

Tennessee Board of Pharmacy
Board meeting
November 5-6, 2014

TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Iris Room
Nashville, TN
November 5-6, 2014

BOARD MEMBER PRESENT

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

STAFF PRESENT

Reginald Dilliard, Executive Director
Stefan Cange, Assistant General Counsel
Terry Grinder, Pharmacist Investigator
Tommy Chrisp, Pharmacist Investigator
Scott Denaburg, Pharmacist Investigator
Rebecca Moak, Pharmacist Investigator
Larry Hill, Pharmacist Investigator
Bob Shutt, Pharmacist Investigator
Andrea Miller, Pharmacist Investigator
Richard Hadden, Pharmacist Investigator
Sheila Bush, Board Administrator
Marc Guilford, Assistant General Counsel

The Tennessee Board of Pharmacy convened on November 5, 2014 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:10 a.m. Dr. Kizer welcome Dr. Wilson to the board. Dr. Dilliard introduced Dr. Dennis McAllister, former president of the National Association of Boards of Pharmacy and a member of the Arizona Board of Pharmacy.

Director's Report

Dr. Dilliard informed the board that he had surveyed other boards of pharmacy concerning the licensing of interns. Dr. Dilliard stated that Tennessee is 1 of 5 states that do not license interns and that the fee associated with licensing interns usually runs between \$25.00 and \$140.00. Dr. Dilliard proposed that the board charge a one- time fee licensing fee of \$100.00 upon entry into pharmacy school and that the intern license will be good for 5 years with the student submitting an affidavit each school year that they are currently enrolled in pharmacy school. Dr. McAllister suggested that the board discuss the licensing of interns with the deans for the different colleges. After discussion, the board decided that Dr. Dilliard should meet with the college deans to discuss licensing interns at the next Triparte meeting scheduled during the Tennessee Pharmacy Associations (TPA) mid-year meeting on February 22-23, 2015.

Dr. Dilliard stated that a request has been made for the board to schedule a meeting in conjunction with the TPA. The TPA annual meeting is scheduled for July 13- 16, 2015 in Murfreesboro, TN. After discussion the board suggested that Dr. Dilliard meet with TPA and discuss how this could work for the board and bring the result to the board at the January 2015 meeting.

Dr. Dilliard informed the board that the Pharmacy Technician Certification Board (PTCB) will begin requiring new candidates to complete a criminal background check. All of their educational programs will have to be approved by ACPE and ASHP effective in 2020. For their recertification process the candidates will be required to complete twenty (20) hours of continuing education hours with one (1) hour in patient safety effective April 2014. PTCB will also require all continuing education hours to be pharmacy technician specific by 2015.

Dr. Dilliard informed that board that we have two new employees, Aileen Lynn is working with the board and Tim Morgan is working with the controlled substance monitoring database

Dr. Dilliard gave the board copies of a draft of updates that will appear on the controlled substance monitoring database website.

Dr. Dilliard presented a copy of the Attorney General's opinion on the question "Is a pharmacy a "health care entity" for purpose of Tenn. Code Ann. § 63-6-602 (a). The answer was yes and that a pharmacy falls within the definition of a "health care entity" as that term is defined in Tenn. Code Ann. § 63-6-601. Dr. Dilliard stated that this request was made by a legislator who was concerned about doctor's owning pharmacies and referring their patients to that pharmacy. Dr. Dilliard stated that he thinks this opinion is good for the board as the rules and regulations are changing for pain clinics with the chronic pain guidelines and that a physician can't decide to open their own pharmacies if a pharmacy decides not to fill the physician's prescriptions. This opinion could also help the board by recognizing a pharmacy as a health care entity.

Waiver

Board rule 1140-02-.02(7)

Entrust Rx

Bradley Wooldridge, D.Ph., pharmacist in charge for Entrust Rx, appeared before the board to request an increase in the pharmacist to technician ratio from 4:1 to 6:1. After discussion, Dr. Bunch made the motion to approve Entrust Rx request to increase the pharmacist to technician ratio to 6:1 with each additional technicians being certified. Dr. Eidson seconded the motion. The motion carried. Dr. Dickenson voted no. If Entrust Rx business model changes they must notify the board.

Appearance

Covenant Health System

Dr. Dilliard presented to the board a request from Covenant Health System for an extension of USP 797 for Fort Sanders Regional Medical Center, Morristown-Hamblen Medical Center, Cumberland County Medical Center, Fort Loudon Medical Center, Parkwest Medical Center, Methodist Medical Center and Claiborne County Hospital. Covenant Health System stated that the construction for all of the pharmacies listed will be completed by the end of May 2015. After discussion, Dr. Bunch made the motion to approve the waiver request from Covenant Health System. Ms. McDaniel seconded the motion. The motion carried. The board also stated that in

the future the request should come from the pharmacist in charge of the facilities so that the board will know that they are aware of the delay.

Waivers

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

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

Dr. Dickenson made the motion to approve the request from **Michael Vasocu, D.Ph.**, to waive the one hundred and sixty (160) internship hours but he must successfully take and pass the MPJE. Ms. McDaniel seconded the motion. The motion carried.

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

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

Dr. Eidson made the motion to approve the request from **Angela Choiniere, 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. Bunch seconded the motion. The motion carried.

Board rule 1140-05-.01 (1)

Dr. Eidson made the motion to approve the request from **Sharon Arthur, D.Ph.**, to grant a six (6) month extension to the fifteen (15) hours of live continuing pharmaceutical education for the 2012-2104 renewal cycle. Dr. Bunch seconded the motion. The motion carried.

Board rule 1140-3-.14 (12)

Dr. Eidson made the motion to approve the request from **Jacqueline Enclade, D.Ph.**, to be pharmacist in charge at Christ Community Health Services, Inc. (Frayser Pharmacy) and Christ Community Health Services, Inc. (Hickory Hill). Dr. Bunch seconded the motion. The motion carried. The board also stated that if the business model changes they must inform the board.

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

Maury Regional Medical Center

Dr. Eidson made the motion to approve the request from **Maury Regional Medical Center** to waive the requirement that the pharmacy have the use of hot and cold running water. Dr. Wilson seconded the motion. The motion carried.

Mr. Jeff Binkley, D.Ph., pharmacist in charge at Maury Regional Medical Center, is also requesting approval to implement bedside delivery. After discussion, Dr. Eidson made the motion to approve the request from Maury Regional Medical Center satellite pharmacy to allow bedside delivery for six (6) months. Maury Regional Medical Center satellite pharmacy must also submit a report on the process and progress of face to face counseling. Dr. Wilson seconded the motion. The motion carried.

