TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Iris Room
Nashville, TN
November 16-17, 2015

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

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

STAFF ABSENT
Scott Denaburg, Pharmacy Investigator

The Tennessee Board of Pharmacy convened on Monday, November 16, 2015, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:00 a.m.

Dr. Dilliard introduced Dr. Rissa Pryse, pharmacist, as the new board member.

Minutes

The minutes from the September 1-2, 2015 board meeting were presented. After discussion, Dr. Bunch made the motion to accept the minutes as presented. Dr. Wilson seconded the motion. The motion carried.

OGC Report

Mr. Cange informed the board that there are 40 cases in the Office of General Counsel and 9 are scheduled for hearing. Mr. Cange also reminded the board of the rulemaking hearing scheduled for December 18, 2015.

Complaint Summary

1.

Complainant pharmacy owner alleged Respondent technician stole various OTC products and approximately $2,100 in cash from the pharmacy.

Board investigator obtained the following evidence:

- A copy of the video disc from when the Respondent was on-duty.
- A chronological log of incidents recorded on the video showing 9 times where products were taken without paying along with multiple entries into the store money safe.
- A copy of money ledgers used to calculate the amount of cash missing.
- A copy of the police report.
- A copy of the arrest warrant.
- A sworn statement from the pharmacist-owner.

According to the police report, Respondent is a pre-pharmacy student.

Prior Discipline: None

Recommendation: Revoke.

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

2.

Complainant physician alleged Respondent pharmacy incorrectly dispensed Hydroxyzine 25mg instead of the prescribed Hydrochlorothiazide 25mg on 12/17/14 and refilled the incorrect medication each month until the error was discovered by the patient's spouse on 6/22/15.

Board investigator obtained dispensing logs and sworn statements from both the PIC and the dispensing pharmacist. The misfill was confirmed however neither pharmacist could specifically remember details of the original filling date. Board investigator feels it is reasonable to conclude that proper counseling could not have occurred since the drugs are not related and are not used for the same indications. Respondent pharmacy has since installed new software that the PIC believes will help prevent this type error. PIC stated that there was no harm to the patient and that the error was documented in the pharmacy's Quality Assurance Incident Report.

Prior Discipline: None

Recommendation: $1,000 civil penalty to Respondent pharmacy for failure to counsel

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

3.

Prior Discipline: None

Recommendation: LOI to PIC for failure to counsel and misfill

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

4.

Prior Discipline: None

Recommendation: $1,000 civil penalty to dispensing pharmacist for failure to counsel, LOW for misfill

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

5.

During a routine inspection, Board investigator questioned a tech affidavit with no corresponding wall certificate. Pharmacist on duty stated the tech had been arrested for prescription fraud. Board investigator contacted a Drug Task Force agent who supplied copies of police reports, a copy of the report prepared by Drug Task Force agent, a copy of the bench warrant, and a signed admission statement from the Respondent.

Board investigator compiled the following timeline:

- January 2012, Respondent had back injuries and was prescribed Lortab.

- End of 2013, Respondent realized hydrocodone addiction.

- February, 2014, Respondent ran out of medication and became desperate.

- March 7, 2014, April 14, 2014, May 1, 2014, June 19, 2014, Respondent called in hydrocodone prescriptions using spouse and child's names and using the physician's name where the Respondent was employed.

- June 20, 2014, Respondent was terminated by employer for calling in fraudulent prescriptions.

- November, 19, 2014, Respondent and spouse met with DTF agent and confessed as well as provided a signed written admission statement. The material was compiled to be presented to Grand Jury at a later date.

- March 3, 2015, Respondent was hired as a pharmacy technician.

- May 19, 2015, Respondent's pharmacy tech registration was issued by Board.

- July 17, 2015, Capias Bench Warrant issued for Respondent.

- August 6, 2015, Respondent was arrested for 9 counts of obtaining controlled substances by fraud.

Prior Discipline: None

Recommendation: Revoke.

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

6.

Complainant patient alleged unprofessional conduct by Respondent pharmacist when Respondent refused to fill patient's pain medication. Patient also alleged the Respondent called her a drug addict and then made derogatory remarks for other pharmacists to see causing her to have difficulty getting the medication filled even though other pharmacies supposedly considered her a "regular, trustworthy patient."

Board investigator obtained a sworn statement from the Respondent. Respondent denied ever calling the patient any names, denied making any derogatory remarks about the patient and denied being unprofessional. Respondent did admit that the patient's prescription was refused because of the pharmacy's "good faith" checklist. The prescriber for the patient was an out of state physician with whom the pharmacist was not familiar. The prescription was for methadone and there was no diagnosis or supporting documentation. Respondent stated that the patient's other pharmacy was called but also did not have a diagnosis or supporting documentation. Respondent used professional judgment and refused to fill the patient's prescription.

Prior Discipline: None

Recommendation: Dismiss.

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

7.

Complainant prescriber's office alleged unauthorized quantities and refills were provided by Respondent pharmacy. Complainant alleged 120 tablets were dispensed even though the prescription was written for 45 plus a number of refills and alleged that the pharmacy refilled the prescription even after the prescriber was no longer employed at that particular clinic.

Board investigator visited the pharmacy and obtained documentation regarding the prescription and the processes used for prescriptions. Education was provided to the pharmacist on dispensing quantities and contacting the prescriber for quantity changes. The total quantity dispensed did not exceed the quantity authorized including refills.

Prior Discipline: None

Recommendation: LOW to Pharmacy and to PIC (PIC listed in companion case 8 below)

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

8.

PIC to companion case 7 above.

Prior Discipline: None

Recommendation: LOW

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

9.

Complainant alleged Respondent pharmacy and the clinic generating prescriptions were forcing patients to patronize the Respondent pharmacy against patients' wishes. Complainant also alleged that Respondent pharmacy refused to transfer prescriptions and was participating with a prescriber to compound a "secret formula" pain cream.

Board investigator interviewed Respondent pharmacist and conducted a thorough inspection of the Respondent pharmacy. Respondent pharmacist claimed to have no knowledge of patients being forced to use the Respondent pharmacy. Pharmacist did admit that the clinic's policy was to e-scribe prescriptions to the Respondent pharmacy but patients had the option of filling there or having them transferred. Investigator educated pharmacist on e-Rx requirements if a prescription is not filled and investigator recommended ceasing the procedure of automatically e-scribing all prescriptions to the Respondent pharmacy. Pharmacist did admit to refusing to divulge the ingredients of a secret formula compound, stating that the prescriber is attempting to obtain a patent and threatened civil action if the pharmacist

gave any other pharmacy the recipe. Pharmacist denied refusing to transfer any other prescriptions except the secret formula. Pharmacist was educated by investigator for the requirements of 1140-2-.01 (9) and 1140-3-.03 (7) (b). Upon a second visit by investigator, Respondent pharmacist stated that the adjoining prescribers' office had been educated not to recommend Respondent pharmacy over any other and had stopped automatically e-scribing all prescriptions to the pharmacy.

Prior Discipline: None

Recommendation: LOW to Pharmacy and to PIC (PIC listed in companion case 10 below)

Dr. Eidson made the motion to issue a **Letter of Warning** to the Pharmacy and to refer this complaint to the Board of Medical Examiners. Dr. Wilson seconded the motion. The motion carried.

10.

PIC to companion case 9 above.

