

Tennessee Board of Pharmacy  
Board Meeting  
November 8, 2016

TENNESSEE BOARD OF PHARMACY  
665 Mainstream Drive, Iris Room  
Nashville, TN  
November 8, 2016

**BOARD MEMBERS PRESENT**

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

**STAFF PRESENT**

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

The Tennessee Board of Pharmacy convened on Tuesday, November 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 9:00 a.m. Dr. Bunch introduced Dr. Katy Wright as the newest board member for East Tennessee. He also recognized Cody McCallie a pharmacy student from South College.

**Minutes**

The minutes from the September 20-21, 2016 were presented. After discussion, Ms. McDaniel made the motion to approve the minutes as presented. Dr. Pryse seconded the motion. The motion carried.

**Financial Report**

Noranda French, Administrative Assistant IV, gave the financial report.

**Office of General Counsel Report**

Mr. Gibbs informed the board that there are 66 cases open for discipline at the Office of General Counsel and 21 of those cases are eligible for a contested hearing. Mr. Gibbs asked the board to consider adding either a third day to the board meetings already schedule or adding litigation days to the months in which the Board does not meet. After discussion, the Board decided to add the additional meetings for contested cases during the months that they are not scheduled to meet.

Mr. Gibbs informed the board that the collaborative practice rules have been signed by Mr. Cange and returned to the Attorney General's Office. Dr. Eidson asked Mr. Cange what corrections were made and why wasn't the correction presented to the board before they were resubmitted to the Attorney General's Office. Mr. Cange stated that was for legal efficiency per the Attorney General.

Mr. Gibbs stated that after he researched the procurement process for a grant proposal, it has been determined that the Office of General Counsel, in collaboration with the Dr. Dilliard, will draft a scope of services for the Request for Grant Proposal (RFGP). The Office of General Counsel has obtained all relevant documents to begin the drafting process with a goal of submitting the RFGP to the procurement office before the Board's next meeting.

## **Complaint Summary**

### **Case 1.**

Complainant patient alleged respondent pharmacy charged a different price to the complainant and spouse for the same medication and quantity. Complainant also alleged respondent pharmacy sent a notice that a prescription had not been paid for even though complainant had a receipt showing it was.

BOP Investigator obtained statements from pharmacy staff explaining that the price difference for complainant and spouse was due to days' supply and different carriers on the complainant's and spouse's insurance. Complainant's antifungal with directions to take 1 tablet and repeat in 5 to 7 days was entered as a 7 day supply and received a \$ 1.63 copay. Spouse's same prescription was entered as just a 2 day supply and received a 46 cents copay. When pharmacy staff became aware of the difference, the days' supply was changed to 7 days and received the \$ 1.63 copay. Staff waived the extra charge to the patient and apologized for the confusion. Staff also updated pharmacy records on the prescription that had flagged as not being paid for in January, so the patient does not have any past due charges.

Recommend: Dismiss

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

### **Case 2.**

During a periodic inspection, BOP Investigator observed 6 patients picking up prescriptions with no counseling and no offer to counsel. At least 1 prescription is known to be a new prescription.

Recommend: \$6,000 civil penalty to pharmacy (stay all but \$1,000 with acceptable CAP). LOI to PIC

Ms. McDaniel made the motion to authorize a formal hearing with a \$6000.00 civil penalty with \$5000.00 stayed with an acceptable plan of correction to the pharmacy and a letter of instruction to the PIC for failure to provide patient counseling. Dr. Pryse seconded the motion. The motion carried.

### **Case 3.**

Pharmacist on duty for Case 2 above.

Recommend: \$1,000 civil penalty?

Dr. Eidson made the motion to authorize a formal hearing with a \$1000.00 civil penalty to the pharmacist on duty with a corrective plan of action. Dr. Pryse seconded the motion. The motion carried.

**Case 4.**

During a periodic inspection, BOP Investigator observed 4 new prescriptions for maintenance medications being dispensed without counseling by the pharmacist. Staff members told Investigator that they had been trained by the company to only ask the pharmacist to counsel when alerted by the computer system. The computer system only alerts counseling if the patient has never had the medication. Investigator provided education and instructed staff to look at receipts to determine whether a prescription is new. Investigator did observe pharmacist counseling on other new prescriptions.

Recommend: LOW

Dr. Edison made the motion to issue a Letter of Warning to the pharmacy for failure to counsel. Dr. Dickenson seconded the motion. The motion carried.

**Case 5.**

Pharmacist and PIC for Case 4 above.