General Discussion

Dr. Eidson recognized Dr. Baeteena Black, executive director of TPA, on her years of service and commitment to the board. Dr. Black will be retiring as executive director of TPA on December 31, 2014.

Consent Order

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

VOLUNTEER SURRENDER (revocation)
Jonathan Grim, D.Ph.

VIOLATED BOARD RULE 11403-.01(1)(a) &(f)
Jessica Boyd, RT-\$50.00 civil penalty
Kristin Alvey, D.Ph.-\$1000.00 civil penalty
Timothy Hiser, D.Ph.-\$1000.00 civil penalty
P & P Compounding Shop- \$1000.00 civil penalty
Rodney McCormick, D.Ph.-\$1000.00 civil penalty
Paul Cook, D.Ph.-\$1000.00 civil penalty
Walgreens Pharmacy #12718- \$1000.00 civil penalty

PROBATION
Jonathan Morrow, D.Ph.
Valerie Dunn, D.Ph.

VIOLATED BOARD RULE 1140-2-.02(1) & (2)
Patricia Kincheloe, D.Ph. -\$500.00 civil penalty

VIOLATED BOARD RULE 1140-03-.07
Rodney McCormick, D.Ph.-\$1000.0 civil penalty

VIOLATED BOARD RULE 1140-01-.12(3)(g)(1)
Rodney McCormick, D.Ph.-\$100.00 civil penalty

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REVOCATION
Melissa Duncan, RT

VIOLATED T.C.A. § 63-10-305(8)
Phillip Bradley, D.Ph.-10 hours of continuing education hours within 6 months

OGC Report

Mr. Cange informed the board that there are ninety-five (95) cases open in the Office of General Counsel with thirty (30) cases listed on the complaint summary, eleven (11) cases in litigation and fourteen (14) of the cases have signed consent orders.

Mr. Cange stated the rules approved at the rulemaking hearing on September 10, 2014 are currently under review at the Attorney General's office. The rules that pertain to drug disposal have been drafted and will be presented to the board at the January 27-28, 2015 meeting for approval to have a rulemaking hearing. Dr. Eidson asked if the board rule is more stringent than federal law concerning the drug disposal program. The board's rule does not allow a pharmacy to take back any medication that has been dispensed to a patient. Mr. Cange stated that usually when a state law is allowed to supersede a federal law there is usually an expressed statement to that effective in the federal law and that is not the case with this law. Mr. Cange presented the board with a draft of the policy which states;

“If DEA Regulations are “STRICTLY FOLLOWED”

Recent changes in federal regulations allow licensed retail pharmacies, hospital pharmacies, manufacturers, wholesalers, distributors, and reverse distributors that have a valid DEA registration to accept returns of unused legend drugs from end-users. These registrants may do so by modifying their DEA registration to serve as collectors of unused legend drugs, and by further complying with all DEA regulations pertaining to this activity.

Therefore, any retail pharmacy, hospital pharmacy, manufacturer, wholesaler, distributor, or reverse distributor that is licensed by the Board and complies with all applicable DEA regulations pertaining to drug disposal **MAY accept returns of unused legend drugs pursuant to DEA rules.**

If DEA regulations are not strictly followed, Board of Pharmacy Rule 1140-03-.04(8) will apply. Rule 1140-03-.04(8) prohibits pharmacy practice sites, pharmacists, pharmacist interns, technicians, or any other place involved in the compounding and dispensing of prescription drugs and devices (except institutional pharmacies pursuant to Rule 1140-04-.10) from accepting returns of any order that has been taken from the premises of that pharmacy practice site or any other place of business.

DEA resources pertaining to drug disposal, including a complete text of the applicable DEA rules, are available at: http://www.deadiversion.usdoj.gov/drug_disposal/

Please contact the Board of Pharmacy with any questions about this policy.

Dr. Bunch asked if the pharmacy can take back drugs before the rules have been promulgated. Mr. Cange stated that as long as the pharmacy is following DEA rules then they could participate in the DEA drug disposal program. After discussion, Dr. Bunch made the motion to accept the policy statement as amended. Ms. McDaniel seconded the motion. The motion carried. Dr. Eidson made the motion to authorize a rulemaking hearing at the January 27, 2015 board meeting. Dr. Smothers seconded the motion. The motion carried.

Mr. Cange informed the board that Dr. Dilliard presented the collaborative practice rules to the board of medical examiners and he presented them to the board of osteopathic examiners. Both boards have selected members from their perspective boards to work with the board of pharmacy on the rules. Mr. Cange suggested that the board appoint two or three members to work on these rules. Dr. Eidson asked what were the concerns expressed by the board of medical examiner and the board of osteopathic examiners. Mr. Cange stated that they had concerns about the amount of leeway that the proposed rules would allow for in terms of the agreement and types of drugs that may prescribe under this agreement. Mr. Cange also stated that some of the members of the boards of medical examiners and osteopathic examiners were not aware of the statute. After discussion, the board decided to send Dr. Kizer, Ms. McDaniel and Dr. Eidson along with Dr. Dilliard to work with the members of the boards of medical examiners and osteopathic examiners.

Mr. Cange informed the board that a package of rules for January will include the rule rewrites as well as proposed long-term care rules, fees for law enforcement access to the CSMD and a couple other items, is being prepared.

Appearance Trucare Pharmacy

Michael Hoover, owner of Trucare Pharmacy, appeared before the board to request the use of a drive-thru window at his pharmacy. The drive-thru window will be placed in front of the store outside of the dispensing area which is in the back of the pharmacy due to the location of the pharmacy within the vicinity of Lake Barkley. Mr. Hoover stated that the drive-thru window will be outfitted with both audio and video equipment and that if the equipment is down, the pharmacist will walk up front to the drive-thru window. After discussion, Dr. Bunch made the motion to approve the placement of the drive-thru window for Trucare Pharmacy after a satisfactory inspection from Dr. Chrisp, pharmacy investigator. Dr. Dickenson seconded the motion. The motion carried.

USP 797 Waivers Erlanger Health System

Allen Broome, director of pharmacy for Erlanger Health System, appeared before the board to request an extension of the USP 797 waiver for Erlanger Baroness Campus Pharmacy, Erlanger East Oncology Infusion Center, Erlanger East Pharmacy, Erlanger Children's Hospital

Pharmacy, Erlanger Children's Oncology and Outpatient Oncology. After discussion, Dr. Eidson approved the extension request for Erlanger Baroness Campus Pharmacy, Erlanger East Oncology Infusion Center, Erlanger East Pharmacy, Erlanger Children's Hospital Pharmacy, Erlanger Children's Oncology and Outpatient Oncology for six (6) months. The approval is based on environmental testing, Dr. Hadden completing an inspection and that the pharmacies only process low to medium risk sterile compounding at each facility. Dr. Wilson seconded the motion. The motion carried.

