

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

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Patricia Beckham, Pharmacy Investigator
Sheila Bush, Administrator Director

The Tennessee Board of Pharmacy convened on Tuesday, January 7, 2020, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 8:02 a.m.

Elections

Dr. Wilson thanked the Board and the Board staff for the cooperation and help during her leadership as president. Dr. Wright made the motion to nominate Dr. Pryse as president. Dr. Breeden seconded the motion. The motion carried. Dr. Breeden made the motion to nominate Dr. Wright as vice president. Dr. McCall seconded the motion. The motion carried.

Minutes

Dr. McCall made the motion to accept the minutes from the November 5-6, 2019 board meeting as amended. Dr. Wright seconded the motion carried

Office of General Counsel Report

Mr. Gibbs informed the board that there are currently 59 cases open for discipline within the Office of General Counsel. Of those 59 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.

Mr. Gibbs informed the board that the second session of the 111th General Assembly will reconvene on January 14, 2020.

Complaint Summary

1.

Respondent pharmacist admitted to diverting controlled substances from patients' prescription bags.

No prior discipline.

Recommend: Revoke pharmacist license

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

2.

Respondent technician admitted to stealing controlled substances.

No prior discipline.

Recommend: Revoke tech registration

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

3.

Complaint alleged the respondent pharmacy had no PIC for a 56 day period.

BOP Investigator found that completed change of PIC forms were not sent to BOP as required. According to documents at the pharmacy, the original PIC went on maternity leave 4/3/19. A temporary PIC was named 4/30/19 but did not sign the paperwork until 5/29/19. The original PIC was reinstated 6/26/19.

No prior discipline.

Recommend: \$50 per month civil penalty for 2 months =\$100

Dr. Rodgers made the motion to authorize a formal hearing with \$50.00 per month civil penalty for a total of \$100.00 to the pharmacy for not having a PIC for 2 months. Dr. Wright seconded the motion. The motion carried.

4.

Complaint alleged fraudulent claims were submitted to third party plans by the respondent pharmacy.

BOP Investigator found the respondent pharmacy in process of closing. The pharmacy had no inventory and was no longer conducting any business. Staff declined to provide a written statement.

The pharmacy located in Tennessee has since closed.

No prior discipline.

Recommend: Close and refer to interested agencies.

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

5.

Complaint alleged fraudulent claims were submitted to third party plans by the respondent pharmacy.

BOP Investigator found the respondent pharmacy in process of closing. The pharmacy had no inventory and was no longer conducting any business. Staff declined to provide a written statement.

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. Wilson seconded the motion. The motion carried

6.

Complainant pharmacist alleged that the respondent pharmacist refused to transfer patients' prescriptions to the complainant's pharmacy.

Respondent pharmacist told BOP Investigator that all requested prescriptions had been transferred and provided profiles that show the status of the prescriptions as "discontinued." Investigator provided education on transfer requirements.

No prior discipline.

Recommend: LOI to reinforce education by Investigator.

Dr. Wright made the motion to issue a Letter of Instruction reinforcing the education given by the Investigator. Dr. Breeden seconded the motion. The motion carried.

7.

Respondent is the pharmacy named in the complaint for Case 6 above.

No prior discipline.

Recommend: Dismiss against the pharmacy

Dr. Wilson made the motion to dismiss the complaint against the pharmacy. Dr. McCall seconded the motion. The motion carried.

8.

Respondent pharmacist could not renew pharmacist's license due to unpaid professional privilege taxes. Respondent worked 10 days on an expired license and filled a total of 161 prescriptions.

Prior discipline:

1998 – License revoked: chemical dependency (reinstated in 1999 – probation for 5 years)

2008 – License revoked: chemical dependency (reinstated in 2009 – probation for 10 years)

Recommend: Civil penalty \$1,000.00

Dr. Wilson made the motion to authorize a formal hearing with a \$1000.00 civil penalty to the pharmacist for working on an expired license. Dr. Rodgers seconded the motion. The motion carried.

9.

Complaint from a patient alleges a failure to counsel on new prescriptions.

