TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Poplar Room
Nashville, TN
January 27-28, 2015

BOARD MEMBERS PRESENT
Jason Kizer, D.Ph., President
Nina Smothers, D.Ph., Vice President
Will Bunch, D.Ph.
Kevin Eidson, D.Ph.
R. Michael Dickenson, 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
Sheila Bush, Administrative Manager

BOARD MEMBER ABSENT
Debra Wilson, D.Ph.

STAFF ABSENT
Rebecca Moak, Pharmacy Investigator

The Tennessee Board of Pharmacy convened on Wednesday, January 27, 2015 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:04 a.m.

Rulemaking Hearing

Mr. Cange, Assistant General Counsel served as moderator for the rulemaking hearing. There were no written or verbal comments from the public regarding the proposed changes. The board decided to amend rule 1140-03-.03 to allow pharmacies to dispose of controlled substance per the Drug Enforcement Agency (DEA) regulations. After discussion, Dr. Eidson made the motion to adopt the rules as amended. Dr. Smothers seconded the motion. A roll call vote was taken.

Elections

Dr. Kizer thanked the Board and Board staff for their cooperation and help during his leadership as president. Dr. Bunch made the motion to nominate Dr. Nina Smothers as president of the board. Dr. Eidson seconded the motion. The motion carried. Dr. Eidson made the motion to nominate Dr. Will Bunch as vice president of the board. Dr. Dickenson seconded the motion. The motion carried.

Financial Report

Ms. Title presented the financial report to the board. Dr. Eidson asked what the cost per vehicles over the last 12 months and the percentage of the CSMD that is assessed to the board and a copy

what was assessed the last fiscal year. Ms. Tittle stated that she will get the additional paperwork and send it to the board. Dr. Eidson asked about signing a contract with the Tennessee Pharmacy Recovery Network (TPRN) and allocating funds to help with the recovery program.

Complaint Summary

1.

Complaint generated from hospital reporting the death of a child with high sodium and glucose levels in which an incorrect TPN solution was suspected as the cause. Lab results and "black box" data from the mixing machine confirmed an incorrect dosage had occurred.

Since this complaint involved high risk sterile compounding and resulted in the death of a child, BOP investigators conducted a thorough investigation, interviewed staff extensively, and reviewed data obtained from the mixing machine. Board investigators believe that human error and a violation of Respondent's own policies and procedures lead to the error. The investigation revealed that several warning signals and discrepancy reports indicating possible incorrect dosages were ignored by staff at Respondent facility. Several process improvements were implemented during the investigation to minimize chances of this occurring again.

Prior Discipline: None.

Recommend:

Ms. McDaniel made the motion to suspend the pharmacy license. Dr. Kizer seconded the motion. After discussion, Ms. McDaniel withdrew her motion. Dr. Eidson made the motion to revoke the pharmacy license. Dr. Bunch seconded the motion. The motion carried. Dr. Eidson made amended the motion to add that the pharmacy be responsible for the cost of the investigation. Dr. Bunch seconded the amendment. The amended motion carried. Dr. Kizer made the motion to issue a letter of reprimand to the PIC, dispensing pharmacist and technician, 8 hours of continuing education in sterile compounding, TPN, technology (machine use) and submit the proof of competency to the investigator. Dr. Bunch seconded the motion. The motion carried.

Case 2.

Complaint alleges unprofessional conduct when a misfill was discovered and the pharmacist gave the patient's mother $1000.00 in cash to not report it. Medical report indicated a child presented with possible overdose of ADHD medicine. Investigators obtained a photo of a label for Quillivant XR Suspension 25mg indicating "Give two teaspoons every morning" (quantity 300ml) before the correction by the pharmacist and a photo of a label indicating "Give 2mls (10mg) every morning" (quantity 60ml) after the correction.

Respondent pharmacist admitted the mistake was "human error" and provided BOP investigators with a sworn statement along with a copy of a release form signed by the mother. Respondent stated the amount was actually $ 400 to help cover medical expenses related verifying the child

had not suffered any harm and in addition, he had previously given the mother some money to take her kids to McDonalds. Respondent stated that new procedures have been implemented to prevent such errors in the future.

Recommend: LOW for misfill.
Dr. Bunch made the motion to issue a Letter of Warning for the misfill. Dr. Eidson seconded the motion. The motion carried.

Case 3.

Complainant prescriber alleged CSMD report showed multiple controlled substance prescriptions which were not authorized by the prescriber. Complainant also alleged that multiple conversations to try to correct the information were not successful and that the pharmacy was unable to produce hard copies of the prescriptions in question.

BOP investigators visited the pharmacy. Findings included:
PIC working under the owner pharmacist's initials for several months before entering his own data;
When BOP investigators asked for printouts on a particular patient, PIC stated there were no prescriptions on the profile, however when a tech was asked later to pull up that patient's record, numerous prescriptions were seen on the profile;
The patient in question is the brother of the PIC;
Some of the questionable prescriptions have now been flagged as "discontinued" in the pharmacy system;
Staff admitted to having a policy to refill 2 days early but no documentation is kept as to why early refills are dispensed;
3 hard copy prescriptions for Hydrocodone/APAP 10/500 could not be located;
1 hard copy prescription for Alprazolam 1mg could not be located;
Some verbal orders were written in black ink but initialed in blue ink by the person receiving the order;
One hard copy was a label but no one could verify it was a call-in or a refill request, however, it was logged in as "written script-brought in;"
Daily print out had numerous days not signed;
Many daily print outs only indicated pharmacist X worked but did not have a signature;
Unable to log into CSMD without investigator's assistance;
Medication from other pharmacies were found on pharmacy shelves still in the other pharmacies' dispensing vials;
General lack of concern by pharmacists and staff;
Claims of no memory of the complainant's communications with staff.

BOP investigators interviewed the prescriber and the pharmacists at the other pharmacies.
The prescriber provided documentation showing many entries on CSMD that the prescriber denies authorizing. Prescriber stated she had been assured that the errors would be corrected but they had not been. Prescriber was concerned with the pharmacist's behavior once confronted about the CSMD report and the request for hard copies.

One other pharmacy responded that because the respondent pharmacy was having financial difficulties, they had sold medication to the respondent pharmacy and also had filled a prescription for them and allowed the respondent pharmacy to pick it up and dispense it to the patient. The other pharmacy denied knowing any reason for their dispensing vial to be sitting on the respondent pharmacy's shelves.

Recommend: Maybe enough to revoke?
but at least monitoring, LOW's for recordkeeping, suggest not filling for family members, CSMD access

Ms. McDaniel made the motion to suspend the pharmacy license for 60 days for the controlled substances. Dr. Kizer seconded the motion. A roll call vote was taken with Dr. Kizer, Dr. Bunch and Ms. McDaniel voting yes and Dr. Eidson and Dr. Dickenson voting no. The motion carried.

Case 4.

Complainant alleged early refills, failure to report controlled substance dispensing to CSMD, and that a former pharmacist with a revoked license is working and dispensing medications.

BOP investigators visited the pharmacy and interviewed staff. Finding include:
PIC and staff were not aware of the 7 day reporting requirements;
Usually check CSMD for new patients;
PIC admitted having a policy allowing refills 2 days early even though BOP investigators had previously warned against having this policy;
PIC admitted to feeling pressured by the former owner who frequents the pharmacy;
PIC admitted to allowing patients to pay cash if insurance is "too soon to refill."
The former owner is a former pharmacist with a revoked license;
The former owner told investigators that some prescribers were ok with early refills;
The new owner encouraged PIC to run a squeaky clean operation and to ensure documentation is in place about any early refills.

Detailed review of records and CSMD reports by BOP investigators did not find anything to contradict verbal statements by staff.

Recommend: This is the same pharmacy as listed in Case 3. Depending on final action on 3, further action on this one may be unnecessary.

Ms. McDaniel made the motion to suspend the pharmacy license for 60 days for the controlled substances. Dr. Kizer seconded the motion. A roll call vote was taken with Dr. Kizer, Dr. Bunch and Ms. McDaniel voting yes and Dr. Eidson and Dr. Dickenson voting no. The motion carried.