Community Health Systems

Jerry Reed, corporate health director of Community Health Systems, appeared before the board to request an extension of the USP 797 waiver for Lafollette Medical Center, Harton Regional Medical Center, Turkey Creek Medical Center and University of Medical Center until April 1, 2015. After discussion, Dr. Eidson made the motion to grant a 6 months waiver for Lafollette Medical Center, Harton Regional Medical Center, Turkey Creek Medical Center and University Medical Center with no high risk compounding, continue the environmental testing and at the end of the 6 months to contact the investigator for inspection. Dr. Bunch seconded the motion. The motion carried.

Dr. Eidson made the motion to deny the request from **Village Pharmacy, Maryville, TN** for a waiver to become compliant with UPS 797 and cease sterile compounding until Village Pharmacy is in compliance with USP 797 and Dr. Hill completes an inspection. Dr. Smothers seconded the motion. The motion carried.

Ms. McDaniel made the motion to approve the request from **Pioneer Community Hospital of Scott, Oneida, TN** to grant a 120 day waiver to become compliant with UPS 797. Dr. Dickenson seconded the motion. Dr. Eidson amended the motion to add the Pioneer Community Hospital of Scott to not do any high risk sterile compounding and to have an environmental testing completed. Ms. McDaniel seconded the amended motion. The motion carried.

Dr. Smothers arrived at the meeting at 2:26 p.m.

Application Review

Ariel Nichols

Ms. Nichols answered yes to the question "Have you ever been charged or convicted (including a nolo contendere plea or guilty plea) of a felony or misdemeanor (other than a minor traffic offenses) whether or not sentence was imposed, suspended, expunged, or whether you were pardoned from any such offenses? Ms. Nichols is serving a misdemeanor diversion probationary period of 11 months and 29 days beginning September 8, 2014 through September 7, 2015 for assault. After discussion, Dr. Dickenson made the motion to defer Ms. Nichols' application for registration as a pharmacy technician until she can appear. Dr. Eidson seconded the motion. The motion carried.

Complaint Summary

1.

Complaint generated by BOP investigator. Respondent was found to have been operating from a new location for approximately 3 months prior to BOP inspection. Respondent distributes prescription devices but no drugs.

Prior discipline: None.

Recommendation: \$100 per month civil penalty, totaling \$300.

Dr. Smothers made the motion to **authorize a formal hearing** with a \$100.00 civil penalty per month for a total of \$300.00 to the respondent for operating from a new location unlicensed Ms. McDaniel seconded the motion. The motion carried.

2.

Complaint generated by BOP investigator. Respondent was found to have been operating from a new location for approximately 5 months prior to being discovered by BOP. Respondent distributes prescription devices but no drugs.

Prior discipline: none

Recommendation: \$100 per month civil penalty, totaling \$500.

Dr. Smothers made the motion to **authorize a formal hearing** with a \$100.00 civil penalty per month for a total of \$500.00 to the respondent for operating from a new location unlicensed Dr. Dickenson seconded the motion. The motion carried.

3.

Complaint generated by BOP investigator performing a periodic inspection.

Numerous deficiencies were discovered and noted below:

- No tech registry or affidavits
- Food and beverages intermingled with medication in the refrigerator
- Dusty shelves and stock bottles with layers of dust
- C2 invoices not signed and dated
- C3 thru C5 invoices not signed and dated
- Biennial inventory completed 4/21/14 for C3 thru C5 and 8/19/14 for C2
- Biennial inventory was not signed and did not state "before opening" or "after closing"
- Some bottles on shelves were not properly labeled with lot number or expiration dates

- Some compounded (non-sterile) products on shelves were not labeled
- Pharmacists not signing daily log or printouts
- 42 compounding components (non-sterile only) were found to be expired but on shelves
- 79 commercial products were found to be expired but still on shelves

BOP investigator issued a non-satisfactory inspection sheet and educated staff about all deficiencies. Some were corrected immediately and pharmacist submitted a plan of action to prevent out-of-dates, dirty shelves and compounding labels.

Prior discipline: Paid a \$500 civil penalty for excessive refills in 2006.

Recommendation: Pharmacy- Written plan of correction within 30 days, with a follow-up inspection within 90 days of receipt of the plan of correction. Civil penalty for expired products, possible civil penalties for other infractions with amount to be determined by the Board.

PIC- 2 years' probation, cannot serve as PIC during term of probation. Additionally must implement and follow pharmacy's plan of correction during the term of probation. Failure to follow the plan of correction will be treated as a violation of a Board order.

Dr. Smothers made the motion to **authorize a formal hearing** with a \$10.00 civil penalty to the pharmacy for the each outdate drugs for a total of \$1210.00, 2 year probation for the pharmacist in charge and he cannot be pic during the probation, a written plan of correction from the pharmacy within 30 days, a Letter of Instruction to management about cleanness in the pharmacy and a Letter of Warning to the pharmacist in charge for the unlabeled compounding products. . Dr. Eidson seconded the motion. Dr. Smothers reaffirmed her motion and Dr. Eidson reaffirmed his seconded. The motion carried.

4.

Complaint was referred from Texas BOP. Complainant (patient) alleged the respondent pharmacy delayed shipping medication after she ordered it on 4/1/14 for a delivery on 4/8/14. On 4/9/14, patient called pharmacy as to why the shipment was not received and was told there was a mistake and the pharmacy would expedite the order. Patient alleges that nobody ever called her back so she transferred her prescription and that the pharmacy's negligence caused unnecessary flare ups of Crohn's disease due to their inefficiency.

Respondent PIC provided a typed response. PIC stated that an 84 day supply was dispensed to patient on 12/19/13 and "several" attempts to contact patient started on 3/7/14 but patient did not return the call until 4/1/14. When attempting to adjudicate patient's insurance, it was discovered that the patient had changed plans 1/1/14 but had not updated her information with the pharmacy. On 4/9/14, the insurance information was updated but then it was discovered that the pharmacy is not an eligible provider for the new plan. Pharmacy staff then worked with the patient to get

the prescription and refills transferred to a pharmacy that could bill her insurance.

Prior discipline: LoW for misfill in 2014.

