

TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Iris Room
Nashville, TN
July 30-31, 2014

BOARD MEMBER PRESENT

Nina Smother, D.Ph., Vice President
Charles Stephens, 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
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
Devin Wells, Deputy General Counsel

BOARD MEMBER ABSENT

Jason Kizer, D.Ph., President

STAFF ABSENT

Richard Hadden, Pharmacist Investigator

The Tennessee Board of Pharmacy convened on July 30, 2014 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:00 a.m. Dr. Smothers welcomed students from Belmont University, Lipscomb University, University of Tennessee and Samford University.

Contested Cases

Zimmer Spine

An officer of Zimmer Spine was present and represented by Kim Looney, Attorney. The Honorable Tom Stovall, Administrative Law Judge presided. Mr. Cange represented the State. Mr. Cange handed out the Notice of Charges. Zimmer Spine is charged with violating T.C.A. §63-10-305 (a) (b) & (c)(4)(8). After discussion, Dr. Dickenson made the motion to accept the state's findings of fact 1-5. Dr. Bunch seconded the motion. The motion carried. Dr. Eidson made the motion to accept the conclusions of law. Dr. Stephens seconded the motion. The motion carried. Dr. Stephens made the motion to assess Zimmer Spine a \$13,700.00 civil penalty and case costs. Dr. Bunch seconded the motion. The motion carried. Ms. McDaniel was recused. Dr. Eidson made the motion that the action taken was to protect the health, safety and welfare of the citizens of Tennessee who receives prescription devices by licensed manufacturer/wholesale/distributors. Dr. Dickenson seconded the motion. The motion carried.

Mitzi Pratt, RT

Ms. Pratt was not present nor represented. The Honorable Tom Stovall, Administrative Law Judge presided. Mr. Cange represented the State. Mr. Cange asked for a motion to proceed in

default. After discussion, Mr. Stovall stated that there wasn't sufficient evidence that Ms. Pratt has been served notice of the hearing and that this case be continued.

Anna R. Ellis, RT

Ms. Ellis was not present nor represented. The Honorable Tom Stovall, Administrative Law Judge presided. Mr. Cange represented the State. Mr. Cange asked for a motion to proceed in default. After discussion, Mr. Stovall stated that there wasn't sufficient evidence that Ms. Pratt has been served notice of the hearing and that this case be continued.

Agreed Orders

Richard Maynard, D.Ph.

Mr. Maynard was present and represented by Frank Scanlon, Attorney. Mr. Cange represented the State. Mr. Cange presented to the board the Agreed Order signed by Mr. Maynard. Mr. Maynard violated board rule has agreed to a 1 year suspension stayed once he has completed an substance abuse evaluation and submitted 10 hours of continuing pharmaceutical education hours in ethics, law or pharmacy practice relating to controlled substances the license will be placed on probation for 1 year. After discussion, Ms. McDaniel made the motion to accept the Agreed Order as presented. Dr. Eidson seconded the motion. The motion carried.

Alisha Dugger, RT

Ms. Dugger was not present nor represented by legal counsel. Mr. Cange represented the State. Mr. Cange presented to the board the Agreed Order signed by Ms. Dugger. Ms. Dugger has agreed to pay a \$100.00 civil penalty. After discussion, Dr. Eidson made the motion to accept the Agreed Order as presented. Ms. McDaniel seconded the motion. The motion carried.

Rebecca Wortham, RT

Ms. Wortham was not presented nor represented by legal counsel. Mr. Cange represented the State. Mr. Cange presented to the board the Agreed Order signed by Ms. Wortham. Ms. Wortham has agreed to have her registration revoked. After discussion, Dr. Eidson made the motion to accept the Agreed Order as presented. Dr. Bunch seconded the motion. The motion carried.

Oxygen Respiratory Care, Inc.

A representative from Oxygen Respiratory Care, Inc. was not present nor were they represented by legal counsel. Mr. Cange represented the State. Mr. Cange presented to the board the Agreed Order signed by Debbie Sprouse, representative of Oxygen Respiratory Care, Inc. Oxygen Respiratory Care, Inc. has agreed to pay a \$600.00 civil penalty. After discussion, Dr. Stephens made the motion to accept the Agreed Order as presented. Dr. Bunch seconded the motion. The motion carried.

First Choice Home Medical Supplies

A representative from First Choice Home Medical Supplies was not present nor were they represented by legal counsel. Mr. Cange represented the State. Mr. Cange presented to the board the Agreed Order signed by the President and CEO of First Choice Home. First Choice Home Medical Supplies has agreed to pay a \$1400.00 civil penalty. After discussion, Dr. Bunch made the motion to accept the Agreed Order as presented. Dr. Stephens seconded the motion. The motion carried.

Complaint Summary

1.

