TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Iris Room
Nashville, TN
March 10-11, 2015

BOARD MEMBERS PRESENT
Nina Smothers D.Ph., President
Will Bunch, D.Ph., Vice President
Kevin Eidson, D.Ph.
R. Michael Dickenson, D.Ph.
Debra Wilson, D. Ph.
Jason Kizer, D.Ph.
Joyce McDaniel, Consumer Member

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

The Tennessee Board of Pharmacy convened on Tuesday, March 10, 2015, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:06 a.m. Dr. Smothers welcomed students from South College, Belmont University and the University of Tennessee.

Minutes

The minutes from the January 27-28, 2015 board meeting were presented. After discussion, Ms. McDaniel made the motion to approve the minutes as presented. Dr. Eidson seconded the motion. The motion carried.

Complaint Summary

1.

Complaint opened based upon referral by CSMD administrator about large numbers of controlled substances dispensed, early refills, and a very extensive patient profile for patient "Joe Blow" at "111 Fictitious Street, Fantasy City, TN." BOP investigators visited respondent pharmacy, reviewed records, interviewed staff and audited some controlled substances.

Findings:

- PIC admitted he has no specific policy regarding filling CS or addressing DEA red flags.
- PIC admitted CSMD is only used if a physician asks them to check on a patient.
- When asked how he knows a patient is a doctor shopper without checking CSMD, PIC responded "we can just tell."

- PIC stated he has a "strict refill policy" then admitted they usually allow 3 to 4 days early on 30 day prescriptions.
- PIC stated he sometimes consults with the prescriber about early refills but does not document those conversations.
- PIC stated "Joe Blow" is a fictitious patient and that BOP and CSMD should have known that. PIC later informed investigators that "Joe Blow" had been deleted and that the pharmacy would now use "Patient Not Real" so BOP and CSMD would know that this is not a real patient. Investigators re-instructed PIC not to use any fake patient names.
- PIC claims his software vendor directed him to use this profile as a dump profile for prescriptions not filled for whatever reason so that the medication would not show up on the actual patients' records.
- PIC stated he was certain no quantities were dispensed to Joe Blow. However, BOP investigators found a majority of Joe Blow's prescriptions showed a quantity was dispensed and those prescriptions were reported to CSMD as being dispensed to Joe Blow. Investigators found that some of those prescriptions were also billed to the actual patients' insurance plans and were never reversed. One prescription was found on Joe Blow's profile, but dispensed and signed as picked up by another patient.

55 out of date drugs were found, most of them in the C2 safe.

Audit findings for a 1 year period revealed the following:

Hydrocodone/APAP 7.5/325	overage of 15,248
Hydrocodone/APAP 10/325	overage of 5,215
Chlordiazepoxide 10mg	overage of 22
Morphine ER 30	overage of 800
Oxycodone 20	overage of 300
Oxycodone 10/325	overage of 31,195
Oxycodone 10	overage of 1,700
Meperidine 50	overage of 603
Methadone 10	overage of 648
Oxycodone 15	overage of 5,682
Diazepam 10mg	shortage of 912
Buprenorphine 8	shortage of 173
Alprazolam 0.5 mg	shortage of 2,207

PIC had claimed to have a "strict refill policy" however, investigators found many early refills but no documentation as to why early refills were dispensed.
Five patient records were selected at random and reviewed in detail for early refills during a 2 year period.:

Refills were dispensed 1 to 3 days early 89 times.
Refills were dispensed 4 to 10 days early 45 times.
Refills were dispensed 11 to 15 days early 14 times.
Refills were dispensed 16 to 20 days early 13 times.
Refills were dispensed 21 to 25 days early 4 times.

Refills were dispensed more than 25 days early 6 times.

Because the initial audit was inconclusive, 6 drugs were selected for a follow-up audit and another periodic inspection was performed. During the follow-up inspection, investigators noted the previous out-of-dates were still at the pharmacy and an additional 39 different products were discovered which had expired since the previous visit. Investigators again reinforced the requirements to remove expired products from the pharmacy and also requested PIC to send copies of return documentation. PIC did comply after the follow-up visit.

Findings of follow-up audit:
Hydrocodone APAP 7.5/325 shortage of 4,944
Hydrocodone APAP 10/325 overage of 1,489
Chlordiazepoxide 10 shortage of 12
Diazepam 10 shortage of 1
Buprenorphine 8 overage of 36
Alprazolam 0.5 overage of 2,265

Prior Discipline: PIC assessed $3,100 civil penalty for unregistered technicians, $2,000 civil penalty for unlicensed practice, May 2014. Pharmacist assessed $2,000 civil penalty for unlicensed practice. Pharmacy assessed $1,000 civil penalty for counseling.

Recommendation: Civil penalty to be determined by the Board for the fake patient. Civil penalty of $10 per out of date product. 2 years of probation with monitoring, quarterly reporting. CE, hours to be determined by the Board, for all pharmacists on staff.

Dr. Eidson made the motion to **authorize a formal hearing** with a $10.00 civil penalty per out dated drug for a total of $940.00, 2 year probation with monitoring and quarterly & inventory report to the pharmacy, a letter of warning to the PIC and pharmacy for using a fake name, transfer of non-dispensed medication, early refills and 6 hours of continuing pharmaceutical hours in pharmacy law in addition to the 30 hours required for license to all pharmacist for 3 years. Dr. Kizer seconded the motion. The motion carried.

2.

Complaint generated from a periodic inspection when BOP investigator suspected several “red flags” were being ignored. A CSMD report was reviewed and BOP investigators visited the pharmacy, reviewed records, interviewed staff, and audited some controlled substances.

<u>Findings:</u>

- At least 2 technicians had keys to the pharmacy. One of those techs had been in possession of a key since 12/12/12. PIC admitted he had given the tech a key, however both the tech and the PIC had previously denied that techs had keys. Only after being confronted did they finally admit it.
- DEA 222 forms were not properly completed.

- C-II invoices were not dated or signed.

An audit from 5/7/14 to 8/25/14 showed the following:

Methadone 10mg short 397
Oxycodone 15mg over 56
Hydromorphone 4mg balanced
Oxycodone/APAP 10/325 over 7,780

Since that audit was inconclusive, a follow up audit was conducted 8/25/14 to 12/2/14:

Methadone 10mg short 268
Oxycodone 15mg over 240
Hydromorphone 4mg balanced
Oxycodone/APAP 10/325 over 752

Compounding records for non-sterile products were reviewed and 25 expired API's were found. 6 prescriptions of "Bi-est" and 2 prescriptions of "Tri-est" compounded aliquots were used in products that were assigned a BUD beyond the expiration of products used. A triple fish suspension used for flavor was being used beyond its expiration date. Butylated hydroxytoluene (BHT) with an expiration date of 11/29/13 had been altered in the computer to show an expiration of 11/29/14, resulting in 12 times the expired BHT was used. Investigators also found 12 prescriptions compounded with Stevia that had incorrectly assigned BUD's. 14 prescriptions for Domperidone for human use were compounded and dispensed from 1/1/14 to 12/5/14. Investigators also discovered that the pharmacy was providing "samples" of compounded products for office use by using the name of the prescriber or a nurse but labeling as "office use."

Prior Discipline: None.

Recommendation: Refer Domperidone violation to FDA. Civil penalty of $10 per out of date product. Civil penalty of $100 per key violation. Establishment of a CAP regarding compounding and inventory control, to be approved by the Executive Director. Quarterly reporting on compliance with CAP to Executive Director for a period of 2 years. Reprimand to PIC for dishonesty about key violation.