BOP Investigator visited the respondent pharmacy and observed that on at least 2 new prescriptions, counseling was not being performed as required. Investigator reviewed previous visits and found that the pharmacy had been previously warned and educated about counseling. In January, the Investigator observed failures to counsel and educated staff. A corrective action plan was requested and it was received in February. Investigator made a follow-up visit in April and observed violations and again educated that new prescriptions must be counseled, not just an offer to counsel. Investigator made a visit in October and observed counseling being performed correctly while a floater pharmacist was on duty. While investigating this complaint in November, the Investigator again observed new prescriptions being dispensed with only an offer to counsel.

No prior discipline.

Recommend: Reprimand and civil penalty \$2,000.00 with no stay.

Dr. Wilson made the motion to authorize a formal hearing with a letter of reprimand and a \$2000.00 civil penalty to the pharmacy. Dr. McCall seconded the motion. The motion carried.

10.

Respondent has been the PIC since at least 2014 for Case 9 above.

No prior discipline.

Recommend: Reprimand and civil penalty \$2,000.00; confirm education of staff on counseling requirements.

Dr. Wilson made the motion to authorize a formal hearing with a letter of reprimand and a \$2000.00 civil penalty to the PIC. Dr. Rodgers seconded the motion. The motion carried. The PIC must show confirmation that the staff has been education on counseling requirements.

11.

Respondent technician was terminated from employment due to positive THC results on a drug screening. It is unknown if the results were from CBD or marijuana.

Respondent denied using any illicit drugs and made reference to other drug tests over the last few years that were all negative. Respondent admitted to eating candy that an acquaintance called “an edible.”

No prior discipline.

Recommend: Suspend until receives an valuation from TPRN.

Dr. Wright made the motion to authorize a formal hearing for suspension of the pharmacy technician registration until they have been evaluated by TPRN and the report has been received. Dr. Wilson seconded the motion. The motion carried.

12.

Respondent technician admitted to police to diverting Oxycodone and Oxymorphone from a pharmacy.

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.

13.

Respondent pharmacy is on probation and under a monitoring contract. The monitoring company reported some issues as non-compliant so BOP Investigators performed a thorough inspection of the pharmacy as well as practices of the PIC/owner and pharmacy staff.

Investigators' findings include the following:

- Failure to counsel and/or offer to counsel as required;
- Failure to research and/or document red flag issues;
- Failure to research and/or document high MME issues;
- Failure to document reasons for Buprenorphine mono-product usage;
- PIC is unable to log into CSMD without assistance; one extender tech under the PIC checks;
- PIC does not perform DUR;
- Techs override DUR without speaking to the pharmacist;
- PIC does not review input information entered by techs;
- PIC does not perform a complete final verification of prescriptions;
- CSOS violations were found;
- Staff members told investigators they find and correct frequent errors made by the PIC.

Prior discipline:

- 2013 - \$1,100 civil penalty
- 2018 – Inappropriate dispensing (2-year monitoring contract; costs)

Recommend: Revoke pharmacy license and collect costs of the investigation.

Dr. Wright made the motion to authorize a formal hearing for revocation of the pharmacy license. Dr. Breeden seconded the motion. The motion carried.

14.

Respondent is the PIC for Case 13 above.

Prior discipline:

- 1997 – Failure to comply with Board's order (probation)
- 2014 – Failed to have technician properly registered (civil penalty)

2014 – Failed to provide patient counseling (civil penalty)

Recommend: Revoke pharmacist's license.

Dr. Rodgers made the motion to authorize a formal hearing for revocation of the pharmacist license. Dr. Wright seconded the motion. The motion carried.

15.

During a pharmacy inspection, BOP Investigator found an unregistered tech and educated about the 90 day rule. On a subsequent visit approximately 6 months later, the Investigator found that the same tech was still not registered.

The tech has since completed the registration.

No prior discipline.

Recommend: Complaint should be against the PIC.

Dr. McCall made the motion to open a complaint against the PIC. Dr. Breeden seconded the motion. The motion carried.

16. 201905910

Respondent is the PIC for Case 15 above.

No prior discipline.

Recommend: \$300.00 civil penalty (\$100 per month for approx. 3 months beyond the 90 day period.)