Prior Discipline: None

Recommendation: LOW

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

11.

Complainant (parent of patient) alleged Respondent pharmacist misfilled a 17 year old child's prescription for Solodyn with the beta-blocker Sotalol and that the same pharmacist refilled the prescription approximately a month later. Complaint states that while attempting the third filling of the prescription, another pharmacist questioned the prescription and discovered the error. Patient allegedly suffered extreme fatigue, dizziness, and headaches during the time period while taking the wrong medication.

Board investigators interviewed Respondent pharmacist. The misfill was confirmed. Respondent had no explanation why a proper DUR and/or proper counseling would not have revealed this error. Respondent could not remember whether counseling occurred. Respondent stated that he did not notice the prescription was written by a dermatologist and also admitted not questioning why this patient would be on beta-blocker therapy. Investigators acquired a copy of the prescription. It was an electronic prescription for Solodyn 80mg 24 hr Tab with DAW 1-No substitution/Brand Medically Necessary printed on the prescription. It also had ICD9 Diagnosis "706.1 Sebaceous Gland Disease-Acne Not Elsewhere Classified."

Prior Discipline: None

Recommendation: $1,000 civil penalty to dispensing pharmacist for failure to counsel, LOW for misfill and improper DUR

Dr. Wilson made the motion to **authorize a formal hearing** with a $1000.00 civil penalty to the dispensing pharmacist for failure to counsel, issue a Letter of Warning for the misfil and improper DUR. Dr. Dickenson seconded the motion. The motion carried.

12.

Pharmacy for Case 11 above.

Prior Discipline: None

Recommendation: $1,000 civil penalty to Respondent pharmacy for failure to counsel, LOI to PIC

Dr. Wilson made the motion to **authorize a formal hearing** with a $1000.00 civil penalty to the pharmacy and a Letter of Instruction to the PIC. Dr. Dickenson seconded the motion. The motion carried.

13.

Pharmacy self-reported a misfill which resulted in a lawsuit. Respondent pharmacist misfilled a prescription for Oxcarbazepine 300mg with Oxcarbazepine 600mg. The patient name, drug name, directions and prescriber were all correct. Only the strength was incorrect. Pharmacy has a strict counseling policy and Respondent pharmacist feels certain that counseling was provided. However, in this case, counseling may not have discovered the error and the prescription was dispensed with the wrong strength.

Prior Discipline: None

Recommendation: LOW to dispensing pharmacist

Dr. Bunch made the motion to issue a **Letter of Warning** to the dispensing pharmacist for the misfil. Dr. Dickenson seconded the motion. The motion carried.

14.

Complainant alleged Respondent pharmacy fills controlled substance prescriptions early.

Board investigator interviewed staff, reviewed prescription records, CSMD records and patient profiles. Investigator noted the following:

12 patients were reviewed for early refills. Only 1 patient had early fills (9 days early in March and 2 days early in April.) Staff was educated on documenting early fill decisions.

12 CSMD reports were compared to patient printouts. 8 CSMD reports were found to have missing information in June, July and August.

Pharmacy filled 4,812 prescriptions in August. 532 were for C2. (11%).

532 C2 prescriptions were reviewed with the following findings:

- 1 prescription was not signed by the prescriber but filled anyway
- 7 prescriptions were assigned incorrect days' supply
- 10 had incorrect prescriber names
- 2 had incorrect directions

Pharmacy had maps in numerous places throughout the pharmacy with a geographical radius of areas saying "ok to fill" and if a patient was from outside the radius it would be the pharmacist's decision. Investigator noted prescriptions by prescribers and for patients from outside the designated areas, but there was no documentation of why the decision was made to fill those prescriptions.

Pharmacist on duty did not have access to CSMD.

Prior Discipline: Respondent pharmacy paid a $260.00 civil penalty for expired medication in 2014. There is pending discipline against Respondent pharmacy.

Recommendation: Reprimand for early refills and CSMD access.

Dr. Eidson made the motion to issue a **Letter of Reprimand** for early refills and not having access CSMD access. The pharmacy is required to submit monthly reports, grant access to the CSMD and document the reason for early refills. Dr. Dickenson seconded the motion. The motion carried.

15.

Complainant patient alleged unprofessional conduct because Respondent pharmacist overstepped his scope of practice causing the patient additional time, energy, gas and annoyance. According to the complaint, the patient had been transported to the E.R. by ambulance and discharged with 4 prescriptions: Prednisone, Carisoprodol, Celebrex, and Hydrocodone. Patient recently moved to Tennessee from another state and told the pharmacist that he only wanted Carisoprodol and Hydrocodone filled because he was not familiar with the other 2 drugs. According to the complaint, the patient felt he was treated as though he was a drug seeking patient because the Respondent pharmacist declined to fill just those 2 medications. Patient stated the pharmacist "simply passed judgment" and believes it is not up to the pharmacist to "practice medicine." Prescription was returned to the patient and patient was able to get the 2 medications filled at another area pharmacy.

Board investigators interviewed the Respondent pharmacist. Respondent stated he used his professional judgment and decided not to fill just the controlled substances since the patient was not known to him and that the patient became argumentative during their discussion. Investigators were satisfied that the

pharmacy and pharmacists are practicing pharmacy and using their professional judgment in making decisions whether to fill prescriptions.

Prior Discipline: None

Recommendation: Dismiss.

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

16.

Board investigator discovered an expired technician registration during a routine inspection on 10/5/15. Registration had expired 8/31/15 and was renewed during the inspection.

Prior Discipline: None

Recommendation: $100 civil penalty to tech. civil penalty of $200 to PIC listed below.

Dr. Eidson made the motion to **authorize a formal hearing** with a $100 civil penalty to the technician for working on an expired registration and a $200.00 civil penalty to the PIC for allowing the technician to work on an expired registration. Ms. McDaniel seconded the motion. The motion carried.

17.

While waiting to be acknowledged for a routine inspection, Board investigators observed at least 5 patients receiving prescriptions without even an offer to counsel. Respondent pharmacist was 1 of 2 on duty behind the counter at that time. Pharmacist was educated on requirements and informed techs and cashiers. Improvement was observed during the inspection.

Prior Discipline: None

Recommendation: $5,000 civil penalty to Respondent pharmacist for failure to counsel reduced to $1,000 with an acceptable plan of correction.

Dr. Eidson made the motion to **authorize a formal hearing** with a $5000.00 civil penalty to the pharmacist for failure to counsel reduced to $1000.00 with an acceptable plan of correction. Dr. Wilson seconded the motion. The motion carried.

18.

While waiting to be acknowledged for a routine inspection, Board investigators observed at least 5 patients receiving prescriptions without even an offer to counsel. Respondent pharmacist was 1 of 2 on duty behind the counter at that time. Pharmacist was educated on requirements and informed techs and cashiers. Improvement was observed during the inspection.

Prior Discipline: None

Recommendation: $5,000 civil penalty to Respondent pharmacist for failure to counsel reduced to $1,000 with an acceptable plan of correction.

Dr. Eidson made the motion to **authorize a formal hearing** with a $5000.00 civil penalty to the pharmacist for failure to counsel reduced to $1000.00 with an acceptable plan of correction. Dr. Wilson seconded the motion. The motion carried.

19.