Dr. Dickenson made the motion **to authorize a formal hearing** with a $1000.00 civil penalty for fraudulent records of drugs dispensed, a $10.00 civil penalty per expired drugs for a total of $250.00, a $100.00 civil penalty per technician for the key violation, a corrective action plan, quarterly reports to the executive director by the PIC, a letter of reprimand to the PIC for being dishonest about the key violation, letter of warning for record keeping discrepancy and refer the use of domperidone to the FDA. Ms. McDaniel seconded the motion. The motion carried.

3.

Complaint alleges unlicensed practice of a pharmacist whose license expired 12/31/14 and could not be renewed due to failure to pay professional privilege taxes.

BOP investigator discovered the privilege tax and penalties had not been paid for 2013 or 2014. Pharmacist was interviewed and provided a sworn statement that he had not participated in any pharmacy duties or filled any prescriptions during the time from 12/31/14 until the date of BOP visit. Pharmacist paid tax and penalties on the day of the visit and began the process of reinstatement. Investigator noted that even though pharmacist stated he had not performed any pharmacist activities, the pharmacist does have a BOP waiver and is currently serving as PIC for 2 separate pharmacy licenses and has had keys and access to both pharmacies during the time period of being expired.

Prior Discipline: PIC required to complete 10 hours of continuing education, October 2014.

Recommendation: Civil penalty of $1,000 per month of unlicensed practice.

Dr. Kizer made the motion to **authorize a formal hearing** with a $1000.00 civil penalty per month of unlicensed practice. Dr. Bunch seconded the motion. The motion carried.

4.

Complaint generated based upon DEA 106 indicating employee pilferage was responsible for losses.

BOP investigator obtained copies of a signed statement by a pharmacy technician admitting to theft of controlled substances and also a statement agreeing that she was responsible for most of the losses. (DEA 106 indicates mostly small quantities [1 to 3 tablets] missing of several drugs. The largest quantities missing were as follows:

91 Alprazolam 1 mg
15 Alprazolam 2mg
100 Adderall XR 15mg
31 Adderall XR 30 mg
15 Oxycodone 15mg
93 Oxycodone 30mg
29 Suboxone 8/2 film
30 Ultram ER 300
106 Ultracet).

Prior Discipline: None.

Recommendation: Revoke.

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

5.

PIC reported noticing small quantities of CS occasionally missing resulting in an internal investigation finding technician diversion.

BOP investigator obtained copies of internal audits, a signed statement admitting theft and consumption of unknown quantities of hydrocodone, temazepam, zolpidem and phentermine, and a sworn statement from the PIC detailing the internal investigation.

Prior Discipline: None.

Recommendation: Revoke.

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

6.

Complainant physician alleged unprofessional conduct by pharmacist that allegedly told a patient that the physician was under investigation and the pharmacist was not comfortable filling those prescriptions.

BOP investigator visited the pharmacy and interviewed the pharmacist (who is also the PIC). Pharmacist denied ever telling the patient that the prescriber was under investigation. Pharmacist provided detailed log of refill requests and documentation of denials, along with a sworn statement to BOP investigator.

Pharmacist was concerned with the following:

- Patient was taking Tylenol #3 from a different prescriber and Norco 5/325 from complainant. Patient gave different reasons for needing to switch between the medications and Pharmacist tried multiple times to verify with the prescriber but never received a return call.

- Patient continually requested early refills for Tylenol 3, Norco, Alprazolam, and Ambien.

- Pharmacist noticed patient also received overlapping prescriptions from mail order but calls attempting to contact prescriber were again never returned.

- Pharmacist became concerned with some family members picking up patient’s medications.

- When patient started to pay cash for prescriptions, Pharmacist made a decision to not fill any more controlled substances for this patient.

Prior Discipline: None.

Recommendation: Dismiss.

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

7.

PIC notified BOP of technician admitting to diversion of controlled substances for sale and personal use.

BOP investigator worked with DEA agents and Sheriff's Dept. Narcotic officers. Copies were obtained of pharmacy audits and arrest records. When arrested, police found a number of opened and unopened stock bottles with the pharmacy's labels; a bag containing hardcopy prescriptions with the pharmacy's labels on backs of the prescriptions; several firearms; a green leafy substance in a plastic bag; a silver grinder; and a digital scale. DEA 106 form indicates the following shortages:

3,348 Hydrodone Bitartrate/APAP 10/325
42,372 Hydrocodone APAP 7.5/325
400 Oxycodone APAP 7.5/325
7,631 Oxycodone APAP 10/325

Prior Discipline: None.

Recommendation: Revoke.

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

8.

Pharmacy loss prevention notified BOP of pilferage by a registered pharmacy technician working on rotation from a pharmacy technician school.

BOP investigator obtained copies of the tech's signed statement admitting to stealing and selling 100 hydrocodone tablets for $2.00 per pill. Investigator also obtained a copy of police report indicating that the technician admitted to police of stealing a minimum of 500 tablets and that the store manager stated to police that video shows respondent taking Hydrocodone and generic Tussionex from the shelf. DEA 106 form from the pharmacy shows the following shortages:

670 Hydrocodone APAP 10/325
649 Alprazolam 1 mg
1,645 ml Hydrocodone-Chlorpheniramine Susp 10mg-8mg/5ml

Prior Discipline: None.

Recommendation: Revoke.

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

9.

PIC notified BOP of possible diversion and impairment of a pharmacist.

BOP investigator visited the pharmacy, obtained records and sworn statements. Respondent pharmacist had a seizure episode while on duty and was taken to the emergency room. Pharmacist's pockets were found to contain the following:

2 empty Meperidine PCA syringes
2 full Meperidine vials
1 Meperidine vial that was half-full.

DEA 106 showed the following shortages:

100 Oxycodone 15mg tablets
320 ml Hydromorphone HCL 2mg/ml amps
60 ml Meperidine 10mg/ml cartridges
344 ml Meperidine 50mg/ml vials
60 ml Hydromorphone 10mg/ml vials

An audit of the MedSelect records revealed the following discrepancies:

From 11/9/14 to 1/20/15, respondent logged out 344 Meperidine 50mg/ml vials to be dispensed to various MedSelect locations, however, a separate report shows those were never placed into those machines.

From 11/23/14 to 1/20/15, 60 Hydromorphone 10mg/ml vials (used to make Hydromorphone PCA syringes) were logged out to be dispensed to MedSelect locations, however, a separate report shows none were placed into those machines.

On 12/13/14, inventory showed 6 Meperidine PCA were in stock. On 1/20/15, inventory showed 4 were in stock, however none had been dispensed to patients.

Pharmacist has subsequently checked into rehab, and notified Board staff of his desire to surrender his license.

Prior Discipline: None.

Recommendation: Accept voluntary surrender.

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

10.

BOP received a DEA 106 indicating shortages due to employee pilferage. A total of 300 Alprazolam 2mg were reported missing.

BOP investigator obtained a written statement from PIC stating that routine audits showed discrepancies so video was reviewed showing respondent on 4 different occasions taking cash and drugs from the pharmacy. Tech was terminated via a termination letter.

Prior Discipline: None.

Recommendation: Revoke.

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

11.

During a periodic inspection, BOP investigator discovered an unregistered tech.

Unregistered tech began performing tech duties 5/27/14.

Application was received at BOP 7/11/14. Additional information and documentation was requested by mail by BOP on 7/22/14. No response was received.

According to investigator, PIC thought that since the application showed "in process" that nothing else needed to be done. Tech denied receiving a letter. Tech has worked unregistered from May 27, 2014 to February 6, 2015.

Prior Discipline: None.

Recommendation: LOI to PIC about the need to remain vigilant regarding registration of technicians.

Dr. Dickenson made the motion to issue a **Letter of Instruction** to the PIC concerning pharmacy technician registrations. Dr. Bunch seconded the motion. The motion carried. Dr. Eidson and Dr. Wilson voted no.

12.