Recommend: LOW and CAP

Dr. Eidson made the motion to dismiss the complaint. Ms. McDaniel seconded the motion. The motion carried.

**Case 6.**

During a periodic inspection, BOP Investigator discovered that respondent technician had been terminated and arrested for controlled substance diversion. Investigator obtained a copy of the tech's written statement admitting to stealing 8,422 Hydrocodone APAP 10/325, 3 Alprazolam 2mg, 3 Oxycodone APAP 10/325 and 15 films of Suboxone 8mg to be sold by the respondent's boyfriend. Thefts occurred between March and May 16, 2016.

Recommend: Revoke tech registration

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

**Case 7.**

Complainant alleged respondent pharmacy does not fully report to CSMD, fills benzodiazepine prescriptions for more than a 30 day supply, and has filled 2 Lorazepam prescriptions for 31 days' supply even though the prescriber only authorized 30 days.

BOP Investigator worked with respondent and CSMD staff and determined there were a few days in 2016 when the data uploaded to CSMD did not all show as received, however there were no notices sent back to the pharmacy. Respondent was able to work with software writers and the CSMD vendor to remedy the problem.

Respondent pharmacy is a long term care, closed door pharmacy and receives orders for a month's supply of medications to be sent to the homes it services. If a month has 31 days, they dispense 31 days' supply to prevent confusion at the homes about when refills are due. Investigator educated staff that the law now limits opioids and benzodiazepines to a 30 day supply, regardless where the patient resides. Respondent pharmacist agreed to stop immediately and notify the homes of the change of policy.

Recommend: LOW for CSMD and LOW for violating Addison Sharp limits.

Dr. Eidson made the motion to issue a Letter of Warning to the pharmacy for violating Addison Sharp limits. Dr. Dickenson seconded the motion. The motion carried.

#### **Case 8.**

Complainant (case worker) alleged being told that a patient self-injected Sustenna Invega into the left upper arm and was also told that a pharmacy representative told the patient to use the medication as directed. The package insert indicates this drug is to be administered IM by a healthcare provider.

Respondent PIC provided a signed written statement that the patient had a doctor's appointment set up for the patient to bring in the medication for the doctor to inject. The medication was shipped to the patient. BOP Investigator found no other information to substantiate the allegations.

Recommend: Dismiss

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

#### **Case 9.**

Four members of a family alleged respondent pharmacist viewed their personal medical information illegally. The complainants live out of state and visit out of state prescribers. They allege that respondent lives in Tennessee and is connected to the complainants via a maze of marriages, divorces, allegations of child abuse, allegations of trespassing, and court battles. They allege respondent had no reason to view their medical records.

BOP Investigator obtained a sworn statement from respondent pharmacist indicating job duties at a cancer clinic in Tennessee include reviewing charts, collecting data, and preparing a spreadsheet for data analysis. Respondent claims he accesses data using a code and does not know a patient's name until he is already in the file. He claims if he had known the names before starting, he would have had another pharmacist review those charts. Respondent also stated his job duties included records from hospitals and clinics in Mississippi, Tennessee, and Arkansas.

BOP Investigator verified through respondent's employer that respondent did actually review all four complainants' medical records, some on multiple dates between November, 2015 and February, 2016, without a valid reason to do so. Although the complainants are part of the same healthcare system, none have any connection to the Tennessee based clinic. It was also verified that respondent pharmacist was never assigned any tasks to review charts for out-of-state clinics. Investigator confirmed that none of the complainants had any cancer related health issues.

Recommend:

Dr. Dickenson made the motion to defer this complaint until the board receives written notification from the Company that the respondent violated HIPPA law. Dr. Eidson seconded the motion. The motion carried.

### **Case 10.**

During a May 17, 2016 sterile compounding periodic inspection, BOP Investigator noted the following: Water heater was not producing hot water; Mini-bag plus system was in use and at least 2 bags were spiked with no BUD; No documentation proving garbing was not needed for the CAI; GAP analysis had not been performed or was not retrievable; Some didactic testing and competencies had not been performed or could not be verified; Pharmacists were not trained in compliance with USP 797 and did not have proper GFT, MF, or didactic testing but were responsible for techs compounding.

Since the facility only does low risk compounding, BOP Investigator provided education and requested a response when the facility was in compliance. Respondent PIC told Investigator that they would comply.

Since no response had been received by August 1, 2016, Investigator re-inspected the facility. PIC did provide documentation that the CAI met exemption requirements. The water heater was repaired May 23, 2016 and was working during the follow-up visit. PIC stated the staff had now been trained on the 28 day BUD for the Mini-Bag system.

