

Board of Pharmacy
Board Meeting
June 13, 2017

TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Iris Room
Nashville, TN
June 13, 2017

BOARD MEMBER PRESENT

Kevin Eidson, D.Ph., President
R. Michael Dickenson, D.Ph., Vice President
Debra Wilson, D.Ph.
Rissa Pryse, D. Ph.
Katy Wright, D.Ph.
Will Bunch, D.Ph.
Lisa Tittle, Consumer Member

STAFF PRESENT

Reginald Dilliard, Executive Director
Matthew Gibbs, Associate General Counsel
Terry Grinder, Pharmacy Investigator
Richard Hadden, Pharmacy Investigator
Scott Denaburg, Pharmacy Investigator
Rebecca Moak, Pharmacy Investigator
Robert Shutt, Pharmacy Investigator
Andrea Miller, Pharmacy Investigator

STAFF ABSENT

Tommy Chrisp, Pharmacy Investigator
Albert Hill, Pharmacy Investigator

The Tennessee Board of Pharmacy convened on Tuesday, June 13 2017, 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. Ms. Jane Young, General Counsel for the Department of Health introduced Ms. Savannah Moror and Mr. Mike Thompson, resident fellows, working with Dr. Dreyzehner, Commissioner for the Department of Health.

Minutes

The minutes from the March 14, 2017 board meeting were presented. Dr. Bunch made the motion to accept the March 14, 2017 board meeting minutes as presented. Dr. Pryse seconded the motion. The motion carried. The minutes from the April 13, 2017 board meeting were presented. Dr. Bunch made the motion to accept the April 13, 2017 board meeting minutes as presented. Dr. Pryse seconded the motion. The motion carried.

Legislative Update

Jeremy Davis, Assistant Commissioner of Legislative Affairs, presented the following Public Chapters to the board;

Public Chapter 392 -Authorizes the department of health to establish a prescription drug donation repository program. Dr. Dickenson will work with the Department to help establish this program.

Public Chapter 355- Authorizes a nursing home to participate in a drug donation repository program until such time as the board for licensing health care facilities promulgates rules to effectuate such participation.

Public Chapter 89- Removes the board of pharmacy's oversight of facilities that distribute dialysate and devices necessary to perform peritoneal kidney dialysis to patients with end stage renal disease if the facility meets certain criteria.

Public Chapter 268- Specifies that any person licensed by the board of pharmacy and holding a valid wholesaler license will be considered to be licensed as a drug distributor until such a time when the board can promulgate rules to implement the third-party logistic provider (3PL) licensing process.

Public Chapter 84- Authorizes rules and policies permitting the administration of medications for adrenal insufficiency in schools.

Public Chapter 112- Requires the commissioners of health and mental health and substance abuse services to produce guidelines on nonresidential buprenorphine treatment by January 1, 2018, and to annually update those guidelines.

Public Chapter 350 - Authorizes a healthcare provider to satisfy one hour of continuing education requirements in exchange for one hour of volunteer healthcare services

Public Chapter 215- Requires state governmental entities that establish or adopt guides to practice to do so through the promulgation of rules.

Public Chapter 240- Authorizes entities that regulate health professionals to issue limited licenses; makes various changes related to reporting of disciplinary matters to licensure entities.

Public Chapter 230 - Authorizes commissioners and chief executive officers of administrative departments to evaluate certain actions by a regulatory board to determine whether the action may constitute a potentially unreasonable restraint of trade.

Senate Bill 1309- Created a new violation for a failed drug screen or refusal by allowing the applicant 3 days to produce a valid prescription or to self-report to a peer assistance program. If the licensee maintains advocacy no action will be taken. If the licensee does not maintain advocacy action will be taken.

OGC Report

Mr. Gibbs informed the board that there are 58 open cases for discipline at the Office of General Counsel and 18 of those cases are eligible for contested hearing.

Mr. Gibbs informed the board that the hormonal contraceptive rules are in the process of being reviewed internally. A rulemaking hearing can be scheduled once the internal review is completed.

Mr. Gibbs asked the board to nominate a designee for collaboration on the 3PL rules. Dr. Dickenson will work with Mr. Gibbs concerning this rule.

Mr. Gibbs informed the board that the Grant Proposal has been approved and the contract is scheduled to take effect September 1, 2017.

Mr. Gibbs gave the following legislative update:

SB1423/HB1327 – Bureau of TennCare to compile a list of 15 prescription drugs which the state spends significant healthcare dollars toward and which have increased in price by 50% over the last five years (or 15% in the last year) (“the list”) and provide the list to the commissioner of health (“Commissioner”). The Commissioner is then required to contact the manufacturers, ascertain reasons for the increase, and report to the General Assembly. The Attorney General is given enforcement powers.

Update – In committee. No action since February of 2017.

SB1181/HB1054 – Caption bill. Allows owners / possessors of misbranded / adulterated drugs 15 days to file written notice requesting a hearing. (T.C.A. § 53-10-106). Current law = 10 days.