During a periodic inspection, BOP investigator discovered an unregistered tech. Unregistered tech began performing tech duties in April, 2014 and an application was filed. Additional information and documentation was requested by mail by BOP on 4/2/14. No response was received. Tech was not working on the day of inspection but the pharmacist-on-duty verified that technician duties had been performed from April 2014 to February 4, 2015.

Prior Discipline: None.

Recommendation: LOI to PIC about the need to remain vigilant regarding registration of technicians.

Dr. Dickenson made the motion to issue a **Letter of Instruction** to the PIC concerning pharmacy technician registrations. Dr. Kizer seconded the motion. The motion carried. Dr. Eidson voted no.

13.

BOP investigator conducting a routine inspection noted at least 89 expired compounded medications (non-sterile), along with 56 unlabeled (no expiration date) compounded medications (non-sterile), and 10 expired components for compounding non-sterile medications. PIC provided a written statement admitting to these findings. Non-sterile compounding area was not clean and Investigator had previously (1/14/14) warned PIC about cleaning and pulling expired products. Pharmacy did not have proper tech registry and affidavits even though PIC was warned also on 1/14/14 inspection.

Pharmacy also does high risk sterile compounding so Investigator did a separate sterile compounding inspection and provided PIC with a list of items (record keeping and policy related) needing immediate correction to be compliant with USP 797. No expired products were noted on the sterile compounding inspection. GAP analysis was in progress and Investigator provided assistance in proper completion. PIC provided investigator with documentation of Clean Room Certification.

Prior Discipline: None.

Recommendation: Civil penalty of $10 per expired drug or component. LOW to PIC for keeping pharmacy and compounding area clean, and for tech registry and affidavits.

Dr. Kizer made the motion to **authorize a formal hearing** with a $10.00 civil penalty per expired drug, a letter of warning to the PIC for keeping the pharmacy and compounding area clean, and for technician registry and affidavits. Dr. Wilson seconded the motion. The motion carried.

14.

Complaint alleges that specialty pharmacy delayed shipment of medication for 4 months. Timeline provided by complainant indicates numerous delays in shipment of medication between August and December 2014. Respondent pharmacy cited internal communication issues, problems with fulfillment pharmacy, and problems contacting complainant's prescriber as reasons for shipment delays. Based on review and investigation, complainant does not appear to have suffered acute harm as a result of shipment delays, but did have to miss work and deal with neurological complications resulting from missed medication.

Prior Discipline: LOW for similar issues in September, 2014, $1,000 civil penalty for similar issues in January, 2015.

Recommendation: LOW.

Dr. Kizer made the motion to **authorize a formal hearing** with a $1000.00 civil penalty for similar issues in January 2015 and a letter warning for similar issues in September 2014. Dr. Eidson seconded the motion. The motion carried.

15.

Complainant alleged respondent pharmacy is missing 60gms of pure Testosterone powder, compounding is being performed after hours, and illegal testosterone creams are being made and delivered to college athletes.

BOP investigators visited the pharmacy, reviewed records, interviewed staff and audited some controlled substances. PIC and the owner pharmacist both gave similar answers and stated a former employee had made the same allegations before leaving employment. According to PIC and the owner, no unexplained after hour's entry showed up on video, only pharmacists have keys to the pharmacy, and there was no shortage of Testosterone found during an internal audit. According to the owner, before leaving the job, the former employee had been seen taking photos of the pharmacy and of compounded products and also accused other employees of wearing a "wire" recording device and had sent some text messages asking who they were wearing the wire for. One employee still had some of those text messages saved on a cell phone and showed investigators.

BOP audit of testosterone did not show any shortage. Both the owner and PIC denied knowing anything about supplying products to college athletes. Deliveries are made but not to any school

or college. All compounding is done pursuant to a prescription order. No sterile compounding is performed. A review of CSMD did not show any unexplained red flags. No other violations were noted.

Prior Discipline: None.

Recommendation: Dismiss.

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

16.

BOP investigator discovered a pharmacy performing sterile compounding without a sterile environment even after previously instructing the pharmacist and staff not to compound sterile product until the hood had been certified and the compounding lab was re-inspected. Investigator returned to the pharmacy per travel log to check for any sterile compounding and was told for a second time that no sterile compounding was being performed.

About one year later, the investigator returned to the pharmacy to find compounding of products that should have been prepared in at least an ISO class 5 environment. The Biological Safety Cabinet was unplugged and had a handwritten sign saying "Not in Use." The BSC appeared to be old, dirty and had several rusty places. The certification sticker on the BSC indicated the last inspection date was 9/25/07 and it failed. There were no bubble point testing's noted for any micron filter use, and no record of endotoxin testing for glassware or other documentation requirements. No requirements of USP 797 were being followed.

Investigator discovered the following products being compounded without following requirements:

- Compounded injectable Triple Mix, AKA Trimix (Alprostadil/Phentolamine/Papaverine)
- Cyclosporin Eye drops
- Tacrolimus Eye drops
- Cyanocobalamin injection for office use
- Verapamil injection
- Sodium Hydroxide Solution (also used in Cyanocobalamin preparation)
- Paraban water injectable to be used in the Cyanocobalamin injection
- Hydroxyprogesterone

The investigator noted that the Pharmacists never reported to prepare CSPs nor did they pay any sterile compounding modifier fees or have available any documentation required to compound CSPs. Sterile CSPs were found to have started as far back as May 31, 2011.

PIC was not knowledgeable of sterile compounding and depended upon a technician that had compounding training and experience. That technician had been terminated 7 days prior to investigator's visit.

Investigator reiterated that sterile compounding be stopped until USP standards were met and inspected for compliance. PIC agreed to comply.

When asked about the CSP of eye drops, the PIC verbally stated he did not know eye drops had to be prepared in a sterile environment when done so for animals.

Other violations included:

- Expired medications of both sterile and non-sterile compounded products.
    - expired drugs/excipients #43 count
    - #78 drugs where the BUD is calculated incorrectly causing drug product to be adulterated
- No updated CSP policies and/or procedures (last set was found dated 2006) and marked N/A.
- No sterile product training documentation (documentation marked N/A).
- Domperidone non-sterile, compounded for human use. Records reviewed show documentation on actual compounding log stating this drug is not approved in US.
- Office Use compounding of sterile products without a sterile compounding license modifier.

A pharmacy technician's name is on most compounding records which were checked and verified by at least four different pharmacists.

Pharmacy students on rotation also were found to have compounded or checked the CSPs.

On January 7, 2015 a letter was sent from the pharmacy attorney informing the Board Office and OGC that the pharmacy had ceased all compounding and enclosed the letter being sent to its patients.

Prior Discipline: None.

Recommendation: 2 years of probation, during which time no compounding of any sort is to take place at the pharmacy. Civil penalty of $1,000 per month sterile compounding was performed at the pharmacy.

Dr. Eidson made the motion to **authorize a formal hearing** with 2 year probation during which no compounding (sterile and non-sterile) can take place, a $1000.00 civil penalty per month that sterile compounding was performed at the pharmacy (March 2013-December 2014), $100.00 civil penalty per out dated sterile drug and $10.00 civil penalty per out dated non-sterile drug, a letter of reprimand to the PIC for not being truthful and refer the use of domperidone to the FDA. Dr. Wilson seconded the motion. After discussion, Dr. Eidson withdrew his motion. After further discussion, Dr. Eidson made the motion to authorize a formal hearing with 5 year probation for the pharmacy with no compounding of USP 795 & 797 standards (can request removal at end of 5years), $1000.00 civil penalty per month (March 2013 –December 2014) for compounding

when they said that they weren't, $100.00 civil penalty for sterile out of date drugs, $10.00 for non-sterile out of date drugs, a letter of reprimand to the pharmacist for not being truthful and refer the use of domperidone to the FDA. Dr. Wilson seconded the motion. The motion carried.

17.

PIC of case 16 above.