Case 5.

Complaint generated based upon information from OGC and CSMD indicating questionable dispensing of large amounts of controlled substances.

BOP investigators visited the pharmacy to conduct an investigation and audit. Investigators were told the PIC was not available and could not be reached so the pharmacist on duty assisted investigators. Findings were as follows:

Office manager was allowed access to the pharmacy without a pharmacist on duty;

Office manager is also a pharmacy technician. Registration expired 11/30/13. Renewed 9/19/14;

Another tech started work 10/2013 and never registered until 9/19/14;

Another tech worked on an expired registration from 2/28/14 to 8/20/14;

Investigators found at least 152 expired medications. Investigators instructed staff to immediately review all shelves and remove expired products. 23 of the expired products were non-sterile compounding products. No sterile compounding is performed at this site.

Audit revealed the following shortages:

Oxycontin 80 mg tab	73 missing
Oxycodone 30 mg tab	2,054 missing
Oxycodone/APAP 10/325	4,609 missing
Alprazolam 2mg tab	71 missing

Hydrocodone/Chlorpheneramine syrup 16,228 ml (33.8 pints) missing.

Procedures regarding preventing diversion were as follows:

ID's are scanned and kept in pharmacy records;
Prescribers are contacted for a diagnosis;
Pharmacist asks patients if they have questions but does not necessarily go through it;
Prescriptions from local pain clinics and hospital discharge patients are filled.

Other concerns noted:
DUR overrides are not password protected. Anyone can override;
Techs override "yellow" DUR's and ask a pharmacist if a "red" DUR comes up;
Technicians access CSMD by using pharmacist's log-in;
Policy allows a 1 or 2 days early refills;
Numerous KY patients see pain doctors in the same building or in the same area;
A third party plan terminated the pharmacy contract because of too many KY patients
All prescriptions (C2, CS, and non-controlled) were all kept together and unfiled since 2/15/14 until 8/19/14 when investigators arrived;

Wholesaler invoices noted the pharmacy's limit had been reached on Opana ER 30mg, Endocet 10/324, Oxycodone 10/325, Oxymorphone 7.5, and Oxycodone 15;
Medicare audit findings showed that some patients traveled over 500 miles to this clinic and this pharmacy.

PIC has voluntarily surrendered his pharmacist's license, citing health reasons.

Recommend: Audit is bad. Probation???Monitoring? And CP for key violation, CP for 3 expired/unregistered techs, CP for expired products, LOW for recordkeeping and filing violations, LOW for techs doing DUR.

Dr. Eidson made the motion to place the pharmacy license on probation for 2 years, monitoring by the pharmacy investigator twice a year, $100.00 civil penalty for the key violation, $2400.00 civil penalty for the three expired/unregistered technicians, $1520.00 civil penalty for the expired drugs, and a Letter of Warning for recordkeeping and filing violations. Ms. McDaniel seconded the motion. The motion carried.

Case 6.

Complaint generated from a referral from OGC alleging high volumes of controlled substances being dispensed.

BOP investigators visited the pharmacy, interviewed staff, reviewed CSMD records and patient profiles.
Findings include the following:

Pharmacy dispenses high volumes of buprenorphine. PIC stated he has very low prices;

Some patients had a high ME 240 or above (1 patient 1,460);

Prescription records for a randomly selected 6 day period showed 3,012 Rx's filled;
551 (18%) of those were controlled substances;
204 were C2 (7% of RX volume, 37% of CS RX)
139 were C3 (5% of RX volume, 25% of CS RX)
191 were C4 (6% of RX volume, 35% of CS RX)
17 were C5; (0.6 % of RX volume, 3% of CS RX)

PIC estimated CS account for 10 % of volume. Records indicate 18 %.

Wholesalers have reduced this pharmacy's allowances by approx. 60% over the past 2+ years.

PIC is present at the pharmacy most of the open hours but is rarely involved in the dispensing process. He is usually located in a closed room office where he also conducts business for another enterprise he owns.

PIC does not check CSMD but stated that other pharmacists do.

PIC was not familiar with some basic pharmacy information such as ratio of CS to non-CS, highest volume drugs, biggest prescribers, etc.

PIC was familiar with most of the patients reviewed by BOP investigators and provided comments on why he was not concerned with high doses of medication. He stated the highest ME patient has cancer and he believed the others have been through various injuries or diseases and seemed stable on their current meds. He also stated he had known most of his customers for a long time.

PIC stated he is personally acquainted with area prescribers but not necessarily with what they are prescribing. He trusts them and does not believe they would violate any rules.

PIC stated there is a pain clinic nearby as well as an emergency department close to the pharmacy, accounting for large volumes of CS.

PIC was receptive to BOP investigators' recommendations, but stated he does not believe any rules are being violated.

Staff pharmacists and technicians were able to provide requested reports on patients and prescribers.

Only 3 pain patient records contained copies of patient contracts.

No patient records reviewed contained copies of urine screens or documentation indicating the prescriber was monitoring the patient.

BOP investigators reviewed "red flags" and suggested more documentation of decisions made involving the dispensing of controlled substances.
Recommend: (Larry recommends LOW to PIC, monitoring at pharmacy's expense, civil penalties in line with recent BOP rulings)

Dr. Dickenson made the motion to issue a Letter of Warning to the PIC for failure to perform PIC duties. Dr. Eidson seconded the motion. The motion carried. Dr. Bunch was recused.

Case 7.

Complainant physician alleged respondent pharmacist misfilled Dexamethasone by changing the strength and directions without authorization and causing the patient to be confused.

BOP investigators confirmed the allegation. Prescriber ordered Dexamethasone 1.5mg, quantity of 18. Take 4.5 mg daily for 3 days, 3 mg daily for 3 days, then 1.5 mg daily for 3 days. Respondent pharmacist claimed the strength could not be located locally and felt the patient needed to get started, but the prescriber could not be reached so the prescription was filled as

Dexamethasone 4 mg, quantity 6, to take 4 mg (1 tablet) daily for 3 days, 2 mg (1/2 tablet) daily for 3 days, then 1 mg (1/4 tablet) daily for 3 days. This resulted in the patient receiving less than the ordered dose. BOP investigators found the 1.5 mg to be available and also found that the respondent pharmacy had 4 mg and 1 mg tablets on the shelf so the correct dosage could have been calculated for the patient. However, it was not.

Recommend: LOW for misfill

Dr. Bunch made the motion to issue a Letter of Warning for the misfill. Ms. McDaniel seconded the motion. The motion carried.

Case 8.

Loss Prevention notified BOP investigator about pharmacy technician being terminated for diversion of controlled substances. LP report indicated multiple negative inventory adjustments were noticed which prompted an internal investigation.

Investigator obtained a copy of a signed statement in which the respondent admitted taking "probably around 300" Hydrocodone 10/325 and "maybe 20" Tramadol, and "might have taken generic Lortab 10/500" but has no idea how much, and "might have taken some generic Xanax 0.5 or 1mg." Respondent admitted using the drugs for personal use and dumping the drugs by the handful into her pocket until she left for lunch or left for the day.

DEA 106 form indicates the following shortages:
Alprazolam 0.5mg = 123
Alprazolam 1mg = 92
Hydrocodone/APAP 10/325 = 2,813
Hydrocodone/APAP 10/500 = 888
Hydrodocone/APAP 5/325 = 186
Hydrocodone/APAP 7.5/325= 1,161

Recommend: Revoke

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

Case 9.

BOP received notification of pharmacy technician being terminated for diversion of controlled substances. LP internal investigation led to the respondent admitting theft.

Investigator obtained a copy of a signed statement in which the respondent admitted taking hydrocodone from work but is not sure how many. Respondent claims to have become addicted after an old friend gave her a hydrocodone in April, 2014. Respondent was arrested by police.

The police report indicates that the respondent again stated she had no idea how many she had stolen.

DEA 106 form indicates the following shortages:
Hydrocodone APAP 10/325 = 1,164
Oxycodone APAP 10/325 = 56

Recommend: Revoke

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

Case 10.