During the August 1, 2016 visit, PIC agreed to complete the overdue GAP analysis by August 5, 2016; only allow techs with completed competencies to compound; have all staff trained by August 12, 2016; update cleaning supplies and affirm a BUD when appropriate.

Since no response had been received by August 23, 2016, Investigator requested a voluntary cease and desist of sterile compounding until all issues were corrected. PIC agreed. No patient issues have been reported.

Timeline:

Initial inspection: 5/17/16

No response, so complaint initiated: 7/12/16

Second inspection 8/1/16

No response, so voluntary C&D 8/23/16

Recommend: Reprimand and costs.

Dr. Wilson made the motion to issue a letter of reprimand and case cost. Dr. Wright seconded the motion. The motion carried.

**Case 11.**

This is the PIC for Case 10 above.

Recommend: Reprimand or LOW?

Dr. Dickenson made the motion to issue a Letter of Warning to the PIC. Dr. Wilson seconded the motion. The motion carried.

**Case 12.**

Complainant pharmacy management reported to BOP that the following were missing due to employee pilferage:

210 Tramadol 50mg, 158 Oxycodone 10/325, 5 Suboxone 8mg/2mg film, 217 ml Promethazine with codeine syrup.

BOP Investigator was told that pharmacy management and loss prevention conducted an interview with respondent and that the respondent verbally admitted to stealing 2 Suboxone 8mg/4mg strips, 1 syringe, 1 ounce of Promethazine, 3 bags of snacks, and 3 drinks. Respondent declined to give them a written admission statement. Respondent was terminated and a police report was filed. Respondent has reportedly left Tennessee. Investigator attempted to make contact but has not been successful.

Recommend: Revoke tech registration

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

**Case 13.**

Complainant patient alleged respondent pharmacist released patient's personal information to another patient. It was also alleged that the pharmacy was aware of the breach but it was 56 days later when the patient was notified by letter.

BOP Investigator obtained a sworn statement from the respondent pharmacist, who is also PIC. PIC explained that a patient dropped off a prescription at the drive-thru window, decided they wanted it back, and the technician accidentally returned the complainant's prescription to the other patient. When respondent became aware what happened, the prescription was retrieved from the incorrect patient and the pharmacy's privacy officer was notified. An apology letter was sent to the complainant patient and training on HIPAA policy was provided to the technician that committed the error. Respondent asserted

that text messages and e-mails were sent to the complainant prior to sending the letter. Investigator confirmed with complainant that text and emails usually meant a prescription was ready so they were ignored. It is unknown if pharmacy staff attempted to call the complainant, however, when BOP Investigator tried to call the complainant, it was discovered that the complainant did not have activated voice mail.

Recommend: LOW

Dr. Eidson made the motion to issue a Letter of Warning to the pharmacy technician for releasing a patient's personal information. Dr. Dickenson seconded the motion. The motion carried.

**Case 14.**

During a periodic inspection, BOP Investigator discovered an unregistered individual performing technician duties. Respondent started as a tech in July, 2015 and did not become registered until September, 2016.

Recommend: \$100 civil penalty to technician

Dr. Eidson made the motion to authorize a formal hearing with a \$100.00 civil penalty to the technician for unlicensed practice. Dr. Wilson seconded the motion. The motion carried.

**Case 15.**

This is PIC for Case 14 above.

Recommend: Civil penalty \$ 1,100 (14 months minus 90 days probation equals 11)

Dr. Wilson made the motion to authorize a formal hearing with a \$1,100.00 civil penalty to the PIC for allowing a pharmacy technician to work with being properly registered with the board. Dr. Eidson seconded the motion. The motion carried.

**Case 16.**

BOP Investigator attempting to perform a periodic inspection discovered 6 technicians working without a pharmacist on duty. When Investigator inquired as to the whereabouts of the pharmacist, a tech told her that the pharmacist was in the restroom, but after waiting several minutes, the pharmacist was contacted via cell phone by the tech. The pharmacist returned in a few minutes with a fast-food cup and admitted being gone from the pharmacy for "maybe 30 minutes." During the pharmacist's absence, Investigator noted that no dispensing occurred but other tech duties were being performed. Investigator also discovered that respondent pharmacy was only reporting weekly to CSMD instead of daily. Pharmacy had neither a daily pharmacist's log, nor a daily prescription printout as required. The last biennial inventory could not be retrieved while Investigator was on-site. Tech registry and tech affidavits could not be retrieved while Investigator was on-site.

Recommend: Reprimand for all listed violations

Dr. Wilson made the motion to reprimand the pharmacy for the listed violations. Dr. Eidson seconded the motion. The motion carried.