Prior Discipline: None.

Recommendation: 2 years of probation, during which time Respondent pharmacist may not serve as PIC of any pharmacy. Civil penalty of $1,000 per month sterile compounding was performed at Respondent pharmacy.

Dr. Kizer made the motion to **authorize a formal hearing** for a 2 year probation, cannot be PIC during the probation, $500.00 civil penalty per month (21 months) for sterile compounding and a letter of reprimand for lack of knowledge concerning sterile compounding. Dr. Eidson seconded the motion. The motion carried.

18.

BOP investigator discovered respondent MWD (oxygen and equipment) moved to a new location approximately 6 weeks prior to the relocation inspection. Manager provided a statement that Medicare allowed 30 days and thought BOP was the same. Manager did not explain the additional 2 weeks.

Prior Discipline: None.

Recommendation: Civil penalty of $100 per month of operation without required inspection.

Dr. Dickenson made the motion to **authorize a formal hearing** with a $100.00 civil penalty per month for operating without the required inspection. Dr. Wilson seconded the motion. The motion carried.

19.

Complainant patient alleged being shorted 29 Alprazolam and being called a liar by the pharmacist on duty.

Respondent pharmacist was interviewed by BOP investigator and provided a sworn statement that the prescription was double counted, an audit count balanced, and the on-hand amount matched the computer count. Respondent pharmacist feels confident the correct amount was dispensed and when he told the patient that none was missing, the patient became angry.

Prior Discipline: None.

Recommendation: Dismiss.

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

20.

This is the pharmacy for Case 19 above. Pharmacy, PIC, and pharmacy supervisor became involved when patient complained to management and accused pharmacist from Case 19 of stealing some Alprazolam. BOP investigator interviewed PIC and obtained a sworn statement that PIC had spoken to the patient, but did not give any extra pills because the pharmacy supervisor did a count at the pharmacy which matched, on-hands matched the computer, and staff had followed the policy of double counting controlled substances.

Prior Discipline: None.

Recommendation: Dismiss.

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

21.

Complainant patient alleged a misfill by receiving another patient's heart medication instead of the prescribed antibiotic. Complainant began medication on June 13 and immediately began feeling ill but continued taking the medication until 29 of 30 had been taken. Complainant went to ER on July 11, was admitted, and stayed in the hospital until July 15. Complainant also believes that because the medication made her heart race, it caused her pacemaker to have to be changed in July instead of November or December as planned. Complainant alleged the pharmacy has unlicensed staff working behind the counter.

BOP investigator interviewed Respondent pharmacist, who provided a sworn statement that when they were notified of the incident, Complainant's cardiologist and PCP were contacted and neither was concerned. The other patient (the one whose prescription was accidentally dispensed to Complainant) was contacted and verified that they had received the correct medication. Respondent pharmacist stated additional checking systems have been implemented to prevent this type error from happening again. Allegations regarding unlicensed staff could not be verified.

Prior Discipline: None.

Recommendation: LOW to dispensing pharmacist for misfill. LOI to PIC, request submission of CAP.

Dr. Bunch made the motion to issue a **Letter of Warning** to the dispensing pharmacist for the misfill, a Letter of Instruction to the PIC and request the submission of CAP. Dr. Kizer seconded the motion.

22.

BOP investigator performing a relocation inspection discovered respondent (Oxygen distributor) had moved on September 1, 2013 without notifying BOP. The corporate contact person providing a statement confirming the date and claimed to be unaware of the notification requirement.

Prior Discipline: None.

Recommendation: Civil penalty of $100 per month of operation without required inspection/notification.

Dr. Dickenson made the motion to **authorize a formal hearing** with a $100.00 civil penalty per month for operating without the required inspection/notification.

23.

Complaint opened based upon report that pharmacy technician had a positive urine screen for Oxycodone/Oxymorphone.

Respondent technician retained an attorney and sent a typed response to BOP. Respondent claims to have been injured at work but did not seek medical attention, which caused severe pain and swelling. Technician had Percocet remaining from gallbladder surgery approx. 3 years previously, so she took a half tablet on Saturday, a half tablet on Sunday, then went for UDS on Monday. Documentation from the pharmacy which dispensed 3 year old prescription took longer than allowed and the technician was terminated from employment. Tech claims to have offered to take another UDS at her own expense since she had not taken any since the 1 total tablet before the last UDS. Respondent also provided a pharmacy printout showing a prescription for 35 Endocet 5/325 on 1/20/11. During approx. 2 year period, patient's printout showed only 6 controlled substance prescriptions out of a total of 29 prescriptions.

Prior Discipline: None.

Recommendation: Dismiss.

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

24.

BOP was notified of 4,524 Alprazolam missing and a pharmacist admitted to removing some from the pharmacy. A copy of a signed statement was provided in which respondent pharmacist wrote he "potentially unknowingly" may have taken a 500 count Alprazolam by putting them in his lab coat then "unknowingly left the store."

Respondent pharmacist claims that he uses his lab coat pockets to help carry drugs back and forth and provided a typed response admitting that he had found a partial Alprazolam bottle at home that he had accidentally taken home.

BOP investigator interviewed respondent and obtained a sworn statement in which respondent denied intentionally removing narcotics from the pharmacy but agreed to follow investigator's recommendation to contact TPA and TPRN for an evaluation. He checked in for an evaluation on January 11.

Prior Discipline: None.

Recommendation: Revoke.

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

25.

Complaint is based upon information received from a pharmacy. Allegations indicate coworkers noticed unusual behavior and a smell of alcohol while on duty so Respondent pharmacist was sent for a "reasonable suspicion" drug screen. A copy of the results of the drug screen show a breath alcohol test of 0.24 and sometime later, 0.15. Respondent pharmacist was suspended without pay for being above the legal and corporate limit. Pharmacist agreed to enter a "last chance agreement" on with employer December 15. The agreement obligates Respondent pharmacist to undergo treatment.

Prior Discipline: None.

Recommendation: Revoke.

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

26.

Complainant patient provided a lengthy typed complaint alleging unprofessional conduct, rude and abusive behavior, and refusing to fill complainant's prescriptions.

BOP investigator followed-up by phone with complainant but no additional information was relayed.

BOP investigator interviewed respondent pharmacist and obtained a sworn statement. Respondent provided a very detailed explanation of his actions including identifying multiple DEA red flags with the patient and treatment. Investigator feels the respondent exercised sound professional judgment and found no evidence of rude or unprofessional conduct.

Prior Discipline: None.

Recommendation: Dismiss.

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

27.

Complaint opened based upon allegations by law enforcement personnel that suspicious activity may be occurring at a pharmacy.

BOP investigators observed the facility during afternoon hours. The pharmacy is located in a strip-mall type area along with several medical and dental offices along with another pharmacy that had recently closed. Respondent pharmacy had recently been inspected for an ownership change and is now the only pharmacy in the immediate area. No violations were noted. Although the mall had a lot of traffic, investigators observed more patients going to the medical and dental offices than were going to the pharmacy. No suspicious activity was observed at the pharmacy.

Prior Discipline: None.

Recommendation: Dismiss.

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

28.

Respondent pharmacist was charged with eight counts of knowingly filling fraudulent prescriptions for a customer. The customer had pled guilty to prescription fraud and claimed the pharmacist knew the prescriptions were fake. Pharmacist denied any knowledge that the prescriptions were fraudulent but did admit to filling the prescriptions and accepted a "Best Interest plea" to four of the eight counts, all "D" felonies, with a four-year period of diversion. Special terms of the agreement require respondent to follow any and all dictates of the BOP and with good and lawful conduct, the charges will ultimately be dismissed and expunged from respondent's record.

Prior Discipline: None.

Recommendation: Revoke.

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

29.