Dr. Wilson made the motion to authorize a formal hearing with a \$300.00 civil penalty to the PIC for allowing a technician to work unregistered. Dr. Breeden seconded the motion. The motion carried.

17.

Respondent is the tech for Case 15 above.

No prior discipline.

Recommend: \$100.00 civil penalty

Dr. Breeden made the motion to authorize a formal hearing with a \$100.00 civil penalty to the pharmacy technician. Dr. Rodgers seconded the motion. The motion carried.

18.

Complainant pharmacy alleged the respondent pharmacy refused to transfer prescriptions.

BOP Investigator visited the respondent pharmacy and obtained statements and gathered information. The allegations could not be confirmed.

No prior discipline.

Recommend: Dismiss

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

19.

Complainant pharmacy alleged the respondent pharmacist refused to transfer prescriptions.

BOP Investigator obtained statements and gathered information. The allegations could not be confirmed.

No prior discipline.

Recommend: Dismiss

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

20.

Respondent tech admitted in writing to diversion of controlled substances.

No prior discipline.

Recommend: Revoke tech registration

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

21.

Complaint alleged several examples of possible insurance fraud against the respondent pharmacy.

BOP Investigator interviewed the pharmacy staff and reviewed documentation, including a letter of explanation and correction as well as a letter of acceptance from the insurance company. Investigator could not confirm the allegations. However, the respondent pharmacy does compounding and provides prescribers with a pre-printed compounding order sheet which may possibly violate FDA regulations.

No prior discipline.

Recommend: Dismiss complaint but forward the order sheet to FDA.

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

22.

Anonymous complaint made several workplace related allegations including:

- Tech ratio is not correct;
- Controlled substances are not secure;
- Employees are not directly supervised by PIC; some are supervised by someone off-site;
- Employees and PIC are not allowed to contact BOP unless approved by corporate;
- Room temperature is not proper for drug storage.

BOP Investigator visited the site and obtained sworn statements. The allegations were all denied. Room temperature charts and refrigeration charts were provided. None of the allegations could be substantiated.

No prior discipline.

Recommend: Dismiss

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

23. pulled for new evidence

24.

Complainant patient alleged the respondent pharmacy may be re-dispensing medications. Patient's medication arrived damaged so the shipment was refused. When the replacement drugs were received, the patient alleged that it had the same dispensing labels. The patient also alleged an improper \$15 copay was applied to the replacement.

The pharmacy shipped replacement drugs and reprinted the dispensing labels to show the original dispensing date so the patient's insurance would not have to be contacted for a re-bill. Respondent denied re-dispensing any drugs. Respondent also stated that the copay has been credited to the patient's account. No violation could be determined.

Unable to determine if prior discipline exists.

Recommend: Dismiss

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

25.

Complaint from a prescriber's clinic alleged the respondent pharmacy is incompetent and does not know how to effectively carry out their duties. Examples given included the following:

- Incorrectly denied filling by not properly utilizing prior authorizations;
- Using incorrect benefits provider;
- Failure to inform the patient and PCP that prescriptions were transferred to a different pharmacy;
- Failure to properly utilize patient copay assistance cards;
- Not delivering medication in a timely manner resulting in worsening symptoms;
- Overall poor patient service.

BOP Investigator reviewed phone logs from the prescriber and documentation provided by the respondent pharmacy. Although there were delays caused by prior authorization requirements, poor communication, and more than one third party plan which resulted in confusion on what pharmacy the patient had to use, the Investigator could not find violations of laws or rules.

Unable to determine if prior discipline exists.

Recommend: Dismiss

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

26.

Complaint alleged a misfill resulted in the patient ingesting 6 to 8 tablets of Bumetanide instead of the prescribed Flecainide.

Although the pharmacy has closed permanently, BOP Investigator was able to determine the dispensing pharmacist and interviewed that pharmacist 2 days before closing. The pharmacist declined to give a written response but stated he was aware of the misfill and had kept the returned Bumetanide to show the similarities between it and the Flecainide tablets. The misfill was confirmed.

No prior discipline.

Recommend: Dismiss against the pharmacy and LOW to the dispensing pharmacist.

