

TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Iris Room
Nashville, TN
March 8-9, 2016

BOARD MEMBERS PRESENT

Will Bunch, D. Ph., President
Kevin Eidson, D.Ph., Vice President
Michael Dickenson, D. Ph.
Debra Wilson, D.Ph.
Rissa Pryse, D.Ph.
Joyce McDaniel, Consumer Member
Nina Smothers, D.Ph.

STAFF PRESENT

Reginald Dilliard, Executive Director
Stefan Cange, Assistant General Counsel
Terry Grinder, Pharmacy Investigator
Tommy Chrisp, Pharmacy Investigator
Richard Hadden, Pharmacy Investigator
Scott Denaburg, Pharmacy Investigator
Rebecca Moak, Pharmacy Investigator
Larry Hill, Pharmacy Investigator
Robert Shutt, Pharmacy Investigator
Andrea Miller, Pharmacy Investigator
Sheila Bush, Administrative Manager

The Tennessee Board of Pharmacy convened on Tuesday, March 8, 2016, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:09 a.m. Dr. Bunch welcomed students from Lipscomb University, South College, University of Tennessee and Union University.

Minutes

The minutes from the January 12-13, 2016 meeting was presented. Dr. Eidson made the motion to approve the minutes as presented. Dr. Smothers seconded the motion. The motion carried.

Presentation

Dr. Mitchell Mutter, Director of Special Project, appeared before the board to present an update of the Chronic Pain Guideline and to ask the board for approval of the policy changes. After discussion, the board decided to defer a decision until tomorrow to allow time for them to read the changes.

OGC Report

Mr. Cange informed the board that there are 31 cases for discipline at the Office of General Counsel with 2 cases to be heard at this meeting. He also stated that the rules are still being reviewed by the Attorney General's Office.

Mr. Cange explained to the board that the grant requisition for the professional assistance program is accepting bids.

Legislation

Mr. Cange informed the board of the following bills being introduced this legislative session that pertain to the board of pharmacy.

SB1882 - TennCare MTM

HB2225 – Statewide collaborative agreement: naloxone

HB1611 – BOP sunset legislation

HB2262 – Prescriber notification of generic equivalents

HB2447 – Requires Office of Vital Records to forward suspected overdose deaths to licensing boards for investigation

HB2571 – TN Prescription Safety Act of 2016

HB2126 – Physician dispensing of opioids and benzodiazepines

SJR0102 – Requires the Board to conduct a survey of pharmacist working conditions and license renewal

HB1768- Allows pharmacies to dispense different quantities of Rx's

Complaint Summary

Case 1.

Anonymous complaint against Respondent pharmacy and pharmacist alleged medications are sometimes advanced to patients, copays are not collected properly, and that pseudoephedrine and C5 cough syrups are sold indiscriminately. Complainant alleged Respondent pharmacist may also have some mental or emotional issues, feels above the law and “sometimes acts like a person that is bipolar.” Complainant also stated that staff at Respondent pharmacy would all deny the allegations and would all tell the same story because Respondent pharmacist is “very good at covering his tracks.”

Board investigator was unable to confirm any allegations and the pharmacy has now sold to a chain pharmacy. Corporate policies will prevent any of the above allegations from occurring,

Prior Discipline: None.

Recommendation: Dismiss

Dr. Dickenson made the motion to **accept counsel’s recommendation**. Dr. Wilson seconded the motion. The motion carried.

Case 2.

Respondent pharmacist for Case 1 above.

Prior Discipline: None.

Recommendation: Dismiss

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

Case 3.

Corporate loss prevention notified the Board of Respondent technician's termination of employment for creating a forged prescription for a non-controlled drug.

Board investigator obtained a copy of Respondent's signed statement admitting she wrote a new prescription for her boyfriend's thyroid medication. Respondent also admits in the statement that she knew writing the unauthorized prescription was wrong.

PIC provided a sworn statement to Board Investigator that he had contacted the prescriber's office and that they denied authorizing the prescription. Board investigator contacted the patient's physician who stated that there was no documentation in the patient's chart authorizing the prescription.

Prior Discipline: None.

Recommendation: Revoke tech registration

Dr. Smothers made the motion to **authorize a formal hearing** for revocation. Dr. Eidson seconded the motion. The motion carried.

Case 4.

Corporate management notified Board that Respondent tech transferred to Tennessee 9/17/14 but did not obtain Tennessee registration until 6/29/15. According to documents provided to Board, Respondent tech admitted the action and worked as a tech approximately 150 days (after the tech probationary period) between 12/20/14 and 6/29/15.

Prior Discipline: None.

Recommendation: \$50 civil penalty.

Dr. Wilson made the motion to **authorize a formal hearing** with a \$50.00 civil penalty to the technician for working on an expired registration. Dr. Pryse seconded the motion. The motion carried.

Case 5.

PIC for Case 4 above.

Prior Discipline:

Recommendation: \$700 civil penalty (10 months, less 3 month probationary).

Dr. Wilson made the motion to **authorize a formal hearing** with a \$700.00 civil penalty for allowing the technician to work on an expired registration. Dr. Pryse seconded the motion. The motion carried.