While waiting to be acknowledged for a routine inspection, Board investigators observed at least 5 patients receiving prescriptions without even an offer to counsel. During the routine inspection, Board investigators discovered a technician with an expired registration. Technician registry and affidavits were not complete. Investigators found patient medications in the pharmacy that had been dispensed from other pharmacies. Some of these medications were in plastic bags with no labeling except the drug name hand-written on the freezer bag. 2 bags of pills were found that had whole tablets and half-tablets mixed in the same bag. One bottle of medication was in a stock bottle that showed an expiration date of several months prior to the day of the inspection. The pharmacist on duty explained that the pharmacy receives those medications mainly from assisted living facilities and those medications are repackaged and re-labeled, then returned to the facility. Investigators educated the pharmacist about this practice and the pharmacist agreed to notify the PIC that this must stop.

Prior Discipline: LOW in 2014 for failing to change prefilters on laminar flow hood quarterly and for failing to document such changes.

Recommendation: $5,000 civil penalty to Respondent pharmacy for failure to counsel, reduced to $1,000 with an acceptable plan of correction, Reprimand for receiving and repackaging previously dispensed medications, and for improperly labeled drugs.

Dr. Wilson made the motion to **authorize a formal hearing** with a $5000.00 civil penalty reduced to $1000.00 with an acceptable plan of correction for failure to counsel and a Letter of Reprimand with 90 day probation for receiving and repackaging previously dispensed medication and improperly labeled drugs. Ms. McDaniel seconded the motion. The motion carried.

20.

PIC of Respondent pharmacy above.

Prior Discipline: None.

Recommendation: $200 CP for expired tech (2 months); LOI for tech registry and affidavits and counseling violations by staff pharmacists; Reprimand for receiving and repackaging previously dispensed medications and for improperly labeled drugs.

Dr. Wilson made the motion to **authorize a formal hearing** with a $5000.00 civil penalty reduced to $1000.00 with an acceptable plan of correction for failure to counsel and a Letter of Reprimand with 90 day probation for receiving and repackaging previously dispensed medication and improperly labeled drugs. Ms. McDaniel seconded the motion. The motion carried.

21.

Complainant patient alleged Respondent pharmacist is practicing medicine without a license and violated the Americans with Disability Act by refusing to dispense a Suboxone partial-fill one day early. Patient paid for a 5 day supply on July 30, and returned on August 3. According to the complaint, the pharmacist refused to dispense the remainder and insisted that she would lose her license if she filled the prescription early. Patient admits reacting and confronting the pharmacist "in a way that, looking back, is truly embarrassing," and "did use rude and vulgar language," but claims it was due to months of consistent provocation and "was merely consequent to the pharmacist's malevolence."

Board investigator interviewed pharmacy staff that recalled the incident on August 3rd. Investigator discovered the Respondent pharmacist was not the pharmacist on duty on the day of the incident. Respondent pharmacist is the PIC. Dispensing pharmacist provided investigator with a sworn statement that professional judgment was used by deciding not to give another partial fill until the day the patient would run out. Pharmacist suggested that since someone else (not the patient) had picked up the original 5 day supply, that person could come the next day and pick up another supply. Pharmacist also offered to transfer the prescription to a store that would be open earlier the next day so the patient could get the medication before going to work. Pharmacist stated she respectfully apologized to the patient but told her there was nothing else she could do. According to the pharmacist, that is when the patient became rude and stayed at the pharmacy staring at the pharmacist, making the pharmacist nervous and uncomfortable. The store manager witnessed the whole interaction and provided a sworn statement to Board investigator. The store manager asked the patient to leave and the patient started yelling obscenities and making derogatory remarks about the pharmacist. Store manager tried to calm the patient but had to threaten to call the police to get the patient to leave because of the loud and vulgar language. Store manager filled out a Trespass Notice to prevent the patient from coming back to that pharmacy. Patient's prescription was transferred to a different pharmacy.

Board investigator reviewed dispensing records and noted that refills are held to the exact day for everyone.

Prior Discipline: None

Recommendation: Dismiss.

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

22.

Complainant patient claims discrimination and unprofessional conduct by Respondent pharmacist for refusing to fill Suboxone. Patient claims the pharmacist said prescriptions from outside the pharmacy's area could not be filled and that the pharmacist would not fill for prescribers that the pharmacist did not know. Complaint states that a pharmacist's job duty is to "Fill Prescriptions" and alleges that any reason for not filling patient's prescriptions may be discriminatory. Patient admits that her fiancé tried to intervene and used vulgar language at the pharmacy so the pharmacy banned her from that store. Patient claims the unprofessional treatment worsened her medical condition to the point of considering suicide and relocating to another area.

Board investigator obtained sworn statements from Respondent pharmacist and other staff members familiar with the incident. Although the pharmacist was attempting to exercise caution and use professional judgment, confusion and poor communication ensued. Respondent pharmacist informed the patient that the Suboxone prescription was from a prescriber in another city and the pharmacist would need to contact the prescriber before deciding whether to fill the prescription and the patient seemed fine with that. However, Respondent went on vacation and had left a note to call the prescriber but Board investigator noted that there was no evidence that anyone from the pharmacy ever tried to contact the prescriber. When the patient's fiancé returned to pick up the prescription a few days later, the pharmacist on duty did not know why the Suboxone was not filled and when the fiancé started yelling and using vulgar language, the pharmacist asked him to leave.

Board investigator contacted complainant who reported having no problem obtaining her medication closer to the prescriber's office.

Prior Discipline: None

Recommendation: Dismiss.

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

23.

Complainant PIC notified Board of tech termination on 9/1/15 due to theft of medications (no controlled substances) without payment and without a prescription. Board investigator interviewed PIC but could not contact Respondent.

Prior Discipline: None

Recommendation: Revoke.

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

24.

Patient's daughter filed complaint alleging unprofessional conduct by 3 locations of Respondent pharmacy. Complainant stated in the complaint that the patient obtained a new prescription for 10 tablets of Hydrocodone to fill a gap because the regular prescription was not due for 5 more days. Pharmacist at the first location initially refused to fill the prescription early but finally agreed to fill it after speaking with the prescriber. Complainant alleged that the regular prescription was filled and ready to pick up 4 days later at location one but that location was closed due to weather so location two was contacted, but told complainant that the prescription could not be transferred without the hard copy. The next day, complainant drove back to location one but it was closed at 11am due to a power outage. Complainant called location three about transferring the prescription that was filled and ready at location one. Location three gave the same answer that they must have the hard copy. Complainant stated that the pharmacist recommended taking the patient to an after-hours clinic to obtain a new prescription but location one later opened and the prescription was obtained.

Board investigator interviewed staff at all three locations. No one could recall the incident but location one staff and supervisor did recall a power outage that caused the pharmacy to be closed for a brief time. Although the patient was inconvenienced, investigator did not determine any violations.

Prior Discipline: None

Recommendation: Dismiss.

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

25.

During a routine inspection, Board investigator discovered a tech on duty without being registered. Upon questioning, the tech had obtained PTCB certification 9/29/12 and was allowed to work as a tech at 2 pharmacy locations which are both under common ownership. Neither PIC was aware that the tech was not registered. Tech worked 10 months at this Respondent pharmacy.

Prior Discipline: None

Recommendation: $100 per month to PIC.

Dr. Eidson made the motion to **authorize a formal hearing** with a civil penalty of $100.00 per month for a total of $1000.00 to the PIC for allowing a technician to work unregistered for ten (10) months. Ms. McDaniel seconded the motion. The motion carried.