Dr. Rodgers made the motion to dismiss the complaint against the pharmacy and issue a Letter of Warning to the dispensing pharmacist. Dr. McCall seconded the motion. The motion carried.

27.

Respondent is the dispensing pharmacist for Case 26 above.

No prior discipline.

Recommend: LOW to dispensing pharmacist for misfill.

Dr. Rodgers made the motion to issue a Letter of Warning to the dispensing pharmacist concerning the misfill. Dr. McCall seconded the motion. The motion carried.

28.

Complaint alleged an incorrect prescriber name was entered at the respondent pharmacy on a prescription for a controlled substance. Complainant prescriber works in a student health system and rarely, if ever, prescribes any controlled substances. However, due to name similarities, the complainant has even been issued a letter from CSMD regarding potential over-prescribing.

Although this complaint only lists one example, the prescriber has had the same issue at several area pharmacies. BOP Investigators have educated pharmacies multiple times and the errors occur less frequently, but are still happening. This particular prescription was transferred from another pharmacy which did use the correct prescriber, however the prescriber name was changed to the incorrect name by the receiving pharmacy.

No prior discipline.

Recommend: Reprimand with corrective plan of action and costs of the investigation.

Dr. Wilson made the motion to authorize a formal hearing for license reprimand with a corrective plan of action and the cost of the investigation. Dr. McCall seconded the motion. The motion carried.

29.

Complainant prescriber alleged a misfill by the respondent pharmacy because the prescriber's order to compound a prescription using Itraconazole capsules was ignored and the pharmacy used bulk powder. According to the prescriber and some literature, the bulk powder is not as effective. Complaint alleged the substitution resulted in the patient showing no clinical improvement.

BOP Investigator interviewed pharmacy staff and reviewed the prescription order, which was a verbal order. There was no notation on the prescription that the prescriber requested capsules instead of powder. Both pharmacists remembered their conversations with the prescriber but neither remembered the subject of capsules vs powders being brought up until after the fact. The allegations could not be confirmed.

Prior discipline

2016 – sterile compounding violations (\$1,000 civil penalty)

Recommend: Dismiss

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

30.

Respondent is the dispensing pharmacist for Case 29 above.

No prior discipline.

Recommend: Dismiss

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

31.

Complaint alleged inappropriate dispensing of controlled substances by the respondent pharmacy because a patient should have enough Gabapentin refills to last until April, but a refill was requested in September. Another allegation stated that the respondent pharmacy filled a Zolpidem prescription under the wrong prescriber's name. It is also alleged that pharmacy staff told the prescriber that some of the Gabapentin prescriptions should have gone under another provider's name.

BOP Investigator reviewed records at the respondent pharmacy and found no issues with the Gabapentin prescriptions. The Zolpidem prescription was actually filled under the correct prescriber, and staff had no memory of ever telling the prescriber that another prescriber's name should have been used on some of the Gabapentin prescriptions. Investigator could not find any evidence to substantiate the allegations.

No prior discipline.

Recommend: Dismiss

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

32. 201805128

Complaint by local police department indicated that a confidential informant alleged illegal activity at the respondent pharmacy and that a certain technician may be taking controlled substances from a pharmacy and selling them for profit.

BOP Investigators conducted an extensive inspection and investigation, including audits and a review of CSMD records for the pharmacy. The controlled substance audit revealed many irregularities including the following shortages:

23,983 Hydrocodone APAP 10/325;
9,435 Oxycodone 15mg;
5,506 Oxycodone 30mg;
571 Alprazolam 0.25mg;
5,750 Alprazolam 0.5mg;
17,666 Alprazolam 1mg;
1,115 Buprenorphine/Nx 8/2 SL tab;
186 Suboxone 8/2 film;
339 Buprenorphine 8mg SL tab.

The audit also showed the following overages:

1,532 Hydrocodone APAP 7.5/325;
411 Hydrocodone APAP 5/325;
94 Clonazepam 1mg.

BOP Investigator noted that even after being advised to conduct a complete CS inventory and report losses to DEA and BOP, the PIC did not do so until 3 months later.