Case 6.

Prescriber's staff alleged unprofessional conduct by Respondent pharmacist. It was alleged the pharmacist refused to fill a pain prescription, yelled at a receptionist on the phone telling the receptionist that the prescription should be professionally corrected, and asking if the clinic had run a CSMD report. When the receptionist told Respondent pharmacist that the clinic was closed for lunch and hung up the phone, the pharmacist came to the clinic. It was alleged that since the pharmacist came next door to the clinic, the pharmacist must have left the pharmacy unsupervised. It was also alleged that the pharmacist verbally attacked office staff and demanded they show pharmacists more respect.

Board investigator interviewed staff members at the clinic as well as the Respondent pharmacist. The day in question was a Saturday. Respondent pharmacist also had a relief pharmacist on duty. The patient usually used another pharmacy, but it was closed and the patient was in pain. The drug prescribed was not available and since it was a Schedule 2 drug, the pharmacist asked the patient to go back to the clinic next door and get the prescription changed. A short while later, the patient returned and said the clinic staff told the patient to wait until Monday and take it to the patient's regular pharmacy. Respondent pharmacist called the clinic to explain the situation but was told they were in the middle of lunch and they hung up the phone. When the pharmacist walked over to the office, words were exchanged with the receptionist, but when the pharmacist spoke directly to the prescriber, the prescription was corrected and the patient received medication.

Prior Discipline: None.

Recommendation: Dismiss

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

Case 7.

Complaint generated after a hospital reported to Board that an 11 month, 29 day old child was admitted for vomiting and diarrhea and it was discovered the child had been given Fluoxetine 20 mg capsules by the Respondent pharmacy, instead of Poly-Vi-Sol Drops. It is unclear how many doses the child may have been given based upon the number of capsules, the time elapsed and family statements about discontinuing the medication.

Board investigator conducted a thorough investigation of the Respondent pharmacy records and interviewed staff. Respondent pharmacy uses automation and bar codes which should prevent this type error. By reconstructing the filling process and interviewing all pharmacists involved in the process on the day of the misfill, investigator determined that the prescription for Poly-Vi-Sol was filled correctly and that a language barrier may have limited counseling effectiveness. Poly-Vi-Sol drops were filled by

one pharmacist. Another pharmacist was on duty when the prescription was picked up. When the cashier was ringing it up, the family presented an insurance card. At this point investigator determined a tech entered insurance info and re-billed the Poly-Vi-Sol, but grabbed a bag with Fluoxetine for another patient and put the new info sheets on it by mistake. A chronology was prepared as follows:

- 8:09am Poly-Vi-Sol drops entered into system, no insurance
- 8:56am Poly-Vi-Sol bagged
- 9:19am Fluoxetine entered into system for another patient
- 11:34am Fluoxetine bagged
- 8:10pm Poly-Vi-Sol re-billed to insurance
- 8:12pm Poly-Vi-Sol leaflet sold with Fluoxetine in bag

9 days later, patient asked for Fluoxetine. Computer said it was ready but could not be found. It was re-prepared and dispensed to the correct patient. Since that time, the child's prescription has been corrected and the father counseled by pharmacist. Several corrective actions have been taken including the following:

- Reviewing SOP and reinforcing that cashiers should verify address first.
- Reinforce counseling requirements and using available translation services to ensure each patient understands.

Prior Discipline: None, but issued LOI related to misfill in 2014.

Recommendation: LOI on filling process.

Dr. Eidson made the motion to issue a **Letter of Warning** to the pharmacy on the filling process and patient counseling. Dr. Dickenson seconded the motion. The motion carried.

Case 8.

Pharmacist on duty when the prescription for Case 7 above was picked up.

Prior Discipline: None.

Recommendation: LOW for misfill.

Dr. Dickenson made the motion to issue a **Letter of Warning** to the dispensing pharmacist for the misfill. Dr. Wilson seconded the motion. The motion carried.

Case 9. 201504845

PIC for Case 7 above.

Prior Discipline: None.

Recommendation: LOI to improve/verify corrective actions.

Dr. Dickenson made the motion to issue a **Letter of Instruction** to the pharmacist in charge to improve and verify corrective actions. Dr. Wilson seconded the motion. The motion carried.

Case 10.

Initial filling pharmacist for Case 7 above.

Prior Discipline: None.

Recommendation: Dismiss.

Dr. Eidson made the motion to **accept counsel's recommendation**. Dr. Smothers seconded the motion. The motion carried.

Case 11.

Respondent is a MWD whose products include legend devices and oxygen. Board investigator approved an opening inspection based upon assurances that an alarm system would be installed. During a periodic inspection, Board investigator discovered an alarm was never installed. Investigator had the manager on-site call the owner who admitted he had "skirted by" that regulation. Investigator directed them to get an alarm installed immediately to protect the merchandise as well as patient records kept on site.

Approximately 2 weeks later, Investigator received notification from the owner that the alarm had been installed. Investigator performed a follow-up inspection approximately 3 ½ months later to find that the alarm had been installed but had never been used because the manager on site was never given the code. Investigator again provided education and directed the firm to immediately start using the alarm.

