

TENNESSEE BOARD OF PHARMACY
665 Mainstream Dr.
Nashville, TN 37243

BOARD MEMBER PRESENT

Debra Wilson, D.Ph., President
Rissa Pryse, D.Ph., Vice President
Katy Wright, D. Ph.
Adam Rodgers, D.Ph.
R. Michael Dickenson, D.Ph.
Melissa McCall, D.Ph.
Lisa Tittle, Consumer Member

STAFF PRESENT

Reginald Dilliard, Executive Director
Matthew Gibbs, Associate General Counsel
Larry Hill, Pharmacy Investigator
Rebecca Moak, Pharmacy Investigator
Robert Shutt, Pharmacy Investigator
Terry Grinder, Pharmacy Investigator
Richard Hadden, Pharmacy Investigator
Derek Johnston, Pharmacy Investigator
Scott Denaburg, Pharmacy Investigator
Rita Golden, Pharmacy Investigator
Patricia Beckham, Pharmacy Investigator
Sheila Bush, Administrator Director

STAFF ABSENT

Andrea Miller, Pharmacy Investigator

The Tennessee Board of Pharmacy convened on Tuesday, May 8, 2019, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 8:03 a.m.

Minutes

Dr. Dickenson made the motion to accept the minutes from the March 12, 2019 board meeting as amended. Dr. Rodgers seconded the motion. The motion carried.

Elections

Dr. Dickenson nominated Dr. Rodgers to the Controlled Substance Database Committee. Ms. Tittle seconded the motion. The motion carried.

Presentation

Wesley Geminn, Chief Pharmacist, Tennessee Department of Mental Health and Substance Abuse Services, presented the 2018 Buprenorphine Treatment Guidelines to the board to adopt as policy. After discussion, Dr. Wright made the motion to adopt the 2018 Buprenorphine

Treatment Guidelines as policy. Dr. Dickenson seconded the motion. The motion carried. Dr. Pryse voted no.

OGC Report

Mr. Gibbs stated that there are 58 cases open for discipline in the Office of General Counsel and 4 of those cases are eligible for contested cases.

Mr. Gibbs informed the board that Tennessee Board of Pharmacy along with the Tennessee Department of Health has been named as two of the defendants contained in the master docket for the National Prescription Opiate Litigation. The Office of the Attorney General is aware of this litigation.

Mr. Gibbs informed the board that the Board's pharmacy intern and pharmacy technician rules are currently in internal review. Executive Order #5, signed by Governor Lee on February 1, 2019, places a 90-day freeze on executive branch rulemaking. No department shall file a rule with the Secretary of State; however, the Governor may grant an exception for the protection of health, safety, and welfare of Tennesseans.

Legislative update:

Mr. Gibbs informed the board of the following bills that are concern the board presently being presented at the Legislator.

SB0202 and SB0475 – Lockable vials

If passed, these bills would have required any opioid or stimulant listed in Schedule II or any benzodiazepine listed in Schedule IV to be dispensed in a lockable vial so long as the medication is in solid oral dosage form and prescribed or dispensed with more than three days of medication. According to the bills, manufacturers would be bear the costs of lockable vials.

SB0202 has been withdrawn. SB0475 has been calendared for a Summer Study.

HB0703

HB0703 excludes the federal Drug Enforcement Agency requirements for the storage of gabapentin, as a Schedule V controlled substance, for a state-licensed wholesale drug distributor who is licensed by this Board and registered with the DEA.

This bill is currently in committees of both chambers.

HB0796

HB0769 doubles the licensure fees for pharmacy benefit managers. Currently, the licensure fee is \$100 for the initial license and \$50 for the renewal of the license. This bill would increase the fees to \$200 and \$100 respectively.

This bill is currently in committees of both chambers.

SB0810 – Signed by Governor Lee on April 9, 2019

- This bill changes the way information (from the CMSD) may be received by a Quality Improvement Committee.
- This bill deletes the “separate order” requirement for CIIIs.
- All controlled substances must be electronically prescribed by January 1, 2021. There are previously codified exceptions to this requirement (e.g. prescriptions issued by veterinarians).
- This bill changes the time allowed to fill the remainder of a partially filled prescription to six months for all schedules of controlled substances. (The *old* language required the partial fill of all schedules of controlled substances to occur within 30 days.) It should be noted that federal law requires the subsequent fill a CII to occur within 30 days. The language of this section, while not expressed, does state “unless federal law requires it to be filled within a shorter timeframe.”
- Pharmacy dispensing software vendors shall update their dispensing software systems to allow for partial filling of controlled substances by January 1, 2021.
- A new definition is codified for palliative care (i.e. high risk of mortality and negatively impacts a patient’s daily bodily functions).
- This bill clarifies that an ICD-10 code is not needed on a prescription when 180 MMEs or less are prescribed for a period of three-day supply or less. This section takes effect on July 1, 2019.
- Partially filling of an opioid is now in the discretion of the prescriber. The prescriber shall place “partial fill” or “PF” on the prescription to indicate a partial fill. It should be noted the MME requirements for 3, 10, and 30-day prescriptions still apply.
- Prescribers may treat a patient with up to 30 days of an opioid and 1,200 MMEs for (surgical) procedures that are more than minimally invasive.
- This bill clarifies “active cancer treatment; palliative care; severe burns; and major physical trauma” under the “exempt” language.
- This bill creates an exception to the entire applicability of TN TOGETHER for opioids approved by the federal Food and Drug Administration to treat upper respiratory symptoms or cough which are prescribed for 14 days or less.
- This bill removes the requirement for the pharmacist to collect a prorated cost-sharing or co-payment from patients for each partial fill. A pharmacist may collect a dispensing fee for each partial fill.