26.

PIC for case 25 above.

Prior Discipline: None

Recommendation: $100 per month to PIC.

Dr. Eidson made the motion to **authorize a formal hearing** with a civil penalty of $100.00 per month for a total of $1000.00 to the PIC for allowing a technician to work unregistered for ten (10) months. Ms. McDaniel seconded the motion. The motion carried.

27.

Respondent pharmacy, second location. During a routine inspection, Board investigator discovered a tech on duty without being registered. Upon questioning, the tech had obtained PTCB certification 9/29/12 and was allowed to work as a tech at 2 pharmacy locations which are both under common ownership. Neither PIC was aware that the tech was not registered. Tech worked 22 months at this Respondent pharmacy.

Prior Discipline: None

Recommendation: $100 per month to PIC.

Dr. Eidson made the motion to **authorize a formal hearing** with a civil penalty of $100.00 per month for a total of $2200.00 to the PIC for allowing a technician to work unregistered for 22 months. Ms. McDaniel seconded the motion. The motion carried.

28.

PIC for case 27 above.

Prior Discipline: None

Recommendation: $100 per month to PIC.

Dr. Eidson made the motion to **authorize a formal hearing** with a civil penalty of $100.00 per month for a total of $2200.00 to the PIC for allowing a technician to work unregistered for 22 months. Ms. McDaniel seconded the motion. The motion carried

29.

Board received information that Respondent pharmacist had been terminated for diversion of controlled substances. Board investigator obtained a sworn statement and admission statement, as well as a copy of the police report. Respondent admitted to stealing controlled substances and also to giving birth to an

NAS baby. Respondent admitted taking 80 to 90 Oxycodone 30mg, about 10 Oxycodone 10mg, 10 to 20 Oxycodone 15mg, approximately 5 Oxycodone/APAP 10. Respondent's written statement also admits these quantities are approximate based upon the Respondent's ability to remember. Police report indicates that Respondent admitted addiction to police interviewer and those drugs, including buprenorphine were also obtained illegally on the street.

Prior Discipline: None

Recommendation: Revoke.

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

30.

Board investigator received information regarding possible violations occurring at Respondent pharmacy. Investigators conducted a thorough inspection of Respondent pharmacy and found the following information and violations:

Incomplete invoices; incomplete or missing C222 forms; numerous C2 drugs had been transferred without sending C222 forms to DEA; transfers of controlled substances documented only by a list of drugs; violation of 5% rule; extremely dirty/dusty shelves; dirty pharmacy; tomatoes in the pharmacy sink; PIC unable to log into CSMD and admitted rarely checking it; technicians without affidavits; no tech registry; a tech without proof of registration (same tech and PIC had been warned previously); verbal orders not initialed; one C2 prescription had been faxed but did not have a signed copy; a total of 71 expired or improperly labeled products were on the pharmacy shelves; pharmacy keeps C2 perpetual inventory but it was not correct; several example prescriptions were pulled to question PIC regarding very different looking signatures but the same prescriber was entered; techs and/or clerks ask patients if they have questions, but counseling is only done when patients answer yes; early refill policy of 2 days; staff admitted wholesalers had cut them off in the past; staff admitted to never refusing to fill a prescription unless it was extremely early; staff admitted filling for cash if it was too early for insurance; staff admitted heavy volume was partly due to accepting patients that had "worn out their welcome elsewhere"; staff admitted filling out of state prescriptions without question.

An audit of 10 controlled substances was conducted but results were inconclusive—4 drugs had shortages, 2 drugs had overages, and 4 drugs balanced.

Prior Discipline: None

Recommendation: 90 days of probation, Reprimand, and a civil penalty of $10 per expired product (total of $710).

Dr. Wilson made the motion to issue a **Letter of Reprimand**, authorize a formal hearing with probation for 90 days and a $10.00 civil penalty for each expired product for a total of $710.00. Dr. Bunch seconded the motion. The motion carried.

31.

PIC for case 30 above.

Prior Discipline: None

Recommendation: 1 year of probation, cannot serve as PIC for a period of 3 years, must complete 15 additional hours of continuing education related to controlled substance dispensing and record-keeping and/or general pharmacy law and ethics.

Dr. Wilson made the motion to **authorize a formal hearing** with 1 year probation, cannot serve as PIC for a period of 3 years, must complete 15 additional hours of continuing education related to controlled substance dispensing and record-keeping and/or general pharmacy law and ethics. Dr. Bunch seconded the motion. The motion carried.

32.

Complaint findings from another HRB investigation were referred to Board. Records provided showed what appeared to be early fills on Amphetamines. Dextroamphetamine-Amphetamine ER 30mg, 30 days' supply appeared to have been dispensed on 8/26/13, and again on 8/28/13. Another prescription for Amphetamine salts 30mg tablets was dispensed on 8/28/13.

Board investigators visited the pharmacy and reviewed records. The combination product was only partially filled on 8/26 and the remainder was dispensed on 8/28. Patient has been on both types of medication for quite some time and there were no indications of filling early at the pharmacy.

Prior Discipline: None

Recommendation: Dismiss.

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

33.

Complainant PIC notified Board investigator of tech termination for diversion of controlled substances. Investigator obtained sworn statement from PIC stating that the tech did admit to theft of drugs. PIC also provided a chronological listing of events and missing quantities from internal investigation which had narrowed the list of potential suspects to just the Respondent tech. Investigator also interviewed the director of nursing and the police investigator that worked the case. A copy of the police report was obtained along with a video of the tech admitting theft and diversion to police.

Prior Discipline: None

Recommendation: Revoke.

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

34.

Complainant patient alleged the prescriber and the Respondent changed his medication without informing him and then refused to give a refund.

Board investigator obtained a sworn statement from PIC of Respondent pharmacy. PIC explained that the prescriber and the pharmacist informed the patient the order was changed so the patient's insurance would cover it. Patient continues to use Respondent pharmacy and continues to use the new medication. No violation found.

Prior Discipline: None

Recommendation: Dismiss.

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

35.

Complainant patient alleged unprofessional conduct by pharmacy refusing to fill pain medication unless patient would transfer all medication. Patient also alleged pharmacist wanted to speak to the prescriber and later the pharmacist became rude and disrespectful when the patient asked if the pharmacist had spoken to the prescriber yet.

Board investigator obtained a sworn statement from PIC of Respondent pharmacy. PIC explained that the prescription was for MS Contin and that the pharmacy's policy states in order to fill pain prescriptions, the patient must agree to have all medications filled at the pharmacy. PIC discovered the patient had a prescription for gabapentin but did not want it filled at Respondent pharmacy so the pain prescription was returned to the patient. No violation found.

Prior Discipline: None

Recommendation: Dismiss.

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

36.

Pharmacy management notified Board that Respondent pharmacist resigned and left the pharmacy before another pharmacist arrived. The pharmacy was not locked by deadbolt as required in policy but did have an electronic lock requiring a name badge or key fob. The technician that was left at the pharmacy reported to management that she was told by the departing pharmacist to finish ringing up patients waiting in line, then leave the department. Tech was able to access the pharmacy by using her name badge. Tech was reprimanded by management for entering the pharmacy and for completing transactions without the presence of a pharmacist.