Complaint alleging medication refill issue. Complainant who lives in Arizona, has had difficulties with a Tennessee-licensed pharmacy, complainant alleges that orders of Enbrel were shipped to her without adequate ice packs. The lack of ice, combined with the time of delivery, resulted in Complainant receiving medication that was allegedly outside the temperature range for safe use. Two of Respondent pharmacy's locations have communicated with Complainant regarding her medication shipment issues. Respondent says that some of its problems are due to recent acquisitions/changes in ownership.

Respondent disagrees with Complainant's assertions that her medication's effectiveness is negatively affected by Respondent's shipping methods. Respondent provided timeline of shipments to Patient from 10/6/10 through 1/24/14. Respondent also indicated that Complainant had received shipments of drugs at similar times in the past, and provided data to Board investigator about shipment processes and efficacy of cooling agents. Respondent also conducted a simulated shipment on the same date as one of the alleged shipments of spoiled products, and the results of this testing showed that the medication was at an acceptable temperature at the time of delivery.

Prior discipline: Yes, 2006 complaint for out of date drugs, civil penalty \$250.00.

Recommendation: **Discuss.**

Dr. Bunch made the motion to dismiss the complaint. Dr. Dickenson seconded the motion. The motion carried.

2.

Complaint alleging unprofessional conduct. Complaint alleging medications error and unprofessional conduct. Complainant was previously receiving Genotropin (Human Growth Hormone) from a specialty pharmacy, which was bought by Respondent pharmacy. Pharmacist working for Respondent denied the prescription refill due to her review of the patient's profile and determination that he did not need HGH; it was her opinion that he fit the profile of a

performance enhancement and not of a deficiency or disease treatment.

PIC informed the patient that Respondent would return his prescription so that his insurance company could find another pharmacy to fill the prescription.

Prior discipline: Yes, see above case.

Recommendation: Discuss.

Dr. Dickenson made the motion to dismiss the complaint. Dr. Bunch seconded the motion. The motion carried.

3.

Complaint alleging medications error and unprofessional conduct. The complainant, a nurse working for a physician, submitted an electronic prescription to Respondent pharmacy for Patient, who lives in Mississippi. The prescription was for Ampyra.

On December 12, 2013 nurse was told by Patient that Respondent told her that the prescription was never received. A new prescription was sent electronically on December 12th from the physician's office.

Patient subsequently called Respondent again and was informed that the prescription was not received. On December 12, 2013, Respondent told the nurse that a signed prescription was not received. According to the investigation report, "The nurse explained that the prescription was sent electronically and that the patient's medication had been withheld for a month and a half due to pharmacy error." The nurse indicated that she wanted to be transferred to an individual who could assist her with this issue. After waiting for 8 minutes on hold, the nurse hung up. The nurse was concerned that the patient could have potentially ended up in the hospital due to not receiving his medication.

Prior discipline: Yes. See above previous case.

Recommendation: Discuss.

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

4.

Complaint alleging unprofessional conduct/controlled substance violations related to sterile compounding practices and dispensing of controlled substances to hospice patients. The complaint was brought by a current employee and forwarded on to Investigator Chrisp for investigation. The employee subsequently wanted to withdraw the complaint, but provided further assistance in the investigation. The investigation included a thorough inspection,

including an inspection of the high risk sterile compounding lab and interviews with pharmacists and technicians on duty. Shipping and prescription logs were reviewed, and it was determined that none the allegations of violations could be substantiated. Additionally, some of the allegations were not violations.

Respondent PIC strongly denied any wrongdoing

Although the inspection did not find any serious issues with Respondent's compounding laboratory, the Investigative report did not that Respondent was not in compliance with USP 797. A waiver request form was left with Respondent.

Prior discipline: Yes. 2008 Complaint regarding patient counseling. June 6/2009 BM, Consent Order/ Civil Penalty \$1,000.

Recommendation: Dismiss.

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

5.

Complaint alleging misfill. A former employee alleges that pharmacist employed by Respondent told a nurse to reuse old tubing for a PCA IV. Pharmacist denies the allegation, but cooperated with investigation. The alleged misfill was initially thought to have resulted in the death of a hospice Patient. However, subsequent investigation showed that the misfill was actually an incorrect injection of volume flow. The patient was monitored and the attending nurse took full responsibility for the misfill. Subsequent review by physician at the hospice determined that the patient died as a result of the disease process and not the misfill.

An additional alleged misfill was discovered, but could not be substantiated. The pharmacist supposedly responsible for the misfill was not employed by Respondent at the time alleged misfill occurred, and employees who were present at that time denied any knowledge of this alleged misfill.

Recommendation: Dismiss.

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

6.

Complaint originally from the Division of Consumer Affairs and forwarded to the BOP. Complainant (patient) alleges that the pharmacy contacted the prescriber requesting new prescriptions for glucose strips without the patient's knowledge. Complainant alleges that the pharmacy initiated the process and that the prescriber merely complied with the pharmacy

request. Complainant was upset because he said he verified that the prescriber did not initiate the process but did authorize the prescription at the pharmacy's request.