Prior Discipline: None.

Recommendation: \$1000 civil penalty for violation Board rules related to MWD facilities.

Dr. Eidson made the motion to **authorize a formal hearing** with a \$1000.00 civil penalty for violation of board rules related to MWD facilities. Dr. Dickenson seconded the motion. The motion carried.

Case 12.

Respondent is a MWD whose products include legend devices, syringes, irrigation trays, disposable hyperinflation systems, dressings, warming blankets, and catheter stabilization devices. During the previous periodic inspection, Board investigator discovered several issues and provided education to the facility staff. Investigator was notified by owner that the issues were corrected. At the next periodic inspection, Investigator discovered similar problems and compiled the following list:

- Wall board broken, crushed and lying on the floor throughout the facility;

- Ceiling had some insulation falling through tiles;
- Some ceiling tiles had signs of water damage;
- Significant dirt and dust located on legend devices, some (at least 5 different types) of which are labeled as sterile;
- A mound of dirt that appeared to be pest related was found near the garage door;
- Temperature and humidity were not tracked. Investigator noted the facility was hot and contained some products required to be kept at certain temperatures and humidity;
- The manager on site was not familiar with Board rules;
- The manager on site could not retrieve any required records;
- Required P&P manual could not be located.

Respondent facility owner has again responded that all items have been corrected. Board investigator conducted a follow-up inspection and found it to be satisfactory.

Prior Discipline: None.

Recommendation: \$1000 civil penalty for violation Board rules related to MWD facilities.

Dr. Eidson made the motion to **authorize a formal hearing** with a \$1000.00 civil penalty for violation of board rules related to MWD facilities. Dr. Smothers seconded the motion. The motion carried.

Case 13.

Periodic inspection revealed 36 prescription products and 20 OTC products which were expired but still on pharmacy shelves. Over 100 additional bottles of OTC products (many which were expired) were found segregated on shelves in the back of the pharmacy, out of patient view. Investigators were told that the 2 pharmacists kept these products for personal use even if they are expired. Most of those products were assorted vitamins, supplements, herbal products, etc. Some unlabeled bottles contained assorted pills. Respondent pharmacy had been educated and cited for expired product previously. Investigators directed pharmacists to remove all outdated products and unlabeled bottles of pills. Respondent has since notified Board staff that some drugs were sent to a reverse distributor and some were taken to the local Sheriff's office for destruction.

Prior Discipline: Counseling Violation 2014 \$1000 civil penalty paid

Recommendation: Civil penalty of \$10 per expired product.

Dr. Smothers made the motion to **authorize a formal hearing** with a \$10.00 civil penalty per expired product. Dr. Wilson seconded the motion. The motion carried.

Case 14.

PIC for Case 13 above.

Prior Discipline: Unregistered Technician, 2014, \$2000 civil penalty paid

Recommendation: Reprimand.

Dr. Eidson made the motion to **authorize a formal hearing** for a reprimand to the pharmacist in charge. Dr. Smothers seconded the motion. The motion carried.

Case 15.

Complainant alleged Respondent pharmacist added refills to a patient's blood pressure medication, gave the patient Z-Paks, antibiotic cream, testosterone, and 20 Xanax, all without a prescription. Complainant also alleged the patient has been sold pseudoephedrine numerous times without giving a driver's license or signing for it. It was also alleged that Respondent pharmacist frequently leaves techs unattended to fill prescriptions without pharmacist supervision.

Board Investigators interviewed Respondent pharmacist as well as the patient mentioned in the complaint. Both provided sworn statements in response. Prescription records were reviewed and verified that the patient has valid prescriptions for the mentioned drugs. NPLEX is used for all pseudoephedrine sales. Respondent pharmacist denied ever leaving the pharmacy unattended, but did suspect that the Complainant had been in the pharmacy when Respondent pharmacist was in the breakroom or doing paperwork.

Prior Discipline: None.

Recommendation: Dismiss

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

Case 16.

Former employee filed 21 allegations against Respondent pharmacist for a wide variety of issues, some of which were not violations. Some of the more serious allegations included:

- Falsifying records to cover the loss of 4,000 Lorazepam;
- Dispensing drugs that are about to expire;
- Leaving the pharmacy after every narcotic prescription is counted;
- Altering prescriptions without prescriber authorization;
- Dispensing wrong medication and refusing to correct the error;
- Refusing to check CSMD;
- Leaving the pharmacy and techs unattended;
- Failure to counsel;
- TennCare fraud;
- Not documenting injections;
- Medicare fraud;
- Billing name brand prices for generic drugs;
- HIPAA violations on a daily basis.

Board Investigators interviewed Respondent pharmacist, staff and store manager. Although the Complainant's identity was not revealed, all parties immediately stated whom they believe filed the complaint. All allegations were denied. An internal investigation for a possible shortage of Lorazepam was resolved prior to Respondent pharmacist starting work at this pharmacy. Investigators decided to conduct a thorough periodic inspection and also audited some controlled substances. No problems or discrepancies were found. Pharmacist demonstrated that she does check CSMD, does document injections and does not know how to fool the computer system into billing incorrectly or committing TennCare or Medicare fraud. Prescription changes are documented and staff had no recollection of any dispensing errors. Respondent pharmacist has only worked at this location for a short time, but Investigators were pleased with some of the policies implemented. None of the allegations could be substantiated.