BOP received notification of pharmacist being terminated for working 17 shifts on an expired pharmacist license.

BOP records indicate the pharmacist's license expired 4/30/2014 and was renewed on 6/16/2014. Employment records indicate the pharmacist worked from 4/30/2014 until 6/8/2014, covering a total of 17 shifts during that time. Employer conducted an internal review and terminated the pharmacist on 6/11/2014.

Recommend: $ 2,000 civil penalty

Dr. Kizer made the motion to accept counsel's recommendation. Dr. Bunch seconded the motion. The motion carried. Dr. Eidson voted no.

Case 11.

Complainant patient alleged unprofessional conduct by the pharmacy/pharmacist for refusing to file insurance on 3 prescriptions and being forced to pay cash. Patient claims to have been told there was a price increase and insurance would not cover the cost of Oxycodone 30 mg but it would still cover Oxycodone 15 mg. However, when the patient obtained a new prescription for the 15 mg, it was also filled as cash. Patient claims to have verified with the insurance company and with the prescriber that it was illegal to force the patient to pay cash.

BOP investigator visited the pharmacy, reviewed records and obtained a sworn statement from the pharmacist. PIC did not remember this particular incident but stated the usual practice is to offer the patient a choice of paying cash or taking the prescription to another pharmacy if insurance does not cover the cost of the medication being dispensed. Investigator found that reimbursement was $56.74 for 110 tablets in the previous month but wholesaler invoices showed a cost of $ 77.82 for 100 tablets. Investigator found that the patient has been using this pharmacy since 2009 and averages 4 to 6 prescriptions per month. All have been billed to insurance except these 3 recent prescriptions. PIC provided a copy of the insurance contract and indicated to investigator that nothing in the contract requires the pharmacy to fill a prescription below cost.

Recommend: Dismiss

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

Case 12.

Complaint received from Maryland Board of Pharmacy. Patient is a Maryland resident receiving medication from a pharmacy located in Tennessee. Patient alleged unprofessional conduct because the pharmacy did not properly bill insurance and a co-payment assistance program properly which resulted in the patient owing $ 695.00 instead of the usual $ 5.00 copay. Patient claimed the pharmacy should have known that the co-payment assistance program could only be used once per month and that the pharmacy filed two claims in April, 2014.

Respondent pharmacy PIC provided a typed response and timeline. PIC stated the patient's copay for each dispensing of Simponi is $ 709.95 which is billed to a co-pay assistance program usually leaving a balance of $ 5.00. A 30 day supply was dispensed on 4/16/14 with no problems. On 4/24/14, the prescriber sent a new prescription to the pharmacy. Pharmacy attempted to contact the patient on 4/25, 4/26 and 4/28, leaving messages each time. Patient called the pharmacy back on 4/28 but spoke to a customer service agent in a different state. Patient requested the medication be shipped 4/29 for delivery on 4/30 and the pharmacy did so. Pharmacy discovered afterwards that the co-pay assistance program would only pay $ 97.65 so that was deducted from $ 709.95 leaving a balance of $ 612.30.

On 5/24/14, patient requested a refill be shipped on 5/29 for delivery on 5/30. This added a copy of $ 709.95 to make a balance due of $ 1,332.00. A message was left on 5/27 for the patient to call to discuss the balance. Patient returned the call on 5/28 and indicated she had a new co-pay assistance card but did not have it with her at that time. Pharmacy shipped the product on 5/29 to be sure the patient did not miss any doses. The new card info was obtained but the effective date was 5/17/14. It paid for the 5/29 dispensing but did not cover the remainder of the 4/29 dispensing.

Patient requested a refill which was dispensed on 7/16/14. In August, the pharmacy decided to waive the $ 612.00 past due balance. Dispensing has since occurred on 8/26/14, 9/24/14 and 10/23/14 with no reported problems.

PIC summarized that patient service was not hindered because of financial concerns and that the pharmacy waived the past due balance, but believes it is the responsibility of the patient or caregiver to understand the specifics of his/her copay assistance program.

Recommend: Dismiss

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

Case 13.

Complaint received from Texas Board of Pharmacy. Patient is a resident of Texas but receives medication from a pharmacy located in Tennessee. Complainant (caregiver of patient) alleged the pharmacy took a $ 400.00 payment for Remicade but did not deliver it as promised and told the patient it is an insurance issue.

PIC provided a typed response and timeline. According to PIC, the patient's copay was $200.00 in December, 2013, but the shipment was cancelled due to the patient's physician not being available during the holidays. In January, 2014, the copay increased to $ 400.00. The order was dispensed 1/13/14. On 2/14/14, another refill was requested and the pharmacy notified the caregiver that the insurance expired on 1/14/14. On 2/19/14, the caregiver provided new insurance information but protested the $ 400.00 copay believing that she had been charged twice ($ 200 for the January order and $ 200 for the December order that was cancelled.)

When the pharmacy began processing the new insurance plan, it discovered that Remicade required a prior authorization and contacted the prescriber on 2/24/14. The pharmacy contacted the insurance company "multiple times" between 3/3 and 3/7 and was told they were waiting on the prescriber to submit a PA. The pharmacy contacted the prescriber on 3/10 to remind him to send the PA info. On 3/11 the pharmacy was told by the insurance that they were still waiting on the physician so the pharmacy contacted the prescriber again to stress the urgency. On 3/17 the pharmacy called the insurance and was told that the info from the prescriber was under review. The pharmacy checked back with the insurance on 3/19, 3/20, 3/21, 3/24, 3/25, 3/26, and 3/27. On 3/27 they were told that the PA was in the appeals process and that a letter had been sent to the prescriber on 3/18 but the turnaround time could be up to 30 days. The pharmacy was told by the insurance that the case was still under review on 3/28, 3/31, 4/1, 4/2, and 4/3.

On 4/7/14, the pharmacy was notified that the PA was approved and the new copay would now be $ 150.00. However, the new insurance plan required the prescription to be dispensed from a pharmacy physically located in Texas. The prescription was transferred to the pharmacy's Texas branch and an attempt to reach the caregiver was made on 4/9. The caregiver did not return the call until 4/22 but she denied authorization to ship the medication and refused to pay the $ 150.00 copay because she still believed she was double billed in December and January.

PIC summarized that although he sympathizes with the patient's caregiver, copays and PA's are not within the pharmacy's control. He denies charging for any medication that was not shipped.

Recommend: Dismiss

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

Case 14.

Complainant patient alleged mail order pharmacy dispensed a prescription of insulin needles that the patient did not request because they were obtained at a local pharmacy 5 days before. Patient claims to have called mail order pharmacy which was not nice or helpful at all and would not refund or credit the cost.

PIC of respondent pharmacy provided a typed response and timeline denying any wrongdoing. PIC explained that the prescriber had provided the patient with a prescription and also transmitted a prescription to the mail order pharmacy. PIC claims this is a common practice with mail order and insurance payors in that the patient has a prescription to fill locally to start and the mail order pharmacy (which typically takes more time to fill) then takes over the dispensing. PIC stated the payor approved the dispensing and the prescription was filled and dispensed. PIC mentioned that the patient gets other prescriptions filled through mail order but for customer satisfaction, the price was refunded and the patient's profile has been flagged "Do not fill insulin pen needles for the patient. She fills them at local pharmacy."

Recommend: Dismiss

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

Case 15.

Complainant patient alleged respondent mail order pharmacy advised around 6/26/14 that his prescription for 90 days of Temazepam could only be dispensed for 30 days at a time so he should use a local pharmacy and that the prescription would be transferred to his local pharmacy. Patient claims the mail order pharmacy then told the local pharmacy that the prescription could not be transferred.

Patient provided the following timeline for allegations:

7/11/14 patient was told by mail order pharmacy that his prescription would be returned to him in 7 to 11 days.

7/29/14 patient called, spoke to 2 different people and was told the prescription should arrive by 7/31/14.

7/30/14 patient received an automated call saying the **medication** would be shipped the next day. Patient called pharmacy and spoke to an agent and a supervisor to cancel the order and was told that the prescription would be returned in 7 to 10 days.