BOP Investigators returned at a later date and conducted a follow-up audit and found the following shortages occurred within a 106 day period:

188 Hydrocodone APAP 7.5/325;
1 Oxycodone 15mg;
11 Alprazolam 0.25mg;
64 Alprazolam 0.5mg;
527 Alprazolam 1mg;
91 Alprazolam 2mg;
45 Buprenorphine/Nx 8/2 SL tabl

The following overages were found to have occurred within the same 106 day period:

829 Hydrocodone APAP 10/325;
292 Hydrocodone APAP 5/325;
8 Oxycodone 30mg;
789 Clonazepam 1mg;
126 Suboxone 8/2 film;
110 Buprenorphine SL tab.

Investigators noted that the PIC does not closely supervise staff dispensing controlled substances and had not noticed repeated reprinting of prescription labels which may be a mechanism of diversion within the

pharmacy. Investigators have not been able to determine who is diverting the controlled substances and the PIC insists that no one is diverting controlled substances.

No prior discipline.

The next case is the same respondent.

Dr. Wright made the motion to authorize a formal hearing for revocation of the pharmacy license. Dr. Rodgers seconded the motion. The motion carried.

33.

This is the same respondent as Case 32 above. As BOP Investigators were investigating the above case, other violations were found including the following:

A technician was allowed to work on an expired registration from 6/1/18 to 11/6/18 (6 months);
Investigators observed a technician dispense medication without proper pharmacist supervision;
Investigators discovered that a technician had a key to the pharmacy;
The pharmacy did not have a current copy of the law book;
Incorrect prescriber names were used on some prescriptions;
Verbal orders were not being initialed;
Transferred prescriptions were not being properly documented;
Food was found in medication refrigerators and freezers;
Out of date vaccines were found;
Tech registry was not being maintained;
CSOS requirements were being violated by allowing non-certificate holders to place and receive orders;
Controlled substance losses were not reported as required;
Investigators noted that the PIC failed to maintain supervision over the dispensing and receiving of controlled substances.

Recommend: Revoke pharmacy license

Dr. Wright made the motion to authorize a formal hearing for revocation of the pharmacy license. Dr. Rodgers seconded the motion. The motion carried

34.

Respondent is the technician with the expired registration in Case 33 above.

No prior discipline.

Recommend: \$100.00 civil penalty

Dr. Wilson made the motion to authorize a formal hearing with a \$100.00 civil penalty to the technician for working on an expired registration. Dr. McCall seconded the motion. The motion.

35.

Respondent is the PIC for Cases 32, 33 and 34.

Prior discipline:

2015 – Failed to dispense prescriptions in strict conformity

Recommend: \$ 1,000.00 civil penalty for key violation; \$ 600.00 civil penalty for expired tech registration; reprimand and probation for audit discrepancies and other violations.

Dr. Wright made the motion to authorize a formal hearing to the PIC with a \$1000.00 civil penalty for key violations, a \$600.00 civil penalty for allowing a technician to work on an unexpired registration, license reprimanded and placed on probation for audit discrepancies and other violations. Dr. Breeden seconded the motion. The motion carried.

36.

Complaint filed by a prescriber alleged the respondent pharmacy incorrectly listed the complainant as prescribing Clonazepam 2mg and Alprazolam 2mg for a patient when actually the medications were prescribed by a different prescriber. According to the complaint, the complainant contacted the respondent pharmacy and this was corrected.

The same complainant alleged a separate incident occurred when the same patient was incorrectly dispensed 69 tablets of Oxycodone 10mg as a completion of a partial fill even though the patient had been changed to Hydrocodone several months prior to the pharmacy completing the partial fill of Oxycodone. The drug had been changed as the prescriber was trying to taper the opioid because the patient was on benzodiazepines. According to the complainant, this caused the tapering plan to have to move backward because of the increase in opioid dosage.

A sworn statement from the dispensing pharmacist stated the partial fill had actually been completed in January but another 69 tablets were dispensed to the patient in July by mistake.

A sworn statement from the PIC stated that due to software issues in January, the partial fill of the remaining 69 tablets dispensed did not get properly closed in the system and was accidentally re-dispensed in July.