Prior Discipline: None.

Recommendation: Dismiss.

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

Case 17.

Complainant alleged Respondent pharmacy and pharmacists filled medication over a 4 month period for a patient with the same name and DOB and billed it to Complainant's insurance.

Board Investigator confirmed the misfill which resulted from a failure of staff to verify the patient's address before dispensing. The PIC (who is also one of the dispensing pharmacists) provided a sworn statement and corrective action plan. Insurance claims were reversed and the patient profiles were corrected. The correct patient did not have insurance so the pharmacy chose not to charge for the medication.

Prior Discipline: None.

Recommendation: LOW for misfill.

Dr. Smothers made the motion to issue a **Letter of Warning** for the misfill. Dr. Wilson seconded the motion. The motion carried.

Case 18.

Respondent is one of the filling pharmacists for Case 17 above.

Prior Discipline: None.

Recommendation: LOW for misfill.

Dr. Smothers made the motion to issue a **Letter of Warning** to the pharmacist for the misfill. Dr. Wilson seconded the motion. The motion carried

Case 19.

Respondent pharmacy for Cases 17 and 18 above.

Prior Discipline: None.

Recommendation: Dismiss.

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

Case 20.

Complainant patient alleged Respondent pharmacy/pharmacist dispensed Lisinopril 20mg instead of the prescribed Lisinopril 20/HCTZ 25mg. Complainant also alleged that no counseling occurred when the new prescription (which was a continuation of previous therapy) was dispensed with the incorrect medicine. Patient reported taking the incorrect medication for 30 days, and that they had to schedule an appointment with the prescriber because of swelling in her legs. A nurse discovered the error at this appointment. Patient reported having long lasting problems with the skin on her legs after the incident.

Board Investigator interviewed Respondent pharmacist as well as the patient. Investigator reviewed prescription files and took photographs of the patient's vial with the incorrect medication. Investigator also observed counseling practices and reported that the pharmacist was observed asking patients if they have any questions but did not talk to patients about their medications unless the patient initiated the conversation. The misfill was confirmed. Investigators feel counseling practices need improvement.

Prior Discipline: None.

Recommendation: LOW for misfill; submit corrective action plan to better implement counseling and prescription verification.

Dr. Wilson made the motion to **authorize a formal hearing** with a \$1000.00 civil penalty to the dispensing pharmacist for failure to provide patient counseling with a correction action plan and a **Letter of Warning** for the misfill. Dr. Eidson seconded the motion. The motion carried.

Case 21.

Respondent pharmacy for Case 20 above.

Prior Discipline: None.

Recommendation: Dismiss.

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

Case 22.

Board was notified by Respondent's employer that Respondent technician appeared to be impaired at work and a drug screen was positive for heroin. Technician was terminated from employment.

Board Investigators interviewed Respondent who admitted addiction and to buying hydrocodone and heroin on the street. Respondent stated the addiction resulted from years of pain treatment that evolved into obtaining hydrocodone from friends then turning to heroin because it was cheaper. Respondent did enter a rehab facility for a 14 day "detox" but left after 9 days, then used drugs again after leaving the facility. Respondent indicated verbally and in her sworn statement that she wishes to voluntarily surrender her registration so she can work on her sobriety.

Prior Discipline: None.

Recommendation: Accept voluntary surrender of tech registration.

Dr. Wilson made the motion to **accept the voluntary surrender** of the technician registration. Dr. Pryse seconded the motion. The motion carried.

Case 23. 201601035

Board Investigator conducted a routine inspection on 2/22/16 and discovered Respondent technician working on a registration that expired 9/30/15.

Prior Discipline: None.

Recommendation: \$50 civil penalty.

Dr. Wilson made the motion to **authorize a formal hearing** with a \$50.00 civil penalty to the technician for working on an expired registration. Dr. Pryse seconded the motion. The motion carried.

Case 24. 201601037

PIC for Case 23 above.

Prior Discipline: None.

Recommendation: \$500 civil penalty.

Dr. Wilson made the motion to **authorize a formal hearing** with a \$500.00 civil penalty to the pharmacist in charge for allowing a technician to work on an expired registration. Dr. Pryse seconded the motion. The motion carried.

Case 25.

Complainant alleged Respondent pharmacy compounds medications that are being diverted “for office use.” Specifically, it was alleged that multiple HRT pellets are prescribed per patient and “extra” pellets are being used on other patients coming to the prescriber’s office.

Board Investigators conducted a thorough inspection, including a sterile compounding inspection, reviewed records and interviewed staff at the Respondent pharmacy. PIC provided a sworn statement that nothing is being dispensed for office use. Investigators did not find any records or documentation to substantiate the allegation.

Prior Discipline: None.

Recommendation: Dismiss.