8/12/14 patient called and spoke to an agent and a supervisor and was told he should receive the prescription by 8/18/14.

8/18/14 patient called and spoke to an agent who said the prescription was mailed on 7/30/14. When patient asked to speak to a supervisor, supervisor told patient that the prescription was mailed 8/12/14 and he should receive the prescription by 8/23/14.

8/25/14 patient reported he had still not received the prescription back.

PIC of respondent pharmacy provided a typed response explaining the 30 day limit was because of the benefit plan and Tenn. restrictions on Benzodiazepines but the customer service agent did not explain it well to the patient. They then realized that the prescription could not be transferred because it had never been filled, so the hardcopy would have to be returned to the patient. PIC states that the agent involved will be coached on how to explain restrictions and options to patients. PIC admits non-adherence to usual procedures which resulted in a delay of returning the prescription. The customer service team failed to properly notify the fulfillment pharmacy that would have resulted in pulling the hardcopy for review by a pharmacist who could read customer service notes and return it to the patient. PIC indicates those employees will be coached to ensure no future delays of this type occur in the future. Staff is being retrained in handling different processes.
Recommend: LOW?

Dr. Dickenson made the motion to issue a Letter of Warning. Ms. McDaniel seconded the motion. The motion carried.

Case 16.

Complainant alleged misfills in July and August by mixing Lortab 10 with Lortab 7.5.

BOP investigator visited the pharmacy, interviewed staff and obtained a sworn statement from PIC. PIC and store manager had both spoken to the patient and asked him to return the medication. Patient claimed that his case manager had the medication and a fax reportedly sent by the case manager indicated the medication had been filled incorrectly. However, when the PIC called to verify the fax, the case manager denied sending it and denied having or controlling the patient's medications. Patient never returned the medication and has switched pharmacies. The pharmacy uses automation but controlled substances are double counted. PIC stated there have been no other complaints of strengths being mixed, staff has not noticed any mix-ups when double counting, and the machine's cassettes are specific to pill size.

Recommend: Dismiss

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

Case 17.

Complainant prescriber alleged pharmacy continued to fill a controlled substance (Lyrica) prescription even after the prescriber has called to cancel it and also was filling for large quantities.

BOP investigator visited the pharmacy, interviewed staff and obtained sworn statements. The pharmacy had no documentation of the prescriber cancelling the prescription. Investigator contacted the prescriber and verified that they had documented they had called the pharmacy to cancel the prescription but did not document who they had spoken to at the pharmacy.

Investigator findings:
Patient received several shipments from mail order and was also filling some at the pharmacy. Pharmacist does not check CSMD frequently and viewed the customer as a friend in need that was allowed to charge medications (outstanding balance of $880 because insurance was cancelled for 6 months.) Pharmacist allowed the patient to obtain all remaining quantity before the RX expired and claims he had no idea the prescriber had cancelled the prescription. Pharmacy staff did not check CSMD or question the patient about quantities being received from mail order. Pharmacist admits he should not have filled the prescription this way but denies knowing the prescriber had cancelled it.

Recommend: Investigator Moak recommends LOW to PIC and possible CP
I'm ok either way. Should have known better but may have been mercy fill

Dr. Eidson made the motion to authorize a formal hearing for six hours of continuing pharmaceutical education to the PIC. Ms. McDaniel seconded the motion. The motion carried.

Case 18.

BOP investigator contacted pharmacy on 11/3/14 and left message to set up an inspection date for a relocation inspection. Investigator's call was never returned. Investigator contacted pharmacy again on 12/2/14 and was told the pharmacy went ahead and moved 11/19/14 because they had to vacate their former location on that date. PIC claimed to be unaware the new site had to be inspected before moving.

Recommend: 1 month civil penalty for PHARMACY.

Dr. Kizer made the motion to authorize a formal hearing with a $1000.00 civil penalty for unlicensed activity. Dr. Bunch seconded the motion. The motion carried.

Case 19.

Complainant (friend of a patient) alleged unprofessional conduct against the pharmacy and pharmacist for charging pain clinic patients $ 40 per session to meet with the pharmacist every 3 months for a 5 to 10 minute counseling session ($ 160 per year).

BOP investigator visited the pharmacy, interviewed the PIC and obtained copies of the notification and the patient evaluation form. PIC explained that this model is based upon APhA models of fee for service for Medication Therapy Management. PIC believes this program will help provide better care to patients and assist prescribers in managing pain medication therapy. The pharmacy's policy is to require the program if the patient uses this pharmacy for pain medication. Investigator educated PIC that "counseling" is required by law and suggested that if this is simply an MTM program, that wording be changed on all literature to medication therapy management instead of medication counseling. Investigator did not find any other violation.

Recommend: Dismiss

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

Case 20.

Complainant (mother of child) alleged an overdose of medication dispensed by the pharmacy resulted in the child being given 14ml of Sulfatrim pediatric suspension twice daily instead of 2.5ml twice daily.

BOP investigator visited the pharmacy, took copies of the electronic prescription and dispensing label, interviewed the dispensing pharmacist and obtained a sworn statement. Prescriber was a nurse practitioner and the directions clearly state "14mL 2 times a day orally 10 day(s)." There is also a notation to "VERIFY DOSAGE FOR 52 POUND PED!" The dispensing pharmacist remembered the prescription and provided a sworn statement that she did look at the package insert for Sulfatrim and also looked on Facts. She dispensed the prescription as written. Pharmacist told investigator that the dosage did fall within the acceptable range, the prescriber's clinic was closed, and that the pharmacist did counsel the mother about the medication, especially to push fluids and a warning about sun sensitivity.

Investigators reviewed common references for dosing calculations. There can be a wide variation of dosages depending upon the symptoms and organisms being targeted. For example, a 52 pound child with otitis media, or common urinary tract infections, the dose would be 11.5ml every 12 hours. However for Pneumocystis Carinii Pneumonia, the dosage listed specifically for a **53** pound child would be 15ml every **6** hours. Other calculations have to be made depending on treatment or prevention of other types of infections, including traveler's diarrhea. The change of dosage to 2.5 mL every 12 hours appears to be sub-therapeutic unless other health conditions exist that were not disclosed. Since the pharmacist did not know the diagnosis at the time of filling, the dosage could have been in an acceptable range. Upon review by investigators, the diagnosis code 599.0 was listed in fine print at the very bottom on the electronic prescription. A search of reference material revealed that 599.0 is the 2014 ICD-9-CM Diagnosis Code for "Urinary tract infection." Although many electronic prescription programs provide this information, it is not common for a pharmacy to have a quick reference guide to look up a diagnosis code. Investigators also reviewed the prescription and found that the prescriber's software actually lists this particular drug and strengths backwards. It lists "trimethoprim-

sulfamethoxazole 200 mg-40 mg/5 mL suspension." Either the names or the strengths should be reversed in the software to prevent confusion in calculations.

Investigators believe the pharmacist made a professional judgment decision with the intention of providing the best patient care possible under the circumstances and did not violate any laws or rules.

Recommend: Dismiss

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

Case 21.

Pharmacist admitted impairment via telephone call to director and followed up with e-mail offering to surrender his pharmacist license and stating he had contacted TPRN.

Recommend: Revoke/indefinite suspension

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

Case 22.

Pharmacy loss prevention notified BOP of pharmacy technician stealing drugs and cash resulting in job termination. According to documentation provided the tech admitted stealing around $160.00 in cash by voiding prescription sales and pocketing cash from customers and also admitted stealing Azithromycin for a friend that could not afford it.

Recommend: Revoke tech registration

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

Case 23.

BOP investigators performed an inspection and investigation on August 20, 2014, based upon information received from a wholesaler and suspicious findings in CSMD. The wholesaler notified BOP that they discontinued doing business with the pharmacy after conducting their own investigation of the pharmacy. A subsequent CSMD report revealed that the pharmacy was filling large quantities of controlled substance prescriptions for patients who were not local written by prescribers that were not local.