Recommendation: Dismiss.

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

5.

Complainant (spouse of patient) alleged a delivery of Ribasphere was delayed 4 times over a course of 3 weeks even though the patient was assured each time that problems had been resolved and the medication would be shipped. Complainant claims the patient's treatment plan was interrupted, possibly compromising his health and that the situation had caused additional stress on the patient and spouse.

Respondent admits multiple failures in processing and communication and provided details that indicate that originally there was a delay due to the patient's insurance forcing a change from the previous pharmacy provider to this pharmacy. Transfers were delayed but finally occurred on 5/8/14. Shipping was scheduled for 5/12/14 however the patient's spouse contacted the pharmacy regarding a dose reduction from 5 doses down to 3 doses per day due to blood cell counts dropping. Shipment was held until the pharmacy could verify the reduced dosage with the prescriber.

A call was placed to the prescriber on 5/13/14 however the tech was put on hold for a long period and eventually hung up. On 5/14/14 the pharmacy sent a fax request to the prescriber but did not receive a response. On 5/16/14, another attempt to call the prescriber went unanswered. On 5/19/14, the prescriber sent a prescription for 2 capsules twice daily. The prescription was processed and the patient was contacted on 5/20/14 to set up delivery but before shipping, the prescriber called and cancelled the prescription and provided a new prescription for 2 capsules in the morning and 1 at night. This new prescription went back into processing, however, a pharmacist performing DUR noticed the dosage was below normal recommendations and held up processing until he could speak to the prescriber regarding the dose.

This pharmacist spoke to the prescriber's medical assistant who stated she would have to call the pharmacy back. On 5/23/14, the pharmacy reports they were still waiting on the prescriber to call back. On 5/27/14, the pharmacy reports they were still waiting on the prescriber's office to call back. On 5/28/14, the prescriber called back to confirm the 3 per day dosage. The order was set up to ship on 6/2/14.

However, due to an inventory system issue, the prescription was not correctly routed so the patient's spouse was contacted to inform them of the inability to ship the order. The pharmacy was told the patient would be traveling so the pharmacy representative agreed to send the medication anywhere in the U.S. if the patient would provide an address of where he was staying. When the spouse called the pharmacy to give the exact address, she spoke with a

different supervisor who promised the order would ship on 6/4/14 for delivery on 6/5/14. However, due to the same system issue that occurred previously, the order did not ship as promised. When the patient's spouse was contacted, she stated she did not want to deal with this pharmacy anymore.

Respondent's typed statement also indicates the following corrective actions have been taken:
The inventory system issue has been corrected.

The pharmacist that became aware of the issue on 6/5/14 has been coached about proper escalation procedures and proper notification to the whole pharmacy team. This could have led to an override with the insurer to allow the patient to obtain the medication at another pharmacy. The technician involved on 5/13/14 has been coached about escalation, communication, and that attempts to call the prescriber back should happen on the same day.

Prior discipline: LoW for misfill in 2014.

Recommendation: Letter of Warning and Reprimand of pharmacy and/or PIC's license. Respondent has already received a letter of warning for misfill related to shipment/processing delays. Executive Director of the Board has met with Respondent to discuss the volume of complaints coming in citing these types of issues. Incident in this case occurred after Director met with Respondent and they assured him that corrective action had been taken.

Dr. Eidson made the motion to **authorize a formal hearing** with a \$1000.00 civil penalty to the pharmacy with an acceptable plan of correction approved by the executive director, 2 year quarterly reports on their process in the pharmacy and a Letter of Warning to the pharmacist in charge. Dr. Dickenson seconded the motion.

6.

Complaint was referred from Missouri BOP. Complainant (patient) alleges Humira was not delivered on time in November 2013, January 2014, and February 2014. Patient alleges that when a delivery promised for 2/25/14 did not arrive, she contacted the pharmacy and was told that her insurance was not valid and that they would look into the matter and get back to her in 7 to 10 days. When she complained about the delay, she was then told they would expedite the matter and resolve it in 48 to 72 hours but the patient states that they did not respond until 2 weeks later. By that time, patient states she was in complete rebound psoriasis.

PIC of respondent pharmacy provided a typed response. PIC asserts that the pharmacy attempted to call complainant on November 9, 10, 12, 14, 16, 19, and 21 and left messages each time but the patient did not call the pharmacy back until 11/26/13, at which time the patient requested delivery be made on 11/27/13 (the day before Thanksgiving.) However, prior to dispensing, it was discovered the patient had an outstanding balance owed to the pharmacy. PIC states that a call was made to the patient but the patient did not return the call until 11/29/13. Payment was processed and the shipment went out on 12/2/13 and another 28 day supply (which was the final refill on the prescription) was sent on 12/17/13 with no problems.

The prescriber was contacted and refills authorized on 1/2/14 and the pharmacy started calling the patient on 1/4/14 but could not leave messages because the patient's voicemail was full. Patient contacted the pharmacy on 1/23/14 and requested her medication be shipped on 1/27/14 to be delivered on 1/28/14. It was shipped as promised but due to extreme weather, it could not be delivered on time. A replacement order was sent at no charge on 1/30/14 and delivered 1/31/14. PIC claims that attempts to contact the patient for her February refill were made on February 14, 15, 18, and 19 but the patient did not return the calls until 2/20/14 at which time the patient requested shipment for 2/25/14 delivery. On 2/24/14, while processing the order, the claim rejected as "coverage terminated."

An attempt to notify the patient was made on 2/25/14 but her voicemail was full. Patient did call the pharmacy later that day and was told about the insurance issue. Patient called again on 2/26/14 to report new coverage however, on 3/1/14, a pharmacy agent discovered that this pharmacy was not a preferred provider and the patient's prescriptions had to be transferred to another pharmacy.

PIC stated that since the patient was not consistent with her refill requests, it is not known whether there was a gap in treatment and PIC does not believe any gap would have been the result of pharmacy actions.

Prior discipline: LoW for misfill in 2014.

Recommendation: Dismiss.

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

7.

Complaint generated from BOP inspection. BOP investigator removed approximately 75 out of date medications from pharmacy shelves. Investigator reported that the expired drugs represented a significant percentage of the pharmacy's stock.

Prior discipline: None.

Recommendation: \$10 per expired product for a total of \$750.

Dr. Smothers made the motion to **authorize a formal hearing** with a \$10.00 civil penalty per expired product for a total of \$750.00. Dr. Wilson seconded the motion. The motion carried.

8.

Complaint from out-of-state patient concerning systemic shipping and processing issues at location of a national pharmacy not licensed in Tennessee.