Investigator noted that a proper DUR or a check of CSMD could have prevented the mistake.

No prior discipline.

Recommend: LOW for pharmacy regarding procedures and software issues.

Dr. Breeden made the motion to issue a Letter of Warning to the pharmacy regarding procedures and software issues. Dr. Wright seconded the motion. The motion carried.

37.

Respondent is the dispensing pharmacist for Case 36 above.

No prior discipline.

Recommend: Reprimand and costs of investigation.

Dr. Rodgers made the motion to authorize a formal hearing for license reprimand and the cost of the investigation. Dr. Breeden seconded the motion. The motion carried.

38.

Complaint alleged possible over dispensing of benzodiazepines based upon quantities and days' supply submitted to CSMD. According to the complaint, a 30 days' supply of Clonazepam was dispensed on 7/25/19 and 8/8/19. A 30 days' supply of Alprazolam was dispensed on 8/22/19 and 9/3/19.

BOP Investigator visited the pharmacy and interviewed the PIC. While reviewing the prescriptions, the Investigator noted the following:

Clonazepam 0.5 mg. on 7/25/19 was for 50 tablets to take 3 times per day which would actually have been a 17 days' supply and the patient should have completed on 8/10/19;

The next prescription was for Clonazepam 1mg to take 3 times daily which the patient should have completed on 9/8/19. However, on 8/22/19, the prescription was changed to Alprazolam 1mg to take 3 times daily;

Then on 9/3/19 a new prescription was issued increasing the dose to 4 times a day with a notation to fill that day. The patient should have had 51 tablets remaining on 9/3/19 which would have lasted approximately 13 days at the increased dose. However, the prescriber documented that the pharmacy was authorized to fill it on the day it was written;

As of November 15, 2019 the patient had not had any more benzodiazepines filled since 9/3/19.

No prior discipline.

Recommend: LOW to enter correct days' supply in CSMD.

Dr. Wilson made the motion to issue a Letter of Warning to the pharmacy to correct days' supply in CSMD. Dr. Wright seconded the motion. The motion carried.

39.

Complaint alleged the respondent pharmacy incorrectly listed the complainant as the prescriber of a Suboxone prescription on 6/4/19. Complainant is a nurse practitioner and fears being disciplined because it appears the NP prescribed the drug even though they are not allowed to do so in Tennessee. The complainant contacted the pharmacy and was told it would be corrected; however it was not corrected as of 9/6/19 or 11/18/19.

BOP Investigator visited the pharmacy and interviewed the PIC as well as the dispensing pharmacist. Investigator was told the error cannot be fixed at store level and "a ticket" had been sent to corporate on 6/11/19 but no action has yet been taken.

No prior discipline.

Recommend: Reprimand to the pharmacy.

Dr. Wright made the motion to authorize a formal hearing for license reprimand and the cost of the investigation. Dr. Breeden seconded the motion. The motion carried.

40.

Respondent is the dispensing pharmacist for Case 39 above.

No prior discipline.

Recommend: LOW for misfill

Dr. Rodgers made the motion to issue a Letter of Warning to the dispensing pharmacist for the misfill. Dr. McCall seconded the motion. The motion carried.

41.

Complaint alleged the respondent pharmacy and staff members are aggressively marketing an expensive vitamin by misleading patients into thinking their provider wants them to take the vitamin and misleading prescribers into thinking the patients are requesting that they be prescribed the vitamin.

PIC of the respondent pharmacy told BOP Investigator that in early 2019, the pharmacy discontinued recommending the vitamin due to fear of insurance audits and now recommends a similar product. PIC stated the vitamin is marketed especially to patients taking vitamin depleting medications and that currently they only has one third party plan that still pays for the vitamin and it appears that plan intends to recoup much of the fees paid to the pharmacy. PIC denied ever trying to pressure patients or prescribers and denied recommending the vitamin solely because insurance would pay for it.

No prior discipline.

Recommend: LOI to avoid unethical conduct.

Dr. Wilson made the motion to issue a Letter of Instruction to the pharmacy on how to avoid unethical conduct. Dr. Wright seconded the motion. The motion carried.

42.