Dr. Smothers made the motion to **accept counsel’s recommendation**. Ms. McDaniel seconded the motion. The motion carried.

Case 26.

Complainant alleged Respondent pharmacy compounds and dispenses prescriptions that are being called or faxed into the pharmacy by unlicensed personnel from the prescriber’s office, even when the prescriber is not present. It was also alleged that compounded sterile products are prescribed in excessive quantities and may be used for “office use.”

Board Investigators conducted a thorough inspection, including a sterile compounding inspection, reviewed records and interviewed staff at the Respondent pharmacy. PIC provided a sworn statement that nothing is being dispensed for office use. PIC also stated to investigators that he has no knowledge of prescriber’s staff authorizing prescriptions without permission. Investigators did not find any records or documentation to substantiate the allegation.

Prior Discipline: None.

Recommendation: Dismiss.

Dr. Dickenson made the motion to **accept counsel’s recommendation**. Dr. Eidson seconded the motion. The motion carried.

Case 27.

Complainant alleged Respondent pharmacy compounds and dispenses prescriptions to patients but bills the prescriber's office at a discounted price in return for patient referrals to the pharmacy. Complainant provided a copy of an invoice from the pharmacy to the prescriber's clinic. Complainant also provided copies of prescriptions which had been billed to the prescriber's clinic. Complainant believes this violates anti-kickback laws.

Board Investigators conducted a thorough inspection, including a sterile compounding inspection, reviewed records and interviewed staff at the Respondent pharmacy. Invoices and prescription files were reviewed. The invoices and prescriptions in question were found to be for the prescriber's personal medication which had been prescribed by his own primary care physician. There was no evidence that prices were discounted nor that any sort of kick-back arrangement exists. Investigators did not find any records or documentation to substantiate the allegation, however they did caution PIC to try to avoid business practices that may be perceived as unprofessional and result in a complaint.

Prior Discipline: None.

Recommendation: Dismiss.

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

Case 28.

During a routine inspection, Board Investigators checked Respondent pharmacy's non-sterile compounding lab and found 32 expired APIs, 15 products with no expiration or package date, and 26 APIs with no expiration but beyond the recommended 3 year shelf life of APIs. Pharmacy had previously stopped any sterile compounding, but plans to resume once it relocates to a different building. PIC was made aware of the products found and agreed to remove them. Education was provided regarding the importance of expiration and beyond use dates. Investigators suggested using USP 795 as a guideline for non-sterile compounding. PIC and staff were also reminded that before resuming sterile compounding, Board Investigators will need to inspect the facility for USP 797 standards.

Prior Discipline: None, but issued cease and desist in 2014 related to sterile compounding.

Recommendation: \$10 civil penalty per expired product.

Dr. Eidson made the motion to **authorize a formal hearing** with a \$10.00 civil penalty per expired product to the pharmacy. Dr. Wilson seconded the motion. The motion carried.

Case 29.

PIC for Case 28 above.

Prior Discipline: None.

Recommendation: Dismiss (DPh is pharmacy owner).

Dr. Eidson made the motion accept counsel's recommendation. Dr. Wilson seconded the motion. After discussion, Dr. Eidson withdrew his motion. Dr. Eidson made the motion to issue a **Letter of Instruction** to the pharmacist in charge concerning the expired product and that the pharmacist in charge submitted a plan of correction. Dr. Dickenson seconded the motion. The motion carried.

Case 30.

During a routine inspection on 12/28/15, Board Investigators discovered Respondent technician performing technician duties even though her registration expired 3/31/13. Both the Respondent and PIC stated the money to renew was sent to Board but they were not sure when. Research by Board staff revealed that the registration renewal fee was sent to Board in May, 2013, but late charges were never paid so it did not renew. Respondent never questioned why a renewed certificate was not received nor why there was not another renewal cycle in 2015. Respondent completed a new application in January, 2016 and received her new registration number on 1/19/16.

Prior Discipline: None.

Recommendation: \$50 civil penalty.

Dr. Eidson made the motion to **authorize a formal hearing** with a \$50.00 civil penalty to the technician for working on an expired registration. Dr. Dickenson seconded the motion. The motion carried.

Case 31. 201505100

PIC for Case 30 above. Technician registration was expired from 4/1/13 to 12/28/15.
9 months in 2013.
12 months in 2014.
12 months in 2015.

33 months total

Prior Discipline: None.

Recommendation: \$3,300 civil penalty

Dr. Eidson made the motion to **authorize a formal hearing** with a \$3300.00 civil penalty to the pharmacist in charge for allowing the technician to work on an expired registration. Dr. Dickenson seconded the motion. The motion carried.

Case 32- omitted in error

Case 33.

Complainant patient alleged Respondent pharmacist refused to sell patient pseudoephedrine, was arrogant, and violated HIPAA rights by asking questions in front of other customers about patient's health, symptoms and other medications the patient was taking. Patient feels it is her right to purchase pseudoephedrine and that the Respondent pharmacist violated that right.