Prior discipline: LoW for misfill in 2014.

Recommendation: Refer to appropriate state board, Florida in this case.

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

9.

Complaint from out-of-state patient concerning systemic shipping and processing issues at location of a national pharmacy not licensed in Tennessee.

Prior discipline: LoW for misfill in 2014.

Recommendation: Refer to appropriate state board, Florida in this case.

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

10.

Complaint from out-of-state patient concerning systemic shipping and processing issues at location of a national pharmacy not licensed in Tennessee.

Prior discipline: LoW for misfill in 2014.

Recommendation: Refer to appropriate state board, Indiana in this case.

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

11.

Complaint generated by BOP staff after pharmacist admitted via telephone to working on an expired pharmacist license from 8/1/14 to 9/9/14.

BOP investigator spoke to pharmacist on 9/11/14. Respondent told investigator that the license most likely lapsed due to a miscommunication between the pharmacist and her accountant. Pharmacist admitted receiving the renewal notice and had acquired all CE, but it did not get renewed. Pharmacist stated she happened to look at the wall certificate and noticed it was expired and contacted BOP office. She had the renewal and fees hand delivered that day. Pharmacist stated to investigator that she reviewed her signature log and had worked as a pharmacist 21 total days during the time the license was lapsed.

Prior discipline: none

Recommendation: Civil penalty \$1000, 21 days unlicensed practice. (Eidson recuse)

Dr. Smothers made the motion to **authorize a formal hearing** with a \$1000.00 civil penalty to the pharmacist for unlicensed practice. Dr. Bunch seconded the motion. The motion carried. Dr. Eidson was recused.

12.

Complaint alleges a misfill by filling a prescription for Enoxaparin 60mg/0.6ml with Enoxaparin 80mg/0.8ml and also alleges proper counseling was not performed.

BOP investigator visited the pharmacy and obtained a sworn statement from the PIC (who is also the dispensing pharmacist.) PIC admitted a mistake was made and could not confirm that counseling occurred. PIC stated that when the mistake was brought to her attention, she contacted the physician, entered the mistake into the pharmacy's quality assurance system, re-trained all staff regarding drugs with multiple strengths, and changed the order of processing so a pharmacist looks at the RX image prior to looking at the data entered.

Prior discipline: None.

Recommendation: Letter of Warning.

Dr. Smothers made the motion to issue a **Letter of Warning** to the pharmacist in charge for the misfill. Ms. McDaniel seconded the motion. The motion carried.

13.

Complaint opened based upon observations by CSMD and TBI personnel that noticed a pharmacy that was supposedly closed appeared to still be operating and that other suspicious activity may be occurring.

BOP investigator visited the facility. While a pharmacy sign was still prominent on the building, the pharmacy itself was closed. The pharmacy is located inside a building with a physician's office and the physician initially owned the pharmacy. BOP was notified 8/21/13 to close the pharmacy license and that all unused medication was returned to suppliers/distributors. BOP investigator did not note any suspicious activity either inside or from the parking lot. Dr. Holt with CSMD confirmed there had been no dispensing from the pharmacy since the closing date.

Prior discipline: None.

Recommendation: Dismiss, but send letter to physician asking them to take the sign down.

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

14.

Complaint generated when BOP investigators discovered multiple prescriptions entered for Vyvance listing the pharmacist as the patient. Upon closer review, investigators noted that hard copies of all but one of the prescriptions were missing and that the hard copy on file contained phrasing indicating it should not have been filled for approximately 6 more weeks.

BOP investigators interviewed the pharmacist and acquired documentation and copies of prescriptions. The prescriber had provided the patient with 3 prescriptions totaling a 90 day supply with notations of when each could be filled. The patient had filled the first prescription at another pharmacy. When it was time for the next prescription, the patient (who is a pharmacist) had gained employment at another pharmacy where she tried to scan and enter her prescriptions into a system that she was not familiar with.

She admitted several attempts were made to fill one prescription and put the other one on hold. She admitted she was unsuccessful at being able to put the other prescription on hold and during the confusion, she accidentally filled the future prescription and took the one actually due back home.

Pharmacist did provide a copy of the prescription which she still had and it was dated a date that would have actually been a late fill on the date the other prescription was filled. A review of both pharmacies' dispensing and transaction records, as well as a review of CSMD reports did not reveal anything that contradicted the pharmacist's explanation.

Prior discipline: None.

Recommendation: Dismiss.

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

15.

Complaint alleges Tramadol was shorted on two occasions and that pharmacy staff was acting unprofessionally by laughing and pointing at patients.

BOP investigator visited the pharmacy and obtained multiple statements. Pharmacy has a policy of having a technician count controls which are then counted again by a pharmacist. Respondents were actually the pharmacists that double counted the prescriptions that were allegedly shorted.

Prior discipline: None.

Recommendation: Dismiss.

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

16.

Complainant (patient) alleged unprofessional conduct against two separate pharmacies related to dispensing a lesser amount than was billed to insurance, requiring enrollment in a monitoring program, and refusing to fill prescriptions due to insurance reimbursement issues.

BOP investigator visited both pharmacies and obtained sworn statements explaining high ME concerns and contacting the prescriber for a lesser quantity. It was also explained that PDAPP is a voluntary program but the pharmacy can refuse service if the patient refuses to enroll. Other allegations were not violations.

Prior discipline: None.

Recommendation: Dismiss.

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

17.

Complaint generated by staff when technician inquired by phone about how to renew technician registration. A very alert staff member noted that the registration had been revoked by consent order that the tech had signed 11/25/2013 and BOP approved 1/23/2014. Staff member also noted the pharmacy name and phone number on caller I.D. during the tech's phone call. A BOP investigator was dispatched to the pharmacy and verified that the tech had been working as a pharmacy technician at that pharmacy since 12/2/2013.

The tech was immediately escorted from the pharmacy and placed on leave pending an investigation. Respondent pharmacy provided a detailed timeline indicating that pre-employment screening on 12/2/2013 did not reveal any negative issues. Personnel documents indicate that the tech falsely answered pre-employment questions relating to disciplinary actions and that during the exit interview the tech stated that she was unaware of the revocation of her registration even though she had signed the consent order for revocation. Respondent's policy is to verify licensure status annually and the review process for this employee would have occurred in November 2014.

Prior discipline: Tech was revoked in 1/2014. Pharmacy received a small fine in about 2007 for distribution of expired products.