Respondent pharmacy provided copies of the correspondence with the Division of Consumer Affairs along with a copy of the electronic prescription order showing that it was transmitted from the prescriber's agent to Respondent pharmacy. Respondent pharmacy denies that they initiated the request and stated that the prescription was unsolicited. Regardless of who initiated the call, there do not appear to be any violations related to the format or the authorization of the prescription.

Prior discipline: None

Recommendation: Dismiss.

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

7.

Complaint generated during opening inspection. Investigator visited pharmacy and found Respondent technician working there without supervision.

- On 11/20/2013 at **4:26 p.m.**, Respondent technician told Investigator Miller that the pharmacist was gone for the day
- Later that day at **4:51 p.m.**, Respondent technician told Investigator Grinder that the pharmacist was not on duty at the time and had been gone about 20 minutes and that this occurs about twice a week.

Respondent technician was instructed by Investigator Grinder to have the pharmacist call immediately upon return to the pharmacy. Later calls from investigators to the pharmacy that day received no answer. The pharmacist eventually called the investigator at 5:28 p.m. and would not confirm that he had returned to the pharmacy. Both Respondent technician and PIC declined to provide a written statement.

Prior discipline: None.

Recommendation: Discuss.

Dr. Eidson made the motion to authorize a formal hearing with a \$1000.00 civil penalty to the pharmacist for leaving the pharmacy unattended, 10 hours of live continuing pharmaceutical education in law in addition to the 30 hours required for renewal within 90 days of the signed consent orders, a Letter of Warning to the pharmacy technician for unlicensed activity (pharmacist not on duty). Ms. McDaniel seconded the motion. The motion carried.

8.

Complaint alleging unprofessional conduct. Complaint generated while Investigators Grinder

was conducted an inspection in November 2013. Allegations against Respondent PIC include the following:

- Failure to retain an up-to-date copy of his license on site.
- Admitting that prescriptions were dispensed in his absence by the pharmacy technician and that he left the pharmacy unsecured.
- Not providing counseling to patients.
- Inadequate record keeping regarding sterile compounding, storage, lack of policy and procedure, quality assurance program, cleaning procedures and various other record keeping concerns.
- The pharmacy was observed to be unclean and unsanitary and the technician was unsupervised
- Unable to locate his required copy of “Tennessee Pharmacy Laws”.
- Record keeping of invoices was inadequate. Respondent PIC was allegedly throwing invoices away.
- Inadequate and insufficient processing of orders.

Respondent PIC declined to respond, except verbally, to the allegations. However subsequent inspections indicated that he has continued to make the required corrections. Respondent PIC had previously been granted a waiver by the Board to serve as PIC at three separate pharmacies located under the same roof.

Prior discipline: None.

Recommendation: Discuss.

Dr. Eidson made the motion to authorize a formal hearing with a \$2000.00 civil penalty to the pharmacy stayed with \$1000.00 civil penalty with an acceptable plan of correction, a \$1000.00 civil penalty to the pharmacist, a \$2000.00 civil penalty to the dispensing pharmacist for patient counseling, 15 hours of live continuing pharmaceutical education hours in recordkeeping, operational standards and pharmacy law, a Letter of Instruction concerning cleanliness of the pharmacy and the key violation to the pharmacist with a \$100.00 civil penalty and patient counseling. Dr. Stephens seconded the motion. The motion carried.

9.

Complaint alleges a misfill by way of improperly labeling as “teaspoonfuls” instead of “ml.” Prescription was for Risperidone 1ml. Complaint alleged improper supervision of a technician by allowing a tech to verify whether an error had been made; a failure to counsel on a new prescription; and unprofessional conduct by pharmacy staff (a pharmacist and a tech) by affirming they had verified that they had prescription was filled correctly even though it was not. In fact, prescription was mistakenly transcribed. Respondent technician admitted to the error and stated she will be more careful in the future. Pharmacist in this matter feels that all actions of the tech ultimately are the responsibility of the pharmacist.

Prior discipline: None.

Recommendation: Discuss

Dr. Eidson made the motion to issue a Letter of Instruction to the technician referencing the duties of a technician. Dr. Bunch seconded the motion. The motion carried.

10.

Complaint alleges a misfill by way of improperly labeling as “teaspoonfuls” instead of “ml.” This complaint concerns the same set of facts as the above item, but pertains to the pharmacist rather than the technician. Complaint alleges improper supervision of a technician by allowing a tech to verify whether an error had been made; a failure to counsel on a new prescription; and unprofessional conduct by a pharmacy staff (a pharmacist and a tech) by affirming they had verified that a prescription was filled correctly even though it was not. The pharmacist admitted to the misfill and to reading the RX incorrectly even after Complainant questioned it. The pharmacist stated this incident has changed the way he practices pharmacy because he is more careful, double checks things now and took a CE course in medication errors to try and prevent this from happening again. The pharmacist does not deny that counseling did not occur but feels that an offer was made. He now realizes that an extra effort to counsel should have been made and states that processes have been changed to correct this issue.