Board investigator obtained a sworn statement from Respondent pharmacist. Respondent stated that he always counsels patients requesting pseudoephedrine to determine their symptoms, medical conditions and other medications. He stated this patient was demanding pseudoephedrine for her runny nose and became angry when he would not sell it to her. Respondent stated he recommended an antihistamine, but the patient stated that would not help. Respondent stated there were no other patients at the pharmacy when the altercation occurred.

Prior Discipline: None.

Recommendation: Dismiss

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

Case 34.

Corporate loss prevention notified the Board that Respondent technician admitted stealing Alprazolam and was terminated from employment.

Board Investigator obtained a copy of Respondent's signed statement admitting to stealing "a bottle" of Alprazolam. Investigator also obtained a copy of DEA 106 showing a total of 789 Alprazolam 2 mg missing.

Prior Discipline: None.

Recommendation: Revoke.

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

Case 35.

Complainant is the father of patient. Complainant alleged Respondent pharmacy, staff and PIC use deceptive trade practices, lie about their names, locations and job duties, allow non-licensed customer service representatives to evaluate and make decisions regarding therapy, pharmacists refuse to do pharmacist duties and PIC does not perform required supervisory duties. According to the complaint,

Complainant attempted to verify and authorize medication to be sent to the patient's physician and was questioned by an unlicensed representative about the patient's therapy to evaluate the protocol.

Complainant alleged the questions regarding protocol and therapy were outside the scope of a customer service representative's allowable duties. Complainant alleged this CSR misled him about her name and location. Complainant was transferred to a pharmacist in Florida who was allegedly rude and argumentative, stated that he only handles clinical questions, and transferred Complainant to a technician that stated she was in Tennessee. Complainant alleged the process used by the pharmacy delayed delivery of the patient's medication.

Respondent pharmacy has locations in multiple states and Board Investigator obtained statements from PIC's involved. The patient's type of medication therapy is handled from the Florida location. The original prescription was received at the Indiana location 10/30/15. Patient's benefit plan required prior approval, which was approved 11/2/15.

The prescription was processed and attempt was made to contact the patient and the physician so that delivery times could be coordinated. Complainant returned the call later that day and spoke to the CSR in Florida. Respondents denied that CSRs perform any duties that would require licensure and stated the CSR only asked questions required to maintain HIPAA privacy. Respondent admits the CSR became defensive and the call became confrontational.

CSR obtained permission to ship the order to the physician's office, but when she asked if the patient had an appointment, Respondent states that the Complainant said he did not want to give any more information to an unlicensed representative and asked to be transferred to a pharmacist. Since the Complainant did not have any clinical questions, the pharmacist believed the call would be better handled by a CSR, but the Complainant disagreed.

Respondent PIC admitted the pharmacist did not handle the situation well and could have done a better job of attempting to de-escalate the situation and address the Complainant's concerns. The call was transferred to a customer service supervisor located in Tennessee. Attempts to contact the physician's office to arrange delivery were unsuccessful on 11/3, 11/4, and 11/5. Contact was made on 11/6, which was a Friday. Since the medication is temperature sensitive, arrangements were made to ship the order to the physician's office on 11/9.

Respondent PIC from Florida location admits this was a very unfortunate customer service incident that should not have escalated and could have been resolved with a higher level of customer service. However, Respondent denies that any laws or rules were violated. Board Investigator reviewed statements and documentation and agrees that better customer service could have been provided, but no laws were broken.

Prior Discipline: None, but issued LOW in 2014.

Recommendation: Dismiss.

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

Case 36.

PIC's for Case 35 above.

Prior Discipline: None.

Recommendation: Dismiss

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

Case 37.

Two physicians, both associated with the same clinic, filed separate complaints against the same Respondent pharmacist. Physician A alleged unprofessional conduct by Respondent pharmacist for the following issues:

- Pharmacist refused to fill a pregnant patient's Hydrocodone even after 3 phone calls with prescriber's office. Pharmacist allegedly called to verify the DEA number, again to verify the quantity of 90 tablets and on the third call the pharmacist demanded diagnosis codes to accompany the narcotic prescription;
- Pharmacist allegedly told prescriber that fibroadenoma is cancer and the patient should be referred to an oncologist;
- Pharmacist allegedly asked prescriber if a biopsy had been performed and requested a copy of pathology results and questioned why the prescriber was treating this patient instead of referring to a cancer specialist. Prescriber claims to have told the pharmacist that fibroadenoma is a benign lesion and is not cancer.

Complainant then alleged that the patient returned to the clinic and relayed the message that the pharmacist had told the patient to "find new physicians because that office does not know what they are doing" and also told the patient that she has cancer and "will have a blue dead baby."

Both Complainant physicians went to the pharmacy to confront the pharmacist in person. Physician A stated the pharmacist used an unprofessional tone, told them she has a right to refuse any prescription, refused to meet with them in private, refused to give her name and was not wearing I.D., a white coat, or any identifying attire.

Physician A instructed the patient to use a different pharmacy and stated the patient has anxiety of having a blue baby and attempting to explain to those all around her that she in fact does not have cancer. Physician A believes the pharmacist's behavior was harmful to the patient and unfairly accused the prescriber of being a bad doctor. Physician A believes that, if nothing else, Respondent pharmacist violated state regulations for not wearing visible identification at all times.