HB0884

2018 Tenn. Pub. Acts ch. 1015, § 4, codified at T.C.A. § 56-7-3114, gives a pharmacist and pharmacy the right to provide information to an insured about the insured's cost share for a prescription drug. Furthermore, the statute prohibits a pharmacy benefits manager ("PBM") from penalizing a pharmacist and / or pharmacy for discussing or selling a lower priced drug to the insured, if one is available.

The proposed bill adds a new subsection to T.C.A. § 56-7-3114. The new subsection forbids a PBM from prohibiting a pharmacy or pharmacist from informing a patient of all relevant options of a prescription medication, including a more affordable alternative. Moreover, a PBM shall not prohibit a pharmacist or pharmacy from accepting cash payments if the cash payments for the same drug are less than an insurance copayment or deductible payment amount.

This bill has been withdrawn.

SB0987

This bill would no longer require TennCare to contract with a pharmacy benefit managers.

This bill is currently in committees of both chambers.

SB1215

Existing law prohibits health insurers from excluding coverage for off-label drug prescriptions provided the off-label use is recognized by "medical literature" or 1 of 6 listed "standard reference compendia". The bill would amend 56-7-2352(c) (1) to eliminate the requirement of recognized use by "medical literature" or "standard reference compendia." The result would be that health insurers would be prohibited from excluding coverage for any off-label prescriptions, whether a recognized off-label use or not.

This bill is currently in committees of both chambers

Complaint Summary

1.

During a periodic inspection of a sterile compounding facility, BOP Investigator discovered the following deficiencies:

Expired cleaning agent being used to clean PEC/CAI. (Approx. 4 months);
Expired IV drugs
Expired IV solutions

Multiple aseptic technique and cleaning violations during Investigator's observation:

Not competent in donning sterile gloves;
Improper cleaning procedure of CAI;

Not using Sterile IPA every 30 minutes and often;
Proper media fill not documented for 2 techs and 2 pharmacists for 6 months;
Proper glove finger sampling not documented for 2 techs and 2 pharmacists for 6 months;
Items going into CAI not properly disinfected first;
Proper aseptic technique bathing in first air not performed correctly;
Pharmacist not aware of dwell time for cleaning agents;
At least 2 pharmacists and 2 techs had no documentation for didactic training;
Dirt/dust observed on floor and on metal CAI stand;
During the 6 month gap in proper documentation, the facility had at least 3 PIC's and several techs terminated or quit. One former PIC indicated 60 hour work weeks and not having adequate staffing were factors in the turnover rate.

No prior discipline.

Recommend:

Dr. Wright made the motion to issue a Letter of Warning to the pharmacy. The motion failed. After further discussion, Dr. Dickenson made the motion to authorize a formal hearing with a \$4000.00 civil penalty all but \$1000.00 stayed with a corrective plan of action, \$10.00 civil penalty per expired drug with a 3 month follow-up. Ms. Tittle seconded the motion. The motion carried.

2.

“PIC #1” for case 1 above.

No prior discipline.

Recommend:

Dr. McCall made the motion to issue a Letter of Warning. Dr. Rodgers seconded the motion. The motion carried.

3.

“PIC #3” for case 1 above.

Prior discipline – chemical dependency.

Recommend:

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

4.

Respondent allegedly forged prescriptions for non-controlled substances and pseudoephedrine for self and a family member.

BOP Investigator determined twenty-one prescriptions for non-CS and pseudoephedrine products were filled for the pharmacist and the pharmacist's mother by using the name of the pharmacist's family physician. When the physician's office questioned the prescriptions, the respondent allegedly said an intern had mistakenly used the wrong prescriber's name and records were changed to an APN that was known to the pharmacist. Both the physician and the APN deny authorizing the prescriptions. Investigator also confirmed the pseudoephedrine purchased 7/11/18 exceeded the daily limit of 3.6 gm.

No prior discipline.

Recommend:

Dr. Pryse made the motion to authorize a formal hearing to suspend the pharmacist license. The suspension will be stayed and the pharmacist license will be placed on probation for 2 years, not allowed to call in prescriptions and no dispensing to herself or family members. Dr. McCall seconded the motion. The motion was amended to add 12 hours of continuing education hours. Dr. McCall seconded the amend motion. The motion carried.

5.

PIC change form submitted to the BOP office showed the former PIC departed on 11/16/18 and the new PIC arrived 1/8/19. CS inventory was not performed by the former PIC and the new PIC did not conduct a CS inventory until 1/11/19.

No prior discipline.

Recommend: \$50 per month each for PIC and for CS inventory, totaling \$200 plus costs of investigation.

Dr. Dickenson made the motion to authorize a formal hearing with a \$50.00 civil penalty for each month that the PIC did not notify the board of the PIC change and that a controlled substance inventory was not done at the time that the new PIC arrived, plus the cost of the investigation. Dr. Rodgers seconded the motion. The motion carried.

6.

Respondent manufacturer changed ownership 10/1/18 but did not notify BOP as required. A change of ownership application was received at BOP office 1/11/19.

No prior discipline.

Recommend: \$400 civil penalty plus cost of investigation

Dr. Wright made the motion to authorize a formal hearing with a \$400.00 civil penalty plus the cost of the investigation to the Respondent. Dr. Dickenson seconded the motion. The motion carried.

7.

Respondent technician admitted in writing to taking Hydrocodone from her employer. BOP Investigator became aware of the diversion from a police investigator concerned that the technician still had an active registration. The diversion had occurred in August of 2017. BOP was made aware of it by the policeman in December, 2018. Pharmacy management did not notify BOP of the diversion.