Recommendation: Letter to tech stating we are aware she worked on a revoked license,

advise that doing so is unlawful, state that this information will be considered by the Board if she ever attempts to reinstate license. Dismiss against the pharmacy.

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

18.

Complaint generated based upon anonymous email alleging that a pharmacy was storing controlled substances, narcotics, old compounds and maintenance medications at the pharmacy's previous location, and that the building is currently being rented as an apartment to someone having "full access" to all of the medications.

BOP investigator was dispatched and discovered drugs including controlled substances being stored at the pharmacy's previous location. Respondent owner provided a typed response admitting that approximately 12 boxes of expired medications were left at the old location because "At that time, I truthfully did not know there was a way to get rid of the medications." BOP investigator also determined that the medications were in a locked area, the renter stated he did not have a key, and the lock did not look to have been forced.

Pharmacy relocation was entered into RBS 7/1/14. Anonymous email was received 10/22/14. Drugs were discovered by BOP investigator 10/23/14. Drugs were moved to the current pharmacy location and a reverse distributor has been contacted. Typed plan of correction includes utilizing a reverse distributor every 6 months and to never store drugs off-site again.

Prior discipline: \$250 CP about 10 years ago.

Recommendation: \$ 250.00 Penalty per month to pharmacy, for total of \$ 1,000.

Dr. Bunch made the motion to **authorize a formal hearing** with a \$250.00 civil penalty per month for a total of \$1000.00 to the pharmacy for the storage of expired drugs off site. Dr. Smothers seconded the motion. The motion carried.

19.

Complaint generated from information from CSMD indicating a pharmacy was incorrectly using a midlevel practitioner's name to fill numerous prescriptions not authorized by that practitioner.

BOP investigator visited the pharmacy and confirmed the allegations. The pharmacy's software defaults to the last prescriber of record for a patient and the incorrect prescriber was not noticed by techs or pharmacists. Respondent provided a typed plan of correction indicating that all prescriptions under that practitioner's name have been reviewed and corrected; a new computer system is now being used and the default program has been deactivated; prescriber will be contacted to apologize and advise of corrective actions taken.

Prior Discipline: Recent LOW for another CSMD-reporting issue where pharmacy's DEA number was being entered instead of prescribers' numbers.

Recommendation: LOW

Dr. Eidson made the motion to issue a **Letter of Warning** to the pharmacy. Dr. Dickenson seconded the motion. The motion carried.

20.

Complaint alleges a 4-year-old child's medication order for compounded azithromycin was incorrectly filled with hydrocodone. Child was admitted to hospital for treatment but recovered. Lab tests confirmed the presence of hydrocodone.

BOP investigator visited the pharmacy and PIC. Respondent PIC admitted to mistakenly using hydrocodone powder to compound the medication and stated that they have now instituted a policy of prohibiting more than one drug in the area where compounding is being conducted.

Prior Discipline: The pharmacy agreed to pay \$190 for out of date drugs in September 2014.

Recommendation: LOW to PIC for misfill and for failure to notify BOP (1140-03-.14 (14)).

Dr. Eidson made the motion to issue a **Letter of Warning** to the PIC for the misfill and failure to notify the board of the misfill. Dr. Smothers seconded the motion. The motion carried.

21.

During a periodic inspection on 10/14/14, BOP investigator noted 2 techs with expired registrations:

Tech 1 expired 8/31/14

Tech 2 expired 9/30/14

Prior Discipline: None on pharmacy, PIC, or technicians.

Recommendation: Civil penalty Tech 1 for two months of expired license practice (\$200), civil penalty to Tech 2 for one month of expired license practice (\$100), civil penalty to PIC for permitting a total of three months of expired license practice (\$300) by the technicians.

Dr. Smothers made the motion to **authorize a formal hearing** with a \$200.00 civil penalty for technician 1 for working on expired registration for two months, a \$100.00 civil penalty to technician 2 for working on an expired registration for one month and a \$300.00 civil penalty to the pic for allowing the technicians to work a total of three months on expired registrations. Ms. McDaniel seconded the motion. The motion carried.

22.

Complaint generated from information provided by loss prevention alleging pharmacist admitted in writing to taking a total of 10 to 15 hydrocodone APAP tablets and occasionally sodium bicarbonate tablets from stock bottles without a prescription and without making payment for either. Pharmacist was also observed on video on one occasion “counting” previously unopened bottles of hydrocodone, and on another occasion diverting and then consuming 3 to 5 tablets of hydrocodone while on shift. A report showing on-hand changes was reviewed indicating numerous times the pharmacist changed on-hand amounts of the missing strengths. A police report was filed. An audit revealed 4,255 hydrocodone APAP 10/325, 151 hydrocodone APAP 7.5/325 tablets, and 500 Phentermine 37.5mg tablets had gone missing between July 2013 and August 2014.

Pharmacist also admitted in writing that the original written statement admitting to only taking sodium bicarbonate was not truthful but denied taking the entire missing quantities. Investigation is on-going.

Prior Discipline: None.

Recommendation: Revoke pharmacist’s license and refer to TPRN. Monitor the on-going investigation for other losses.

Dr. Eidson made the motion to **authorize a formal hearing** for revocation to the pharmacist and refer him to TPRN. Dr. Wilson seconded the motion. The motion carried.

23. Intentionally skipped

24.

Complainant (insurance auditor) alleged fraudulent billing for medications not purchased (specifically Lipitor 20mg and Vancomycin 250mg).

BOP investigator visited the pharmacy and reviewed audit findings and pharmacy invoice records. Investigator noted that a large overstock quantity of Lipitor (brand name) was purchased prior to the audit and was gradually dispensed. Some of the prior months’ invoices were not allowed by the auditor. Vancomycin invoices could not be located at the pharmacy. Pharmacy has since changed wholesalers but the former wholesaler was contacted but stated they could not provide sales information due to a software change. Investigator contacted prescriber’s office and verified that the medication was appropriately authorized for the listed patient during the time period the billing took place. No discrepancies were found between prescriber’s orders and pharmacy’s dispensing records. The allegations cannot be substantiated.

Prior Discipline:

Recommend: Dismiss

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

Dr. Bunch made the motion to adjourn at 5:00 p.m. Dr. Eidson seconded the motion. The motion carried.

November 6, 2014

The Tennessee Board of Pharmacy reconvened on Thursday, November 6, 2014 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members were present, the meeting was called to order at 8:05 a.m., by Dr. Kizer, president.

Minutes

Dr. Smothers made the motion to approve the minutes as amended. Ms. McDaniel seconded the motion. The motion carried.

Complaint Summary

25.