Board investigator interviewed Respondent pharmacist who claimed the resignation involved a mandatory drug test which the pharmacist refused to take on that day and so the pharmacist called management and resigned. Respondent pharmacist claims to have secured the pharmacy and did not think the tech had access to the pharmacy. Pharmacist could not recall what he had done with the keys to the pharmacy.

Board investigator interviewed the technician involved. Tech stated the pharmacist refused drug screening because the test makes him too sick to work but that he stated he would take it the next day. Management would not allow that so the pharmacist resigned by telephone, told the tech to check out the waiting patients (estimated 5 or 6 patients) and that another pharmacist was en route to the pharmacy. Tech stated she thought Respondent pharmacist was at the front of the store and did not know he had left the building. Tech told investigator that Respondent pharmacist had previously given his badge access to a part time clerk and that the pharmacist used an actual key. Clerk allegedly kept the badge even when not working in the pharmacy. Clerk has now turned in the badge to store management.

Board investigator interviewed HR coordinator who confirmed that the Respondent pharmacist refused a drug screen, claiming it made him gag and he was too busy but that he would take it the next day. That was not acceptable to HR and the pharmacist resigned.

Board investigator noted there appears to be 2 separate key violations, a lack of security, a lack of oversight, an unsupervised tech with access to the pharmacy, dispensing without the presence of a pharmacist and potentially a lack of counseling. Circumstances also bring into question the judgment of the pharmacist's actions and the refusal for drug screening.

Prior Discipline: None

Recommendation: Reprimand to Respondent pharmacist, and civil penalty of $100 to Respondent pharmacist for key violation.

Dr. Wilson made the motion issue a **Letter of Reprimand** and to authorize a formal hearing with a $100.00 civil penalty to the pharmacist for the key violation. Dr. Bunch seconded the motion. The motion died. After further discussion, Dr. Eidson made the motion to authorize a formal hearing with a $100.00 civil penalty for the key violation and an evaluation by the Tennessee Pharmacy Recovery Network within 90 days. Dr. Dickenson seconded the motion. The motion carried.

37.

Respondent tech for case 36 above.

Prior Discipline: None

Recommendation: LOW.

Dr. Eidson made the motion to issue a **Letter of Warning** to the technician concerning the key violation. Dr. Dickenson seconded the motion. The motion carried.

38.

Respondent pharmacy for cases 36 and 37 above.

Prior Discipline: None

Recommendation: Dismiss.

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

39.

Complainant prescriber alleged pharmacy failed to correct CSMD entries even after multiple calls requesting they do so. Prescriber discovered pharmacy incorrectly entered the prescriber's name on a CS prescription and it was showing up in CSMD. Prescriber denied authorizing the prescription and spoke to the pharmacist at least 5 or 6 times over a several months period about correcting the information. Prescriber alleged the pharmacist responded that there was a computer glitch and nothing could be done about it.

Board investigator obtained a sworn statement from the Respondent pharmacist stating that corporate software required a "ticket" to make corrections and the pharmacist had sent a request several times. Pharmacist did provide investigator with copies of e-mailed requests to have the error fixed. Pharmacist received an e-mail approximately 9 months later stating the error had been fixed.

Board investigator spoke to CSMD staff who indicated the corporate office had been having problems submitting data for corrections.

Prior Discipline: None

Recommendation: LOW.

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

40.

Pharmacist for case 39 above did follow company P&P to request correction in CSMD, but did not follow up to verify the correction except when prodded to do so by the prescriber.

Prior Discipline: None

Recommendation: Dismiss.

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

41.

Complainant patient alleged a partial mis-fill. Patient was given 20 of 30 pills of Doxycycline 150mg due to the pharmacy running out of stock. Patient returned days later and was told the remaining 10 pills looked different but were the same thing. Both bottles were labeled Doxycycline. Patient then experienced being incredibly sleep, dizzy, light-headed, and very irritable. Patient discovered she had been given Doxepin instead of Doxycycline.

Board investigator obtained a sworn statement from the dispensing pharmacist who is also PIC. Respondent pharmacist admitted accidentally filling the remainder of the prescription with the wrong drug. Pharmacist stated counseling was performed on the initial prescription and did admit telling the patient that the remaining 10 pills given to the patient were the same drug but from a different manufacturer.

Prior Discipline: None

Recommendation: Dismiss as to pharmacy.

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

42.

This is PIC and dispensing pharmacist for case 41 above.

Prior Discipline: None

Recommendation: LOW.

Dr. Bunch made the motion to issue a **Letter of Warning**. Dr. Wilson seconded the motion. The motion carried.

43.

Complainant spouse of patient alleged unprofessional conduct by Respondent pharmacist telling the patient and spouse how to live their life so they had their prescriptions transferred. The patient's prescriber accidentally sent a new prescription for diabetic strips to the Respondent pharmacy. Complainant alleged the Respondent pharmacist would not fill the prescription and said he had thrown it away. Complainant alleged the patient did without the strips for 7 days even though his glucose should be checked every day.

Board investigator obtained a sworn statement from Respondent pharmacist stating that a new prescription had been received electronically. It was assumed it was an error since all other prescriptions for this patient had been transferred so the prescription was deleted. Respondent stated the patient's spouse was told to contact the prescriber and have the prescription sent to the other pharmacy.

Prior Discipline: None

Recommendation: Dismiss.

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

44.

Complaint generated from news article about pharmacist being arrested for diversion. Board investigator conducted an investigation and obtained documents and statements but Respondent pharmacist only admitted that she had hydrocodone prescribed by a physician and did reprint the label and paid for a prescription that was not authorized. Pharmacy audit revealed shortages not admitted to by the Respondent.

Drug shortages reported by pharmacy were:

- 875 Hydrocodone APAP 10-500
- 6,210 Hydrocodone APAP 10-325
- 30 Hydrocodone APAP 5-500
- 104 Hydrocodone APAP 7.5-325
- 92 Hydrocodone APAP 5-325
- 252 Hydrocodone BT- Ibuprofen

Criminal charges were filed and a long legal process concluded with a plea agreement for the following: payment of fine and costs; $9,000 restitution to former employer; 4 years sentence suspended to supervised probation; 11 months, 29 days sentence suspended to supervised probation; no drug possession or usage without valid prescription; random drug screens; and restrained from practice of pharmacy unless granted leave by court after petition.

Respondent agreed to plead guilty to: Theft over $1,000; forgery; simple possession of C3; simple possession of C4.

Convictions were not reported to Board as required in 1140-2-.01 (17).

Prior Discipline: None

Recommendation: Revoke.

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

45.

Complainant PIC notified Board and DEA of employee pilferage resulting in termination of Respondent technician.

Shortages reported by pharmacy on DEA 106:
12,756 Hydrocodone APAP 10-325
773 Hydrocodone APAP 7.5-325

Criminal charges were filed resulting in a court settlement. Respondent plead guilty to theft of property over $1,000 and received deferred prosecution with 4 years supervised probation. Respondent did report the conviction along with a letter asking to "please permanently revoke my Board of Pharmacy licenses."

Prior Discipline: None

Recommendation: Revoke.

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

46.

Complainant patient alleged pharmacy shorted 18 pills of Suboxone and had also made 3 other mistakes in the past 6 weeks. The other alleged mistakes included receiving someone else's Phenergan prescription, being shorted 50 diabetes test strips, and receiving 2 different kinds and colors of Cymbalta in the same bottle. According to the complaint, those three issues were resolved with no problem.