No prior discipline.

Recommend: Revoke tech registration;

- Question of discipline against the pharmacy.

Dr. Dickenson made the motion to authorize a formal hearing for revocation of the pharmacy technician registration and a \$100.00 civil penalty to the pharmacy for failure to report the diversion to the board. Dr. Rodgers seconded the motion. The motion carried.

8.

Respondent technician admitted in writing to diverting controlled substances.

No prior discipline.

Recommend: Revoke tech registration.

Dr. Dickenson made the motion to authorize a formal hearing for revocation for the pharmacy technician registration. Ms. Tittle seconded the motion. The motion carried.

9.

Complaint alleged rude conduct by pharmacy employees and the denial to fill controlled substances for the complainant unless a pain contract was signed and all other medications for the patient were transferred to the respondent pharmacy.

BOP Investigator interviewed pharmacy staff and the PIC. The policy of the pharmacy is to ask opioid patients to sign a pain contract and transfer all other medications to the pharmacy unless the opioid is for a one-time or limited supply fill. PIC indicated that the policy is in place so that clinical judgement regarding diagnosis codes and treatment could be utilized to coordinate patient care.

Investigator could not identify any violation of laws or rules.

No prior discipline.

Recommend: Dismiss

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

10.

Complaint alleges a failure to counsel and warn of side effects. It states the patient was prescribed Trazodone at bedtime for insomnia, for 14 days. According to the complaint, the prescription was picked up at the drive-thru and no counseling occurred regarding adverse reactions resulting from abrupt discontinuation. No refills were ordered and there was no advice given for appropriate follow-up. The complaint also alleges that neither the prescriber, the pharmacy, nor the manufacturer made any effort to warn about the consequences of off-label use of Trazodone for insomnia. The patient committed suicide three days after the 14-day supply ended.

BOP Investigators could not prove whether counseling did or did not occur, but did observe staff routinely making offers to counsel. Investigators did observe an intern dispensing a new prescription but only offered counseling. Investigators reviewed counseling rules with all staff, including the intern, regarding mandatory counseling on new prescriptions. Investigators also reviewed prescription records and found that the prescription was originally sent electronically to another pharmacy but was then transferred to the respondent pharmacy for dispensing. To be thorough, Investigators did visit both locations, however dispensing did occur from the respondent pharmacy. The dispensing pharmacist did not remember details about this prescription and could not remember specifically if it was counseled but her normal procedure would be to counsel on new prescriptions.

Prior discipline – 2009 counseling violation.

Recommend: LOW and recommend all staff (including interns) review counseling requirements for new or refilled prescriptions.

Dr. Dickenson made the motion to issue a Letter of Instruction. Dr. Pryse seconded the motion. The motion carried.

11.

BOP conducted a joint inspection with DEA at respondent pharmacy. Some record keeping violations were discovered and reviewed with the owner. A shortage of Hydrocodone 10/325 was researched but not all of the shortage could be explained. While on-site, BOP Investigators observed three counseling violations which were discussed with staff.

Prior discipline – 2011 unregistered technician employed and on duty.

Recommend: \$3,000 civil penalty for counseling violations with all but \$1,000 stayed with an acceptable plan of correction. Assess costs. Follow-up audits to be conducted to determine cause of shortage and to review record keeping.

Dr. Wright made the motion to authorize a formal hearing with a \$3000.00 civil penalty with all but \$1000.00 stayed with an acceptable plane of correction for counseling violations and assessed cost. A follow-up audit will be conducted to determine the cause of the shortage and to review record keeping. Dr. Rodgers seconded the motion. The motion carried.

12.

Respondent is PIC and owner for Case 11 above.

No prior discipline.

Recommend: \$1,000 civil penalty for counseling.

Dr. Wright made the motion to authorize a formal hearing with a \$1000.00 civil penalty for counseling violations. Dr. Rodgers seconded the motion. The motion carried.

13.

During a periodic inspection, BOP Investigator discovered ninety (90) expired ingredients and excipients for use in non-sterile compounding. No sterile compounding occurs at this location. Investigator also found vaccines being stored in a refrigerator without a temperature gauge.

Respondent sent verification that all expired/unsanitary compounding components have been returned to a reverse distributor and a thermometer was placed in the vaccine storage refrigerator.

Prior discipline - 2010 unregistered technician employed and on duty.

Recommend: \$10 per component = \$900 civil penalty and LOW for vaccine storage.

Dr. Dickenson made the motion to authorize a formal hearing with a \$10.00 civil penalty for each expired ingredients and excipients for use in non-sterile compounding for a total of \$900.00 and a Letter of Warning for the vaccine storage in a refrigerator without a temperature gauge to the pharmacy. Ms. Tittle seconded the motion. The motion carried.

14.

Respondent is PIC for Case 13 above.

Prior discipline – same as for case #13.

Recommend: LOW for expired excipients and lack of temperature gauge for vaccines.

Dr. Dickenson made the motion to issue a Letter of Warning to the PIC for the expired excipients and lack of temperature gauge for the vaccines. Ms. Tittle seconded the motion.

15.

BOP Investigator discovered an unlicensed facility conducting business as a wholesale/distributor and oxygen supplier. The facility was open approximately seven weeks before becoming licensed.

No prior discipline.

Recommend: \$200 civil penalty

Ms. Tittle made the motion to authorize a formal hearing with a \$200.00 civil penalty for unlicensed practice. Dr. Dickenson seconded the motion. The motion carried.

16.