**Case 17.**

This is PIC for Case 16 above.

Recommend: Reprimand for all listed violations

Dr. Eidson made the motion to issue a Letter of Warning to the PIC for the pharmacist leaving the pharmacy unattended. Dr. Pryse seconded the motion. The motion carried. Dr. Eidson made the motion to reprimand the PIC for violating the pharmacist to technician ratio and not having an updated biennial inventory. Ms. McDaniel seconded the motion. The motion carried.

**Case 18.**

This is the pharmacist on duty for Case 16 above.

Recommend: LOW

Dr. Eidson made the motion to reprimand the pharmacist on duty for leaving the pharmacy unattended and violating the pharmacist to technician ratio. Dr. Wilson seconded the motion. The motion carried.

**Case 19.**

During a periodic inspection on 9/8/16, BOP Investigator discovered respondent pharmacist's license had expired 8/31/16. Respondent was relieved of duty until the license could be renewed. Investigator was told by respondent that she may have confused renewal with obtaining CE's.

Recommend: \$1,000 civil penalty?

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

**Case 20.**

This is the PIC for Case 19 above.

Recommend: \$1,000 civil penalty?

Dr. Wilson made the motion to authorize a formal hearing with a \$1000.00 civil penalty to the PIC for allowing a pharmacist to work unlicensed. Ms. McDaniel seconded the motion. The motion carried.

**Case 21.**

Complainant patient alleged respondent pharmacist shorted 1 tablet of Alprazolam 0.25mg and went on to state this had happened on 3 different occasions.

BOP Investigator visited the pharmacy and obtained statements. A double count procedure is in effect and if someone claims a shortage, inventory is counted and compared to computer on-hands. No discrepancies were found. PIC stated that the patient became angry with respondent pharmacist when respondent would not give the patient the PIC's personal cell number. Investigator did not find anything to substantiate the allegation.

Recommend: Dismiss

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

**Case 22.**

BOP was notified by pharmacy management that respondent pharmacist admitted to forging prescriptions for a family member (son-in-law) for non-controlled substances. After admitting wrongdoing in writing, stating the son-in-law had no knowledge of the prescriptions, and providing a statement that she was retiring from pharmacy, respondent sent a letter of resignation asking complainants to support her in obtaining a hospital pharmacy position. Pharmacy management made the decision to terminate the pharmacist for gross misconduct rather than accept a resignation. The internal investigation file was reviewed by BOP Investigators. Z-pak and Flexeril prescriptions were generated by respondent in respondent's son-in-law's name, using the name of an orthopedic surgeon's physician assistant located in Texas. The scheme was discovered when a pharmacy in Maine called to get a copy, and called the prescriber to verify. The prescriber became concerned and called the complainant pharmacy and happened to speak to the respondent. According to a message from the prescriber, respondent said the prescriptions "had been deactivated and everything was fine." When asked why authorities were not notified when the pharmacist became aware the prescriptions were forged, the prescriber reported that the pharmacist stated that was against pharmacy policy.

Recommend: Revoke/voluntary retirement

Dr. Wilson made the motion to authorize a formal hearing for revocation. Ms. McDaniel seconded the motion. The motion carried. Dr. Eidson and Dr. Dickenson voted no.

**Case 23.**

BOP was notified by a pharmacy benefits representative that an unlicensed pharmacy was shipping prescription supplies into Tennessee. Complainant provided a pharmacy name and address.

BOP Investigator confirmed a licensed pharmacy is located at the physical address but a planned name change of the pharmacy was never sent to BOP. Product was being shipped into Tennessee for about a

year under the former name according to the current PIC. PIC indicated he had filled out a name change application but the operations manager wanted to wait until a new PIC was named before sending both changes to BOP.

Investigator determined 1140-01-.08 was violated for 12 months.

Recommend: \$1,200 civil penalty to pharmacy

Ms. McDaniel made the motion to dismiss. The motion died for a lack of second. After further discussion, Dr. Dickenson made the motion to authorize a formal hearing with a \$1200.00 civil penalty. Dr. Wilson seconded the motion. The motion carried. Ms. McDaniel voted no.

#### **Case 24.**

Complainant pharmacy reported losses of controlled substances which prompted a joint investigation with DEA and BOP. BOP Investigator was told by PIC that respondent tech had been acting suspiciously and when questioned, became very defensive and walked out. PIC believes respondent is responsible for the shortages. There was no admission statement or video proof linking the respondent to the missing drugs.