When questioned about the daily activities of the pharmacy PIC stated that a normal day consists of filling 20 to 30 prescriptions, that he believed controlled substance prescriptions accounted for

30% of the business, that the most dispensed drug is Oxycodone 30 mg, and that the largest quantity he could remember filling was for 180 tablets.

The investigation reveals that their actual percentage of control substances is 57.6% for the time period of 3/17/14 to 8/20/14.

When questioned about how it is decided to fill or decline a prescription, PIC stated he had recently stopped filling prescriptions from certain prescribers. (The prescribers mentioned by PIC had been raided by DEA 13 days prior to our visit.) PIC also stated that he no longer fills for any prescriber out of state. When questioned about the reason to cut the doctors off, PIC stated that he was unsure of whether they were helping the patient. PIC stated he told the patients who saw those doctors that it was too much to be prescribed and if the prescriber didn't decrease their dose they would need to get another doctor or he would not fill the prescriptions for them any longer. When questioned about filling for out of state patients, specifically Kentucky, PIC stated that he fills for them because he knows that Kentucky has a law that does not allow mid-level practitioners to write for more than an emergency supply of a controlled substance. PIC believes that patients are having trouble finding the medications.

PIC stated that his early fill process was to usually never fill a prescription more than 2 days early.

An evaluation of 14 patient CSMD records provided the following information:

Patient Address	Prescriber Address	ME
KY	**GA**	**450**
KY	**GA**	**430**
KY	**GA**	**278**
AL	**GA**	**330**
KY	**GA**	**278**
AL	**GA**	**330**
TN	**TN**	**225**
KY	**TN**	**180**
TN	**TN**	**135**
TN	**TN**	**0 (benzodiazepines)**
TN	**TN**	**360**
TN	**TN**	**165**
TN	**TN**	**135**
TN	**TN**	**315**

Summary: Five patients from Kentucky, four of the five are seen by a doctor in Georgia. Two patients from Alabama are seen by a doctor in Georgia, Seven patients from Tennessee seen by a Tennessee prescriber
Patient ME summary, one patient ME 450, one patient ME 430, one patient ME 360, two patients ME 330, one patient ME 315, two patients ME 278, one patient ME 225, one patient ME 180, one patient ME 165, two patients ME 135, one patient ME zero due to only being on benzodiazepines.

Investigators returned to the pharmacy on December 2, 2014 and had PIC run reports for daily prescription summaries for the time periods of 3/17/14 to 8/20/14 and 8/21/14 to 12/2/14.

For the time period of 3/17/14 to 8/20/14 the reports show that the ratio of CS prescriptions was 57.6%. However, CS prescriptions sales account for 95% of the total store revenue. Of the 95% ratio, 88 % of that was cash sales (includes cash discount card) and 12 % was insurance.

The total store dollar sales were $300,494.47. Control Substance dollar sales were $285,945.67. Total script count was 1405 with 809 being controls. The daily average prescription count was 12.7 prescriptions per day (Controls and non-controls assuming the store was open as scheduled five days per week). Cost of goods sold for all prescriptions is reported as 129,488.23 for a difference of $171,006.24.

For the time period of 8/21/14 to 12/2/14 the reports show that the ratio of CS prescriptions was 35.4%. The CS prescription sales account for 83.5% of the total store revenue. Cash sales (including the cash discount card) are 94% and insurance sales are 6%.

The total store dollar sales were $75,115.62. Control Substance dollar sales were $62,690.49. Total script count was 763 with 270 being controls. The daily average prescription count was 10.9 per day. Cost of goods sold for all prescriptions is reported as 49,699.02 for a difference of $25,427.60.

Investigators' review of 46 C II prescriptions filled between 7/23/14 to 7/31/14 showed the following:

16 (50%) of patients had a home address in Kentucky and accounted for 27 (59%) of the CS prescriptions
5 (16%) live in Alabama and accounted for 7 (15%) of the CS prescriptions
11 (34%) live in Tennessee and accounted for 12 (26%) of the CS prescriptions.
23 (50%) of the prescriptions were written by providers whose offices were raided by the DEA on August 7, 2014.
2 prescriptions were from different doctors in Florida. Both patients have Kentucky home addresses. They are filled sequentially in order in the prescription file.
8 prescriptions were from three prescribers located in Tennessee but several counties away.

Audit info from first visit 8/20/2014

Drug	Beginning on hand 3/14/14	Purchased	Dispensed	Calculated on hand	Actual on hand 8/20/2014	Difference
Alprazolam 0.5mg	327	1500	1290	537	537	None
Alprazolam 1mg	300	3000	2033	1267	1153	Short 114

Alprazolam 2mg	254	4000	3450	804	767	Short 37
Hcd/apap 10/325	409	3500	2945	964	973	9 over
Tramadol	Not counted	500	111	??	330	??
Carisoprodol 350mg	910	1000	532	1378	476	Short 902

Audit from second visit on 12/2/2014

Drug	Beginning on hand 8/20/2014	Purchased	Dispensed	Calculated on hand	Actual	Difference
Alprazolam 0.5mg	537	1000	725	812	810	Short 2
Alprazolam 1mg	1153	500	1223	430	390	Short 40
Alprazolam 2mg	767	500	780	487	500	Over 13
Hcd/apap 10/325	973	1000	1750	223	223	None
Tramadol 50mg	330	0	180	150	150	None
Carisoprodol 350mg	476	1000	404	1072	1072	None

There is a slight difference in the amounts ordered and dispensed for each time period even though it is 5 months for first visit vs 4 months for second visit. The pharmacy was cut off from their primary wholesaler and has struggled obtaining a large wholesaler to conduct business with. The pharmacy has been using what is typically considered a secondary wholesaler and has been able to get only limited amounts of controlled substances for a while. That partially explains the decrease in sales and volume between the time periods. This decrease may also be attributed to the education provided during the first visit (PIC has been documenting refusals and using professional judgment) as well as the 2 prescribers in GA being closed.

In summary, many of the prescriptions had multiple red flags that should have alerted the pharmacist to exercise better professional judgment in whether or not to fill the prescriptions. The red flags in particular are patients driving long distances to visit prescribers and/or pharmacies, presenting prescriptions resulting in therapeutic duplications (up to four immediate release opioids for one patient), presenting with the same diagnosis (or not having a diagnosis), receiving the same combination of controlled substance prescriptions, paying cash for prescriptions, and coming in groups with the same prescriptions from the same prescriber.

Recommend: Revoke pharmacy and PIC

Dr. Kizer made the motion to authorize a formal hearing for revocation for the pharmacy and the PIC license. Dr. Bunch seconded the motion. The motion carried.

Case 24.

On August 27, 2014 BOP investigators conducted an inspection and investigation based upon information from CSMD indicating large quantities of controlled substances were being dispensed to patients who were not local written by prescribers that were not local.

During the investigation, controlled substance prescriptions were retrieved that showed multiple patients with home addresses in KY that saw prescribers located in Florida and Georgia and other parts of Tennessee which were several counties away. A few examples are given of what mileage certain patients traveled by estimation to the prescriber office, and then to the pharmacy.

Example 1	Patient's home to prescriber's office	about…1043 miles (15 hours)
	Prescriber's office to pharmacy	about…892 (13 hours)
Example 2	Patient's home to prescriber's office	about…381 miles (6 hours)
	Prescriber's office to pharmacy	about…230 miles (3.5 hrs)
Example 3	Patient's home to prescriber's office	about…288 miles (4.5 hrs)
	Prescriber's office to pharmacy	about…233 miles (3.5 hrs)
Example 4	Patient's home to prescriber's office	about…235 miles (4 hours)
	Prescriber's office to pharmacy	about…68 miles (1 hour)
Example 5	Patient's home to prescriber's office	about…282 miles (5 hours)
	Prescriber's office to pharmacy	about…73 miles (1 hour)

Maps were printed showing the most direct way from the patient's home to the prescriber's office and then the direction to the pharmacy which is not in the line of that same path to return to the patient's home.

Investigators confirmed that most prescriptions observed were for patients from out of state. Most of the prescriptions were written by out of state providers. Many prescriptions reviewed were not listed on the CSMD while others filled the same day were on CSMD. PIC could not give any explanation other than "software issues." Some misfills were also noted while reviewing prescription files.