Prior discipline: None.

Recommendation: Discuss.

Dr. Bunch made the motion to issue a Letter of Warning to the pharmacist in charge for the misfill. Dr. Eidson seconded the motion. Dr. Bunch amended the motion to authorize a formal hearing with a \$1000.00 civil penalty to the pharmacist in charge and the dispensing pharmacist for failure to counsel. Dr. Eidson seconded the amended motion. The amended motion carried. The original motion carried.

11.

Complainant alleges a misfill of a refill prescription of Amitriptyline for Patient on October 5, 2013. The prescription was supposed to be prescribed as 10 mg but was filled as 100 mg. The result was the patient overdosed and was admitted into the hospital for observation. Respondent pharmacist took full responsibility for the error and told Investigators that he has added additional checks to ensure this will not happen again. Respondent pharmacist also asserted that he could not remember if he or another pharmacist filled the prescription and claims he has not seen the vial or pills to verify the allegation.

**Recommendation: Letter of Warning, LOI on notifying BOP
regarding serious injury or death.**

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

12.

Complaint of alleged theft of controlled substances. Owner of Pharmacy discovered a large quantity (500) of missing Zolpidem tablets in January 2014. After a careful auditing, viewing of video recordings and an inventory of records with the pharmacy manager it was suspected that a part time employee, Respondent Pharmacist, was responsible for the theft. In a meeting with Respondent Pharmacist on February 13, 2014; Respondent admitted to the theft, relinquished his keys to the pharmacy manager and resigned.

Prior discipline: None.

Recommendation: Revoke.

Dr. Eidson made the motion to authorize a formal hearing for revocation along with referring the licensee to the Tennessee Pharmacy Recovery Network (TRPN). Ms. McDaniel seconded the motion. The motion carried.

13.

Complaint alleged unprofessional conduct. Complainant alleged that Respondent Pharmacy parted ways with their wholesaler in early 2013 and committed a multitude of violations to secure a new wholesaler. Complainant states that employees were told to not inform patients or doctor-owned pharmacies about the situation and to lie to them and tell them drugs were on backorder or there were problems with the manufacturer. She further alleges that the pharmacy engaged in activities to procure drugs that were illegal, although the actions cited by Complainant appear to be purchases of drugs from other wholesalers or pharmacies, things which are not necessarily illegal. Complainant also alleges that Respondent has shipped drugs to patients in states where it is not licensed.

Respondent, which holds both pharmacy and wholesaler/distributor licenses, changed locations in May 2012, it notified the Board that its pharmacy operation had relocated, but did not notify the Board that its wholesale operation had also relocated until May 2013.

Prior discipline: None.

Recommendation: Discuss.

Dr. Bunch made the motion to dismiss the complaint. Dr. Dickenson seconded the motion. The motion carried.

14.

Complaint alleging diversion. Respondent was a certified pharmacy technician (registered in TN) working at a pharmacy in Mississippi. She was terminated on 2-4-2012 for theft. Respondent signed a written admission on 2-14-2012 for using and diverting Alprazolam, Adipex and hydrocodone after a pharmacy loss prevention report indicated a large amount of missing drugs. Her Tennessee license expires on 2-28-2015.

Prior discipline: None.

Recommendation: Revoke.

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

15.

Respondent pharmacist was disciplined in Oregon in 2011 and she surrendered her Oregon license on June 15, 2012 due to not completing CE credits. Investigator Grinder discussed with her in March 2013 about her lack of CE as being a problem to getting her license renewed in Tennessee. Respondent indicates that because of her husband's health problems she has been unable to get her CE credits but plans to obtain them by on-line courses and attending on site updates. Respondent initially indicated to Board staff that she did not intend to renew her Tennessee license, which expired on 2/24/14. Respondent has since re-applied for licensure, but her application has been held. Respondent is in the process of being excluded from receiving reimbursement from federal health programs.

Prior discipline: Yes, in Oregon in 2011.

Recommendation: Deny application for licensure.

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

16.

Complaint alleged medication refill problems. Complainant claims that he ordered some medication via mail order from Respondent, and that that medication was tainted with a "foreign substance". Complainant states that it was not the first time he received tainted medication from Respondent and he wanted the "tainted" medication he received to be tested to determine the foreign substance. Respondent denies any problems with the dispensing and the purity of their medications and provided replacement medication to Complainant.

Prior discipline: None.

Recommendation: Dismiss.

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

17.

Respondent pharmacist was terminated for diversion of controlled substances. In an email of 2-17-2014 to Executive Director Dillard, Respondent claims that due to a sinus infection he unlawfully consumed Tussionex and Hycodan on 2-6-2014. Respondent was arrested by local police subsequent to his termination. Respondent stated in his email that he accepted full responsibility for his actions and desired to clear the matter up. New information received from Respondent's former employer on 2-27-2014 indicates a larger loss of medication than originally claimed (filed amended DEA 106). Respondent has undergone evaluation for substance abuse and was found not to have addiction issues.