Complainant, a prescriber with authority to issue prescriptions for controlled substances, asserts a pharmacy refused to fill any of the Complainant's controlled-substance prescriptions.

Respondent, a pharmacy that allegedly refused to fill Complainant's controlled substance prescriptions, stated Complainant's patients appeared at the pharmacy with prescriptions from the Complaint that:

- Exceed maximum dosage levels.
- Create high-risk drug combinations.
- Create dangerous combinations based upon prescriptions from other prescribers for the same, mutual patient(s); and
- Exhibited a pattern of prescribing similar controlled substance combinations for multiple patients.

Respondent produced documentation which showed multiple attempts by pharmacists to contact the Complainant were either:

- Unanswered from the Complainant; or

- Answered by Complainant's staff with insufficient information such that the pharmacists utilized professional judgment and refused to fill specific controlled substance prescriptions

Example – 74-year-old patient appeared at the pharmacy with prescriptions for Xanax, temazepam, and Adderall

- Complainant did not provide a substantive explanation to the pharmacist after inquiring about medical necessity

Investigation further showed Respondent uses a tiered system of incorporating “corresponding responsibility” into work flow. Under the system, a store-level pharmacist documents notes regarding questionable prescription(s) from any prescriber which (notes) are available to any pharmacist under the company's umbrella. The store-level pharmacist is empowered to block a single controlled substance prescription from a single prescriber or all controlled substance prescriptions from a single prescriber. These types of blocks do not apply to other pharmacists, even pharmacist serving on the same shift as the blocking pharmacist.

Respondent's corporate office developed data-driven analytical tools under the direction of (the corporate office's) investigators and scientists. If the two types of above-mentioned blocks – single controlled substance prescriptions or all controlled substance prescriptions from a single prescriber – happen with enough regularity, the corporate office may, by utilizing a system of escalating checks with multiple layers of research and review along with a higher threshold of concern, institute a block across all stores for all controlled substance prescriptions for a single prescriber (“corporate block”). The corporate office relies upon the professional knowledge of pharmacists (employed at the corporate level as part of a “block committee”), who have access to a wide array of in-house data points generated by the aforementioned analytical tools *and* the notes / reports of store-level pharmacists, to reach a decision regarding the corporate block. The corporate block is based, in part, on the presence of unresolved “red flags” or the combination of unresolved “red flags” in dispensing patterns as indicated by the analytical tools.

According to the Respondent, the entire system of escalating checks is designed to fight abuse and misuse of controlled substances.

- The Complainant received a corporate block in a written communication from the Respondent which also contained information regarding an appeal of the decision to block all of the Complainant's controlled substance prescriptions. As of August 21, 2019, the complainant has not responded to the correspondence.

- Appeals: prescribers are given the opportunity to submit additional prescribing information to the same committee for consideration. As the committee is only looking internally at in-store data, the prescriber may have external information which creates a holistic picture and removes red flags. The appeals process is rolling and ongoing.

- Complaint's corporate block began with the store-level pharmacists' notes and professional decision-making in refusing to fill certain controlled substance prescriptions. After enough blocks occurred at the store level, the corporate office utilized its analytical tools in conjunction with store-level unresolved red flags and determined a corporate block was necessary.

No prior discipline.

Recommendation: Dismiss

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

**Presentation
USP Standards**

Dr. Miller, pharmacist investigator, presented to the board an update of USP Standards. After discussion, Dr. Wilson made the motion to authorize Mr. Gibbs to introduce a caption bill through legislation to change the statute to include all applicable USP standards. Dr. Wright seconded the motion. The motion carried.

Appearance

Lorencia Cole, RT

Ms. Cole 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 offenses) whether or not sentence was imposed or suspended?" Ms. Cole pled guilty to Conspiracy to Distribute and to Possess with Intent to Distribute Xanax on 2/9/2012. She was placed on probation for 2 years. Ms. Cole was granted early release from probation on 11/21/2013. After discussion, Dr. Wilson made the motion to approve Ms. Cole's application for registration as a pharmacy technician. Dr. McCall seconded the motion. The motion carried. Dr. Wright voted no.