During a periodic inspection, BOP Investigator found the following violations:

1. A technician was working on a registration that had been expired approx. 11 months;
2. A pharmacy technician student did not have the required name badge;
3. Eleven expired or no-date compounding ingredients/excipients
4. Food being stored in vaccine freezer
5. Verbal prescriptions not initialed as required
6. Refrigerator with no monitoring of temperature
7. Technicians accessing CSMD by using pharmacist's user name and password

PIC has responded that all compliance issues have been corrected.

No prior discipline.

Recommend: LOI for proper I.D. for students; \$110 civil penalty for expired compounding ingredients; LOW for remaining violations.

Dr. Dickenson made the motion to authorize a formal hearing with a \$110.00 civil penalty for expired compounding ingredients, a Letter of Instruction for proper I.D. for students and a Letter of Warning for the remaining violations to the pharmacy. Dr. Pryse seconded the motion. The motion carried.

17.

Respondent is PIC for Case 16 above.

No prior discipline.

Recommend: \$1,100 civil penalty for expired tech; LOI for proper I.D. for students; LOW for remaining violations.

Dr. Wright made the motion to authorize a formal hearing with an \$1100.00 civil penalty for the pharmacy technician working on an expired registration, a Letter of Instruction for proper I.D. for students and a Letter of Warning for the remaining violations. Dr. Rodgers seconded the motion. The motion carried.

18.

Respondent is the technician for Case 16 above.

No prior discipline.

Recommend: \$100 civil penalty

Dr. Dickenson made the motion to authorize a formal hearing with a \$100.00 civil penalty to the technician for working on an expired registration. Dr. Rodgers seconded the motion. The motion carried.

19.

BOP Investigator observed the sale of Claritin D by a technician without a pharmacist counseling. Staff told the investigator they did not counsel on pseudoephedrine products and did not know it was a requirement. Other violations found during the periodic inspection included technician affidavits could not be located and there was no technician registry. Investigator requested a CAPA (corrective action and preventative action) plan on 3/19/19. It was received on 4/10/19 stating corrective actions have been taken.

No prior discipline.

Recommend: \$1,000 civil penalty for staff's failure to counsel. Educate all staff about the law.

Dr. Dickenson made the motion to authorize a formal hearing with a \$1000.00 civil penalty stayed with an acceptable plan of correction for failure to counsel to the pharmacy. Dr. Pryse seconded the motion. The motion carried.

20.

Respondent is the PIC and DPh on duty for Case 19 above.

No prior discipline

Recommend: \$1,000 civil penalty for counseling violation. Educate all staff about the law.

Dr. Dickenson made the motion to authorize a formal hearing with a \$1000.00 civil penalty for failure to counsel. Dr. Pryse seconded the motion. The motion carried.

21.

Respondent technician admitted in writing to stealing controlled substances since November of 2018. Pharmacy inventory shortages discovered are as follows:
589 Alprazolam 2 mg; 3,342 Hydrocodone 10/325; 3,253 Hydrocodone 7.5/325; 4,170 ml of Promethazine with Codeine syrup.

No prior discipline.

Recommend: Revoke tech registration

Dr. Rodgers made the motion to authorize a formal hearing for revocation. Ms. Tittle seconded the motion. The motion carried. After further discussion, Dr. Rodgers made the motion to issue a Letter of Warning to the pharmacy. Dr. McCall seconded the motion. The motion carried.

22.

Respondent is the PIC for Case 21 above.

No prior discipline.

Recommend:

Dr. Rodgers made the motion to dismiss the complaint. Dr. McCall seconded the motion. The motion carried.

23.

Anonymous Complaint was received through a state complaint hotline. The complainant alleged unlicensed practice and misconduct by forcing patients to use a dispensary owned by the same person who owned the clinic.

BOP Investigators met with the clinic owner who stated there was physician dispensing for a very limited number of people but that everyone was allowed to get their medications wherever they desired to go. When someone from TDMHSAS informed the clinic that an OBOT license is required and no physician dispensing can occur, dispensing ceased immediately. Regarding unlicensed practice, Investigators determined the clinic functioned as an OBOT from August of 2018 until becoming licensed in November of 2018. Neither complaint involves TBOP.

No prior discipline.

Recommend: Refer the complaint and case file to the appropriate agency.

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

24.

Complaint was generated from a PIC change form indicating the former PIC left on 1/14/19 and the successor PIC started on 2/10/19.

BOP Investigator determined the former PIC had planned a medical leave but management did not plan accordingly and the successor PIC was named 26 days after leave had started.

No prior discipline.

Recommend: Dismiss

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

25.

During a periodic inspection, BOP Investigator discovered the PIC was on planned medical leave for a total of 63 days from 12/24/18 until 2/25/19. The PIC was unaware of notification requirements and management did not appoint a PIC during the absence.

NO prior discipline.

Recommend:

Dr. Rodgers made the motion to authorize a formal hearing with a \$200.00 civil penalty to the pharmacy for failure to appoint a PIC. Ms. Tittle seconded the motion. The motion carried.

26.

Respondent (a technician) failed the first drug screen submitted after a return to work subsequent to completing a recovery program.

BOP Investigator contacted the respondent who admitted the allegation, admitted to not currently being in a recovery program, does not plan to work as a technician and is willing to surrender the technician registration.

No prior discipline.

Recommend: Accept voluntary surrender of tech registration.

Dr. Dickenson made the motion to accept the voluntary surrender of the pharmacy technician registration. Ms. Tittle seconded the motion. The motion carried.

27.

An in-house investigation by the complainant, including video footage, indicates the Respondent diverted controlled substances on multiple occasions. Law enforcement was notified. Respondent denied the allegations to management verbally. BOP Investigator attempted to contact the respondent however no response has been received.