Update – In committee. No action since February of 2017.

SB1119/HB0830 – Medical Cannabis Access Act

Update – Assigned to General Subcommittee of Senate Judiciary Committee in March of 2017.

SB0518 / HB1222 – Allows dialysate to be distributed directly to end-users. Prescription must be reviewed by a Tennessee-licensed pharmacist. Records must be kept for two years.

Update – Bill signed by governor on April 5, 2017, and became Public Chapter 89. Bill will take effect on July 1, 2017.

SB0385 / HB0694 – Adds FDA approved canabidiol to the list of exceptions found in the criminal definition of marijuana (T.C.A. § 39-17-402(16))

Update – Bill signed by governor on April 12, 2017, and became Public Chapter 120. Bill to take effect upon becoming law.

SB0268 / HB1148 – Caption bill. Allows out-of-state pharmacies 21 days to report out-of-state discipline to the TN BOP. Current law requires 14 days to report. (T.C.A. § 63-10-216)

Update - Any person licensed by the board of pharmacy under this section and holding a valid wholesaler license is considered to be licensed as a drug distributor until such a time when the board can promulgate rules to implement the third-party logistic provider (3PL) licensing process.

- Bill signed by governor on May 4, 2017, and became Public Chapter 268. Bill to take effect upon becoming law.

SB0974 / HB0936 – Removes requirement of an in-state institution of higher learning obtaining

DEA registration prior to conducting research on low-THC cannabis oil.

Update - Bill assigned to General Subcommittee of Senate Judiciary Committee. No action has been taken on this bill since March of 2017.

SB1258/HB0630 – Changes definition of device to things “used in to administer a prescription drug.”

Update - Bill assigned to General Subcommittee of Senate Health and Welfare Committee. No action has been taken on this bill since March of 2017.

SB1320 / HB0519 – Requires a report to be submitted to committees of the General Assembly regarding the quantity and kinds of drugs disposed of in the pharmacy drug disposal program and the number and geographic distribution of participating pharmacies.

Update – An amendment to this bill completely changed the bill language. New bill authorizes nursing homes to participate in a drug repository program under title 63.

Signed by the governor on May 11, 2017, became Public Chapter 355, took effect upon becoming law.

SB0429 / HB0137 – Deletes the Nina Norman Prescription Drug Donation Act of 1996. Adds a drug repository program.

Update - Bill signed by governor on May 19, 2017, and became Public Chapter 392.

- This bill does require rulemaking and took effect immediately for rulemaking purposes. All other aspects of the bill take effect on January 1, 2018.

SB1309 / HB 1067 - Health practitioners (pharmacists, pharmacy techs) violate the practice act by **refusing a drug screen or testing positive for any drug** (e.g. cannabis, cocaine, opiates, amphetamines and methamphetamines, PCP) on a drug screen

- Three days following notification of a refused / failed drug screen, the practitioner can:

- 1.) Produce a lawful prescription for the drug
- 2.) Produce a valid medical reason for taking the drug; OR
- 3.) Report to the peer assistance program (referred by employer / self)

- So long as the practitioner complies with the terms and conditions of the peer assistance provider, the practitioner’s license shall not be suspended / revoked for refusal to submit to a drug test or a positive result on a confirmed dug test

- License shall be suspended if the practitioner fails to comply with the terms and conditions of the peer assistance provider

Complaint Summary

Case 1.

Complainant alleged unprofessional conduct and HIPAA violations during two interactions with respondent pharmacy. Complainant is working in Tennessee but lives in another state and forgot a new C2 prescription at his regular pharmacy on both occasions. On occasion one, a 3 day emergency supply was ordered by the prescriber and the patient's regular pharmacy mailed the "on-hold" prescription to the Tennessee pharmacy, but it did not arrive until patient had run out of the emergency supply. According to pharmacists, the patient became verbally abusive, so the "on-hold" prescription was declined when it arrived. Pharmacists also told BOP Investigator that it took several phone calls over a 3 week period to get the prescriber to send a prescription for the emergency supply. So, when the patient once again forgot to bring an original prescription from home, pharmacists declined to call for an emergency supply. Pharmacists stated the patient again became verbally abusive and threatened to call an attorney. Pharmacists told Investigator this type aggressive behavior had been seen in adults on high doses of ADHD medications and thought it should be reported to the prescriber, so the prescriber was contacted.

Recommend: Dismiss

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

Case 2.

Respondent is PIC for Case 1 above.

Recommend: Dismiss

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

Case 3.

Complainant alleged unprofessional conduct by "being treated like a criminal," and being denied service. Complainant alleged that a Levaquin prescription was presented to respondent pharmacy but since he was not in their system, he had to fill out a registration form. He was then asked why he wanted to fill the prescription there instead of his regular pharmacy, and was told he should buy everything at one place.