Many large quantities of non-controls were also found on the drug shelves. Drug usage conveyed that extrapolated out, this stock would last as a 3 to 4 year supply, indicating inventory balancing was occurring.

Pharmacy Technician stated that they have a policy of allowing two days early but has seen three days early on some fills. The technician estimated that half of their patients are from KY and they drive three to four hours to get there and most pay cash.

The PIC stated that he will never fill a prescription more than three days early. He estimated that 40% of patients pay with cash and 30 to 40% of the prescriptions are controlled substances. PIC claimed he would only fill prescriptions if he had a relationship with the prescriber, however he later changed that statement. One of the most frequent prescribers had been raided by DEA 20 days before our visit.

When asked about the high number of KY controlled substance patients, PIC stated that patients tell him that there are no pain clinics in KY and that they have gone to 20 other pharmacies and no one will fill the patients' prescriptions. PIC believes he is providing a service that patients cannot get elsewhere.

PIC stated that he and his technician discussed that very morning about a new policy to stop accepting out of state prescriber prescriptions. (The tech was later asked about this meeting and denied the meeting or hearing about this new policy.)

A drug usage report was run from 06/10/2013 to 08/27/2014. The following numbers were found in regards to controls vs. Non-controls:

Non-controls:	3204	about 64%
Controls:	1768	about 36%
Total Dispensed:	4972	

Investigators referred to CFR 1306.04 and read it. PIC claimed to be unfamiliar with these requirements or any "red flags." PIC claimed that poor professional decisions, poor recordkeeping, and incomplete reporting to CSMD were not deliberate. PIC claimed he believed patients that told him there are no pain clinics in Kentucky and that patients tell him they have no insurance and he is much cheaper than other pharmacies. PIC claimed he relies on the prescriber to decide appropriate therapy for patients. PIC claimed the large quantities of non-controlled drugs are not for inventory balancing, but rather because he buys a lot when he knows a price is going up.

Other areas of notice:

- Ordering Oxycodone 30mg tablets from three Wholesalers within the same month.
- Some invoices missing
- Large Gaps in dates of invoices

Red Flags:

- No documentation of discussion for patients with Morphine Equivalents of 135, 180, 195, 270, 225, 315 or research to see if there were issues of why the high Equivalents.

- No documentation noted for patients on Morphine, Oxycodone, carisoprodol, and clonazepam.
- Multiple patients with same addresses
- Multiple patients with same prescriber
- Multiple patients with same pain medications prescribed
- Patients driving long distances to prescribers
- Patients driving long distances to the pharmacy
- Patients paying cash for controlled substances
- Patients coming in groups

While investigators were on-site, a call came in from a Florida number asking directions to the pharmacy. Later, a car with Arkansas tags pulled up with 4 people inside. Two people came in with Kentucky addresses with prescriptions from a Florida prescriber, however the tech declined to fill the prescriptions and those patients returned to the car, had a discussion with the others in the car, then left.

Because of large gaps in recordkeeping, an audit was performed using information provided by wholesalers. That audit revealed multiple discrepancies in inventory, mostly shortages as follows:

Alprazolam 1mg	5,112 missing
Alprazolam 2mg	3,341 missing
Hydrocodone/APAP 10/325	8,100 missing
Oxycodone 15mg	235 missing
Oxycodone 30mg	2,759 overage

Recommend: Poor DUR, poor recordkeeping, multiple shortages on CS, multiple red flags ignored---revoke pharmacy and PIC

Dr. Dickenson made the motion to authorize a formal hearing for revocation of the pharmacy and PIC license. Dr. Kizer seconded the motion.

Case 25. 201400239 Fresenius Medical Care Rx

Complainant technician with retail experience alleges that technicians in respondent mail order facility have been allowed to work unsupervised.
BOP investigator visited the pharmacy, observed operations and interviewed staff. At the time of the visit, 5 pharmacists and 9 certified pharmacy technicians were on duty. Investigator was told

that the facility typically stays at a 1:2 ratio or below. Pharmacy is laid out in cubicles so techs and pharmacists cannot see each other without getting up and going to the cubicle. Pharmacists sign off on verbal orders taken by techs, answer all patient or clinical questions and do all outbound transfers. No medication is kept at this location. Filling of mediation is contracted out so this facility functions only for prescription entry, billing, counseling, questions and phone work. Pharmacists stated that they have had in-services at the facility when all pharmacists were away from their cubicles in the meeting, but techs can still simply come to the conference room and get them if needed.
Allegation could not be substantiated and no violation was found.

Recommend: Dismiss

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

Case 26.

Complainant patient alleged a misfill by being given someone else's medication without counseling and unprofessional conduct by a pharmacist who accidentally stuck the patient with a syringe that had already been used on another patient (patient's son).

BOP investigator interviewed complainant and also visited the pharmacy and interviewed staff.

Pharmacist 1 admitted misfill by receiving a phoned-in order for Tramadol for a patient with the same initials and date of birth as complainant. Complainant's name was picked in error and the prescription was dispensed. Failure to counsel was not admitted but dispensing pharmacist claimed this was the first notification the pharmacist had received regarding this misfill.

Pharmacist 2 admitted that the accidental double-stick occurred. Pharmacist 2 gave a statement that both patients were counseled about flu shots. Pharmacist 2 gave a flu shot to patient 1, then stuck patient 2 with the empty syringe instead of the other full syringe. Pharmacist 2 stated he was in a hurry and under pressure and once he realized what he had done, he disinfected the injection site again and gave patient 2 a flu shot with the correct syringe. Pharmacist 2 provided a written statement including "The only thing is this patient had 2 sterilized injections, one with medicine and one without, a little more time and [inconvenience], not much."

At the time of BOP investigator meeting with Pharmacist 2, Pharmacist 2 had already been terminated from pharmacy due to forging another patient's signature on flu statement and waiver. That was not the same patient as complainant.

Investigator discovered this pharmacy had also been the subject of a news report about misfiling another patient's medication. The report indicated a patient received Crestor instead of the prescribed muscle relaxer. The news report claims the misfill was confirmed by a pharmacy spokesman.

Recommend: Pharmacist 1- LOI for misfill, civil penalty for failure to counsel.
Pharmacist 2-LOW for double stick? Maybe more since he does not seem concerned how dangerous this could have been? Possibly file OSHA report?
Pharmacy-civil penalty for failure to counsel.
Possible letter to pharmacy due to both events happening at the same pharmacy on different days with different pharmacists taking into account the news story which would indicate a pattern of misfills.

Dr. Dickenson made the motion to issue a Letter of Instruction for the misfill and a $1000.00 civil penalty for failure to counsel to pharmacist 1; continuing education for immunizations and one year probation for pharmacist 2 and a $1000.00 civil penalty to the pharmacy for failure to counsel. Dr. Bunch seconded the motion. The motion carried.

Case 27.
OIG notified BOP of alleged drug diversion by a Tenncare/Medicare recipient in which the investigation revealed some prescriptions at respondent pharmacy had been written for liquid but were filled with tablets.

BOP investigators visited the pharmacy, reviewed prescription files and interviewed staff. Three prescriptions were found to have been computer generated in error by the prescriber as "acetaminophen-hydrocodone solution 325mg-10mg/15ml orally, dispense #120" and had a Sig of "1 tab(s) qid 30 day(s). Pharmacist stated he had verified the prescriptions were supposed to be tablets and had documented the change on one of the prescriptions. Pharmacist was educated to always document changes even if it had been prior approved. BOP investigators did not find any violations and the prescriptions were filled correctly.

Recommend: Dismiss

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

Case 28.

Pharmacy management and loss prevention reported termination of pharmacy technician for theft of controlled substances and provided a copy of a signed admission statement along with other supporting documentation and police reports. Since higher quantities are missing than were admitted to, investigation of other employees continues.

Recommend: Revoke tech registration, continue investigation.

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

Case 29.

