.

No prior discipline.

Recommend: Civil penalty \$100 per month for a total of \$1200.00.

Dr. Rodgers made the motion to authorize a formal hearing with a \$1200.00 civil penalty for unlicensed practice. Dr. Breeden seconded the motion. The motion carried.

52.

Anonymous complaint alleges respondent pharmacy has issues "due to dangerously short staffing." Among issues alleged are long waits, having to make multiple trips, rude staff, and failure to transfer prescriptions as requested.

BOP Investigator reviewed prescription volume and staffing. A staff pharmacist declined to answer whether staffing was adequate. The PIC stated that customers are responding to customer satisfaction surveys that the pharmacy is short-staffed, and pointed out that four of the last five surveys comment on the pharmacy being understaffed.

Management provide information on volume and staffing. The pharmacy averages about twenty prescriptions per hour. One pharmacist is scheduled with overlap of two hours twice a week on some weeks. Weekdays, there are usually two techs on duty for most of the hours with a third tech overlapping for five or six hours per day. One of the techs also services as a cashier and another tech works the drive-thru. There are no robotics or counting machines used in the filling process. There were some days when the pharmacist had no techs during the last one or two hours of the day. Investigator noted that the pharmacist on duty was verifying prescriptions, answering phone calls, ringing up prescriptions as needed, counseling and answering questions.

In response to the allegation of failure to transfer prescriptions, BOP Investigator was told that the electronic transfer system sometimes fails and the transferring pharmacy has to call to get a verbal transfer. Investigator provided education about transfer requirements.

Recommend: LOW and authorize Executive Director to meet with pharmacy management.

Dr. Rodgers made a motion to issue a Letter of Warning and to authorize the Executive Director to meet with pharmacy management. Dr. Pryse seconded the motion. The motion carried.

Discussion

Dr. Dilliard information the board that USP 800 and UPS 825 scheduled to become effective December 1, 2019 has been delayed. An appeal has been file and a new panel has been appointed to review the appeal. At this time, USP 800 and USP 825 are not enforceable at this time. Dr. Pryse suggested that the board leave the rules as is. Dr. McCall suggested more education and a report from the investigators. The Board will continue to enforce UPS 797.

Consent Orders

Dr. Rodgers made the motion to accept the following consent orders as presented. Dr. McCall seconded the motion. The motion carried.

SUSPENSION

Cody Allen Peeler, D.Ph.

VIOLATED BOARD RULE 1140-03-.01 (1)(a)

Tennessee CVS Pharmacy, #7608 Roderick D. Deal, D.Ph Perkins Drugs James Perkins, D.Ph

VIOLATED BOARD RULE 1140-01-.08 (1)

Insightra Medical

VIOLATED T.C.A. § 53-13-310 (a)

Riggs Drugs Jonathan Broyles, D.Ph.

VIOLATED BOARD RULE 1140-07-.02

Omnicare of Memphis

VIOLATED T.C.A § 53-11-106 (a) (1) (b)

Town & Country, lic #2286

REPRIMAND

Riddle Drugs #3

AGREED ORDER

Dr. Rodgers made the motion approve the following agreed order as presented. Dr. McCall seconded the motion. The motion carried.

ORDER OF COMPLIANCE

Carli Ferrara, RT

Appearance/Application Review Macy Whitcraft, RT

Ms. Whitcraft answered "no" 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 offenses) whether or not sentence was imposed or suspended?" Ms. Whitcraft pled guilty to Possession of drug paraphernalia and simple possession 5/19/15; pled guilty to domestic assault 12/12/13; probation violation (drug related) 1/6/2017. After discussion, Dr. Pryse made the motion to approved Ms. Whitcraft's application for registration as a pharmacy technician. Dr. Breeden seconded the motion. The motion carried.

Waivers

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

Dr. Rodgers made the motion to approve the request from **Dale Robinson, D.Ph.** to waive the remaining 15 live continuing education hours needed to reinstate his pharmacist license but must successfully take and pass the NAPELX and the MPJE. Dr. Pryse seconded the motion. The motion carried.

Dr. McCall made the motion to approve the request from **Ellen McCormick, D.Ph.** to waive the three hundred and twenty (320) internship hours and the NAPLEX but must successfully take and pass the MPJE. Dr. Pryse seconded the motion. The motion carried.

Dr. Pryse made the motion to approve the request from **Stephanie Spitznogle, D.Ph.** to waive the one hundred and sixty (160) internship hours but must successfully take and pass the MPJE. Dr. Rodgers seconded the motion. The motion carried.

Dr. Pryse made the motion to approve the request from **Michael Dejos**, **D.Ph.** to waive the one hundred and sixty (160) internship hours but must successfully take and pass the MPJE. Dr. McCall seconded the motion. The motion carried.

Dr. Pryse made the motion to approve the request from **Jennifer Curran, Pharm.D.** to waive the one hundred and sixty (160) internship hours but must successfully take and pass the MPJE. Dr. Rodgers seconded the motion. The motion carried.