Pharmacy loss prevention reported technician diversion and provided a copy of investigative file, audits, and a signed admission statement. Tech admitted stealing approx. 7,000 Hydrocodone APAP 10/325 and 240 ml of Promethazine with Codeine cough syrup to give to an ex-fiance to sell. DEA 106 form was filed showing the following shortages:

8,720 Hydrocodone APAP 10/325
1,040 ml Promethazine with Codeine Syrup

Prior Discipline: None.

Recommendation: Revoke.

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

30.

Independent pharmacy where respondent had worked for approx. 7 months and a chain pharmacy where respondent had worked for 7 days, both reported CS losses and admissions by respondent to stealing drugs for personal use and to give to others.

DEA 106 from chain pharmacy indicated the following shortages:

12 Hydrocodone APAP 5/325
10 Hydrocodone APAP 10/325
2 Alprazolam 1mg
7 Oxycodone 5mg
4 Oxycodone 10/325

DEA 106 from independent pharmacy indicated the following shortages:

560 Hydrocodone APAP 10/325

Prior Discipline: None.

Recommendation: Revoke.

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

31.

CSMD staff noticed respondent pharmacy reports dispensing large amounts of CS, inconsistent days' supply, and patients that see multiple prescribers.

BOP investigators visited the pharmacy, reviewed records, and interviewed staff. Technicians and pharmacists provided consistent answers on policy and procedures. PIC exhibited great concern for practicing pharmacy in a professional manner and providing proper care to patients. Thorough documentation was provided to investigators detailing refusals to fill CS for certain patients, and pharmacy uses a Controlled Medication Evaluation form that CS patients have to complete as part of their patient profile. Large amounts of CS, especially Buprenorphine, come primarily from a single clinic with multiple prescribers. PIC has visited the clinic twice to observe operations and talk to the prescribers. PIC is comfortable with the practice. Inconsistent days' supply entries were mostly attributable to Buprenorphine and Tenncare requirements for days' supply entry. In order to get paid and best serve the patients, days' supply has to be entered according to Tenncare requirements.

BOP investigators agreed after conducting the investigation that the pharmacy is proactively attempting to monitor and provide good patient care for patients on CS.

Prior Discipline: None.

Recommendation: Dismiss.

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

32.

Complaint was originally sent to Division of Consumer Affairs who referred it to BOP. Patient alleged a misfill caused harm and resulted in a hospital stay, lost income and pain and suffering for which the pharmacy should have to pay. Patient's spouse allegedly called the pharmacy about medication looking different and was told by someone at the pharmacy that it was common to change manufacturers so if everything looked correct on the labels that the patient should not be concerned. Patient became sick, had severe headache, dizziness, racing heart and vomiting. Patient said the medications were tested at the ER and again in the cardiac unit, and 2 of 3 prescriptions contained the wrong drug. Complaint stated it was determined that the patient was suffering withdrawal from not having the right medication and that when pharmacy was contacted again, patient's spouse received an apology for the mistake and was told that students often fill prescriptions. Complaint stated patient was offered $3,000 and told to "take it or leave it."

BOP investigator visited the pharmacy, obtained records and statements, and interviewed the PIC. According to a typed statement, PIC became aware of the allegations 2 days after the patient's caregiver had picked them up. Prescriptions should have been Fluoxetine and Methylphenidate. Patient's spouse told PIC that "someone in the pharmacy" had told him that a different manufacturer may have been dispensed so he searched the internet and found that the Methylphenidate was a different manufacturer but did not search the Fluoxetine until later and discovered that the pills were actually Ciprofloxacin. PIC expressed concern, asked that the incorrect medication be quarantined so no more were taken, filled the proper medication and contacted the prescriber. Prescriber told PIC the incident would be charted but no further action was necessary. PIC performed an inventory review and there was no discrepancy with on-hand balances of Fluoxetine or for Ciprofloxacin. The next day, PIC received a call from patient's spouse that the patient had to go to ER and was kept for 23 hours and was feeling better after restarting Fluoxetine. PIC again called prescriber and was told the ill effects were likely from not taking Fluoxetine and not from taking Ciprofloxacin.

PIC was not able to speak directly to patient because the spouse always said the patient was "unable and unavailable" to speak to PIC even though PIC asked. Alleged misfills were never returned to the pharmacy for verification. PIC denied blaming any errors on students. Since the on-hands were both correct, an error could not be determined. The rest of the complaint deals with issues and requests for payments that are not within the authority of BOP.

Prior Discipline: None.

Recommendation: Dismiss.

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

33.

BOP investigator performed an opening inspection on 1/20/15 and discovered the respondent started having prescription devices in September, 2014.

Prior Discipline: None.

Recommendation: Civil penalty of $100 per month of operation without required inspection.

Dr. Wilson made the motion to **authorize a formal hearing** with a $100.00 civil penalty per month for operating without the required inspection. Dr. Eidson seconded the motion. The motion carried.

34.

Complainant alleged respondent pharmacy's prescription forms for doctors and patients to print and fill out are illegal, that they imply an indication for treatment of pain with no scientific based study, and had at least one coded prescription.

BOP investigator reviewed prescription forms from the pharmacy and found only that the forms have suggested compounds under the titles of "Commonly Used for Pain Management," "Commonly Used for Neuropathic Pain," "Miscellaneous Specialty Creams," "Wound Gels," and "Oncology Pain Cream." All products had specific names and percentages. No coded prescriptions were found. Investigator cautioned PIC about FDA interpretations of compounding versus manufacturing and about DEA decisions regarding pre-printed order forms for controlled substances. PIC agreed to research those issues and adjust accordingly to avoid problems with those agencies.

Prior Discipline: None.

Recommendation: Dismiss.

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

35.

Complainant patient alleged receiving Propranolol instead of Protonix prescribed as an antacid following heart surgery. Medication was taken once daily for 28 days before the error was discovered, during which time the patient claims to have suffered migraines, low blood pressure, burping, dizziness, being light headed, chest and lung discomfort, bad heartburn, heavy coughing, and premature or skipped heartbeats. When prescriber became aware of the error, the propranolol was stopped immediately because the patient was already on a beta-blocker. Patient began feeling better in 7 to 10 days. Patient was upset that the pharmacy seemed unconcerned about the error and only offered to refund the cost of the propranolol.

BOP Investigator conducted a thorough investigation, interviewed staff, obtained copies of records and labels, and obtained sworn statements. The misfill was confirmed. Patient's other beta-blocker was confirmed to be Metoprolol Tartrate 25mg twice daily. The root cause of the error appears to be that technicians use "short codes" to bring up drug names. In this case, the technician typed in "Pro40" in anticipation it would be Protonix 40, and did not notice that it pulled up Propranolol 40. Neither the pre-verification pharmacist nor the final check pharmacist noticed the error and PIC indicated that frequent interruptions and being the busy time of day were contributing factors.

Investigator noted that patient counseling was occurring even before announcing her presence and occurred both days of the investigation. However, staff could not provide an explanation how or even if proper counseling or DUR occurred for dispensing a beta-blocker instead of an antacid without questioning why the patient was being placed on two similar action beta-blockers. PIC pointed out that the patient electronically declined to be counseled during the

payment process. Investigator educated PIC about counseling and DUR and PIC confirmed understanding.

Staff and documentation indicate that the prescriber was contacted but was not concerned and stated to the pharmacist that the patient had not suffered any adverse events. PIC stated he did speak to the patient and apologized for the mistake and offered to refund the price of the medication as well as gas money so he could speak to the patient in person.

A plan of correction encourages techs to double check selected medications and seek a second opinion if something is questionable. A system of performing "post fill audits" has been implemented where data is again re-checked for accuracy, however, these audits may not be completed before the medication is dispensed, so PIC has placed a limit of 30 in the queue at a time to decrease the number of patients getting prescriptions that have been checked and dispensed but have not been subjected to a "post fill audit."