Prior discipline: None.

Recommendation: Discuss.

Dr. Eidson made the motion to authorize a formal hearing for the respondent's license to be placed on probation for 1 year for consuming a controlled substance without authorization from a licensed prescriber. Dr. Stephens seconded the motion. The motion carried.

18.

Complaint alleges medication refill issues regarding a gap in medication therapy. The following are the notes of Investigator Denaburg's summary to the file.

11-15-2013 – Complainant alleged problems with medication refills from Respondent.

In the complaint, Patient was on three anti-retroviral medications to treat HIV, which he had to take daily with no interruptions or be at a health risk. He was without medication for four (4) days.

A response from PIC 1 agreed with PIC 2 (both PICs work at different locations owned by Respondent) that problems related to acquisition of new company caused issues with medication refills.

The response explains that Patient was sent a 90 day supply of medication on August 3, 2013. This was noted as the last refill on his prescription.

10-13-2013 – the prescription of Patient was integrated into the Respondent Pharmacy 1's

system with no refills.

10-28-2013 – a new prescription was received.

10-31-2013 – prescriber contacted the pharmacy for a status on the medication delivery. Unlicensed employee of Respondent was found to have failed to communicate to both the prescriber and patient that there was an issue with the patient's retail benefit.

11-27-2013 – medication shipped to patient.

12-3-2013 – two additional medications shipped to patient.

Prior discipline: Yes. In 2006 a complaint for out of date drugs. c/o-c/p \$250.00.

Recommendation: Discuss.

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

19.

Complaint alleging unprofessional conduct.

In December 2013, Prescriber complained that many of her patients were having issues getting refills from Respondent pharmacy. A complaint was received in February 2014 from Mother regarding a prescription of Nutropin injection for her daughter. Mother indicated that it took 6 phone calls to Respondent before medication was shipped, and when prescription arrived it was missing the pen needles to inject the medication.

A response from PIC at Respondent pharmacy indicated that the reason for the pen needles not being sent was due there not being an active prescription for the needles on file. The prescription was sent to Mother and daughter in Connecticut, where a separate prescription for the needles is required by law.

PIC further explained that the problem with Daughter's prescription was a combination of receiving it on a holiday weekend (Thanksgiving) and lack of pharmacy staff, both of which he claims have been corrected. He also indicated that his records showed that the patient did receive the needles and no doses were missed. He does not believe that Respondent was at fault because it was the responsibility of the patient to ask for a separate prescription order for the needles.

Prior discipline: Unknown

Recommendation: Discuss.

Dr. Dickenson made the motion to dismiss the complaint. Dr. Bunch seconded the motion. The

motion carried.

20.

Complaint alleging unprofessional conduct. Alleged shipping of prescriptions and samples of compounded medications into Tennessee prior to obtaining license for pharmacy and DPH.

An allegation by a licensed Tennessee pharmacist was received in the Board of Pharmacy office on March 12, 2013 reporting dispensing activity from an out of state compounding pharmacy that was dispensing samples of compounded products to prescriber offices and compounded non-sterile products to residents in Tennessee without being licensed.

According to the investigation, faxed records show a total of fifty-one (51) prescriptions that were mailed to patients in Tennessee. In March 2013 the pharmacy and PIC were granted licenses. Some prescriptions were shipped before the licenses were approved.

The allegations were proven accurate and substantiated. Respondent pharmacy is currently the subject of disciplinary proceedings in California (where it is located), the Board there is seeking revocation or suspension of the facility and the pharmacist-owners' licenses.

Prior discipline: Unknown

Recommendation: Revoke. Civil penalties for unlawfully dispensed prescriptions.

Ms. McDaniel made the motion to authorize a formal hearing for revocation with a \$1000.00 civil penalty for each prescription dispensed before respondent was issued a Tennessee license. Dr. Stephens seconded the motion. The motion carried.

21.

Complaint alleging unlicensed activity. Investigators received an anonymous tip regarding an ad on line of a physician dispensing from an alleged "pharmacy". Investigators visited physician and requested that he change the language of his online advertisement which referred to his physician dispensary as a pharmacy. Physician complied with Investigators' request.

Prior discipline: Unknown.

Recommendation: Dismiss.

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

22.

Complaint alleging unprofessional conduct. Complaint generated during a periodic inspection on

March 20, 2012. The following violations were noted:

- No technician's registry or affidavits on site. The pharmacy had previously suffered a fire and all previous lists were destroyed and not replaced. No inspections since the reopening of the pharmacy. However, a new list was being created at the time of the inspection.
- (15) Drugs in-date. There were 18 out of date items in the compounding lab.
- (38) DEA form 222 Copy 3 on hand and completed. The PIC had failed to date his CII invoices and 222 copy 3 forms.
- Unauthorized compounding of products for physician's office use and other products for hospital/clinic use.

Prior discipline: None.

Recommendation: Discuss.