Board investigator obtained sworn statements and reviewed records. Statements indicate audited amounts for Suboxone balanced and also that 60 pills were on-hand to fill a prescription for 75 and the remaining 15 were dispensed the next day. Pharmacy policy is to double count all CS prescriptions. If quantities balance, no replacements are dispensed. Regarding the other alleged mistakes, there was no documentation that those incidents were reported to the corporate Quality Assurance program. Current

PIC was appointed May 1, 2015. Suboxone incident occurred May 19. The alleged previous mistakes would have occurred prior to the current PIC.

Prior Discipline: None

Recommendation: Dismiss.

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

47.

Dispensing pharmacist for Suboxone issue in case 46 above.

Prior Discipline: None

Recommendation: Dismiss.

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

48.

Complaint opened based upon news report of Respondent pharmacist being charged with animal cruelty. Although that case is on-going, the report mentioned 2 prior convictions for animal cruelty against this same Respondent. Board did not have any record of the prior convictions being reported as required in 1140-2-.01 (17).

Board investigator interviewed Respondent and obtained a sworn statement. Respondent claimed to believe that only felonies had to be reported and that both convictions were misdemeanors. Respondent stated that, in both instances, the problems resulting in charges were addressed, a guilty plea was entered, and court costs were paid. Respondent stated that from both a time and economic perspective, it seemed like the wise thing to do. Respondent admitted to his misunderstanding of reporting requirements and has since read the applicable rule.

Prior Discipline: None

Recommendation: Reprimand.

Dr. Wilson made the motion to issue a **Letter of Reprimand**. Ms. McDaniel seconded the motion. The motion carried. Dr. Dickenson voted no and Dr. Eidson abstained.

49.

Complainant pharmacy notified Board and DEA of tech termination due to diversion of Alprazolam. Supporting documentation and DEA 106 were sent to Board office. Internal investigation had narrowed suspicions to the Respondent tech and loss prevention experts reported seeing Respondent stealing Alprazolam from the pharmacy. DEA 106 form showed the following quantities missing:

- 11 Alprazolam 0.25mg
- 62 Alprazolam 0.5mg
- 32 Alprazolam 1mg
- 111 Alprazolam 2mg
- 108 Hydrocodone APAP 5-325mg

According to pharmacy documents, Respondent tech stopped coming to work May 30 so pharmacy attempted contact by phone and certified mail. Tech was terminated June 11 and was not present for the termination meeting.

Prior Discipline: None

Recommendation: Revoke.

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

50.

Patient alleged a 90 day supply of Synthroid shipped by Respondent pharmacy remained at high temperatures for an extended period. Package was left in black mailbox in direct sunlight on a 97 degree day. Patient was concerned that the efficacy of the medication was compromised due to incorrect storage and shipment method and tried to call the pharmacy twice. Patient provided package directions for controlled temperatures for storage and excursions.

Respondent is an out of state mail order pharmacy. Response indicated pharmacy staff did speak to patient and tried to address concerns even though Respondent felt that precautions used for shipping would have been more than sufficient to protect the drug. Response stated it stores medication according to manufacturer's recommendation and uses packaging with cold gel packs in a foam shipping container. Pharmacy reported it follows or exceeds manufacturer guidelines for shipping and excursions.

Prior Discipline: None

Recommendation: Dismiss.

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

51.

Complaint opened based upon notice from FDA of a voluntary recall by Respondent compounding pharmacy. The notice stated that FDA investigators and state inspectors observed significant deficiencies raising concerns about products distributed between 11/1/14 and 9/3/15 by Respondent. FDA also reported receiving several adverse events potentially associated with drug products from the Respondent.

Respondent is an out-of-state compounding pharmacy which closed its Tennessee license 6/3/15 due to a lack of Tennessee licensed PIC. Board investigator contacted Respondent pharmacy. Respondent provided records indicating that only 1 Tennessee resident received any product from this pharmacy during the recall period. It was a Tri-mix product dispensed 4/28/15 with a use-by date of 10/19/15. Patient did not respond to the recall letter sent by mail.

Prior Discipline: None

Recommendation: Close and flag.

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

52.

Board received court documents signed 9/8/15 indicating Respondent tech plead 'nolo contender' to forgery (TCA 39-14-114) stemming from a 2/12/13 arrest for altering prescriptions. Tech registration expired 4/30/13 and has not been renewed.

Prior Discipline: None

Recommendation: Close and flag.

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

53.

Complainant PIC provided a sworn statement that during an internal investigation, respondent tech was caught on video stealing Hydrocodone from the pharmacy robot. Board investigator obtained a copy of a voluntary statement in which Respondent technician admitted taking about 500 pills in March, then starting in May, taking 12 to 14 per day amounting to 2,100 pills from May until present. Respondent's statement lists the strengths as Hydrocodone 5, 7.5, 10, and Vicoprofen 7.5.

Prior Discipline: None

Recommendation: Revoke.

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

54.

Complainant PIC provided a sworn statement that during an internal investigation, respondent tech was caught on video stealing Hydrocodone and also admitted to stealing a few tablets on 2 occasions. Over 12,000 tablets were discovered missing. Board investigator obtained a copy of the respondent's voluntary statement, admitting to stealing by dropping some hydrocodone bottles from the top shelf into some boxes to be taken out as trash and also stealing some from a return to stock.

Prior Discipline: None

Recommendation: Revoke.

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

55.

Complainant patient alleged Respondent pharmacy forced her to get her prescription compound at Respondent pharmacy by telling her that her regular pharmacy could not compound it. Patient also alleged being told the price would be $15 but when she received the medication, Medicare had been billed $1,332.78, putting her in the coverage gap for the rest of the year. Patient feels the pharmacy was misleading about compounding the medication and feels that if she had been told the true cost of the medication, she would have refused to have it filled.

Board investigator visited the pharmacy, interviewed staff and reviewed records. Owner pharmacist denied that anyone would have told patient that another pharmacy could not compound a product but did admit that the patient made a reasonable assumption that she would be told the total cost of the prescription and not just the copay. Owner stated when staff brought the matter to his attention, the claim was reversed and the patient was allowed to keep the medication at no charge. Computer records were shown to investigator showing the claim reversal.

Prior Discipline: None

Recommendation: Dismiss.

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

56.

Anonymous complaint alleged illegal compounding and promoting Sildenafil for unapproved use. Complaint stated that pre-printed prescription pads are delivered to medical doctors by the pharmacy's

sales reps and that the prescriptions insinuate that it is identical to Viagra which is misleading and deceptive. Complainant also alleged that there is no justification for their claims of efficacy and that it is impossible to know what elements are included in the compound which could lead to allergic reactions.

Board investigators visited the pharmacy and interviewed staff. A copy of the above referenced prescription pad was reviewed with pharmacist owner. The RX is for Sildenafil 20mg, take 2 to 5 tablets as needed for sexual activity. The disclaimer at the bottom states the following:
"NOTE: This is the FDA approved generic of Revatio®20mg tablet. The FDA has not approved generic Viagra® even though the active ingredient is identical, just in a different strength."

Investigators reviewed a package insert for Sildenafil 20mg, stating, in part, "indicated for the treatment of pulmonary arterial hypertension."