Prior Discipline: LOW to staff pharmacist, LOI to PIC in 2012, PIC assessed $100 civil penalty for unregistered technician in June, 2014.

Recommendation: LOW to dispensing pharmacist for misfill. LOI to PIC, request submission of CAP.

Dr. Kizer made the motion to issue a **Letter of Warning** to the dispensing pharmacist of the misfill, a Letter of Instruction to the PIC and request submission of CAP. Dr. Bunch seconded the motion. The motion carried.

36.

Complainant physician alleged unlicensed practice of medicine (Rule 0880-02-14(10) by a pharmacist using lasers to treat patients without a supervising physician, or, if there is a supervising physician, that Respondent pharmacist's advertisements for the medspa violated T.C.A. 63-1-153, which requires all advertisements to include the name of the supervising physician.

Respondent pharmacist owns a medspa which offers laser treatments to patients.

BOP investigator interviewed respondent pharmacist and discovered there is a medical director for the clinic, but also confirmed that advertisements for the medspa did not contain information required by statute and BME rules.

Prior Discipline: None.

Recommendation: Dismiss complaint as it pertains to Respondent pharmacist. Refer to BME.

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

37.

Complaint dated 12/21/14 and was received at BOP 12/30/14. Complainant patient alleged respondent pharmacy failed to send a vacation supply of medication even after numerous verbal and written requests and following all instructions from the pharmacy. Patient planned to leave the country on 1/8/15 and return 4/15/15. Patient claims to not be able to get past customer service operators and has also sent letters to no avail. Patient claims to have no recourse other than to reschedule or cancel vacation at great expense simply to receive medications.

PIC for respondent pharmacy provided a typed response and chronological summary. PIC denies patient ever mentioning "vacation refills" or indicating any sort of urgency. PIC worked with PBM in order to provide a more accurate response to BOP. PIC indicates that neither the pharmacy nor PBM have any records or phone recordings of the patient asking for vacation supplies. Also, PIC stated the patient's online profile did not reflect any request that was stopped or had any failure to complete. Patient did file a corporate complaint on 12/21/14.

Prior Discipline: LOW for similar issues in September, 2014, $1,000 civil penalty for similar issues in January, 2015.

Recommendation: Dismiss.

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

38.

BOP investigator attempting to perform a periodic inspection discovered Respondent MWD had moved without notice. Investigator was able to contact the manager who gave a statement the firm had moved in September, 2014.

Prior Discipline: None.

Recommendation: Civil penalty of $100 per month of operation without required inspection/notification.

Dr. Dickenson made the motion to **authorize a formal hearing** with a $100.00 civil penalty per month for operating without the required inspection/notification. Ms. McDaniel seconded the motion. The motion carried.

39.

Complaint alleged early refills of controlled substances (Xanax, Norco, Soma) for a particular patient.

BOP investigator reviewed pharmacy records, patient's profile, and CSMD printout. Investigator developed a worksheet to research each of the above drugs individually. The findings for a 19 month time period were as follows:

Norco was filled a total of 8 days late over the time period. Patient has a pattern of alternating early and late refills.

Carisoprodol was filled a total of 7 days late. Patient has a pattern of alternating early and late refills.

Alprazolam therapy had only started for a 15 month time period. During those 15 months, refills totaled 14 days early (approx. 1 day early each month.) However, during the period of January 2014 to July 2014, there were a total of 11 days early. This drug was being filled at multiple pharmacy locations that share a common database. Investigator educated pharmacists and staff about professional judgment for early refills and suggested documentation when decisions were made to fill early.

Prior Discipline: Pharmacy assessed $1,000 civil penalty for counseling, December, 2009. Staff pharmacist assessed $1,000 civil penalty for counseling, December, 2009.

Recommendation: Dismiss.

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

40.

Complainant patient alleged being shorted 10 tablets of pain medication, unprofessional conduct because of long wait times and a blatant disregard for patients.

BOP investigators visited the pharmacy and obtained sworn statements from PIC and lead technician. PIC confirmed the patient was shorted 10 tablets of Percocet 10/325 when an audit was conducted after receiving a call from the patient. PIC stated she apologized and gave the patient the 10 additional pills. Technician stated that the prescription was filled during "rush hour" but estimated it did not take more than 20 to 35 minutes. PIC and tech both stated that prescriptions are scanned when received. Documents were provided to investigators that show a scanned in time of 5:38:19 and a sold time of 5:51:00. However, investigators reviewed other documentation containing PIC's explanation that the patient was told the approximate wait time would be about 20 minutes, but that it took longer due to rush hour, that patient had complained to store management and the prescription was eventually dispensed.

Prior Discipline: Pharmacy issued LOW for misfill, April, 2011.

Recommendation: LOW to dispensing pharmacist for misfill. LOI to PIC, request submission of CAP.

Dr. Wilson made the motion to issue a **Letter of Warning** to the dispensing pharmacist of the misfill, a Letter of Instruction to the PIC and request submission of CAP. Dr. Eidson seconded the motion. The motion carried.

41.

Employer notified BOP of respondent technician's admission to having a substance abuse problem and distributing drugs for sale. Technician denied to employer that any drugs were stolen from the pharmacy. Employer noted that the technician voluntarily entered a rehab center but recommended BOP suspend the technician registration for at least one year until all counseling programs were completed.

BOP investigator discovered that after the letter was sent, respondent technician was terminated because of drug use, has left his family and cannot be found. Investigator interviewed known acquaintances and friends of the technician who told Investigator that the technician has a major drug problem but they did not know where to find him.

Prior Discipline: None.

Recommendation: Revoke.

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

42.

During a periodic inspection on 12/4/14, BOP investigator discovered respondent pharmacy was performing high risk sterile compounding. However, the PIC had responded to the BOP survey on 12/6/12 that no sterile compounding was being performed. Investigator was told that a part-time pharmacist was responsible for the compounding part of the business but PIC was the person responding to the survey. Investigator met with the compounding pharmacist on 12/8/14. The pharmacy mainly compounds vitamin injections from non-sterile powders. Batches of 100ml are produced then dispensed in 1.5ml per patient orders which are then picked up by a representative of a weight loss clinic to take to the clinic for administration to the patient. Although the clean room has been approved by the certification company and some aseptic practices were in place, BOP had not been notified that the pharmacy was performing sterile compounding. The pharmacy has not been doing any sterility testing, media fill testing or annual competency evaluations and documentation. No GAP analysis had been completed. Required quarterly reports have not been submitted. Investigator asked that all sterile compounding be stopped until all paperwork, testing and GAP analysis could be completed and reviewed and the pharmacist agreed to do so, then the next day advised that sterile compounding will be discontinued altogether.

Investigator compiled the following timeline:

12/4/12, Clean room was initially certified by Southeastern Certification

12/6/12, PIC responded to BOP sterile compounding survey that no sterile compounding was being conducted.

3/8/13, records indicate the first batch of sterile products was compounded.

12/4/14, Investigator discovered high risk sterile compounding was being performed without BOP being advised. Compounding was halted voluntarily.

12/8/14, Investigator met with compounding pharmacist who agreed to stop sterile compounding until issues were corrected and reviewed by investigator.

12/9/14, Compounding pharmacist sent email to investigator notifying that the decision had been made to discontinue sterile compounding, however the GAP analysis would be completed and past modifier fees and quarterly reports will be submitted.

PIC has not been involved in compounding, but did fill out the survey. Although it was answered correctly for that particular day, PIC knew that sterile compounding was going to be performed and the certification had actually happened 2 days prior to his filling out the survey. PIC claims to have failed to understand that BOP would be interested in knowing that sterile compounding was about to begin.

Prior Discipline: None.

Recommendation: 2 years of probation, during which time no compounding of any sort is to take place at the pharmacy.