Respondent pharmacy staff admitted to BOP Investigator that they did tell complainant that it was better to fill all prescriptions at the same pharmacy, especially since his regular pharmacy was in the same area. The pharmacist was concerned with potential drug interactions but did agree to fill the prescription. However, the patient asked for the prescription back and threw down the new patient form.

Recommend: Dismiss

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

Case 4.

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BOP Investigator observed a pharmacy technician give prescriptions to 3 different patients without even offering counseling. Respondent pharmacy and PIC had been educated previously about counseling. PIC admitted to Investigator that they do well for a while after being educated but fall back into bad habits. Investigator did observe counseling on new prescriptions during the visit, and observed the pharmacist talking to patients if they had questions, but believes the failure to offer on refills was due to a failure to supervise staff properly and remind them of the requirements.

Recommend:

Dr. Dickenson made the motion to issue a **Letter of Instruction** to the PIC for failure to supervise staff properly. Dr. Wilson seconded the motion. The motion carried.

Case 5.

Respondent is the pharmacy for Case 4 above.

Recommend:

Dr. Dickenson made the motion to issue a **Letter of Instruction** to the pharmacy for failure to supervise staff properly. Dr. Pryse seconded the motion. The motion carried.

Case 6.

Respondent technician admitted in a signed statement to stealing “around 400” Tramadol for personal use.

Recommend: Revoke

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

Case 7.

Complaint alleges respondent pharmacy is repackaging medications from various pharmacies for assisted living facilities, but instead of bringing them to the respondent pharmacy, a pharmacist is sent to repackage drugs at the homes.

BOP Investigator obtained a sworn statement from the pharmacy owner who admitted the allegation but believed that by going to the home, there was no violation for receiving/repackaging the medication.

Recommend: LOW

Dr. Dickenson made the motion to issue **cease and desist letter** for violating board rule 1140-03-.08. Dr. Wilson seconded the motion. The motion carried.

Case 8.

Respondent is the PIC for Case 7 above. According to the respondent’s sworn statement, this involves V.A. drugs but the pharmacist goes to the home, verifies the medication in the vial, and puts them in a cold seal card by date and time, similar to a medication minder. Proper labeling of the cards was not mentioned in the statement. However, Investigator verified with respondent that a blank label is printed with drug and directions to put on top of the card. Then the description of the pill and expiration date from the V.A. bottle is handwritten on it.

Recommend: LOW

Dr. Wilson made the motion to issue **cease and desist letter** for violating board rule 1140-03-.08. Dr. Pryse seconded the motion. The motion carried

Case 9.

Complainant alleged a misfill when finding Spironolactone 100mg and 50mg in the same vial. Complainant is not certain if any of the incorrect strength were taken before noticing the difference in tablets. Complainant notified the pharmacy and the medication was corrected.

Respondent is the dispensing pharmacist that performed visual verification before releasing the medication. Respondent told BOP Investigator about several safeguards that help prevent such errors but assumes there may not have been enough tablets in the open bottle to completely fill the prescription, so a full bottle was opened to complete the fill but nobody noticed it was not the same strength. Investigator observed respondent's visual verification process. Respondent pours out a sample of tablets into the lid and compares them to the image on the computer screen. Pharmacy staff members have been told to work on one prescription at a time and be aware of their job/task. They are also working on ways to prevent this error from happening in the future.

Recommend: LOW to responsible pharmacist

Dr. Wright made the motion to issue a **Letter of Warning** to the responsible pharmacist for the misfill. Ms. Tittle seconded the motion. The motion carried.

Case 10.

Respondent is PIC for Case 9 above.

Recommend: No violation by PIC. Dismiss.

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

Case 11.

Respondent is the pharmacy for Cases 9 and 10 above.

Recommend: No violation by pharmacy. Dismiss.

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

Case 12.

Anonymous complaint alleged respondent pharmacy sells "expired, opened and unauthorized supplies." Four very specific examples involving diabetic test strips were given as "The following are reports from patients..." No patient names were given and no contact information was provided by the complainant.

BOP Investigator visited respondent pharmacy to inspect pharmacy stock and all diabetic supplies. Investigator found no expired products, no opened products, and no broken seals on strips. Investigator visited the pharmacy a few days later to interview the PIC. PIC provided a sworn statement that only in-

date, sealed packages from VAWD approved wholesalers are dispensed at this pharmacy. All allegations were denied.

Recommend: Dismiss

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

Case 13.

Respondent is the PIC for Case 12 above.

Recommend: Dismiss

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

Case 14.

Complaint alleged respondent pharmacy's third party audit had non-controlled medication shortages that could not be reconciled with pharmacy's invoices. It also alleged respondent pharmacy compounded a product using bulk powder, which is a violation of Medicare regulations. The audit resulted in respondent pharmacy's third party contract being terminated with that particular company.

BOP Investigator obtained statements from the pharmacy owner who admitted the compounding issue and to having at least one item that could not be reconciled to invoices.