BOP Investigator interviewed the respondent technician who provided a sworn statement denying stealing or forging prescriptions. Respondent was aware some drugs were missing a few months ago due to a wholesaler error but seemed unaware of recent losses.

Nothing else substantiated the allegations against this particular technician. The joint investigation is ongoing with BOP and DEA.

Recommend: Dismiss at this time pending findings from the investigation.

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

#### **Case 25.**

Complainant alleged early fills of Alprazolam and Mixed Amphetamines by respondent pharmacy. Allegations are that the CSMD showed 90 Alprazolam 1mg filled twice on 6/7/16. Mixed Amphetamines were filled twice on 5/28/16.

BOP Investigator reviewed records and interviewed PIC, who was familiar with the issue. According to the PIC there was some sort of problem with the CSMD that caused a duplicate reporting on the dates in question. Patient records only indicate one filling. PIC stated another pharmacist had contacted CSMD but was unable to correct the problem so it was passed on to the district manager who provided the pharmacy with a contact person to assist. Now it appears that all the fillings have been removed from

CSMD rather than the duplicates. PIC is now working to have that issue corrected. There does not appear to be any fault at the pharmacy level.

Recommend: Dismiss

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

## **Case 26.**

Complainant alleged respondent pharmacy filled 90 Alprazolam 0.5mg (1 t.i.d.) 10 days early on 2/9/16 without physician approval. It is also alleged that respondent pharmacy filled a prescription on 10/15/15 based upon a clarification call from a nurse but not authorized by a prescriber; that a prescription was entered and filled as being authorized on 7/11/15 even though the prescriber is closed on Saturday and when questioned, pharmacy staff altered the date; and that an Alprazolam prescription was actually filled 20 days early on 7/11/15.

BOP Investigator conducted a lengthy investigation and addressed each allegation. The Alprazolam that was filled 10 days early was not dispensed 10 days early. Medication is bubble packed and processed early for billing purposes but is not dispensed until it is due. Investigator reviewed that patient's profile and did not see any early fills.

In response to the allegation of filling without authorization based upon a clarification call from a nurse, PIC stated a refill request had been sent to the prescriber on 10/15/15 and he understood the nurse's call to be authorizing the refill.

Regarding the Saturday prescription, records indicate that an insurance re-bill was attempted and staff did not realize at the time that the date authorized automatically changed in the system but it was later corrected by staff.

The Alprazolam prescription filled 20 days early was due to the prescriber authorizing a fill on 7/1/15 and again on 7/11/15 assuming the 7/11/15 prescription would not be filled until the previous supply ran out. However, instructions on the 7/11/15 order only said "cancel all previous RX's." PIC stated he did not understand that to mean to hold off filling the prescription. Investigator verified from CSMD records that this patient does not routinely receive early refills, however, this was dispensed approximately 12 days early. It should be noted that the next Alprazolam prescription for this patient was not dispensed until 10/15/15.

Investigator educated staff on the importance of DUR, clarification and documentation.

Recommend: Dismiss

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

**Case 27.**

Complainant alleged respondent pharmacy filled 90 Clonazepam 0.5mg on 9/14/15 (5 days early) with a written date of 9/10/15 even though the prescription was not authorized until 9/15/15. It is also alleged that another prescription was filled 24 days early.

BOP Investigator reviewed pharmacy records. The prescriptions in question were for patients at an adult disability center that requires packaged medications. The pharmacy was using a process called “cycle billing” which caused the billing date to appear as the filled date. If a prescription has no refills remaining, it is assigned a new number, billed, and then the prescriber is contacted for authorization. When the authorization is received, the prescription is reversed and rebilled, then the prescription is filled. Investigator reviewed a delivery manifest showing the prescription was not delivered until 9/21/15.

Investigator reviewed the prescription records for the early refill. Records show a 30 day supply was dispensed 7/23/15 then again on 8/20/15 so it would only have been 3 days early.

Investigator concluded that although prescriptions were not dispensed to patients without prescriber authorization and were not routinely filled early, the billing practices lead to incorrect dates being reported to CSMD. PIC told investigator that the pharmacy has discontinued the billing practice and no longer includes controlled substances in “cycle billing.”

Recommend: Letter of Instruction for proper recordkeeping

Dr. Dickenson made the motion to issue a Letter of Warning for proper recordkeeping. Dr. Wilson seconded the motion. The motion carried.

**Case 28.**

While investigating a case of tech diversion, BOP Investigator discovered the diversion occurred when the pharmacist on duty left the tech unsupervised in the pharmacy while the pharmacist went to lunch. Respondent pharmacist told Investigator that he thought it was not uncommon for a pharmacist to leave the pharmacy for a lunch break and the tech asked to stay inside the pharmacy with the lights off. Respondent stated he agreed since at that time he had no reason to suspect the tech of any wrongdoing. Respondent was reprimanded by corporate management.