BOP investigator was asked to accompany DEA agents to conduct an audit of respondent pharmacy. DEA had received allegations that legend drugs and controlled substances were being dispensed without prescriber authorization.

Audit numbers from 5/22/13 to 9/13/13 showed the following results:

Tramadol 50 mg tab	3,516 short
Lorazepam 1 mg tab	336 short
Diazepam 5 mg tab	508 short

Audit numbers from 9/23/13 (using change of PIC numbers) to 3/31/14 showed the following results:

Tramadol 50 mg tab	602 short
Lorazepam 1 mg tab	947 over
Diazepam 5 mg	130 short

(Former PIC continued to work as a pharmacist until February 2014.)

Technicians were interviewed and sworn statements taken by BOP investigator. Three techs all provided sworn statements that they had observed pharmacist (previous PIC) on several occasions, refill medications by reprinting a label instead of obtaining authorization. Tramadol, Valium, warfarin, and maintenance meds were specifically mentioned. One tech mentioned a specific case where the tech contacted the prescriber for a warfarin refill for a regular patient and was told by the prescriber's office that the patient had not been seen in "several years." Patient

profiles reviewed indicate regular refills were dispensed at the pharmacy using the same prescriber name.

Dispensing records show that warfarin was continuously refilled through 2011, 2012, and up to 5/23/13, even though the prescriber had not authorized warfarin since 2010. A technician's note on 5/16/13, stating that the prescriber had cancelled all refills for warfarin because the patient had not been seen since 2010, was ignored by the pharmacist who refilled the warfarin anyway on May 23, 2013.

BOP investigator interviewed pharmacist who provided a sworn statement admitting he refilled warfarin one time for a patient due to a family emergency but denied ever refilling any controlled substances. About a week later, pharmacist called BOP investigator and requested to meet so he could change his statement. Investigator met with pharmacist who stated he felt bad for lying to the investigator and wanted to set things right. Pharmacist provided another sworn statement that he had refilled Tramadol without authorization "about 3-4 times before Tramadol became a controlled drug in Tenn." He also admitted he did this by reprinting a label. He denied billing insurance and claims he only collected the copay and lost money to help the patient. He provided another sworn statement that he did refill a Diazepam prescription "2-3 times" without authorization.

Pharmacy has been sold and a new PIC is in place as of October 2013. Prior PIC was apparently continued to work there until February 2014, when he left for medical reasons.

Prior discipline: There appears to have been a LOW to at least the pharmacy (possibly also the pharmacist) in 2008 due to "security issues" (200705924), and there was a LOI in 2011 due to a compounded OTC product being dispensed "without a proper prescriber-patient-pharmacist relationship."

Recommend: Based upon the shortages, ignoring laws, poor professional judgment, and attempted deception with BOP investigator, revocation of pharmacist's license and civil penalties of \$1000.00 per improperly filled prescription (3 or 4 Tramadol +2 or 3 diazepam + 16 warfarin prescriptions since February 2011, for a total of about \$21,000.00). Dismiss against pharmacy, dismiss vs technicians that were cooperative during the investigations. Continue monitoring case vs technician who was arrested for diversion

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

26.

Complainant physician alleged possible unprofessional conduct by respondent pharmacy and pharmacist refusing to fill his patients' prescriptions for Buprenorphine even though he is licensed in multiple states and has the required "X" number issued by DEA.

BOP investigator visited the pharmacy and obtained sworn statements from pharmacists

indicating they had tried to resolve questions about the prescriber's practice address, TN license, and whether a separate X-number was needed to practice in different states. According to pharmacists, they contacted a male person at BME that told them the prescriber needed an X-number for Tennessee and advised them not to fill the prescriber's prescriptions.

BOP investigator educated pharmacists about federal regulations regarding the X number and the fact that only one X number is issued per prescriber and it does not have to be state-specific.

Prior discipline: None.

Recommend: Dismiss

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

27.

Complaint generated based upon CSMD reports showing large quantities of controlled substances being dispensed to patients from other states obtaining prescriptions from a third state (for example, patients from Kentucky seeing a doctor in Georgia, then filling scrip in TN).

BOP investigators visited the pharmacy, extensively reviewed records and interviewed staff. Investigators noted large quantities of controlled substances being dispensed and poor record keeping as indicated by an audit of 10 common drugs resulting in only 2 of those balancing; 3 had significant shortages; 5 had significant overages. Although the pharmacy is located in middle Tennessee, many patients live in Kentucky and see prescribers in Georgia while some patients live in Kentucky or Alabama and see prescribers in Florida. Some live in Florida, see prescribers in Florida but come to this pharmacy to have their prescriptions filled. Other less significant patterns were also noted. Investigators also noted that many prescriptions supposedly from the same prescriber had widely varying signatures; however there was no concern or documentation by the pharmacist that any attempt was made to verify the prescriptions were not forgeries.

Pharmacy prescription volume is 37.26% cash and 35.5% controlled substances, however, controlled substance sales are 52.3% cash. Many patients are above 225 Morphine Equivalents daily dosage. Many patients are prescribed the same drugs and dosages. Some prescribers are ordering new prescriptions early. Some patients are seeing multiple prescribers and obtaining early fills. Some local prescribers were also noted as routinely prescribing an opioid, a benzodiazepine, and carisoprodol.

During the respondent pharmacist's interview, he stated that a wholesaler had discontinued selling controlled substances to the pharmacy. Investigators discovered the pharmacy is currently ordering from 4 wholesalers.

Pharmacist stated he checks CSMD, calls the prescriber, checks when the prescription was first filled, calls KASPER if the patient is from Kentucky and checks their driver's license. If

everything is ok, he will fill their prescriptions. There was no documentation that any prescriptions were refused.

Pharmacist stated he no longer fills prescriptions from out-of-state prescribers and that he only fills for out-of-state patients if they see a local prescriber. Both he and the technician stated these policies were enacted about 3 weeks prior to BOP visit. However, investigators noted that records show the pharmacy has continued to fill for out-of-state patients and prescribers. When questioned, the pharmacist stated he continues to fill for established patients.

A lengthy review and report was prepared by investigators, however to summarize, it appears that improper DUR and poor professional judgment is being used along with poor record keeping.

Recommendation: Limitation of pharmacy's license to prohibit dispensing of controlled substances; same limitation on PIC's license. This substantial discipline is being recommended base on factors including: shortages, failure to conduct drug utilization and regimen review, failure to fulfill corresponding responsibility, highly suspect combinations of drugs being prescribed, other suspicious patterns (family members all getting same prescriptions, high amounts, early refills)

Ms. McDaniel made the motion to **authorize a formal hearing** for revocation of the pharmacist license, revoke the pharmacy's ability to dispense controlled substances for one year. Dr. Dickenson seconded the motion. The motion carried.