Pharmacy management reported termination of pharmacy technician for theft of controlled substances and provided a copy of a signed admission statement. An audit revealed the following shortages which match the tech's admission statement:
9 tablets of Oxycodone 30 mg
12 tablets of Oxycontin 15 mg
27 tablets of Oxycodone/APAP 10/325 mg

Recommend: Revoke tech registration

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

Case 30.

During a routine inspection, BOP investigator discovered a staff pharmacist had been working on an expired license from 2/1/14 until 7/25/14. License was renewed on 7/25/14 and will expire again on 1/31/16. No statements were given by pharmacist or PIC.

Recommend: ??? Was $1000 per month, but recently another case that was self-reported was LOW

Dr. Kizer made the motion to authorize a formal hearing with a $1000.00 civil penalty per month for a total of $6000.00 to the pharmacist for working on an expired license. Dr. Bunch seconded the motion. The motion carried.

Reinstatement
T. Patrick Rowan

Dr. Rowan requested to have his licensed reinstated. Dr. Rowan's license was suspended on 07/27/2012. After discussion, Dr. Bunch made the motion to reinstate Dr. Rowan's license. Dr. Rowan's license will be on five (5) year probation once he has completed all the necessary requirements for reinstatement with the following conditions. Dr. Dickenson seconded the motion. The motion carried.

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

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

(c) The Respondent shall not obtain or attempt to obtain any prescriptions in the Respondent's name for any legend drugs, controlled substances or devices containing

same from the physician other than the Respondent's primary physician or from any other health care provider, such as a nurse practitioner, physician's assistant or psychiatrist;

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

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

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

(g) The Respondent shall successfully complete the Multistate Pharmacy Jurisprudence Examination

(h) The Respondent shall not serve as pharmacist-in-charge the respondent's pharmacist-in-charge shall submit to the Board quarterly reports detailing Respondent's work performance for a period of three (3) years from the state date of Probation; the Respondent may not work more than 40 hours over a 5 day period, however, the Respondent may petition the Board for a modification of this time limitation after (2) years from the start date of Probation;

(i) Respondent shall not work as a "floater" for a period of three (3) years from the start of Probation, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without permission of the Board;

(j) Respondent shall complete a period of pharmacy internship for a minimum of one hundred and sixty (160) hours and must be completed within ninety (90) consecutive days.

Appearance
Methodist University Hospital Outpatient Pharmacy

Chris Hilty, Pharmacy Manager for Methodist University Hospital Outpatient Pharmacy, appeared before the board to request the use of a room on the 7th floor of the hospital as a part of the outpatient pharmacy to be used as a satellite pharmacy where they will only dispense medication. The location will have a licensed pharmacist on duty at all times. After discussion, Dr. Eidson made the motion to approve a four (4) month waiver for this operation but if the business model changes within the four (4) months extension, he must notify the board. Dr. Kizer seconded the motion. The motion carried.

Accredo

Rich Palomb, R.Ph., Senior Director of Pharmacy Regulatory Affairs, appeared before the board to request that their pharmacy license include Building 1680. Accredo pharmacy license includes buildings 1620 and 1640. After discussion, Ms. McDaniel made the motion to include Building 1680 under Accredo pharmacy license. Dr. Kizer seconded the motion. The motion carried. Dr. Eidson suggested that the board consider adding language concerning a campus license in the rules as the board is in the process of updating their rules.

Appearance/Application Review
Shuntella Wynn, RT

Ms. Wynn is appearing before the board to request reinstatement of her pharmacy technician registration. Ms. Wynn pharmacy technician registration was revoked on November 18, 2009. After discussion, Dr. Kizer made the motion to approve Ms. Wynn request to reapply for registration as a pharmacy technician. Ms. Wynn's registration will be on probation for five (5) years and she must submit drug screen results for one year and then random drug screen results for the term of the probation along with any changes in recovery. Dr. Bunch seconded the motion. The motion carried.

Tennelle Sample, RT

Ms. Sample is appearing before the board to request approval to reapply for registration as a pharmacy technician. Ms. Sample request to reapply was denied by the board at the November 13-14, 2013 board meeting. The board requested that Ms. Sample submit to and submit the results of substance abuse and a psychological evaluation. After discussion, Ms. McDaniel made the motion to approve Ms. Sample's request to reapply for registration as a pharmacy technician. Dr. Bunch seconded the motion. A roll call vote was taken with Ms. McDaniel, Dr. Bunch and Dr. Kizer voting yes. Dr. Eidson and Dr. Dickenson voted no.

Agreed Order

Mr. Cange presented an agreed order from Nuvasive, Inc. Nuvasive, Inc. violated board rule 1140-01-.08(1) and 1140-01-.09(1) and agreed to pay an $8700.00 civil penalty. After discussion, Ms. McDaniel made the motion to accept the agreed order as presented. Dr. Bunch seconded the motion. The motion carried.

USP797 Waivers

Dr. Eidson made the motion to approve the request for a waiver extension from **Baptist Memorial Hospital, Memphis** until July 1, 2015 and if there are any further delays to notify the board immediately. Dr. Kizer seconded the motion. The motion carried. Dr. Smother was recused.

Dr. Dickenson made the motion to approve the request from **Sumner Regional Medical Center** to grant a 180 day waiver to become compliant with USP 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request for a waiver extension from **St. Thomas West Pharmacy** until June 10, 2015. Dr. Kizer seconded the motion. The motion carried.

Ms. McDaniel made the motion to approve the request from **Highlands Medical Center** to grant a 180 day waiver to become compliant with USP 797. Dr. Kizer seconded the motion. The motion carried.

Ms. McDaniel made the motion to approve the request for a waiver extension from **Centennial Medical** for one month. Dr. Kizer seconded the motion. The motion carried.

Ms. McDaniel made the motion to approve the request for a waiver extension from **United Regional Medical Center** for 90 days. Dr. Dickenson seconded the motion. The motion carried.

Dr. Dickenson made the motion to approve the request from **Lincoln Medical Pharmacy** to grant a 180 day waiver to become compliant with USP 797. Ms. McDaniel seconded the motion. The motion carried.

Waivers

Board rule 1140-03-.14(12)

Dr. Eidson made the motion to defer the request from **Enrique Hernandez, D.Ph., to** be pharmacist in charge at ASC Pharmacy and ASC Pharmacy, Inc. until we receive additional information concerning the operation of each pharmacy. Dr. Dickenson seconded the motion. The motion carried

Board rule 1140-05-.01(1)

Ms. McDaniel made the motion to deny the request from Nanjundram Kesarla, D.Ph. to waive the live continuing pharmaceutical education hours needed to reinstate her pharmacist license. Dr. Dickenson seconded the motion. The motion carried. Dr. Eidson voted no.

Dr. Dickenson made the motion to approve the request from H. Nestor Stewart, R.Ph., to waive the continuing pharmaceutical education hours needed for renewal. Dr. Bunch seconded the motion. The motion carried.

Ms. McDaniel left the meeting at 4:50 p.m.

Board rule 1140-01-.07

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

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

Dr. Dickenson made the motion to approve the request from **Mona Benrashid, 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 **William McKenzie, R.Ph**., to waive the one hundred and sixty (160) internship hours but he must successfully take and pass the MPJE. Dr. Dickerson seconded the motion. The motion carried.

Appearance
NuscriptRx

Beauman Dick appeared before the board to request the use of a long-term care automated dispensing machine made by NuScriptRx. After discussion, Dr. Kizer made the motion to approve the use of the automated dispensing machine used by NuScriptRx. Dr. Bunch seconded the motion. The motion carried.

January 28, 2015

The Tennessee Board of Pharmacy reconvened on Wednesday, January 2, 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. Kizer, president

Appearance
Biosimilar Biological Products

Tim Byler, State and External Affairs, Jim McCade, Clinical Development and Candie Phipps, Director of State Government Affairs, from Novartis Pharmaceuticals/Sandoz, made a presentation before the board concerning Biosimilar Biological Products**.**

Director's Report

Dr. Dilliard asked the board for clarification of the requirement under USP 797 that requires all testing to be completed every year. Dr. Dilliard stated that licensees believe this requirement means every calendar year not 12 months. Dr. Dilliard asked the board to make a statement that this requirement means every 12 months and not calendar year. After discussion, Dr. Kizer made the motion that the intent of the requirement is that all testing for USP 797 to be completed every 12 months and not calendar year. Dr. Eidson seconded the motion. The motion carried.