Recommend: Reprimand for improper supervision of tech and violating pharmacy security rules.

Dr. Wilson made the motion to issue reprimand to the pharmacy for improper supervision of a technician and violating pharmacy security rules. Dr. Pryse seconded the motion. The motion carried.

**Case 29.**

This is the PIC for Case 28 above. Respondent told BOP Investigator that he was unaware the staff pharmacist would leave the pharmacy and go to lunch. PIC denied ever personally leaving a tech unsupervised in the pharmacy.

Recommend: LOI for PIC responsibilities of staff

Dr. Dickenson made the motion to issue a Letter of Instruction to the PIC concerning responsibilities of the staff. Dr. Wright seconded the motion. The motion carried.

**Case 30.**

Complainant alleged respondent specialty pharmacy refused to dispense HGH and questioned their authority to refuse to fill the prescription. Complaint was forwarded to TBOP from the Attorney General's office in New York. Their letter stated it was their position that the pharmacy needed to dispense the medication or issue a medical necessity denial which the patient could appeal. Respondent pharmacy responded that their refusal to dispense the medication was not a denial of benefits, therefore it could not be appealed. The patient had originally complained to some consumer agencies which had all referred the complaint to other agencies before it was finally sent to TBOP.

BOP Investigator conducted an extensive investigation, interviewing and obtaining statements from respondent staff. HGH has very strict guidelines that specialty pharmacies must adhere to and verify it is appropriate therapy for each patient. A pharmacist cannot dispense it if there is a concern it is being used for off-label uses. Investigator obtained a sworn statement from the Tennessee based pharmacist stating that professional judgment, education, skill and experience was used in the evaluation, review and processing of this prescription according to federal and state regulations and the standard operating procedures of the pharmacy.

Recommend: Dismiss

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

**Case 31.**

Complaint was received from the Attorney General of Washington. Patient had filed a complaint through them and it was forwarded to TBOP. Patient reported receiving prescriptions that had not been prescribed and were not wanted. Patient claimed prescriptions were received on 5/31/16, 6/27/16, and 7/21/16, each with a copay of \$150. Patient tried to call the pharmacy twice with no response.

During the investigation, BOP Investigator discovered the prescription had not been processed and filled from the licensed pharmacy, but from a suite upstairs that was not physically connected to the pharmacy which was being used as a sort of mail order pharmacy. Investigator was told that staff had been

working in the upstairs suite since January, 2016. Investigator asked that operations cease in the upstairs pharmacy until it was properly licensed.

The prescriptions in question were reviewed. Records verified that 3 shipments were sent to the patient. All except the first order have since been reversed and deleted. Copays were never collected.

Investigator inquired about the origin and the process for filling the prescriptions to be mailed. The staff pharmacist was unsure about the arrangement but stated someone named "Eugene" contacts doctors, the doctors fax prescriptions which are filled then mailed. The pharmacy owner told Investigator that "Eugene" is an off-site billing consultant and is believed to be residing in Florida. "Eugene" and his staff connect with prescribers across the country that fax the prescriptions to this Tennessee based pharmacy to be filled and mailed. Nobody knew "Eugene's" last name or address.

The prescription in question is a pre-printed formula sheet for compounded topicals. The patient lives in Washington. The prescriber listed on the sheet is from Washington.

Investigator was able to obtain "Eugene's" last name and an email address. A response has been requested.

Recommend: Reprimand for shipping medications not authorized by the patient.  
Civil penalty for operating an unlicensed pharmacy.  
Refer pertinent information to Florida and Washington BOP's.

Ms. McDaniel made the motion to authorize a formal hearing for revocation. After discussion, Ms. McDaniel withdrew her motion. Dr. Wilson made the motion to authorize a formal hearing for reprimand for shipping medication not authorized by the patient, a \$1000.00 civil penalty per month for unlicensed practice and refer to the Florida State Board of Pharmacy and Washington State Board of Pharmacy. Dr. Dickenson seconded the motion.  
The motion carried.

### **Case 32.**

A complaint was opened against a pharmacy and this respondent as PIC. During the investigation BOP Investigator discovered respondent had not been PIC at that pharmacy since November, 2015. BOP had not received the change of PIC form. The pharmacy owner is responsible for notifying BOP. Investigator determined this respondent fulfilled her obligations by conducting a controlled substance inventory and completing the PIC change statement. It could not be determined whether it was actually faxed or mailed to BOP but it was on file at the pharmacy.