28.

Complaint generated after BOP inspection revealed dispensing of large quantities of controlled substances to out of area and out of state patients along with consistent early filling of controlled substances.

BOP investigators visited the pharmacy, did an extensive review of records and interviewed staff. Investigators noted that approximately 90% of the pharmacy volume involves prescriptions from one prescriber, who owns the pain clinic and weight loss center located in the same building, and also owns the pharmacy. The pharmacy only accepts cash payment for pain medications.

Respondent pharmacist estimated 75-80% of the pharmacy's patients are from Kentucky, however, records indicate 90.7%. Pharmacist stated that there are no pain clinics in Kentucky and feels the pharmacy is providing a needed service to Kentucky patients that could not otherwise get pain treatment. Pharmacist denied being cut-off or restricted by any wholesaler but when investigators presented evidence to the contrary, the pharmacist admitted that she had received a letter. Pharmacy currently orders from 2 different wholesalers. Pharmacist denied "inventory balancing" to prevent being cut off but large quantities of inexpensive non-controlled drugs were stockpiled in several areas. Many of them were nearing their expiration date.

Pharmacist stated that when the pharmacy originally opened, it had struggled until they started filling pain prescriptions on a cash-only basis. Pharmacist admitted to not using the CSMD, but feels sure the prescriber does. Investigators determined that the pharmacist had checked the CSMD one time between June 2012 and June 2014.

Pharmacist stated she is comfortable with the prescriptions because she knows there is a valid doctor-patient relationship and she hears the prescriber talking to patients. Pharmacist stated the prescriber requires an MRI and urine screening but no documentation is kept in the pharmacy. Pharmacist stated she knows the prescriber checks KASPER because the prescriber uses the pharmacist's password to log in.

For early refills, the pharmacist stated that if the owner wrote the prescription, she will fill it. She also commented that since the prescriber owns the clinic and pays the bills, she will fill any of his prescriptions.

Oxycodone 30mg is the most frequently prescribed controlled substance and investigators discovered that some controlled substances owned by the pharmacy are actually stored in the prescriber's office. After investigators were advised that all overstock and outside storage areas had been emptied and brought back to the pharmacy, the pharmacist called investigators, after they had left, that another 1,200 Oxycodone had been located and returned to the pharmacy.

Many patients had an ME of greater than 120. Some were as high as 375.

Dispensing records from 5/1/13 to 6/10/14 show the following numbers dispensed:

Oxycodone 30 mg tab	169,661
Phentermine 37.5 mg tab	32,162
Alprazolam 2mg tab	13,055
Alprazolam 1mg tab	19,675

Follow-up audit 6/10/14 to 8/12/14 show the following numbers dispensed:

202 prescriptions for Oxycodone 30 mg tab	22,343
156 prescriptions for Phentermine 37.5 mg tab	4,680

About 35% of prescriptions filled were for controlled substances at the first visit. However, the follow-up audit from 6/10/14 to 8/12/14 showed the ratio had increased to 57.7%

87 patient profiles were reviewed. 80 of them were from Kentucky. 81 of them received Oxycodone plus some combination of benzodiazepine, gabapentin, muscle relaxer, NSAID, H2 antagonist and vitamins.

Drug audits proved inconclusive due to poor record keeping. Phentermine 37.5 had an overage of 1 tablet. Alprazolam 2mg had a shortage of 9 tablets. Oxycodone 30 mg had an overage of 2,702 tablets.

Recommendation: Limitation of pharmacy's license to prohibit dispensing of controlled

substances; same limitation on PIC's license. This substantial discipline is being recommended based on factors including: lack of independent judgment exercised by pharmacist in charge, failure to conduct drug utilization and regimen review, failure to fulfill corresponding responsibility, "red flags" on patients, attempted deception of investigators regarding inventory balancing, improper storage of controlled substances, poor record keeping during June 204 audit (which hampered investigations)

Ms. McDaniel made the motion to **authorize a formal hearing** for revocation for both pharmacist and the pharmacy. Dr. Eidson seconded the motion. The motion carried.

29.

Complaint alleged various violations of USP 797 standards at Respondent pharmacy. BOP investigator visited pharmacy and addressed USP 797 standards with staff and PIC, however none of the specific allegations in the complaint were substantiated.

Prior discipline: None.

Recommend: Dismiss

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

30.

Complaint alleged Respondent pharmacist behaved unprofessionally and discriminated against them by first verifying and then refusing to fill a controlled substance prescription after Complainant's insurance denied coverage.

Prior discipline: None.

Recommend: Dismiss

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

**Order Modification
Brenda Tate, D.Ph.**

Dr. Tate appeared before the board to request that she be allowed to float Dr. Tate's pharmacist license was placed on probation for five years beginning 2/1/2013 and she would not be allowed to be float for 3 years from the date of probation. After discussion, Dr. Smothers made the motion to amend Dr. Tate's consent order and allow her to be a floater at the Fred's Pharmacy locations in Tennessee and Kentucky. Ms. McDaniel seconded the motion. The motion carried.

Tennessee Board of Pharmacy
Board meeting
November 5-6, 2014

James Don Wilson. D. Ph.

Dr. Wilson appeared before the board to request that he be allowed to be PIC. Dr. Wilson's pharmacist license was placed on indefinite probation beginning 1/20/2010 and he would not be allowed to be PIC for 5 years from the date of probation. After discussion, Ms. McDaniel made the motion to amend Dr. Wilson's consent order and allow him to be the PIC at Brownsville Apothecary in Brownsville, Tennessee. Dr. Bunch seconded the motion. The motion carried.

**Appearance/USP 797
East Tennessee Children's Hospital**

Linda Elias, D.Ph., pharmacy manager for East Tennessee Children's Hospital, appeared before the board to request and extension of the USP 797 waiver that was approved at the March 11-12, 2014 board meeting. After discussion, Dr. Eidson made the motion to grant another 180 day extension to East Tennessee Children's Hospital. Dr. Smothers seconded the motion. The motion carried.

Dr. Eidson asked Dr. Dilliard for a list of all pharmacies that were granted waivers of the USP 797.

Dr. Bunch made the motion to adjourn. Dr. Dickenson seconded the motion. The motion carried.

These minutes were approved and ratified at the January 27-28, 2015 board meeting.