Dr. Stephens made the motion to authorize a formal hearing with a \$10.00 civil penalty per out of date drug and a Letter of Instruction. Dr. Eidson seconded the motion. The motion carried.

23.

Complaint alleging diversion and impairment. A co-worker witnessed Respondent pharmacist self-administering Kytril, Phenergan, Benadryl and Decadron without a prescription on September 16, 2013 while the two were at work. Other suspected previous incidents occurred but were not documented. An update on March 3, 2014 indicated that Mr. Wooden has not admitted to any wrong doing and that he has legitimate prescriptions and medical condition. A Cornerstone evaluation was inconclusive and there is not enough definitive proof and the allegations were not substantiated despite typed statements from employer and coworkers.

Prior discipline: None.

Recommendation: Dismiss.

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

24.

Complaint alleging misfill. Complainant alleged that his wife had been given the wrong medication from what the prescription was written. He indicated that this is not the first time this has happened. Photographs of the misfill were taken.

The label for Olanzapine was placed on stock bottle of Onglyza. Complainant's wife became hypoglycemic but recovered and corrective actions have been taken. The allegations were proven correct.

Prior discipline: None.

Recommendation: Letter of Warning.

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

25.

Complaint generated from a wholesaler report of suspicious ordering and termination of business with Respondent pharmacy. Investigators reviewed CSMD reports and then visited Respondent pharmacy. Records were reviewed and staff was interviewed. Three Investigators were satisfied with recordkeeping, DUR, and CSMD usage by employees at Respondent pharmacy. Investigators were also satisfied with Respondent's controlled substance policies and interviews with staff. Respondent pharmacy provided good documentation and answers to all questions asked by Investigators.

Prior discipline: None.

Recommendation: Dismiss.

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

26.

Complaint alleges misfill. Prescription for $\frac{3}{4}$ tsp. Augmentin was labeled as "give 3.75 tsp Augmentin." Pharmacist took responsibility for misfill, but investigation revealed that Respondent technician did not alert her to the new prescription to counsel when the prescription was picked up and was unaware of the report of the misfill because Respondent technician took the call. Respondent technician also admitted to inputting the prescription and counseling the patient on the prescription at the time of dispensation.

Prior discipline: None.

Recommendation: Discuss.

Dr. Stephens made the motion to authorize a formal hearing with a \$1000.00 civil penalty to the pharmacy with an acceptable plan of correction, the dispensing pharmacist, a Letter of Instruction to the pharmacist in charge, a Letter of Instruction to the technician with a \$50.00 civil penalty. Dr. Dickenson seconded the motion. The motion carried. Dr. Eidson voted no.

27.

Complaint alleged misfill. Complainant alleged that prescription was filled and dispensed with the wrong prescriber's name. Respondent pharmacist stated that Nurse Practitioner with

prescriptive authority had ordered all of the patient's medication electronically so they were all filled under Nurse Practitioner's name. Complainant wanted supervising physician's name on the labels instead.

Prior discipline: None.

Recommendation: Dismiss.

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

28.

Complaint originated with Oklahoma Board of Pharmacy. Respondent pharmacy was cited for numerous violations of law in consent order with Oklahoma Board. Although Respondent neither admitted nor denied any of these allegations, Respondent was ordered to pay civil penalties totaling \$520,200.00, suspended from operating for 5 days, and placed on probation for 3 years.

Prior discipline: None.

Recommendation: Revoke.

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

Waivers

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

Ms. McDaniel made the motion to approve the request from **Signature Healthcare of St. Peters** to waive the requirement for the pharmacy (automated dispensing machine) to have hot and cold running water. Dr. Bunch seconded the motion. The motion carried.

Stephen Ingram, D.Ph. submitted a request from **Woodridge Hospital** to waive the requirement that the pharmacy to be one hundred and eighty (180) square feet. The board determined that under the institutional rules this pharmacy would not require a waiver of space since institutional rules only state that sufficient space should be allowed.

Board rule 1140-1-.13(h) & (g) (1)

Dr. Bunch made the motion to deny the request from **Smyrna Pharmacy & Wellness** to waive the requirement of the access to the department by someone other than the pharmacist, pharmacy interns and pharmacy technicians who are practicing at the pharmacy and that only the pharmacist practicing at the pharmacy and pharmacist authorized by the pharmacist in charge are allowed to be in possession of any keys or other access devices. Dr. Eidson seconded the motion.

The motion carried.

Board rule 1140-03-.14(12)

Dr. Eidson made the motion to authorize **James Simmons, D.Ph.** to be pharmacist in charge at Pharmerica Memphis, PharMerica at St. Frances and PharMerica at Signature of Methodist automated dispensing machines. Dr. Bunch seconded the motion. The motion carried.

Dr. Eidson made the motion to authorize **Joyce Broyles, D.Ph.** to be pharmacist in charge at Methodist Extended Care Hospital and the automated dispensing machines at Alliance Health Services, Inc., Methodist Hospice Residence. Dr. Bunch seconded the motion. The motion carried.