Recommend: Dismiss

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

**Case 33.**

During a periodic inspection on 9/16/16, BOP Investigator noted 154 expired prescription products mingled with non-expired product on the pharmacy shelves and also 23 expired OTC products kept in the pharmacy. This is notable because respondent pharmacy is on probation and currently under a monitoring agreement. On 9/2/16 (14 days prior to BOP visit), the monitor had found and removed expired products from the pharmacy shelves and placed them in a box for return to a reverse distributor.

Investigator discovered Stahist AD which contains pseudoephedrine, in OTC section of the store instead of being behind the counter.

Investigator reviewed 100 legend prescriptions and discovered 5 were taken verbally by non-certified technicians.

Investigator discovered the pharmacy failed to submit CSMD reports on September 7, 8, 10, 13, 14, and 15.

Investigator observed a store employee pressuring and arguing with the pharmacist to fill a prescription for buprenorphine for a patient. When asked about BOP's stance, Investigator informed the employee that the pharmacist is expected to use their clinical and professional judgment in deciding whether to fill a prescription.

Investigator was told by staff that TOSHA had recently notified the pharmacy about a customer complaint regarding roaches in the pharmacy. TOSHA requested documentation of remedy or further action may be taken. PIC told Investigator that a pest company had been called to come professionally spray the pharmacy.

During the inspection, a customer brought a dog that was not a service dog into the store. Investigator asked an employee to tell the customer to take the dog outside. The employee argued that it was hot outside so Investigator had to ask a second time to have the dog taken out of the store.

Recommend: Revoke

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

**Case 34.**

This is PIC for Case 33 above. PIC is also on probation with BOP.

Recommend: Revoke

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

**Case 35.**

Complaint opened based upon a settlement between respondent pharmacy and the U.S. Attorney's office. It was noted that the claims settled by the agreement are allegations only, and there has been no determination of liability. Respondent pharmacy's owner stated that there was no admission of guilt in the settlement. The allegations involved claims to TennCare and Medicare primarily during the period of February 2011 through May, 2012. A payment schedule was agreed upon in which the U.S. government will receive roughly 49% of the recovery and the State of Tennessee will receive roughly 33%.

Recommend: LOW

Dr. Eidson made the motion to dismiss the complaint. Dr. Wright seconded the motion. The motion carried. Ms. McDaniel voted no.

**Case 36.**

This is the PIC for Case 35 above.

Recommend: LOW

Dr. Wright made the motion to dismiss the complaint. Dr. Dickenson seconded the motion. The motion carried. Ms. McDaniel voted no.

**Case 37. and Case 38.**

Anonymous complaint was received alleging respondent pharmacist had an unreported DUI.

Respondent's employer reported diversion of 1,064 Phentermine 37.5mg and that the respondent was the primary suspect.

On 11/2/16, BOP received respondent's offer to voluntarily surrender his pharmacist's license and a note indicating he will enter Talbott recovery on 11/7/16.

Recommend: Accept voluntary surrender

Dr. Eidson made the motion to authorize a formal hearing with a voluntary surrender. Dr. Wilson seconded the motion. The motion carried. This decision was for case # 37 & #38.

**Case 39.**

During a periodic inspection on 8/29/16, BOP Investigator discovered respondent performing technician duties without a technician registration. Respondent admitted starting work as a tech in November, 2015 but not starting the registration process until May, 2016. BOP staff was contacted and verified there were issues on the respondent's background check and that BOP had requested court documents from respondent in June, 2016. BOP did not receive a response. Investigator informed respondent and the

pharmacist on duty that respondent could not work as a tech until the application was approved and Investigator also advised respondent to answer the request for court documents as soon as possible so a decision could be made. As of 11/3/16, BOP has still not received the information and respondent remains unregistered.

Recommend: \$100 civil penalty for unlicensed activity

Dr. Dickenson made the motion to authorize a formal hearing with a \$100.00 civil penalty to the technician for unlicensed activity. Dr. Pryse seconded the motion. The motion carried.

**Case 40.**

This is the PIC for Case 39 above. Allowed unregistered tech to work 9 months, minus 3 months probationary, equal 6 months.

Recommend: \$600 civil penalty to PIC

Dr. Wilson made the motion to authorize a formal hearing with a \$600.00 civil penalty to the PIC for allowing the technician to work for 6 months unlicensed. Dr. Pryse seconded the motion. The motion carried.

**Case 41.**

Respondent pharmacist self-reported addiction to drugs and requested his pharmacist license be suspended while he works with TPRN.