Physician B is the director of the risk management committee for the clinic and provided a typed statement that he interviewed and confirmed the patient's version of the incident. Physician B also indicated in the statement that he directly witnessed the pharmacist's refusal to identify herself. Physician B's statement indicates that he received a similar complaint against the same pharmacist a few days later from a patient with post-operative pain from compound fractures of both legs and an arm but the pharmacist questioned the prescription and told the patient she should find another doctor. However, Physician B's complaint letter did not specifically mention the encounter along with Physician A at the pharmacy.

Board Investigator interviewed pharmacy staff and obtained sworn statements. According to staff, the patient brought in a prescription for Hydrocodone APAP 10/325 that did not have a DEA number on it so Pharmacist 1 instructed a tech to call and get the number but the tech had to leave a message. Meanwhile, Pharmacist 1 checked the CSMD and did not see any narcotics. Pharmacist 1 called the clinic to let them know the patient had not been on any narcotics and "Norco T.I.D. is kinda high dose." A shift change was about to occur and this information was relayed to Pharmacist 2 (who is the Respondent pharmacist) as she was about to come on duty. Neither pharmacist felt comfortable filling the T.I.D. 10/325 dose for an opioid naïve patient that was 7 months pregnant. Respondent pharmacist 2 contacted the prescriber (Physician A) and stated the prescriber said in the phone conversation that the patient has cancer, but when Respondent pharmacist asked what type, the prescriber mumbled something about a lump in the patient's breast and stated there was no biopsy. Respondent pharmacist stated that both physicians entered the pharmacy and Physician B began shouting because of the way Respondent pharmacist had spoken to Physician A. Respondent pharmacist then called for store management.

The store manager provided a sworn statement that he deferred to the pharmacist's professional judgment and that Physician B left very upset.

Staff technicians provided sworn statements that were consistent in basic recounts of the situation. None reported unprofessional behavior by either pharmacist but did agree the physicians became loud and unprofessional at the pharmacy.

Respondent pharmacist denied allegations she was not wearing any identification, pointing to her embroidered lab coat. A large picture with a name tag and her title also hangs in view of the pharmacy counter. Respondent further denies making claims related to the death of the patient's child.

Prior Discipline: None.

Recommendation: Dismiss.

Dr. Smothers made the motion to **accept counsel's recommendation** and to refer to the Board of Medical Examiners. Dr. Pryse seconded the motion. The motion carried.

Appearance

Board rule 1140-02-.07(a)

Kevin Hartman, D.Ph., owner of NPS Specialty Pharmacy appeared before the board to request an increase of the pharmacist to technician ratio from 4:1 to 5:1. After discussion, Dr. Smothers made the motion to approve the request to increase the pharmacist to technician ration to 5:1 as long as the additional technician is a certified technician. Ms. McDaniel seconded the motion. The motion carried.

Reinstatement

Collis Campbell

Dr. Campbell requested to have his licensed reinstated. Dr. Campbell's license was suspended indefinitely on 01/12/2012. After discussion, Dr. Eidson made the motion to reinstate Dr. Campbell's license. Dr. Campbell's license will be on five (5) year probation once he has completed all the necessary requirements for reinstatement with the following conditions. Ms. McDaniel 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 three (3) years from the start date of probation; however, after a period of two (2) years' probation the respondent may petition the Board for a modification of this Consent Order to remove the restrictions upon show of good causes. The Respondent shall not work as a "floater" for a period of three (3) years, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without permission of the Board;

(i) Respondent shall complete all provisions required for the reinstatement of her 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

Appearance

Vanderbilt University Medical Center

James Manfred appeared before the board to ask for approval of Asteres ScriptCenter kiosk. The kiosk will be located outside of the Vanderbilt Medical Center Outpatient Pharmacy and Medical Center East Pharmacy for employees to pick up their prescriptions. After discussion, the board decided to defer this request until the May 10-11, 2016 board meeting.

Request to Reapply

LaShay Sharp, RT

Ms. Sharp appeared before the board to request approval to reapply for registration as a pharmacy technician. Ms. Sharp's registration was revoked by the board on January 28, 2015. After discussion, Ms. McDaniel made the motion to grant Ms. Sharp's request to reapply for registration as a pharmacy technician. Dr. Dickenson seconded the motion. The motion carried. Dr. Eidson abstained.

Waivers

Board rule 1140-03-.14(12)

Dr. Smothers made the motion to approve the request from Emily Haskins, Pharm.D. to be the pharmacist in charge at HealthSouth Cane Creek Hospital, Martin, TN and Van's Institutional Pharmacy, Martin, TN. Dr. Wilson seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from Scott Faw, D.Ph. to be the pharmacist in charge at Lebanon HMA, LLC located at 1411 Baddour Pkwy, Lebanon, TN and 500 Park Avenue, Lebanon, TN. Dr. Wilson seconded the motion. The motion carried.