Recommend: Reprimand and costs

Dr. Wilson made the motion to **reprimand** the pharmacy license and to assess cost. Dr. Wright seconded the motion. The motion carried.

Case 15.

Respondent is PIC and owner for Case 14 above.

Recommend: LOW

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

Case 16.

BOP was notified that respondent pharmacist had been terminated for gross misconduct due to working while impaired and failing an alcohol test.

Respondent refused to cooperate with TPRN volunteers and BOP Investigator. Investigator obtained sworn statements from several staff members relaying stories of respondent showing up late, sleeping on the floor while on duty, having a strong scent of alcohol, yelling counseling across the pharmacy, sitting in his car with the motor running and windshield wipers on (it was not raining) instead of coming in and opening the pharmacy, looking unshaven and disheveled with uncombed hair and a wrinkled shirt, seeming to be incoherent and having trouble keeping his eyes open. Staff members indicated respondent had shown a "decline in his behavior over the past 3 months."

Management took respondent for a drug test which showed a blood alcohol level higher than the legal limit.

Recommend: Revoke

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

Case 17.

Complaint alleged respondent pharmacist has been stealing prescription pads and forging prescriptions for personal use for Esgic, Pyridium, several antibiotics, Zofran, and other forms of Fioricet tablets. Complainant stated that the prescriber denied authorizing the prescriptions.

BOP Investigator interviewed respondent who denied forging prescriptions and claimed the prescriptions had been authorized by a prescriber. Investigator attempted to contact the prescriber and discovered the prescriber has moved to another state. Investigator was unable to reach the prescriber for verification. However, the respondent told Investigator that she has been retired and has not practiced in Tennessee for more than 3 years. According to a follow-up statement from complainant, charges were filed with police but they have since been dropped after a detective spoke to the physician. Respondent wants to end this complaint and not incur any additional investigative costs so she wants to surrender her pharmacist's license.

Recommend: Accept voluntary surrender and costs

Dr. Dickenson made the motion to **accept the voluntary surrender** and to assess cost. Dr. Wilson seconded the motion. The motion carried.

Case 18.

While working a separate case, BOP Investigators were told respondent pharmacy may be selling Testosterone without prescriptions. BOP Investigators interviewed pharmacists and the owner and obtained invoice and dispensing/distributing records for all testosterone products, including powders and injectables for years 2014, 2015, and 2016.

The audit was extensive and thorough but no significant shortage or overage was found.

Recommend: Dismiss

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

Case 19.

Complaint alleged a misfill by respondent resulted in patient taking 13,300mg of Gabapentin in 8 hours, causing hospitalization in ICU for 4 days.

BOP Investigator reviewed dispensing records and interviewed staff, including the dispensing pharmacist/PIC. According to a sworn statement by the pharmacist, the patient's Humalog label was incorrectly placed on the vial for Gabapentin.

Investigator interviewed the patient who had noticed the incorrect label and set the bottle aside on a night stand so it could be returned later to the pharmacy to get the label changed. The patient had to go out of

town before being able to return to the pharmacy. The patient also takes Cholestyramine that is mixed in orange juice. The patient asked his girlfriend to get the Cholestyramine off the night stand and mix it in juice in preparation for his trip. The Cholestyramine was actually on the dresser so the Gabapentin from the night stand was mixed with juice, using the directions from the incorrect label for Humalog calling for “19 units under the skin with each meal.” 19 Gabapentin capsules were opened and placed in each bottle of juice. The patient consumed 1 bottle of juice containing 19 capsules worth of Gabapentin at 6 a.m. and another bottle containing 19 capsules worth of Gabapentin later. The patient became sleepy, felt bad, was “wobbly” and had twitching of the face. Lab tests at the hospital confirmed an overdose of Gabapentin and the patient was placed in ICU for monitoring. The patient told BOP Investigator that his primary care physician was very concerned about the overdose and the patient still has residual twitching of the face. The patient was taking Gabapentin for neuropathy but says he was told he can no longer take it.

Recommend: LOW to the responsible pharmacist

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

Case 20.

Respondent is the pharmacy where the misfill from Case 19 above occurred.

Recommend: Dismiss against the pharmacy

Dr. Wilson made the motion to **accept counsel’s recommendation**. Dr. Dickenson seconded the motion. After discussion, Dr. Wilson withdrew her motion and Dr. Dickenson withdrew his seconded. The motion died. After further discussion, Dr. Wilson made the motion to **dismiss** the complaint against the pharmacy. Dr. Dickenson seconded the motion. The motion carried.

Case 21.

BOP office was notified by pharmacy management that an internal investigation was being conducted on respondent after noticing respondent had multiple CS discrepancies and accessed the Lortab and Percocet bins in ED cabinets numerous times to “cycle count.” It was noted through transaction documentation that narcotic discrepancies were created by respondent while cycle counting. When confronted, respondent resigned without admitting guilt.