USP 797 Compliance

Ms. McDaniel made the motion to defer the request from **Medicine Shoppe, Clarksville, TN** to grant a 180 day waiver to become compliant with UPS 797. Dr. Bunch seconded the motion. The motion carried.

Ms. McDaniel made the motion to approve the request from **Excellerx, Memphis, TN** to grant a 180 day waiver being on October 9, 2014 to become compliant with UPS 797. Dr. Bunch seconded the motion. The motion carried.

Ms. McDaniel made the motion to approve the request from **Vanderbilt University Medical Center Hospital Pharmacy, Nashville, TN** to grant a 180 day waiver beginning on October 9, 2014 to become compliant with UPS 797. Dr. Bunch seconded the motion. The motion carried.

Ms. McDaniel made the motion to approve the request from **VUMC Green Hills Medicine Pharmacy, Nashville, TN** to grant a 180 day waiver being on October 9, 2014 to become compliant with UPS 797. Dr. Bunch seconded the motion. The motion carried.

Ms. McDaniel made the motion to approve the request from **Delta Medical Center, Memphis, TN** to grant a 180 day waiver being on October 9, 2014 to become compliant with UPS 797. Dr. Bunch seconded the motion. The motion carried.

Ms. McDaniel made the motion to approve the request from **Cumberland Vital Care, Crossville, TN** to grant a 180 day waiver being on October 9, 2014 to become compliant with UPS 797. Dr. Bunch seconded the motion. The motion carried.

Ms. McDaniel made the motion to approve the request from **VICC Cool Springs Pharmacy, Franklin, TN** to grant a 180 day waiver being on October 9, 2014 to become compliant with UPS 797. Dr. Bunch seconded the motion. The motion carried.

Ms. McDaniel made the motion to approve the request from **Vanderbilt Health Pharmacy, Nashville, TN** to grant a 180 day waiver being on October 9, 2014 to become compliant with UPS 797. Dr. Bunch seconded the motion. The motion carried

Dr. Eidson made the motion to adjourn at 4:45 p.m. Dr. Bunch seconded the motion. The motion carried.

July 31, 2014

The Tennessee Board of Pharmacy reconvened on Thursday, July 30, 2014 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members were present, the meeting was called to order at 8:08 a.m., by Dr. Kizer, president.

Minutes

Dr. Eidson made the motion to approve the minutes from the May 28-29, 2014 board meeting as amended. Dr. Smothers seconded the motion. The motion carried.

Appearance

Jeff Ockerman, Director of Health Planning for the Department of Health, spoke to the board about the development and implementation of the state health plan.

Phoenix Long Term Care Medication Carts

Mark Steiz, representative of Phoenix, LTC reappeared before the board concerning the use of automated e-med box as a 1st dose machine. Mr. Steiz appeared at the May 28-29, 2014 board meeting but the board deferred his request until this meeting with the hopes that the long term care rules would be discussed. The long term care rules are not complete at this time. Dr. Stephens stated that the current rules state that the machine must be licensed as a pharmacy and restocked by a pharmacist or a registered pharmacy technician under the supervision of a pharmacist. Mr. Steiz stated that the machine can be used as an emergency kit. After discussion, Dr. Stephens made the motion to approve the stat-safe machine to be used in Tennessee as an E-Kit or an automated dispensing machine depending on the policy and procedures of the purchaser. Dr. Bunch seconded the motion. The motion carried. Dr. Eidson made the motion that a pharmacist and/or a registered pharmacy technician under direct supervision of a pharmacist stock the machine. Dr. Smothers seconded the motion. The motion carried.

Application Review

Brittney McKinnie, RT

Ms. McKinnie answered yes to the question that asked “have you ever been charged or convicted (including a nolo contendere plea or guilty plea) of a felony or misdemeanor (other than minor

traffic offenses) whether or not sentence was imposed, suspended, expunged, or whether you were pardoned from such offense? Documentation submitted shows that Ms. McKinnie pled guilty to domestic assault on July 8, 2009 and was given judicial diversion. On December 12, 2012, Ms. McKinnie was found guilty of theft and sentence to 11 months and 29 days unsupervised probation and 48 hours in jail. After discussion, Ms. McDaniel made the motion to approve Ms. McKinnie's application for registration as a pharmacy technician. Dr. Stephens seconded the motion. The motion carried.

Appearance

Asteres Prescription Pick-Up

Sandra Vredevelde, pharmacist in charge for Memorial Hospital, reappeared before the board to ask for approval of the Asteres Prescription Pick-Up kiosk. The kiosk will be set up at Memorial Health Care System in Hixson, TN for employees to use to pick up their prescriptions. Dr. Vredevelde informed the board that Asteres has developed a two-way camera that will allow face to face counseling and it allow the pharmacist to verify the identification needed to pick up controlled substances. After discussion, Dr. Smothers made the motion to approve this business model. Ms. McDaniel seconded the motion. Dr. Eidson amended the motion to state that the approval of this business model is only for the Hixson, TN location. Ms. McDaniel seconded the amended motion. The motion carried. The original motion carried as amended.