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

Dr. Smothers made the motion to approve the request from Kroger Pharmacy Friends for Life that the pharmacy is at least 180 square feet have hot and cold running water and refrigeration. Dr. Wilson seconded the motion. The motion carried.

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

Dr. Smothers made the motion to approve the request from Laura Isolani, D.Ph., to waive the one hundred and sixty (160) internship hours but she must successfully take and pass the MPJE. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from Toya Harris, D.Ph., to waive the one hundred and sixty (160) internship hours but she must successfully take and pass the MPJE. Dr. Dickenson seconded the motion. The motion carried.

Board rule 1140-01-.05 (3)

Dr. Pryse made the motion to approve the request from Eman Gad El Rab, D.Ph. to waive the Test of Spoken English. Ms. McDaniel seconded the motion. The motion carried. Dr. Eidson and Dr. Dickenson voted no.

Consent Orders

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

VIOLATED BOARD RULE 1140-11-.04
Super Discount Drugs, LLC

VIOLATED BOARD RULE 1140-2-.02 (1)
William Pack, D.Ph.

VOLUNTARILY SURRENDER (revocation)

Tennessee Board of Pharmacy
Board Meeting
March 8-9, 2016

Robert Safford, D.Ph.

REVOCATION

Paul Collins, D.Ph.
Elizabeth Dawn Braden-Wilhoit, RT
Chantelle Davis, RT
Rachel Raines, RT

PROBATION

Marshall Jones, Jr., D.Ph. (3yrs)

VIOLATED BOARD RULE 1140-3-.01 (1)(a) & (f)

James Backers, D.Ph.
CVS Pharmacy #5636

REPRIMAND

Smyrna Pharmacy & Wellness

Agreed Orders

Mr. Cange presented an agreed order signed by CVS Pharmacy #3963. CVS Pharmacy #3963 has agreed to a \$1000.00 civil penalty for failure to provide patient counseling and case cost. Dr. Wilson made the motion to accept the agreed order as presented. Dr. Smothers seconded the motion. The motion carried.

Director's Report

Dr. Dilliard thanked the board for allowing him to attend the TALKOM conference on February 15-16, 2016. Dr. Dilliard stated that the conference included discussion concerning accepting sterile compounding inspections from other states and diversion continuing education hours for pharmacy technician upon recertification.

Dr. Dilliard asked the board for approval to attend MALTAGON scheduled for October 9-12, 2016 in Austin, TX. After discussion, Ms. McDaniel made the motion to approve travel for board members and the executive director to attend MALTAGON in Austin, TX. Dr. Wilson seconded the motion. The motion carried.

The meeting adjourned at 3:50 p.m.

March 9, 2016

The Tennessee Board of Pharmacy reconvened on Wednesday, March 9, 2016 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members were present, the meeting was called to order at 8:01 a.m., by Dr. Bunch, president. Dr. Dickenson was absent.

**Reinstatement
April Anglea, D.Ph.**

Dr. Anglea requested to have her licensed reinstated. Dr. Anglea's license was revoked on 09/02/2015. After discussion, Dr. Smothers made the motion to reinstate Dr. Anglea's license. Dr. Anglea's license will be on five (5) year probation once she has completed all the necessary requirements for reinstatement with the following conditions. Ms. McDaniel seconded the motion. The motion carried.

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

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

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

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

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

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

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

(h) The Respondent shall not serve as pharmacist-in-charge for a period of three (3) years from the start date of probation; however, after a period of two (2) years' probation the respondent may petition the

Board for a modification of this Consent Order to remove the restrictions upon show of good causes. The Respondent shall not work as a “floater” for a period of three (3) years, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without permission of the Board;

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

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;

Director Report

Dr. Grinder gave a brief overview on the number of pharmacy inspections, investigations, and training (national and in house) that the investigators have conducted and/or participated in.

Dr. Dilliard informed the board that the 2015 law books are scheduled to be delivered on March 17, 2016.

General Discussion

Dr. Mutter appeared before the board yesterday to ask that the board adopt the policy changes to the chronic pain guidelines. The board decided to defer the decision until they had an opportunity to read the changes. After discussion, Dr. Eidson made the motion to adopt the policy changes to the chronic pain guidelines. Dr. Pryse seconded the motion. The motion carried.

Contested Case

Megan N. Inman, RT

Ms. Inman was not present nor represented by legal counsel. Mr. Cange represented the State. Mr. Steve Darnell was the Administrative Law Judge. Mr. Cange asked to proceed in default. Dr. Eidson made the motion to proceed in default. Dr. Smothers seconded the motion. The motion carried. Mr. Cange passed out the Notice of Charges. Ms. Inman is charged with violating T.C.A. 53-10-104 (a) and (b) and T.C.A. §63-10-305. After discussion, Dr. Smothers made the motion to revoke Ms. Inman registration as a pharmacy technician and case cost. Ms. McDaniel seconded the motion. The motion carried. Dr. Eidson made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Smothers seconded the motion. The motion carried.

Dr. Eidson made the motion to adjourn at 9:00 a.m. Dr. Wilson seconded the motion. The motion carried.

These minutes were approved and ratified at the May 10-11, 2016 board meeting.