BOP Investigator conducted a thorough investigation and interviewed numerous staff members of the pharmacy and the hospital. Five sworn statements were taken. The thoroughness of reports detailing respondent’s suspicious activities along with interviews of hospital staff that interacted with respondent point to the high probability that respondent diverted controlled substances from several Automated Dispensing machines throughout the hospital.

BOP Investigator spoke to respondent who denied allegations but asked about surrendering her tech registration.

Recommend: Revoke and costs

Dr. Wright made the motion to **authorize a formal hearing for revocation** and to assess cost. Dr. Pryse seconded the motion. The motion carried.

Case 22.

Complainant alleged being dispensed a new prescription without proper counseling by merely being asked by a cashier if complainant needed to speak to a pharmacist. Complainant was contacted by telephone and more specific information was relayed to Investigator. Complainant was aware of BOP's counseling requirements, and since this prescription was for a dosage change from an Endocrinologist, complainant felt BOP rules had been violated because the pharmacist did not come out to counsel.

BOP Investigators discovered respondent pharmacist was PIC at the time of dispensing, but had been terminated the day before Investigators arrived at the dispensing pharmacy. Management verified termination was not drug related. The new PIC was very familiar with counseling requirements and stated his goal is for strict compliance.

Respondent pharmacist was contacted by telephone. Respondent was not aware of the counseling complaint, but stated it was her policy to always counsel on new prescriptions. Respondent could not recall the Complainant picking up the prescription nor could she recall counseling the patient about the medication or dosage change.

Based upon Respondent's statement and the specific details from the Complainant, it appears likely that there may have been a misunderstanding by the pharmacist and/or pharmacy staff about the need and importance of counseling on all new prescriptions. Patient understood her medication and knew about the dosage change so there was no patient harm. However, the patient was aware of counseling requirements and knew she did not receive mandatory counseling.

Recommend: LOW for requirements and importance of counseling on all new prescriptions.

Dr. Dickenson made the motion to issue a **Letter of Warning** to the dispensing pharmacist for failure to counsel on all new prescriptions. Dr. Wilson seconded the motion. The motion carried.

Case 23.

Respondent is the dispensing pharmacy for Case 22 above. Although the new PIC seems dedicated to being sure counseling occurs, prior to his arrival, there may have been "offers to counsel" instead of mandatory counseling.

Recommend: LOW for requirements and importance of counseling on all new prescriptions.

Dr. Wilson made the motion to issue a **Letter of Warning** to the PIC for failure to counsel on all new prescriptions. Dr. Pryse seconded the motion. The motion carried.

Case 24.

While investigating another complaint at a mail-order type pharmacy, BOP Investigators became aware that respondent pharmacists were not performing a final check prior to medications being shipped to patients. Investigators also discovered that medication returns were accepted and placed back into stock. Pharmacy dispenses Lidocaine ointment, Diclofenac gel and Fluocinonide cream to patients via US Postal Service. Prescription orders are received via fax to the pharmacy by out of state prescribers for out of state patients. Prescriptions are processed and billed to the patient or patient's insurance, labels are printed, and then medications are labeled and packed for shipping. Respondent pharmacists admitted there was no final check by pharmacists. Respondents also admitted that if a patient refused shipment or returned the medication, inventory was placed back into stock and reused. Investigators directed Respondents to correct both issues immediately and provide a written plan of action. The original complaint is still being investigated, however, Investigators felt BOP should be presented with these known violations.

Recommend: Reprimand to respondent dispensing pharmacist

Dr. Wilson made the motion to **reprimand** the dispensing pharmacist for not performing a final check prior to medication being shipped and accepting returned medication and placing in back into stock. Dr. Wright seconded the motion. The motion carried.

Case 25.

Respondent is the PIC for Case 24 above. In addition to allowing the same violations noted above, BOP Investigators found that Respondent has not been working the required time to be PIC.

Recommend: Reprimand as above and also for failure to meet PIC requirements.

Dr. Wilson made the motion to **reprimand** the PIC license for failure to meet PIC requirements. Dr. Bunch seconded the motion. The motion carried.

Case 26.

Respondent pharmacy submitted a DEA 106 showing a loss of 22,593 Oxycodone 30 mg and indicating it was due to employee pilferage. BOP and DEA performed an audit for Oxycodone 15mg, Oxycodone 30mg, Hydrocodone APAP 7.5/325mg, Hydrocodone APAP 10/325mg, Morphine Sulfate 30mg IR, Oxymorphone 30mg, Methadone 10mg, Alprazolam 1mg, Alprazolam 2mg, and Tramadol 50mg. All except the Oxycodone 30mg had less than a 3% variance (over or under).

Respondent pharmacy is small and employees work in close proximity to each other and the owner/PIC. Investigators believe drug shortages should have been noticed before reaching 22,593 tablets. The suspected employee was arrested and legal action is still pending.