No prior discipline.

Recommend: Revoke tech registration

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

28.

The biological mother of a child complained the respondent pharmacist (who is the child's step-mother) used her position as a pharmacist to persuade a co-worker to legally prescribe amoxicillin, even though the child is allergic to it. Complaint stated the biological mother has complete non-emergency medical decision making authority for the child.

Respondent told BOP Investigator the child stayed with Respondent and husband on the weekend referenced in the complaint and the child was sick with an ear infection. The respondent contacted the ER and was instructed to bring the child in. The respondent and her husband (the child's biological father) took the child to the ER and the child was prescribed amoxicillin. When the respondent contacted the complainant about taking the child to the ER, the complainant told the respondent the child was allergic to amoxicillin. None of the medication was ingested and the next morning the child was taken to a walk-in clinic and prescribed a different antibiotic. Respondent also stated the child has taken Augmentin without issue after supposedly being allergic to amoxicillin. Investigator could not find any violation of pharmacy laws or rules.

No prior discipline.

Recommend: Dismiss

Dr. Rodgers made the motion to accept counsel's recommendation. Dr. McCall seconded the motion. The motion carried. Dr. Wright was recused.

29.

Anonymous complaint alleged the respondent pharmacy illegally compounds peptides. The complaint states the peptide is only allowed for research purposes, has no USP monograph and is not listed on the approved list of API's.

Respondent denies the allegations and provided a written statement that peptides are not compounded in the Tennessee facility. BOP Investigator reports that none have ever been seen at this facility during periodic inspections.

Prior discipline – Reprimand for minor compounding violations.

Recommend: Dismiss

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

30.

Anonymous complaint alleged the respondent pharmacy illegally compounds peptides. The complaint states the peptide is only allowed for research purposes, has no USP monograph and is not listed on the approved list of API's.

Respondent is licensed as an out-of-state pharmacy. BOP Investigator met with a representative who admits compounding the peptide patient specific by a physician's order, and that FDA has inspected the facility and has not requested them to stop.

No prior discipline.

Recommend: Close and refer to FDA for consideration

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

31.

PIC of respondent pharmacy reported a misfill that stemmed from incorrect math when converting from Baclofen tablets to Baclofen powder to make a suspension for a pediatric patient. Patient was hospitalized but has since been discharged.

BOP Investigator found that a technician had incorrectly calculated the conversion and the checking pharmacist was not aware of the change in calculations and only confirmed ingredients.

No prior discipline.

Recommend: LOW and request a POC to prevent reoccurrence

Dr. Wright made the motion to issue a Letter of Warning for the misfill to the pharmacy. Dr. Dickenson seconded the motion. The motion carried.

32.

Respondent was the final check pharmacist for Case 31 above.

No prior discipline.

Recommend: LOW

Dr. Wright made the motion to issue a Letter of Warning to the pharmacist who completed the final check. Dr. McCall seconded the motion. The motion carried.

33.

Respondent is the compounding pharmacy technician for Case 31 above.

No prior discipline.

Recommend: LOW

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

34.

Complaint alleges the respondent pharmacy dispenses prescriptions to mix at home instead of compounding the mixture prior to dispensing. Patients are being instructed to mix at the time of use for use in foot baths and nasal irrigation solutions. Some products are being used off label such as eye and ear drops being used for nasal irrigation and topical solutions and/or creams are being added to foot bath soaks.

BOP Investigator determined the respondent pharmacy is dispensing unit-of-use products that are easily added to neti-pots or foot baths. The pharmacy does obtain patient specific prescriptions from prescribers. The prescriptions do not instruct the pharmacy to mix prior to dispensing. The pharmacy will repackage smaller unit of use products into a larger bottle for those who may have difficulty using the unit of use product (e.g. taking the top off a drop container). The products being used are FDA approved medications that are being used for off-label purposes, but are being dispensed as prescribed. The pharmacy provided medical literature studies showing such treatments can be very effective in treating chronic inflammation or infection of the nasal passages and feet.

No prior discipline.

Recommend: Dismiss

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

35. 201902074

In a joint inspection follow-up, DEA agents and BOP Investigators arrived to an open but unattended pharmacy. All entrance doors from outside were unlocked and the CS safe had the safe key in the lock. There were no employees present. When the pharmacist arrived, he stated he had gone upstairs to use the restroom. Investigators noted that the upstairs area was not part of the pharmacy because one has to exit the pharmacy to a community hallway of the office building, and then ride an elevator upstairs. It was decided that BOP would conduct a full inspection while on-site. The pharmacy has been licensed for less than one year.

Deficiencies were noted as follows:

Pharmacist had no name tag;

Verbal orders reviewed were not initialed properly by the receiver;

Pharmacy had no hot water;

Opening CS inventory was not signed and dated as required;

1 CS invoice was not dated as required;

1 CS prescription did not list supervising/collaborating physician;

1 CS prescription was not manually signed;

Pharmacy fills prescriptions from a physician prescribing greater than 90% of buprenorphine patients with notation "naloxone allergy" but the pharmacy does not have any documentation about the allergies.

Since opening, all prescriptions filled equal 49.9% cash. 26% of all prescriptions were C-3 thru C-5 but were paid by cash 87% of the time.

Non-local patients with non-local prescribers presented prescriptions to the pharmacy. The pharmacy did not have explanatory documentation. Investigator also noted patients living at the same address with the same diagnosis.

Eleven drugs were selected for audit. Discrepancies are as follows:

Oxycodone APAP 10/325, short 92; Hydrocodone APAP 10/325, over 90; Buprenorphine 8mg, short 3.5; Carisoprodol 350, short 1; Oxycodone 30, short 3.