Owner pharmacist denied compounding this product and stated to investigators that it is simply a matter of dispensing 20mg tablets for an "off-label" use.

Prior Discipline: None

Recommendation: Refer to FDA.

Dr. Dickenson made the motion to **dismiss**. The motion failed for lack of second. Ms. McDaniel made the motion to accept counsel's recommendation. Dr. Wilson seconded the motion. The motion carried.

57.

PIC for case 56 above.

Prior Discipline: None

Recommendation: Refer to FDA.

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

58.

Complaint opened after inspecting compounding pharmacy for USP 797 standards.

Board investigators had received information that pharmacy was performing sterile compounding prior to being inspected by Board. Tri-mix was specifically mentioned by the anonymous informant. Investigators had previously told Respondent pharmacy owner that no sterile compounding should be performed prior to a Board inspection. Respondent pharmacy received the Board sterile modifier but was not ready for inspection at that time. In the following weeks, owner notified Board of being ready to begin sterile compounding and 3 Board investigators arrived for inspection. The Tri-mix information was questioned and reports requested from the pharmacy indicated that 2 prescriptions had been

compounded and 1 of those had been dispensed to a patient. Also, a gentamycin sterile irrigation had been compounded and dispensed. A sterile eye drop had been compounded but reportedly was sent for lab analysis and not dispensed.
Board investigators identified the following concerns with sterility and aseptic techniques:

No GAP analysis had been completed.
No surface sampling had been performed.
No glove fingertip testing had been performed.
No trash can in anteroom.
No towels in anteroom.
Tacky mat in wrong location.
No line of demarcation.
Vials being used were not sterile, nor sterilized.
No autoclave.
Posted garbing procedure was in wrong order for proper garbing and gowning.
SOP stated many procedures that were not being performed and actually not applicable.
Certification company diagrams showed gauges in wrong locations.
Clean room was not clean and had string on floor and spillage on shelf.
Buffer room had not been cleaned from the day before.
Performing syringe to syringe mixing without verifying stability.
Temperature and humidity logs do not have locations noted.
Mixing beaker and stirring rod were in sink but staff could not determine what it had been used to mix.
Staff was not thoroughly familiar with USP 797 requirements or the reasons for them.

Board investigators asked that sterile compounding cease until all concerns were corrected and Board could re-inspect. Out of an abundance of caution, investigators also suggested recalling products that had already been dispensed. Pharmacist owner agreed to both suggestions and will notify Board when issues are corrected.

Prior Discipline: None

Recommendation: 90 days of probation, $1000 civil penalty.

Dr. Eidson made the motion to **authorize a formal hearing** to the pharmacy with suspension of the sterile compounding modifier, a $1000.00 civil penalty for not being in compliance with USP 797, the PIC will not be allowed to process sterile compounding products until the pharmacy is USP 797 compliant. The pharmacy must appear before the board to have the sterile compounding modifier reinstated. Dr. Wilson seconded the motion. The motion carried.

59.

PIC for case 58 above.

Prior Discipline: None

Recommendation: Reprimand, $1000 civil penalty.

Dr. Eidson made the motion to **authorize a formal hearing** with a $1000.00 civil penalty and not be allowed to process sterile compounding products until the pharmacy is USP 797 compliant. Dr. Wilson seconded the motion. The motion carried.

Consent Orders

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

VIOLATED BOARD RULE 1140-3-.01(1) (a) & (f)
Robert Fannon, D.Ph. $1000.00 civil penalty
Rick's Drug $1000.00 civil penalty

VOLUNTEER SURRENDER (Revocation)
Jeremy Jay Joiner, D.Ph.

REVOCATION
Kara Lea King, RT
Evelyn Haynes, RT
Robin Lea Hayes, RT
Jessica Turner, RT
Jessie Smith, RT
Elizabeth Mayes, RT

VIOLATED BOARD RULE 1140-01-.13(3) (g) (1)
Madison Pharmacy, Inc.-$100.00 civil penalty

REINSTATEMENT
Raquelle Woodard, D.Ph.
T. Patrick Rowan, D.Ph.
Nancy Kemp, D. Ph.
Jeremy Bowles, D.Ph.
Patrick Ailey, D. Ph.

PROBATION
Aaron Flinchum, D. Ph.
Mark's Pharmacy, Inc.

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

REVOCATION
Kayla Stedman
Larisa

Investigation Report

Dr. Grinder informed the board that the investigators have conducted 56 sterile compounding inspections, 277 pharmacy inspections, 171 manufacturer/wholesale/distributor inspections and 1 researcher inspections since September 2015. Dr. Grinder also informed the board that he has created a policy and procedure manual for the investigators.

Order Modification
Jeannie Garvey, RT

Ms. Garvey is appearing before the board to ask for an order modification of the agreed order approved by the board at the January 27-28, 2015 board meeting. The agreed order placed Ms. Garvey's pharmacy technician registration on probation for 5 years with monthly drug screens for 1 year then quarterly for the remaining 4 years and she is not allowed to work behind the counter in the pharmacy for 3 years from the start of her probation. After discussion, Ms. McDaniel made the motion to modify the original agreed order by placing Ms. Garvey's pharmacy technician registration on probation for 1 year with all the requirements listed in the original order to remain. Dr. Wilson seconded the motion. The motion carried.

Christy Newbaker, D.Ph.

Dr. Newbaker appeared before the board at the September 1-2, 2015 board meeting to request that the probation status on her pharmacist license to be lifted. Dr. Newbaker's pharmacist license was placed on a 2 year probation on 3/13/2013. The board deferred the order modification until the November 16-17, 2015 board meeting. Mr. Wells explained to the board that he has reviewed all the documents concerning Dr. Newbaker's disciplinary action taken by the board and makes the recommendation to the board that the lift the probation. Dr. Bunch made the motion to approve the order modification to lift the probation status on Dr. Newbaker's pharmacist license. Dr. Eidson seconded the motion. The motion carried.

Appearance
Brittany Lindsey, RT

Ms. Lindsey 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 a minor traffic offenses) whether or not sentence was imposed, suspended, expunged, or whether you were pardoned from any such offense?' Ms. Lindsey pled guilty to prostitution on 6/12/2015 and was sentence to 9 month probation this charge will be dismissed March 12, 2016. After discussion, Ms. McDaniel made the motion to approve Ms. Lindsey's application for registration as a pharmacy technician. Ms. McDaniel withdrew her motion. After further discussion, Dr. Bunch made the motion to approve Ms. Lindsey's application for registration as a pharmacy technician with 2 year probation with quarterly drug testing. Dr. Wilson seconded the motion. The motion carried. Dr. Eidson abstained.

Bedside Delivery
Kroger Pharmacy #486

Cindy Fisher, Pharm. D., Clinical Care Coordinator and Jeff Porter, Marketing, for Kroger Pharmacy, appeared before the board to request approval of their Bedside Delivery business model with Methodist

South Hospital, Memphis, TN. After discussion, Dr. Wilson made the motion to approve Kroger Pharmacy #486 bedside delivery attestation following adaptions: using a courier services to deliver the medication to the hospital; the pharmacist keep all medications brought to the hospital by the courier service in his possession at all times (will not leave with the hospital staff); and approval to dispense scheduled III, IV and V prescription for bedside delivery pursuant to prescription transmitted by the hospital prescribing practitioner or his/her agent under compliance rule 1140-03-.04(1). Any changes to this business model must be reported to the board. Dr. Eidson seconded the motion. The motion carried.