Recommend: LOW for stricter control and monitoring for diversion

Dr. Wright made the motion to issue a **Letter of Warning** to the pharmacy for stricter control and monitoring for diversion. Dr. Bunch seconded the motion. The motion carried.

Case 27.

Respondent is PIC and owner of the pharmacy in Case 26 above. Respondent is the only pharmacist and the only person that orders Schedule 2 drugs. Investigators believe Respondent should have noticed large quantities of Oxycodone 30mg coming in but no record of large quantities going out. It is believed that the loss accumulated between 1/26/14 and 9/28/16. It has been noticed that Oxycodone 30mg orders are substantially less than they were before the suspected employee was terminated.

Recommend: Reprimand as PIC

Dr. Pryse made the motion to **authorize a formal hearing** with 2 year probation, monthly reports of controlled substances invoices and dispensing records. Dr. Wright seconded the motion. The motion carried.

Case 28.

Complainant alleged a misfill by getting Hydrocodone APAP 5/325 instead of Furosemide. Patient took the incorrect medication for almost 2 weeks before realizing with help from the prescriber that it was not Furosemide. Patient is a CHF patient and did experience edema and made a trip to the ER and to her regular prescriber. Patient has since recovered. Complainant also alleged calling the pharmacy the day

after dispensing to question the medication looking different and was informed that sometimes medications come from different companies and look different.

BOP Investigator worked with 3 levels of management since the particular brand of Hydrocodone APAP that was in the patient's bottle has not been carried in the pharmacy since 2002-2003. Respondent management levels were not able to explain how the incorrect medication got into the bottle. Corporate management did verify that the brand in the bottle was last used at this pharmacy in 2002, that it is not currently listed in the company's system, and CS inventories use a scanner to scan NDC numbers so the product could not have been at the pharmacy during regular CS inventory counts. Investigator worked with management to verify the patient had no record of ever being prescribed Hydrocodone APAP in CSMD for KY, AL or TN.

Respondent pharmacy offered to compensate the patient for expenses and inconvenience, however the patient stated she just wanted to know how this could happen. Neither the corporate investigation nor BOP investigation provided an explanation. It is known that the patient returned the bottle containing the wrong medication, the patient did have edema during the 2 weeks of taking the wrong medication, and the prescriber noticed the error and treated the edema. Respondent staff members could not recall the patient calling to inquire about the different appearance from her usual medication. However, Investigators believe any such call should be handled as an opportunity to correct any potential error before it results in harm to the patient.

Recommend: LOI to have DPH handle all questions of different looking meds and take each call seriously.

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

Case 29.

Respondent is PIC for Case 28 above.

Recommend: LOI as above.

Dr. Bunch made the motion to **dismiss** this complaint. Dr. Pryse seconded the motion. The motion carried.

Case 30.

Complainant pharmacy reported a loss of 839 Phentermine 37.5mg due to employee pilferage. The employee was terminated from employment. A video was provided by the pharmacy.

BOP Investigator watched the video footage and agrees the respondent exhibits odd activity involving bottles of the missing drug, but diversion is not clear. Investigator corresponded via email with respondent to attempt to get a statement. Respondent would never confirm a meeting date and time and eventually stopped responding to emails, texts, and phone calls from Investigator. A letter offering a chance to provide BOP with a response was sent to Respondent on 3/27/17. To date, the letter has not been returned and a response has not been received.

Recommend: Revoke tech registration

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

Case 31.

Respondent pharmacy appears on the list of top dispensing pharmacies. DEA also opened a case file because of the pharmacy's volume. BOP and DEA jointly conducted an on-site inspection and audit. Audit results and recordkeeping were acceptable. BOP Investigator interviewed pharmacists and discussed the high volume as well as documentation for pharmacists deciding whether to fill prescriptions. "Red flags" and MME were discussed. Documentation was provided to Investigator showing that the pharmacy routinely refuses to fill prescriptions that are suspicious, out of area, or have unknown patients or prescribers. Pharmacists regularly communicate with local prescribers and request diagnosis and explanation of therapy for any patient they are not familiar with. The nearby addiction treatment physician does try to taper patients when possible and notifies the pharmacy if a patient is discharged for any reason.

Investigator recommended that documentation policies be reinforced with all staff members, especially pharmacists and technicians so that everyone knows what to document. Pharmacy will be due a periodic inspection within 90 days so a follow-up will be conducted at the same time. Education along with strengthening policies already in place should be sufficient.

Recommend: Dismiss

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

Case 32.

During a periodic inspection on 4/7/17, BOP Investigator noticed that respondent's pharmacist license expired 7/31/16. Respondent thought an office manager had renewed it. License was renewed and reinstated 4/21/17. Respondent (who was also PIC) practiced on an expired license from 8/1/16 to 4/21/17 (approx. 9 months.)