Dr. Eidson made the motion to **authorize a formal hearing** with a 2 year probation to the pharmacy with no USP 795 or USP 797 compounding being performed and a letter of warning to the PIC. Dr. Kizer seconded the motion. The motion carried.

43.

Complaint alleged unprofessional conduct when pharmacist misread a veterinary prescription for prednisolone as prednisone and argued with the customer to the point of both of them losing their tempers. Patient is a dog with an enlarged liver and owner claimed that prednisone could prove fatal so the dog has to take prednisolone.

BOP investigator interviewed complainant by phone and was told that if the prescription had been filled, his dog could have been injured. Investigator also contacted the UT College of Veterinary Medicine who confirmed that even though prednisone is metabolized to prednisolone by the liver, the process could be compromised in a dog with an enlarged liver.

Prior Discipline: None.

Recommendation: LOI to pharmacist regarding professional conduct.

Dr. Wilson made the motion to issue a **Letter of Instruction** to the pharmacist regarding professional conduct. Dr. Eidson seconded the motion. The motion carried.

44.

Pharmacy owner notified BOP of the arrest by narcotics detectives of respondent technician for selling prescription medications and the subsequent discovery of 18,000 Hydrocodone APAP 10/500 missing from the pharmacy. Pharmacy filed a DEA 106, notified BOP investigator and filed a report with the county Sheriff and city Police. Pharmacy's plan of correction included installation of cameras and not allowing anyone into the pharmacy area until cameras are installed.

BOP investigator could not locate respondent technician so a letter asking for a response was sent to the address on file at BOP. There was no response to the letter. Arrest records were found on-line, but to date, no court documents were located.

Prior Discipline: None.

Recommendation: Revoke.

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

45.

BOP received a letter from respondent pharmacy's attorney stating "on 26 occasions between June 2013 and May 2014, the pharmacy inadvertently sent drugs to a few patients located in the State of Tennessee." The letter claims it was because of a "mistaken belief" that a license was not required but the pharmacy now understands its licensure requirements and has taken steps to ensure the error will not be repeated.

Prior Discipline: None.

Recommendation: Civil penalty to be determined by the Board for each product sent to Tennessee patients during time Respondent pharmacy was unlicensed.

Dr. Eidson made the motion to issue a **cease and desist letter**. Dr. Bunch seconded the motion. The motion carried.

46.

Pharmacy loss prevention notified BOP of respondent pharmacy technician's admission to stealing Phentermine and Azithromycin from the pharmacy. A letter from BOP to the technician asking for a response was unanswered.

Prior Discipline: None.

Recommendation: Revoke.

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

47.

TPRN notified BOP that respondent pharmacist had a positive urine screen for ethyl alcohol metabolites and a follow-up hair specimen positive test. TPRN removed advocacy pending an evaluation for relapse. Follow-up information from TPRN indicates respondent has been unwilling to attend an evaluation session.

Prior Discipline: Respondent's license appears to have been reinstated in 2007 with the requirement that Respondent maintain TPRN advocacy for a period of 15 years. Respondent violated that order in 2009, and their licensed was revoked. Files reviewed by attorney do not indicate when Respondent's license was subsequently reinstated.

Recommendation: Revoke.

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

48.

Complaint alleged that respondent forged continuing education hours needed for reinstatement of their pharmacist license. The respondent's pharmacist license expired on 06/30/2012.

Prior Discipline: None

Recommendation: Discuss

Dr. Eidson made the motion to issue a **Letter of Reprimand** to the PIC for falsifying the document for reporting continuing education and to submit an additional 8 live hours (4 in law and 4 general) along with the required 30 hours needed for renewal of the pharmacist license. Dr. Bunch seconded the motion. The motion carried.

OGC Report

Mr. Cange stated that there are 47 cases in the Office of General Counsel and 17 are set for contested case hearings.

Mr. Cange informed the board that the rules have been prepped for internal review and would like to the board to authorize a rulemaking hearing for July 28, 2015. After discussion, the board decided to add July 28, 2015 as a board meeting date to discuss and review the rules.

Mr. Cange presented House Bill 572, which refers to Biosimilar Biological Products.

Mr. Cange informed the board of the Supreme Court decision concerning the North Carolina Dental Board vs the Federal Trade Commission. The was an antitrust case the and the court upheld the ruling.

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

Terry Cost, D.Ph., owner of **Middle Tennessee Pharmacy Services**, appeared before the board to request an increase in the pharmacist to technician ratio from 4:1 to 6:1. After discussion, Dr. Eidson made the motion to approve the request to increase the pharmacist to technician ration to 6:1 as long as the additional technicians are certified pharmacy technicians. Dr. Bunch seconded the motion. The motion carried. The board also requested that the pharmacist in charge submit a statement stating that they understand the responsibility and to notify the board if there are any changes.

Terry Cost, D.Ph., owner of **East Tennessee Pharmacy Services**, appeared before the board to request an increase in the pharmacist to technician ratio from 4:1 to 6:1. After discussion, Dr. Eidson made the motion to approve the request to increase the pharmacist to technician ration to 6:1 as long as the additional technicians are certified pharmacy technicians. Dr. Bunch seconded the motion. The motion carried. The board also requested that the pharmacist in charge submit a statement stating that they understand the responsibility and to notify the board if there are any changes.

Terry Cost, D.Ph., owner of **Guardian Mid-South Pharmacy**, appeared before the board to request an increase in the pharmacist to technician ratio from 4:1 to 6:1. After discussion, Dr. Kizer made the motion to approve the request to increase the pharmacist to technician ration to 6:1 as long as the additional technicians are certified pharmacy technicians. Dr. Bunch seconded the motion. The motion carried. The board also requested that the pharmacist in charge submit a statement stating that they understand the responsibility and to notify the board if there are any changes.

Order Modifications
Matthew Hobbs, Pharm.D.

Dr. Hobbs appeared before the board to request that he be allowed to be PIC. Dr. Hobbs signed a consent order on 3/13/2013 placing his pharmacist license on 5 year probation and he would not be allowed to be PIC for 3 years of probation. After discussion, Dr. Eidson made the motion to amend Dr. Hobbs' consent order and allow him to be PIC at Cunningham Drug Co., New Tazewell,TN. Dr. Bunch seconded the motion. The motion carried

Robert McLean, D.Ph.

Dr. McLean appeared before the board to request that he be allowed to be a floater. Dr. McLean signed a consent order on 12/19/2012 placing his pharmacist license on 10 year probation and he would not be allowed to be float for 3 years of probation. After discussion, Dr. Dickenson made the motion to amend Dr. McLean's consent order and allow him to be floater. Dr. Wilson seconded the motion. The motion carried

USP 797 Waiver Extensions
Physicians Regional Medical Center

Dr. Stephen Turski, appeared before the board to request a 3 year waiver extension of compliance with USP 797 standards. Physician Regional Medical Center is in the process of building a new hospital. After discussion, Dr. Dickenson made the motion to grant Physicians Regional Medical Center a 6 month waiver with the understanding that they must get a glove box in the pharmacy that they are still located. Dr. Kizer seconded the motion. The motion carried.

Application Review
Twyler Thomas, RT

Ms. Thomas answered yes to the questions that asked "Have you ever been charged or convicted (including nolo contendere plea or guilty pleas) of a felony or misdemeanor (other than minor traffic offenses) whether or not sentence was imposed, suspended, expunged, or whether you were pardoned from any such offenses?" Ms. Thomas stated that she was convicted of bank fraud on November 29, 2001 and sentence to probation. After discussion, Ms. McDaniel made the motion to approve Ms. Thomas application for registration as a pharmacy technician. Dr. Bunch seconded the motion. The motion carried.