Waivers
Board rule 1140-01-.04 (1)
Daniel Bradley, D.Ph.

Dr. Dickenson made the motion to deny Dr. Bradley's request to waive the remaining 200 internship hours of the 400 requirement needed for licensure by examination. Dr. Bradley submitted his application for license by examination prior to the rule change that went into effect on June 22, 2015. Dr. Eidson seconded the motion. The motion carried.

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

Dr. Eidson made the motion to approve the request from NuScript Rx for the two (2) automated dispensing machines that the pharmacy to be 180 square feet and hot and cold running water at the Tennessee Veterans Home, Humboldt, TN. Dr. Bunch seconded the motion. The motion carried.

Dr. Wilson made the motion to approve the request from **Ampharm** for the automated dispensing machine that the pharmacy to be 180 square feet. Dr. Pryse seconded the motion. The motion carried.

Board rule 1140-03-.14 (12)

Dr. Wilson made the motion to approve the request from **John Christopher White, D.Ph**. to be the pharmacist in charge of the automated dispensing machines located at Signature of St. Francis Healthcare, Pharmerica, Pharmerica at Signature of St. Peter's Villa, Memphis, TN, Pharmerica at Dove Health and Rehab, Collierville, TN and Pharmerica at Signature Healthcare of Methodist, Memphis, TN. Ms. McDaniel seconded the motion. The motion carried.

Dr. Wilson made the motion to approve the request from **Med-SN** to have one pharmacist be the pharmacist in charge at Signature of Primacy Health and Rehab and Pharmerica. Dr. Bunch seconded the motion. The motion carried. Dr. Eidson voted no.

Dr. Bunch made the motion to approve the request from **Kyle McCann, D.Ph**. to be the pharmacist in charge at Express Rx, Inc. and Express Rx Compounding Center. Dr. Dickenson seconded the motion. The motion carried.

Dr. Wilson made the motion to approve the request from **Brad Medling, D. Ph**., to be the pharmacist in charge of the tow (2) automated dispensing machines located at the Tennessee Veterans Home in Humboldt, TN. Dr. Pryse seconded the motion. The motion carried.

Dr. Wilson made the motion to approve the request from **Brad Hopkins, D. Ph**., to be the pharmacist in charge of the automated dispensing machines located at the Behavioral Healthcare Center in Martin, TN and Behavioral Healthcare Center in Columbia, TN. Dr. Pryse seconded the motion. The motion carried.

Board rule 1140-01-.07 (3)(a), (b) & (c)

Ms. McDaniel made the motion to approve the request from **Nanette Harris, D.Ph**., to waive the one hundred and sixty (160) internship hours but she 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 **Debra Nicholas D.Ph**., to waive the one hundred and sixty (160) internship hours but he must successfully take and pass the MPJE. Dr. Bunch seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Sherry Heinrichs, 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.

Director's Report

Dr. Dilliard informed the board of the audit results from the State of Tennessee Comptroller's Office.

Dr. Dilliard presented a request from Jamie Johnson, D.Ph., to grant continuing education hours for attending the Healthy Kitchen, Healthy Lives Conference presented by the Harvard School of Public in partnership with the Culinary Institute of America. After discussion, Dr. Eidson made the motion to approve 2 hours of continuing pharmaceutical education for this conference. Dr. Bunch seconded the motion. The motion carried.

Dr. Dilliard informed the board that LexisNexis would print the 2011 pharmacy law book at $9.66 each if they order 3000 copies or $28,980.00 for the law book with eBooks. Dr. Eidson stated that he want to know the price for printing a new law book with the current rules and statutes. Dr. Dilliard stated that he will contact LexisNexis and have the information at the December 18, 2015 rulemaking hearing meeting.

Dr. Dilliard presented a request to the board from Megan Kroll, D.Ph. to waive the one (1) year requirement to transfer on out of state license. Dr. Kroll has accepted a residency at LeBonheur Children's Hospital and the University of Tennessee Health Science Center. After discussion, Dr. Eidson made the motion to deny Dr. Kroll request to waive the one (1) year requirement to transfer on an out of state license. Dr. Kroll will need to take the NAPLEX or adhere to the one (1) year requirement. Dr. Dickenson seconded the motion. The motion carried.

Dr. Bunch made the motion to adjourn at 4:07 p.m. Dr. Eidson seconded the motion. The motion carried.

November 17, 2015

The Tennessee Board of Pharmacy reconvened on Tuesday, November 17, 2015 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members were present, the meeting was called to order at 8:05 a.m. by Dr. Smothers, president.

Contested Case
Bethany Johnson Robbins, D.Ph.

Dr. Robbins was present and represented by attorneys Jason Whatley and Cory Richey. Mr. Cange represented the State of Tennessee and Mr. Tom Stovall was the Administrative Law Judge. Mr. Cange passed out the Notice of Charges. Dr. Robbins has been charged with violating T.C.A. §63-10-305 (4), (6) and T. C. A. §63-10-305 (8). After discussion, Dr. Bunch made the motion to accept the Findings of Fact. Dr. Wilson seconded the motion. The motion carried. Dr. Dickenson made the motion to accept the Conclusion of Law with the correction that this is a pharmacist license not a pharmacy technician registration. Dr. Eidson seconded the motion. After further discussion, Dr. Dickenson amended the motion to include numbers 15 thru 18 in the Notice of Charges. Dr. Eidson seconded the amended motion. Dr. Dickenson withdrew the motion. Dr. Dickenson restated the motion to accept the Conclusions of Law with the correction that this is a pharmacist license not a pharmacy technician registration and to include the violations listed as 13, 14, 15, 16 and 17. Dr. Eidson seconded the motion. The motion carried. Ms. McDaniel made the motion to place Dr. Robbins' pharmacist license on ten (10) year probation and asses case cost. Dr. Bunch seconded the motion. The motion carried. Dr. Eidson and Dr. Dickenson voted no. Ms. McDaniel made the motion to assess a $5,000.00 civil penalty. Dr. Dickenson seconded the motion. The motion carried. Ms. McDaniel made the motion to that the cost must be paid 30 days after receipt of the assessment of cost has been issued. Dr. Bunch seconded the motion. The motion carried. Dr. Dickenson made the motion that Dr. Robbins has one (1) year to pay the civil penalty. Ms. McDaniel seconded the motion. The motion carried. Dr. Eidson made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Dickenson seconded the motion. The motion carried.

Agreed Order

Mr. Cange presented an agreed order in the name of Christy Jacobi, D.Ph. Dr. Jacobi agreed to a $600.00 civil penalty for working on an expired pharmacist license from January 2015 until July 2014. Dr. Bunch made the motion to accept the agreed order as presented. Dr. Pryse seconded the motion. The motion carried.

General Discussion

Dr. Dilliard asked the board to place the request from MedSN on hold until more research could be done. Med-SN is requesting that one pharmacist be listed as the PIC for Advanced Diagnostic Imaging and Comprehensive Arthritis Care. The board agreed to withhold the request until further research could be done on this issue.

Dr. Bunch made the motion to adjourn at 12:53 p.m. Dr. Eidson seconded the motion. The motion carried.

The minutes were approved and ratified as amended at the January 12-13, 2016 board meeting.