Recommend: Civil penalty \$1,000 per month for 9 months = \$9,000

Dr. Wright made the motion to **authorize a formal hearing** to the pharmacist with a civil penalty of \$1,000.00 per month working on an expired license for 9 months for a total of \$9,000.00. Dr. Wilson seconded the motion. The motion.

Case 33.

BOP office received a DEA 106 indicating a loss of controlled substances by employee pilferage. The suspected employee was terminated and police were called. Legal action against the technician is still pending. BOP Investigator was told by a police officer that respondent technician did admit to stealing 200 Oxycodone 30mg tablets. No other information can be obtained because the case is going to be presented to a Grand Jury.

Recommend: Revoke tech registration

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

Case 34.

Complainant patient filed complaint on 1/27/16 and filed a duplicate copy on 2/7/17 that alleged a misfill by respondent pharmacy when patient received Gabapentin tablets mixed with the patient's bottle for Ibuprofen. Patient alleged being sick while mistakenly taking Gabapentin before discovering the error. According to the complaint, other allegations of being shorted 2 Oxycodone tablets and failing to return patient's debit card were resolved prior to filing the complaint. Patient also feels respondent pharmacy played a part in getting the patient "flagged" as a doctor shopper and feels the pharmacy is "judging" patients. Allegations regarding pain clinic issues were forwarded to BIV.

BOP Investigator visited respondent pharmacy and interviewed the current PIC. The dispensing pharmacist for complainant's Ibuprofen no longer works at respondent pharmacy. The current PIC spoke to the patient on 2/1/17 about the alleged misfill but said the patient no longer had the incorrect pills so he could not confirm. PIC also stated all drugs are kept on perpetual inventory and all drugs balanced. There were no notes left by the previous PIC regarding a misfill or any corrective action. A new written prescription for Ibuprofen was filled and counseled on 2/1/17.

Investigator interviewed the previous PIC (who was the dispensing pharmacist) by telephone. Pharmacist was PIC through the end of January. Pharmacist was very familiar with the patient but stated she was unaware of the alleged misfill.

Regarding other allegations, respondent pharmacy is owned by the pain clinic next door but pharmacists report feeling free to exercise their professional judgment without pressure from the owners. Pharmacists are comfortable making decisions whether to fill a particular patient's medication. Neither pharmacist remembered any issue with this particular patient. None of the allegations could be confirmed. Respondent pharmacy is in process of changing ownership.

Recommend: Dismiss

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

Case 35.

Respondent is the dispensing pharmacist for Case 34 above.

Recommend: Dismiss

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

Appearance

Brandi Landum, RT

Ms. Lanham is applying for registration as a pharmacy technician. She marked "no" to the question that asked "Have you ever been convicted (including nolo contendere plea or guilty plea) of a felony or misdemeanor (other than a minor traffic offense) whether or not sentence was imposed or suspended?"

Documentation submitted indicated that Ms. Lanham plead guilty to theft over \$1000.00. She is placed deferment with 3 year supervised probation set to end on February 1, 2019. She has paid restitution. After discussion, Dr. Dickenson made the motion to approve Ms. Lanham's application for registration as a pharmacy technician. Dr. Wilson seconded the motion. The motion carried.

Request to reapply
Deena J. Nance, RT

Ms. Nance requested to approval to reapply for registration as a pharmacy technician. Ms. Nance license was revoked on 03/14/2017. After discussion, Dr. Bunch made the motion to approve Ms. Nance's request to reapply for registration as a pharmacy technician. Ms. Nance's registration will be on five (5) year probation once she has completed all the necessary requirements for to reapply with the following conditions. Dr. Wilson seconded the motion. The motion carried.

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

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

(c) The Respondent shall not obtain or attempt to obtain any prescriptions in the Respondent's name for any legend drugs, controlled substances or devices containing same from a physician other than the Respondent's primary physician or from any other health care provider, such as a nurse practitioner, physician's assistant or psychiatrist;

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

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

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

(g) The Respondent shall comply with all of the terms and conditions of the extended aftercare contract she entered into with the Tennessee Pharmacist Recovery Network. Respondent shall return a copy of said contract with this consent order to the Board Office.

Financial Report

Noranda French, Administrative Assistant IV, gave the financial report.

Order Modification Enoch Hartman III

Dr. Hartman appeared before the board to request that he be allowed to be PIC. Dr. Hartman signed a consent order on 05/12/2015 placing his pharmacist license on 5 year probation and he would not be allowed to be PIC for 3 years of probation. After discussion, Dr. Wright made the motion to amend Dr. Hartman's consent order and allow him to be PIC at Nashville Pharmacy Services. Dr. Pryse seconded the motion. The motion carried.

Presentation Enclara

John Loxterman, VP, Chief Compliance Officer, Loren Brook, Pharm. D., EVP Client Services and Joseph Buchanan, RN, CHPN, Director, Client Satisfaction, appeared before the board to ask for approval of E³. E³ would be used to interface with Hospice EMRs that will allow the Hospice Nurse to refill medication, request non-controlled medications for dispensing and initiate controlled substances e-prescriptions for dispensing. After discussing, Dr. Wilson made the motion to approve this business model. Dr. Dickenson seconded the motion. The motion carried. Enclara will be required to appear before the board in one year for updates.