Recommend: Accept voluntary surrender

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

**Appearance**

**Cipher Pharmaceuticals (manufacturer)**

Cipher Pharmaceuticals, Inc., is applying for a manufacturer license in Tennessee. Documentation submitted indicates that the President of the company pled guilty in Federal Court to 1 count of conspiracy to commit a misdemeanor violation of the Food, Drug, and Cosmetic Act. He agreed to a 3 year probation, \$5000.00 fine, in lieu of restitution, a \$25,000.00 payment to the Crime Victims Fund and a \$25.00 special assessment on May 1, 2008. His probation was terminated on April 30, 2011. After discussion, Dr. Eidson made the motion to approve Cipher Pharmaceuticals US, LLC application for license as a manufacturer in Tennessee. Dr. Dickenson seconded the motion. The motion carried.

**Brittany Reid, RT**

Ms. Reid answered yes to the question that asked “Have you ever been charged or convicted (including a nolo contendere pleas or guilty plea) of a felony or misdemeanor (other than a minor traffic offense) whether or not sentence was imposed, suspended, expunged or whether you were pardoned from such offenses? Ms. Reid is on probation until January 2017 for “theft of less than \$50.00”. She was charged with possession of drug paraphernalia on 4/13/16; assault, domestic bodily injury on 3/11/2012; driving under the influence 10/11/2011 and failure to appear on 11/9/2015. After discussion, Dr. Eidson made the motion to approve Ms. Reid’s application for registration as a pharmacy technician with the condition that she submits quarterly attendance reports from Narcotics Anonymous and drug screens for 2 years. Dr. Dickenson seconded the motion. The motion carried.

**Waiver**

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

**Vanderbilt Integrated Pharmacy**

Jim Manfred, Director of Vanderbilt Pharmacy, appeared before the board to request an increase in the pharmacist to technician ratio from 4:1 to 5:1. After discussion, Dr. Wright made the motion to approve the request to change the pharmacist to technician ration from 4:1 to 5:1 with all technicians being certified. Dr. Eidson seconded the motion. The motion carried.

**Board rule 1140-03-.14 (12)**

Dr. Dickenson made the motion to approve the request from **Brantley L. Wescott, Pharm. D.** to be the pharmacist in charge at RARx, LP TN and Acclaim Fertility Pharmacy, LLC. Dr. Price seconded the motion. The motion carried.

**Consent Orders**

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

**VIOLATED BOARD RULE 1140-2-.02(1)**

Wayne Barker, R.Ph.  
Dennis R. Norris, D.Ph

**VIOLATED BOARD RULE 1140-09-.01(2)**

JCM Enterprises  
Citron Pharma, Inc.

**REVOCATION**

Tasha Turman, RT  
Jerrica Bright, RT  
Terrance Shaw, RT

**REPRIMAND**

A & A Home Health Equipment, Inc.  
Sourcemark, LLC

**Director's Report**

Dr. Dilliard informed the board that the committee for collaborative contraceptive met on November 1, 2016 and that the next meeting is scheduled for December 13, 2016.

Dr. Dilliard explained to the board that he, Dr. Geminn, and Dr. Reagan have been working on establishing Naxlone training. Sara Melton at ETSU has developed a training program for pharmacist as well as for unlicensed individuals on how to use Naxlone. The next process will be to have the program uploaded on website.

Dr. Dilliard informed the board that Dr. Rebecca Moak complete critical point training for sterile compounding. He also informed the board that Dr. Scott Denaburg attended a meeting with the FDA.

**General Discussion**

Dr. Bunch asked Dr. Cost to present an update on provider status for pharmacist. Dr. Micah Cost, Director, Tennessee Pharmacist Association, explained to the board of Federal Senate Bill314/ House Bill592 will amend title XVIII of the Social Security Act to provide for coverage under the Medicare program of pharmacist services.

Dr. Cost also explained to the board that Dr. Lucy Atkins has been working with the Department of Health and the Center for Disease Control on a grant to train 100 pharmacies to be credential in diabetes and self- management education. This will allow pharmacies to be listed as Diabetes Self -Management Education Centers across the state.

Dr. Cost stated that TennCare has established a medication therapy management advisory group and the first meeting were held on November 7, 2016. This meeting was to establish how TNCare and incorporate pharmacist in MTM not allow as it is known through CMS but also into their patient centers medical home model and their episodes of care.

Ms. McDaniel made the motion to adjourn at 2:37 p.m... Dr. Eidson seconded the motion. The motion carried.

**The minutes were approved and ratified at the January 24, 2017 board meeting.**