No prior discipline.

Recommend:

Dr. Rodgers made the motion to authorize a formal hearing for revocation to the pharmacy. Dr. Wright seconded the motion. The motion carried.

36.

Respondent is the PIC and owner for Case 35 above.

Prior discipline – Respondent failed to report convictions to the Board resulting in revocation. Respondent's license was reinstated, through Board action, on July 31, 2014.

Recommend:

Dr. Wright made the motion to authorize a formal hearing for revocation to the pharmacist. Ms. Tittle seconded the motion. The motion carried.

37.

Anonymous complaint alleged improper compounding and compounding medications for office use.

BOP Investigation confirmed at least five different occasions when a topical anesthetic cream was compounded and dispensed for office use. Investigator also discovered the pharmacy was compounding with expired API's; using dirty equipment; had inaccurate compounding records because the manufacturer's expiration dates was listed incorrectly; and that compounding records do not indicate that non-sterile compounding was properly supervised or checked by a pharmacist.

No prior discipline.

Recommend:

Dr. Wright made the motion to issue a Letter of Warning. After discussion, Dr. Dickenson made the motion to authorize a formal hearing with 2 year probation, 5 year monitoring contract, a corrective action plan, a \$1000.00 civil penalty or cease from compounding. D. Pryse seconded the motion. After further discussion, Dr. Dickenson withdrew his motion. Dr. Rodgers made the motion to authorize a formal hearing with 2 year probation, a 5 year monitoring contract, a \$2500.00 civil penalty or cease & desist compounding and the civil penalty stayed. Dr. Dickenson seconded the motion. The motion carried.

38.

Respondent is PIC for Case 37 above.

No prior discipline.

Recommend:

Dr. Wright made the motion to authorize a formal hearing to reprimand the PIC license and submit 15 hours of continuing education hours in non-sterile compounding. Dr. Dickenson seconded the motion. The motion carried.

39.

Respondent is staff pharmacist for Case 37 above.

No prior discipline.

Recommend:

Dr. Wright made the motion to authorize a formal hearing to reprimand the PIC license and submit 10 hours of continuing education hours in non-sterile compounding. Dr. Dickenson seconded the motion. The motion carried.

40.

Summary – Respondent pharmacy allegedly made consented to the requests of a prescriber regarding a minor patient’s pharmaceutical needs (e.g. PCA pump, pulse oximeter, naloxone drip, and carrier fluid). The pharmacy ultimately did not provide all requested items, even though it was stated the pharmacy was capable. The pharmacy caused delays in the patient receiving care.

Complaint alleged substandard care by the respondent pharmacy resulting in patient harm after being discharged from the hospital. Specific details provided in the letter of complaint are as follows:

Oct. 12: Care coordinators contacted respondent pharmacy regarding discharge plans. PCA (patient controlled analgesia,) pulse oximeter, naloxone drip (to counteract narcotic induced itching), and carrier fluid orders were faxed to the pharmacy. Respondent informed the caller that naloxone was not stocked but would be ordered.

Oct 13: Physician spoke to a pharmacist and gave the schedule of all the next doses of medications and the pharmacist assured the physician everything could be handled by the pharmacy and would be delivered to the hospital before the patient is discharged at 6pm. At 5:30pm, the physician was notified that several things were missing from the order so a new order was sent. At 7pm, the physician was notified the new order was not acceptable because all components were not on the same page. A new order was sent to meet the single page requirement. At 10pm the physician was notified by an inpatient nurse that carrier fluid was not available from the respondent pharmacy even though the pharmacist had assured the physician that everything would be taken care of, except the naloxone that had to be ordered. Hospital supplies were given to the patient so he could still go home. At nearly midnight, a home health nurse called the physician on-call to report there was no pulse ox equipment and the father of the patient told the physician that the nurse didn't have a bracket that was necessary to properly attach "something" but the physician did not want to dwell on yet another problem that wasn't going to be solved at 2am.

Oct 15: Respondent pharmacy contacted the clinic nurse manager and told her to get a pulse ox or the pharmacy would remove the PCA from the home. Pharmacy staff also commented that the naloxone drip didn't make sense since it would counteract the pain medicine. Later in the day, the patient's oncologist called the pharmacy regarding the naloxone and was told they never received an order. So another order was sent but the physician was told that the pharmacy was working on a UPS order and could not check to see if they had received the order yet. The physician gave a cell number and asked to be called back when the pharmacy could check but nobody from the pharmacy ever called.

Oct. 16. The clinic care coordinator attempted to call the pharmacy's care coordinator but never got through, and could not leave a message because the voice mailbox was full. The pharmacy was also called several times and the clinic care coordinator was told the pharmacy was trying to get approval for naloxone to be used at home.

Oct 17: Care coordinator again called the pharmacy and was told they were trying to get approval.

Oct 18: Someone from the respondent pharmacy called the Hematology/Oncology inpatient nursing unit to report that the pharmacy was unwilling to provide the child with a naloxone drip because it must be mixed daily.

Complainant believes the pharmacy should have been honest and forthcoming regarding what they could and could not provide, but instead confirmed that everything could be done by the respondent pharmacy. Complainant also states the patient was exposed to potential harm by the substandard care.

BOP Investigator interviewed pharmacists and reviewed orders and documentation. Nothing contradicts the allegations made by the complainant. Nothing explains the poor communication nor the failures to provide all services or follow-up as promised.

PIC was interviewed and recalled the incident because of multiple phone conversations with the pharmacist on duty that weekend. PIC told the Investigator that she does not believe it was a system failure, but instead was a failure of the pharmacist.