Dr. Dilliard asked the board to approve the executive director, Dr. David Todd Bess and the investigators to attend the Tennessee Pharmacy Association Mid-Year meeting scheduled for February 22-24, 2015. After discussion, Dr. Eidson made the motion to approve the request. Dr. Kizer seconded the motion. The motion carried.

Dr. Dilliard asked the board to approve travel for the executive director and Dr. Grinder to Talkom2 attend in Dallas, TX on February 9-10, 2015. After discussion, Dr. Eidson made the motion to authorize travel to the meeting in Dallas, TX. Dr. Bunch seconded the motion. The motion carried.

Dr. Dilliard informed the board of the upcoming updates and asked the board members to consider attending as well. The updates are scheduled for the following dates: February7-8, 2015, Murfreesboro, TN; February 28, 2015, Chattanooga, TN; March 8, 2015, Franklin, TN; March 14, 2015, Cookeville, TN; March 21, 2015, Jackson, TN; April 12, 2015, Knoxville, TN; April 24, 2015, Kingsport, TN and May 3, 2015, Memphis, TN.

Contested Cases

Andrew Savage, RT

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

Ashley Morton, RT

Ms. Morton was not present nor represented by legal counsel. Mr. Devin Wells represented the State. Ms. Joyce Grimes Safely was the Administrative Law Judge. Mr. Wells asked for a motion to proceed in default. After discussion, Dr. Eidson made the motion to proceed in default. Dr. Bunch seconded the motion. The motion carried. Mr. Wells passed out the Notice of Charges. Ms. Morton is charged with violating T.C.A. § 53-10-104(a), (b) and T. C. A. §63-10-305. After discussion, Dr. Eidson made the motion to revoke Ms. Morton's registration as a pharmacy technician. Dr. Kizer 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.

Aymbur B. Graham, RT

Ms. Graham was not present nor represented by legal counsel. Mr. Devin Wells represented the State. Ms. Joyce Grimes Safely was the Administrative Law Judge. Mr. Wells asked for a motion to proceed in default. The board voted to proceed in default. Mr. Wells passed out the Notice of Charges. Ms. Graham is charged with violating T.C.A. § 53-10-104(a), (b) and T. C. A. §63-10-305. After discussion, Dr. Eidson made the motion to revoke Ms. Graham's registration as a pharmacy technician. Dr. Kizer seconded the motion. The motion carried. Dr. Dickenson made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Kizer seconded the motion. The motion carried.

Derek Kirby, RT

Mr. Kirby was not present nor represented by legal counsel. Mr. Wells represented the State. Ms. Joyce Grimes Safely was the Administrative Law Judge. Mr. Wells asked for a motion to proceed in default. The board voted to proceed in default. Mr. Wells passed out the Notice of Charges. Mr. Kirby is charged with violating T.C.A. § 53-10-104(a), (b) and T. C. A. §63-10-305. After discussion, Dr. Eidson made the motion to revoke Mr. Kirby's registration as a pharmacy technician. Dr. Kizer seconded the motion. The motion carried. Dr. Dickenson made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Kizer seconded the motion. The motion carried.

Respiratory Home Care, Inc.,(manufacturer/wholesale/distributor)

A representative nor attorney for Respiratory Home Care, Inc., were present. Mr. Wells represented the State. Ms. Joyce Grimes Safely was the Administrative Law Judge. Mr. Wells asked for a motion to proceed in default. The board voted to proceed in default. Mr. Wells passed out the Notice of Charges. Respiratory Home Care, Inc., is charged with violating board rule 1140-01-.08(1), 1140-01-.09(1)(a) and(2) and T. C. A. § 63-10-305(8). After discussion, Dr. Dickenson made the motion to assess a $1,100.00 civil penalty and case cost to Respiratory Home Care, Inc. Dr. Kizer 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. Ms. McDaniel seconded the motion. The motion carried.

Consent Orders

Dr. Kizer made the motion to accept the following consent orders as presented. Dr. Eidson seconded the motion. The motion carried**.**

VIOLATED BOARD RULE 1140-2-.02(1)
Tabitha Pruitt, RT-$100.00 civil penalty-paid
Gabrielle Garner, RT-$100.00 civil penalty-paid

VIOLATED BOARD RULE 1140-03-.11
Stewart Plaza Pharmacy-$1210.00 civil penalty-paid
Rx-Perts Pharmacy-$750.00 civil penalty-paid

VIOLATED BOARD RULE 1140-3-01 (1)(a) & (f)
Walgreens Pharmacy #1015-$1000.00 civil penalty-paid
Walgreens Pharmacy #13891-$1000.00 civil penalty-paid

PROBATION
H. Nestor Stewart, D.Ph.

VIOLATED BOARD RULE 1140-2-.02(1) & (2)
Clayton Dick, D.Ph.-$200.00 civil penalty-paid

VIOLATED BOARD RULE 1140-1-13
Hanger Orthopedic Group, Inc.-$500.00 civil penalty-paid
Hollister Incorporated-$300.00 civil penalty-paid

ORDER MODIFICATION
Brenda Tate, D.Ph.

VIOLATED BOARD RULE 1140-1-.08
Cave's Drug Store-$1000.00 civil penalty-paid

OGC Report

Mr. Cange passed out copies of rules that he feels needs to be cleaned up and asked the board to authorize a rulemaking hearing. After discussion, the board decided to delay authorizing a rulemaking hearing until they can review the rules and make changes if necessary.

Agreed Orders

Jennie Garvey, RT

Mr. Cange presented an agreed order to the board in the name of Jennie Garvey, RT with 5 year probation. After discussion, Dr. Kizer made the motion to amend the agreed order to add monthly drug screenings for 1 year and quarterly until the end of her probation and not to work behind the counter in the pharmacy for 3 years from the start date of her probation. Dr. Bunch

seconded the amended motion. The motion carried. Dr. Kizer made the motion to approve the agreed order as amended. Dr. Bunch seconded the motion. The motion carried.

Dr. Bunch made the motion to accept the following agreed order as presented. Dr. Kizer seconded the motion. The motion carried.

John Comer, D.Ph.

Dr. Eidson made the motion to accept the following agreed order as presented. Dr. Dickenson seconded the motion. The motion carried.

Ashley McKinney, RT

Dr. Eidson made the motion to accept the following agreed order as presented. Dr. Bunch seconded the motion. The motion carried.

LaShay Sharpe, RT

Dr. Dickenson made the motion to accept the following agreed order as presented. Dr. Eidson seconded the motion. The motion carried.

Advanced Home Care

Dr. Bunch made the motion to accept the following agreed order as presented. Ms. McDaniel seconded the motion. The motion carried.

Mark McGill, D.Ph.

Dr. Dickenson made the motion to accept the following agreed order as presented. Ms. McDaniel seconded the motion. The motion carried.

Scenic City Medical

Dr. Kizer made the motion to accept the following agreed order as presented. Dr. Bunch seconded the motion. The motion carried.

Mary Hamby, RT

Ms. McDaniel made the motion to accept the following agreed order as presented. Dr. Bunch seconded the motion. The motion carried.

James Catron, D.Ph.

Dr. Kizer made the motion to accept the following agreed order as presented. Dr. Eidson seconded the motion. The motion carried.

Tonya Brenner, RT

Dr. Kizer made the motion to accept the following agreed order as presented. Dr. Eidson seconded the motion. The motion carried.

Wellness Store Compounding Pharmacy
Robin Terrero, D.Ph.

Dr. Bunch made the motion to accept the following agreed order as presented. Dr. Eidson seconded the motion. The motion carried.

Accredo Health Group

Dr. Bunch made the motion to adjourn at 12:57 p.m. Dr. Eidson seconded the motion. The motion carried.

These minutes were approved and ratified at the March 10-11, 2015 board meeting.