Jennifer Choate, RT

Ms. Choate 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. Choate pled guilty to Public Intoxication on 12/12/18 and was granted 1 year deferment with probation. After discussion, Dr. Wright made the motion to approve Ms. Choate's application for registration as a pharmacy technician. Dr. Breeden seconded the motion. The motion carried.

Angela Gilbert, RT

Ms. Gilbert 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. Gilbert was arrested on 01/16/2019 for failure to report a suspected crime. Ms. Gilbert's court appearance is scheduled for January 23, 2020. After discussion, Dr. Wright made the motion to approve Ms. Gilbert's application for registration as a pharmacy technician. Dr. Breeden seconded the motion. The motion carried.

Director's Report

Dr. Dilliard asked the board for authorization to represent them in the Endo vs Staubus lawsuit. After discussion, Dr. McCall made the motion authorizing Dr. Dilliard to represent the board in the Endo vs Staubus lawsuit. Dr. Breeden seconded the motion. The motion carried.

Tennessee Board of Pharmacy
Board Meeting
January 7, 2020

Dr. Dilliard informed the board of the pharmacy updates and asked the board to consider attending as well. The pharmacy updates are scheduled for the following dates and locations: January 25, 2020, Kingsport, TN; February 1, 2020 Chattanooga, TN; March 1, 2020, Franklin, TN; March 7, 2020, Murfreesboro, TN; March 15, 2020, Knoxville, TN; April 4, 2020, Jackson, TN and April 26, 2020, Memphis, TN.

Consent Orders

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

REPRIMAND

Tracy Eschelbacher, D.Ph.
Cookeville Pharmacy, LLC dba Andy's Pharmacy
Hardin Medical Center

VIOLATED BOARD RULE 1140-02-.02 (1)

Amanda Bearden, RT-\$100.00 civil penalty

VOLUNTARILY SURRENDER (same as revocation)

Suzanne Middleton, RT
Isiah Pigram, RT
Bridgett Patterson, RT
Fidah E A-Abed, RT

PROBATION

Leslie Turner, D.Ph.

Presentation

Katherine Twomey, Pharm.D. appeared before the board to present the business model for Script2U pharmacy. Script2U pharmacy will operate as a central fil pharmacy

Order Modification

Kelley Ledet, D.Ph.

Dr. Ledet appeared before the board to request that her probationary status be lifted. Dr. Ledet's was issued a conditional license on 11/9/18. After discussion, Dr. Rodgers made the motion to lift Dr. Ledet's probationary status. Dr. Wilson seconded the motion. The motion carried.

Waiver

Board rule 1140-03-.08

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 repackage it and would not repackage controlled substances. After discussion, Dr. McCall made the motion to grant a pilot program for six (6) months to Tallent Drug Co to repackage. This

pilot program will not include federal controlled substances. Dr. Wilson seconded the motion. The motion carried.

Board rule 1140-01-05

Dr. Wright made the motion to approve the request from **Imuwahen Uzzio, Pharm. D.** to grant an extension of NABP rule that requires an application to wait one year after several fail attempts to pass the NAPLEX. Dr. Wilson seconded the motion. The motion carried.

Board rule 1140-1-13 (3) (d)

Dr. Wright made the motion to approve the request from **Tennessee Vaccination Services, LLC** to waive the requirement for the pharmacy to be 180 square feet. Tennessee Vaccination Services, LLC will be 140 square feet. Dr. Breeden seconded the motion. The motion carried.

Board rule 1140-03-.14 (12)

Dr. Rodgers made the motion to approve Brandon Trull, Pharm.D. to be PIC of Trull Family Compounding Pharmacy and Trull Family Pharmacy for one year. Dr. Breeden seconded the motion. The motion carried. Dr. Trull must appear before the board if he has not hired a pharmacist to be PIC of one the pharmacy.

Public Comment

Dr. Baeteena Black issued an invitation to the board to attend PRN Conference scheduled March 6-8, 2020 at RT Lodge, Maryville TN.

Dr. Breeden made the motion to adjourn at 3:09 p.m. Dr. McCall seconded the motion. The motion carried.

The minutes were ratified and approved as amended at the April 2, 2020 telephonic Board Meeting.