The dispensing pharmacist remembered the situation very well and told the Investigator she left the company because of this incident and has not returned to the work force since. She also stated some factors leading to the incident include a lot of changes in management and staff, a reduction in staff, and a lengthy timeframe without a manager. She believes this failure to deliver proper care resulted from lack of leadership, inadequate staffing and overall system failure. She also stated that company policy prevented her from adjusting orders and obtaining needed materials.

Recommend: Reprimand and costs

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

41.

Respondent is the dispensing pharmacist for Case 40 above.

No prior discipline.

Recommend: LOI 1140-02-.01 (7)

Dr. Rodgers made the motion to issue a Letter of Warning to the pharmacy. Dr. McCall seconded the motion. The motion carried.

42.

Complaint alleged misconduct at the respondent pharmacy by way of aggressive marketing by a pharmacy technician for Sildenafil and a particular brand of multivitamin. It is alleged the technician gets patient information and uses it to bill for prescriptions created even though the patients deny asking for it. Patients' insurance plans are reportedly being billed without the patients' knowledge.

During the investigation, BOP Investigator discovered the technician was falsely claiming to be a certified pharmacy technician. Documentation such as email correspondence lists the technician as the “Pharmacy Owner/Manager,” however the Investigator determined that is not true, although the tech hopes to someday be the owner. The same technician was also untruthful about having approval for off-site storage of prescription files, messages, licenses and old computers. Respondent pharmacy staff could not produce any formal collaborative pharmacy practice agreement for the process used to create prescription orders for the two primary drugs being marketed, and according to statements made to the Investigator, the listed prescriber on the prescriptions in question authorized the prescriptions without seeing the patients. Many of the prescriptions were treated as verbal orders received by the non-certified tech. Other orders were filled from the pharmacy’s “call-in” prescription pads and the prescriber came in occasionally to sign the signature line, which also violates tamper resistant requirements.

Investigator interviewed the prescribing physician who insists nothing shady was going on and that he did have a verbal agreement with the pharmacy to serve as an intermediary sometimes between the doctor and the patient.

Recommend: Reprimand for misconduct by the pharmacy staff. Cost of the investigation.

Dr. Dickenson made the motion to defer this complaint until the next meeting. Dr. McCall seconded the motion. The motion carried.

43.

Respondent is PIC for Case 42 above.

No prior discipline.

Recommend: Reprimand for allowing uncertified tech to function as a certified tech.

Dr. Dickenson made the motion to defer this complaint until the next meeting. Dr. McCall seconded the motion. The motion carried.

44.

Respondent is the tech for Case 42 above.

No prior discipline.

Recommend:

Dr. Dickenson made the motion to defer this complaint until the next meeting. Dr. McCall seconded the motion. The motion carried.

45.

Complainant transferred prescriptions to the respondent pharmacy because the former pharmacy refused to order brand name Norvasc. Respondent pharmacy ordered and dispensed the brand name, however, the patient still felt that it was not name brand.

BOP Investigator verified the prescription, the dispensing label, and the invoice, all showing the drug dispensed was name brand.

No prior discipline.

Recommend: Dismiss

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

Application Review

Tiffany Conger, RT

Ms. Conger answered "no" to the question that asked "Have you ever been 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 or suspended?" Ms. Conger pled guilty to DUI 2nd Offense on 9/29/2014; pled guilty of DUI 1st Offense 10/10/2016. After discussion, Dr. Dickenson made the motion to approve Ms. Conger's application for registration as a pharmacy technician. Dr. Wright seconded the motion. The motion carried.

Nichole Murley, RT

Ms. Murley answered "yes" to the question that asked "Are you currently participating in a supervised rehabilitation program or professional assistance program that monitors you to assure that you do not consume alcohol and/or do not engage in the illegal use of illicit or controlled substance?"; "Have you ever been 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 or suspended?" Documentation submitted states that Ms. Murley was convicted of DUI on 6/17/2010 in TN and DUI 1st Offense 10/29/2014 in Southaven, MS. After discussion, Dr. Dickenson made the motion to approve Ms. Conger's application for registration as a pharmacy technician. Ms. Tittle seconded the motion. The motion carried.

Jasmine Logan, RT

Ms. Logan answered "yes" to the question that asked "At any time within the past two years, have you engaged in the illegal use of illicit or controlled substances?"; Are you currently participating in a supervised rehabilitation program or professional assistance program that monitors you to assure that you do not consume alcohol and/or do not engage in the illegal use of illicit or controlled substances?" ;"Have you ever been 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 or suspended?"; "In relation to the performance of your professional services in any profession: Have you ever entered into any settlement of any legal action?" and "In relation to the performance of your professional services in any profession: Are there any legal actions pending against you or to which you are party?" Ms. Logan pled guilty to domestic assault on 9/7/2017; pled guilty to possession of Schedule IV on 3/2/18. After discussion, Dr. Wright made the motion to approve Ms. Conger's application for registration as a pharmacy technician. Dr. Rodgers seconded the motion. The motion carried.

Order Modification
Jilbear Hatch, D.Ph.

Dr. Hatch appeared before the board to request that the probation on his license be lifted. Dr. Hatch's license was placed on probation on 9/28/17. The probation status on his Utah pharmacist license has been lifted. After discussion, Dr. Wright made the motion to approve Dr. Hatch's request to have the probation on his license lifted. Dr. Dickenson seconded the motion. The motion carried.