Ohio Pharmacy Counseling Services

Donald Orleck, Jr., appeared before the board for direction concerning his company's MTM call center located in Ohio. Mr. Orleck would like to process and manage. The board explained to Mr. Orleck that all the pharmacists and the facility must be licensed in Tennessee plus the pharmacist in charge.

Chronic Pain Guidelines

Dr. Mitchell Mutter, Director of Special Projects for the Department of Health, presented the final draft of the chronic pain guidelines to the board. Dr. Mutter stated that the Department of Health will develop a website for education. After discussion, Dr. Eidson made the motion to adopt the chronic pain guidelines as policy. Ms. McDaniel seconded the motion. The motion carried.

McFarland Pharmacy and Apothecary Board rule 1140-02-.02(7)

Jonathan Darnell, D.Ph., pharmacist in charge of McFarland Pharmacy and Apothecary appeared before the board to request an increase of the pharmacy to tech ratio from 4:1 to 5:1. After discussion, Dr. Stephens made the motion to increase the pharmacist to tech ratio at McFarland Pharmacy and Apothecary to 5:1. Ms. McDaniel seconded the motion. The motion carried.

OGC Report

Mr. Cange informed the board that the compounding rules have been filed with the Secretary of State's office and will become effective on October 9, 2014. Mr. Cange also presented the collaborative practice rules and asked the board to appoint a member or two to form a committee with member(s) from the Medical and Osteopathic boards as the Collaborative Practice Act requires that the rules be promulgated "in collaboration with" these boards. After discussion, Ms. McDaniel nominated Dr. Eidson to work on the Collaborative Practice Act committee. Dr. Bunch seconded the motion. The motion carried.

Mr. Cange informed the board that according to Public Chapter 932 that they are to consider setting a fee for reports issued by the Controlled Substance Monitoring Database to law enforcement. After discussion, Dr. Bunch made the motion to allow the executive director to approve the fee for the reports to law enforcement. Dr. Dickenson seconded the motion. The motion carried.

Application Review

Zachary Allan Storer, D.Ph.

Dr. Storer answered yes to the question that asked "Have you ever voluntarily surrendered your pharmacist license or any pharmacist registration issued by a federal or state controlled substance authority? And "Are you presently or have you within the past five years ever participated in a chemical substance rehabilitation program?" In the documentation submitted, Dr. Storer pled guilty to DUI September 2005, May 2009 and August 2010. He stated that voluntarily surrendered his KY pharmacist license and entered a 5 year contract with Kentucky Professional Recovery Network. After discussion, Ms. McDaniel made the motion requesting the Dr. Storer appear before the board at the next scheduled meeting. Dr. Smothers seconded the motion. The motion carried.

Consent Orders

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

VIOLATED BOARD RULE 1140-9-01(2)
Specialized Medical Services-\$400.00 civil penalty

VIOLATED BOARD RULE 1140-2-.02(1) & (2)
Preston E. Cates, D.Ph.-\$3700.00 civil penalty
Wesley Cowan, D.Ph.-\$500.00 civil penalty
Pa M. Jatta, D.Ph.-\$200.00 civil penalty

PROBATION

Susan S. Brooks, D.Ph.

Tennessee Board of Pharmacy
Board Meeting
July 30-31, 2014

VIOLATED BOARD RULE 1140-03-.11

Oakley Pharmacy, Inc. dba Dale Hollow Health Mart-\$260.00 civil penalty

VOLUNTARY SURRENDER (REVOCATION)

Kimberly Hawkins, D.Ph.

ORDER MODIFICATION

Kevin Lyles, D.Ph.

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

Janice Ruth Gentry, RT-\$100.00 civil penalty

Glenda Stepp, RT-\$100.00 civil penalty

REVOCATION

Crystal Marie Hunt, RT

VIOLATED BOARD RULE 1140-9-.01(1)

Phoenix Meds, Inc.-\$1200.00 civil penalty

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

Zachary Medley, D.Ph.-\$1000.00 civil penalty

VIOLATED BOARD RULE 1140-03.03(6) (a)

Dwight A. Disney, D.Ph.-10 hours of continuing education within six (6) months

REINSTATEMENT

Sean Harrison

Mr. Cange presented to the board the consent order for Gallatin Welding Supply. Gallatin Welding Supply is charged with violated board rule 1140-9-01(2). Gallatin Welding Supply is asking the board to accept the consent order with a negotiated civil penalty of \$15,300.00. After discussion, Dr. Smothers made the motion to accept the consent order with the civil penalty of \$15,300.00. Dr. Bunch seconded the motion. The motion carried.

Dr. Eidson made the motion to adjourn at 12:00p.m. Ms. McDaniel seconded the motion. The motion carried.

These minutes were approved and ratified as amended at the September 10-11, 2014 board meeting.