Dr. McCall made the motion to approve the request from **Nathan Rouse, Pharm. D.** to waive the one hundred and sixty (160) internship hours but must successfully take and pass the MPJE. Dr. Breeden seconded the motion. The motion carried.

Board rule 1140-02-.02 (7)

Tim Haley. D.Ph., Director of Pharmacy for ContinuumRx, is requesting modification of the pharmacist to tech ratio. Clinical Solutions Pharmacy current ratio is 4:1 and they would like to change it to 6:1. After discussion, Dr. Rodgers made the motion to deny the waiver request. Dr. McCall seconded the motion. The motion carried.

Board rule 1140-03-.12(5)

Dr. McCall made the motion to approve the request from **BriovaRx Pharmacy** to delivery medications to the pharmacy suites located in Franklin, TN and Nashville, TN. Dr. Breeden seconded the motion. The motion carried. They will not be delivery controlled substances.

Board rule 1140-01-(13)93) (d) and 1140-03-.14 (13)

Dr. Pryse made the motion to approve the request from **Vanderbilt Children's Surgery and Clinics** to waive the requirement for the pharmacy to be 180 square feet and to allow Ashley Houser to be the PIC at Vanderbilt Children's Hospital and Vanderbilt Children's Surgery and Clinics. DR. Rodgers seconded the motion. The motion carried.

Discussion

Dr. Dilliard asked the board to approve travel for board members, investigator and the executive director to attend the Tennessee Pharmacist Association Winter Meeting scheduled for February 22-25, 2020 in Nashville, TN. After discussion, Dr. Pryse made the motion to authorize travel for board members, investigators and the executive director to attend the Tennessee Pharmacist Association Winter Meeting scheduled for February 22-25, 2020 in Nashville, TN. Dr. McCall seconded the motion. The motion carried.

Dr. Rodgers made the motion to adjourn at 3:22 p.m. Dr. Pryse seconded the motion. The motion carried.

November 6, 2019

The Tennessee Board of Pharmacy reconvened on Wednesday, November 6, 2019 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members were present, the meeting was called to order at 8:09 a.m., by Dr. Wilson, president.

Contested Cases Stormy Nicole Gamble, RT

Ms. Gamble was not present nor represented by legal counsel. Mr. Gibbs represented the State. Mr. Phillip Hilliard was the Administrative Law Judge. Mr. Gibbs asked to proceed in default. Dr. Rodgers made the motion to proceed in default. Dr. McCall seconded the motion. The motion carried. Mr. Gibbs passed out the Notice of Charges. Ms. Gamble is charged with violating T.C.A. §63-10-305 (6). After discussion, Dr. McCall made the motion to revoked Ms. Gamble's registration as a pharmacy technician and assess case cost. Dr. Breeden seconded the motion. Dr. Rodgers 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.

Corey Parham, RT

Mr. Parham was not present nor represented by legal counsel. Mr. Gibbs represented the State. Mr. Phillip Hilliard was the Administrative Law Judge. Mr. Gibbs asked to proceed in default. Dr. Rodgers made the motion to proceed in default. Dr. Pryse seconded the motion. The motion carried. Mr. Gibbs passed out the Notice of Charges. Mr. Parham is charged with violating T.C.A. §53-10-104 (a), T.C.A. §53-10-104 (b), T.C.A. §53-10-105 (a), T.C.A. §53-11-402 (a)(3)., T.C. A §63-10-305 (4) and T.C.A §63-10-305 (6)After discussion, Dr. Rodgers made the motion to revoked Mr. Parham's registration as a pharmacy technician and assess case cost. Dr. Breeden seconded the motion. Dr. McCall made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Rodgers seconded the motion. The motion carried.

Order Modification Erica Lee, Pharm. D.

Dr. Lee appeared before the board to request that the probation status be lifted from his pharmacist license. Dr. Lee signed a consent order on 07/03/2018 placing her pharmacist license on conditional status. Dr. Lee has completed her probationary status with the OH Board of Pharmacy. After discussion, Dr. Rodgers made the motion request for order modification to lift the probationary/conditional status. Dr. McCall seconded the motion. The motion carried.

Appearance

Dr. Micha Cost, Executive Director for the Tennessee of Pharmacy Association appeared before the board to request an extension of the Tech Check Tech Pilot Program. The Tech Check Tech Pilot Program was approved by the board at the May 1-2, 2018 board meeting. After discussion, Dr. Pryse made the motion to grant the extension for the Tech Check Tech Pilot Program for 2 more years. Dr. Breeden seconded the motion. The motion carried.

Dr. Christopher Patterson, PIC for Tallent Drug Co., is requesting clarification of the repacking dispense medication. Dr. Patterson stated that he would not re-dispense the medication only repackaging it. After discussion, Dr. Pryse made the motion to move this discussion until the January 7-8, 2020 board meeting. Dr. McCall seconded the motion. The motion carried.

Dr. Pryse made the motion to adjourn at 12:00 p.m. Dr. McCall seconded the motion. The motion carried.

The minutes were approved and ratified as amended at the January 7, 2020 board meeting.