Waivers

USP 797 Waiver Extensions

Dr. Kizer made the motion to approve the request from **Baptist Memorial Hospital, Tipton, TN** to grant a 90 day waiver to become compliance with USP 797. Dr. Wilson seconded the motion. The motion carried.

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

Dr. Wilson made the motion to approve the request from **Horizon Medical Center** automated dispensing machine to grant a waiver that the pharmacy to be 180 square feet and the requirement for hot and cold running water. Dr. Bunch seconded the motion. The motion carried.

Board rule 1140-01-.07

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

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

Dr. Kizer made the motion to approve the request from **Candace Apple Fox, D.Ph**., to waive the one hundred and sixty (160) internship hours but she must successfully take and pass the MPJE. Dr. Bunch seconded the motion. The motion carried.

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

Director's Report

Dr. Dilliard informed the board that he would like for them to consider funding to the TPRN for pharmacy technician and pharmacist to be able to use their services. Dr. Dilliard explained that the Board of Nursing has a fee attached to each renewal that helps fund their recovery program. Dr. Dilliard will check into the contracts already established with the State to see what the board would need to do to start this process.

Dr. Dilliard gave the board an update on collaborative practice and informed the board that the one point of contention concerns controlled substances.

Dr. Dilliard informed the board of some of the bills in legislation that pertain to the board of pharmacy and the controlled substance monitoring database.

Dr. Dilliard asked the board for approval to attend the annual NABP meeting scheduled for May 16-19, 2015 in New Orleans, LA. Dr. Dilliard also asked the board to nominate a board member as a delegate. After discussion, the board approved all board members and the executive director to attend the NABP annual meeting scheduled for May 16-19, 2015 in New Orleans, LA.

Dr. Dilliard asked the board for approval to attend the TPA annual meeting scheduled for July 13-16, 2015 in Murfreesboro, TN along with the booth fees. After discussion, Dr. Eidson made the motion

to approve the pharmacy investigators and the executive director to attend the TPA annual meeting and the booth fees. Dr. Dickenson seconded the motion. The motion carried.

Dr. Dilliard gave the board copies of the Controlled Substance Monitoring Database legislative report. Dr. Dilliard also informed the board that we are having problems with pharmacies keying prescriptions under the physician's name that they didn't write. Dr. Dilliard stated that pharmacies are required to correct these problems in a timely manner, if they don't the board may need to take action against the pharmacies. He also stated that the pharmacy technicians who are entering the information in the database need to make sure that they key in the correct information for the correct physician.

Dr. Eidson made the motion to adjourn at 4:50 pm. Dr. Bunch seconded the motion. The motion carried.

March 11, 2015

The Tennessee Board of Pharmacy reconvened on Wednesday, March 11, 2015 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members were present, the meeting was called to order at 8:00 a.m., by Dr. Smothers, president.

General Discussion

Dr. Dilliard asked the board to consider changing board rule 1140-03-.14(13) which states "The designated pharmacist in charge at a particular pharmacy practice site shall be on duty a minimum of fifty percent (50%) of the hours that the pharmacy is in operation. Except, in any event, the pharmacist in charge shall not be required to be on duty more than an average of forty (40) hours per week". Dr. Dilliard stated that he has received several telephone calls concerning this issue because some pharmacist would like to 32 hours a week.

Consent Orders

Dr. Eidson made the motion to accept the consent orders as presented. Dr. Bunch seconded the motion. The motion carried.

VIOLATED BOARD RULE 1140-03-.06(6)
Michael Lingerfelt, D.Ph.

REVOCATION
Rachel Webb, RT
Patrick Ailey, D.Ph. (volunteer surrender)
Katherine Cantrell, RT
Amanda Reynolds, RT

VIOLATED BOARD RULE 1140-2-.02(1)
Andrianna Taylor, RT-

VIOLATED BOARD RULE 1140-01-.08
Care Solutions, Inc.

Contested Cases

Corder's Community Pharmacy, Inc.

A representative from Corder's Community Pharmacy, Inc. was not present nor represented by legal counsel. Mr. Cange represented the State. Mrs. Joyce Grimes Safely was the Administrative Law Judge. Mr. Cange asked to proceed in default. The board voted to proceed in default. Mr. Cange passed out the Notice of Charges. Corder's Community Pharmacy license was summarily suspended at the July 7, 2014 board meeting. After discussion, Dr. Kizer made the motion to revoke Corder's Community Pharmacy license and to assess case cost. Dr. Dickenson seconded the motion. The motion carried. Dr. Kizer made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Dickenson seconded the motion. The motion carried. Dr. Eidson was recused.

Nathaniel Beaumia, RT

Mr. Beaumia was not present nor represented by legal counsel. Mr. Cange represented the State. Mrs. Joyce Grimes Safely was the Administrative Law Judge. Mr. Cange asked to proceed in default. The board voted to proceed in default. Mr. Cange passed out the Notice of Charges. Mr. Beaumia is charged with violating board rule, 1140-2-.02(1). After discussion, Dr. Eidson made the motion to assess a $100.00 civil penalty to Mr. Beaumia for violating board rule 1140-2-02 (1). Dr. Bunch seconded the motion. The motion carried. Dr. Kizer made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Bunch seconded the motion. The motion carried.

Ashley Corder, D.Ph.

Dr. Corder was not present nor represented by legal counsel. Mr. Cange represented the State. Mrs. Joyce Safely Grimes was the Administrative Law Judge. Mr. Cange asked to proceed in default. The board voted to proceed in default. Mr. Cange passed out the Notice of Charges. Dr. Corder is charged with violating T.C.A § 63-10-305 (4), (6) and (8). After discussion, Dr. Dickenson made the motion to revoke Dr. Corder's pharmacist license and to assess case cost. The motion was amended to have the order corrected numerical. Dr. Wilson seconded the motion. The motion carried. Dr. Kizer made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Dickenson seconded the motion. The motion carried. Dr. Eidson was recused.

Amanda Maddox, RT

Ms. Maddox was not present nor represented by legal counsel. Mr. Cange represented the State. Mrs. Joyce Safely Grimes was the Administrative Law Judge. Mr. Cange asked to proceed in default. The board voted to proceed in default. Mr. Cange passed out the Notice of Charges. Mrs.

Maddox is charged with violating T.C.A § 63-10-305 (4). After discussion, Dr. Dickenson made the motion to revoke Ms. Maddox's pharmacy technician registration and to assess case cost. Dr. Kizer 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. Bunch seconded the motion. The motion carried.

Narecus M. Cox, RT

Mr. Cox was not present nor represented by legal counsel. Mr. Cange represented the State. Mrs. Joyce Safely Grimes was the Administrative Law Judge. Mr. Cange asked to proceed in default. The board voted to proceed in default. Mr. Cange passed out the Notice of Charges. Mr. Cox is charged with violating T.C.A § 63-10-305 (4). After discussion, Dr. Dickenson made the motion to revoke Mr. Cox's pharmacy technician registration and to assess case cost. Dr. Eidson seconded the motion. The motion carried. Dr. Kizer made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Eidson seconded the motion. The motion carried.

Agreed Orders

Dr. Bunch made the motion to accept the following agreed orders for revocation as presented. Ms. McDaniel seconded the motion. The motion carried.
Meikai Mapp, RT
Wanda Musgrave

Shataria Richardson, RT

Mr. Cange presented an agreed order to the board in the name of Shataria Richardson, RT with 5 year probation with monthly drug screens for one year and random drug screens for the remaining 4 years and she cannot serve as a pharmacy technician in the traditional behind-the counter setting for a period of 3 years. Ms. McDaniel made the motion to accept the agreed order as presented. Dr. Kizer seconded the motion. The motion carried. Dr. Dickenson voted no.

Dr. Kizer made the motion to adjourn at 1:28p.m. Dr. Bunch seconded the motion. The motion carried.

The minutes were approved as amended at the May 11-12, 2015 board meeting.