CHI Memorial Hospital

Sandy Vredeveild, D.Ph., Director of Pharmacy Services, appeared before the board to ask for approval of to install a Scriptcenter Kiosk at Memorial Hospital for employee use. The board approved a Scriptcenter Kiosk at CHI Memorial, Hixson, TN at the July 30-31, 2014 board meeting. After discussion, Dr. Wright made the motion to approve this business model for Memorial Hospital (main hospital). Dr. Wilson seconded the motion. The motion carried.

Waiver

Board rule 1140-01-.01 (6)

Dr. Dickenson made the motion to deny the request from Alex Queensbury, D.Ph., to waive the one year requirement for reciprocity. Dr. Wright seconded the motion. The motion carried.

Board rule 1140-01-13(d), (e) and 1140-03-.14(12)

Board of Pharmacy
Board Meeting
June 13, 2017

Dr. Wilson made the motion to approve the request from **Allenhill Specialty Pharmacy** that the pharmacy to be 180 square feet, have hot and cold running water and Randall Allen, D.Ph. to be PIC of this location and Allenhill Pharmacy and Medical Supply. Dr. Bunch seconded the motion. The motion carried.

Board rule 1140-02-.02 (7)
Solutions Pharmacy

Thomas Beard, D.Ph., pharmacist in charge of Solutions Pharmacy appeared before the board to request an increase of the pharmacy to tech ratio from 4:1 to 6:1. After discussion, Dr. Wilson made the motion to increase the pharmacist to tech ratio to 6:1 for non-sterile products and 4:1 for sterile products. Dr. Dickenson seconded the motion. The motion carried.

Board rule 1140-01-.7 (3) (b) 5

Dr. Dickenson made the motion to approve the request from Rhett Ezell, **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.

Consent Orders

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

REVOCATION
Elise J. Wilson, RT

VIOLATED BOARD RULE 1140-01-.08 (3) (a) (1)
Priority Care Pharmacy, LLC

VIOLATED BOARD RULE 1140-03-.12
Walgreens Pharmacy #3866
Janet Jones, D.Ph. –

VOLUNTARILY SURRENDER (same as revocation)
Amanda L. Fellows, RT

Mr. Stefan Cange, Assistant General Counsel, presented a signed consent order from Triad Isotopes for violating board rule 1140-03-.02. Triad Isotopes, pharmacy license, will be reprimanded and assessed case cost. Dr. Bunch made the motion to accept the consent order as presented. Dr. Wright seconded the motion. The motion carried.

Director's Report

Board of Pharmacy
Board Meeting
June 13, 2017

Dr. Eidson congratulated Dr. Dilliard on being appointed to the NABP Executive Committee at the NABP Annual Meeting held in Orlando, FL. Dr. Eidson also asked that Dr. Dilliard give a brief overview of each of the meetings that he will be attending on the behalf of the board.

Dr. Dilliard asked the board to approve travel and expenses for board members, pharmacy investigators and the executive director to attend the Tennessee Pharmacist Association Summer Meeting scheduled for July 7-9, 2017 in Kingsport, TN. Dr. Pryse made the motion to approve travel and expenses for board members, pharmacy investigators and the executive director to attend the Tennessee Pharmacist Association Summer Meeting scheduled for July 7-9, 2017 in Kingsport, TN. Dr. Wilson seconded the motion. The motion carried.

Dr. Dilliard asked the board to approve travel and expenses for board members and the executive director to attend the NABP District III meeting scheduled for August 6-8, 2017 in Louisville, KY. Dr. Wright made the motion to approve travel and expenses for board members and the executive director to attend the NABP District III meeting scheduled for August 6-8, 2017 in Louisville, KY. Dr. Pryse seconded the motion. The motion carried.

Dr. Dilliard asked the board to approve travel and expenses for board members, pharmacy investigators and the executive director to attend MALTA-GON scheduled for in October 22-25, 2017 in Charleston, SC. Dr. Wilson made the motion to approve travel and expenses for board members, pharmacy investigators and the executive director to attend MALTA-GON scheduled for in October 22-25, 2017 in Charleston, SC. Ms. Tittle seconded the motion. The motion carried.

Dr. Dilliard asked the board to nominate a member to help with MPJE Item Writing schedule for July 31-August 31, 2017. Dr. Dilliard stated that Dr. Hadden usually participates in the MPJE Item Writing but he would also like for a board member to assist. After discussion, Dr. Wright and Dr. Wilson will help with the MPJE Item Writing.

Dr. Wilson made the motion to adjourn at 3:50 p.m. Dr. Pryse seconded the motion. The motion carried.

The minutes were approved and ratified at the July 12, 2017 board meeting.