Waiver

Board rule 1140-01-.05(4)
Marcus Maddox, Pharm. D.,

Dr. Dickenson made the motion to approve Marcus Maddox, Pharm. D., request to retake the NAPLEX and extended his application pass the one year requirement. Dr. Maddox has until 12/31/19 to successfully complete the requirements for licensure as a pharmacist. Dr. Rodger's seconded the motion. The motion carried.

Reinstatement
Katherine Nola, D.Ph.

Dr. Nola requested to have his licensed reinstated. Dr. Nola's license was voluntarily surrendered on 01/27/2017. After discussion, Dr. Rodgers made the motion to reinstate Dr. Nola's license. Dr. Nola's license will be on five (5) year probation once she has completed all the necessary requirements for reinstatement with the following conditions. Ms. Tittle seconded the motion. The motion carried.

- (a) The Respondent shall completely abstain from the consumption of alcohol or any other drugs, except as specified in;
- (b) The Respondent shall be able to consume legend drugs or controlled substances prescribed by the Respondent's primary physician, except in the case of an emergency or upon proper referral from the Respondent's primary physician. The Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary physician each time the Respondent changes primary physicians;
- (c) The Respondent shall not obtain or attempt to obtain any prescriptions in the Respondent's name for any legend drugs, controlled substances or devices containing

- same from the physician other than the Respondent's primary physician or from any other health care provider, such as a nurse practitioner, physician's assistant or psychiatrist;
- (d) The Respondent shall destroy any unused controlled substances prescribed under the provisions of subsection (b) no later than thirty (30) days following the completion of the prescribed course of treatment;
 - (e) The Respondent shall report to the Board, in writing, the ingestion of any and all legend drugs or controlled substances (a copy of the prescription will satisfy the requirement);
 - (f) The Respondent shall submit to random sampling of urine, blood or bodily tissues for the presence of drugs and alcohol, at the Respondent's own expense, by agents of the Board, such as the Tennessee Pharmacist Recovery Network for as long as the Respondent has an active license. In the event that the sampling indicates the presence of drugs for which the Respondent does not have a valid prescription or the sampling indicates the presence of alcohol, then formal disciplinary charges may be brought against the Respondent which could result in the revocation of the Respondent's remaining term of probation or the suspension or revocation of the Respondent's license to engage in the practice of pharmacy. Prior to such disciplinary charges being heard by the Board, the Respondent's license may be summarily suspended;
 - (g) The Respondent shall successfully complete the Multistate Pharmacy Jurisprudence Examination
 - (h) The Respondent shall not serve as pharmacist-in-charge the respondent's pharmacist-in-charge shall submit to the Board quarterly reports detailing Respondent's work performance for a period of three (3) years from the state date of Probation; the Respondent may not work more than 40 hours over a 5 day period, however, the Respondent may petition the Board for a modification of this time limitation after (2) years from the start date of Probation;
 - (i) Respondent shall not work as a "floater" for a period of three (3) years from the start of Probation, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without permission of the Board;
 - (j) Respondent shall complete a period of pharmacy internship for a minimum of one hundred and sixty (160) hours and must be completed within ninety (90) consecutive days.

Presentation

ONE Tennessee Healthcare Collaborative

Ms. Carla Saunders, CEO, of ONE Tennessee Healthcare Collaborative appeared before the board. ONE Tennessee Healthcare Collaborative has partnered with Vanderbilt and Tennessee Department of Health to develop a mobile continuing education application to provide high value opioid prescribing and pain management education to healthcare providers in Tennessee. The course content is based on 12 educational competencies identified through the TN Together and is being developed and accredited through Vanderbilt.

Waivers

Board rule 1140-02-.02 (7)

Dr. Charles Wall, PIC of Advanced Specialty Pharmacy of Knoxville dba Heartland Apothecary is requesting modification of the pharmacist to tech ratio. Advanced Specialty Pharmacy of Knoxville dba Heartland Apothecary current ratio is 4:1 and they would like to change it to 6:1. After discussion, Dr. Rodgers made the motion to approve the waiver request. Any changes to the modification will need to be brought before the board. Dr. McCall seconded the motion. The motion carried

Board rule 1140-03-.14 (12)

Dr. Rodgers made the motion to approve Charles Wall, D.Ph. to be PIC of Advanced Specialty Pharmacy of Knoxville dba Heartland Apothecary and Heartland Infusion in Knoxville, TN. Dr. McCall seconded the motion. The motion carried.

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

Dr. Dickenson made the motion to approve the request from **Joseph Barone, Pharm.D.** to waive the one hundred and sixty (160) internship hours but must successfully take and pass the MPJE. Ms. Tittle seconded the motion. The motion carried.

Dr. Dickenson made the motion to approve the request from **Joseph Sciasci, Pharm.D.** to waive the one hundred and sixty (160) internship hours but must successfully take and pass the MPJE. Dr. McCall seconded the motion. The motion carried.

Board rule 1140-01-.04 (6)

Dr. Rodgers made the motion to approve the request from Sarah Morris, Pharm.D. to waive the one year requirement for licensure as a pharmacist by reciprocity. Dr. Morris has been licensed in CA since October 2018 and has been accepted into a PGY2 residency at St. Jude's which is scheduled to begin August 1, 2019. Dr. Wright seconded the motion. The motion carried. After discussion, Dr. Rodgers made the motion for the Dr. Dilliard and Mr. Gibbs to review and approve these types of request in the future. Dr. Wright seconded the motion. The motion carried.

Consent Orders

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

VOLUNTARY SURRENDER (same as revocation)

Bonnie Stinson, RT

Kathleen Waffird, RT

Therasia Carney, RT

Tennessee Board of Pharmacy
Board Meeting
May 8, 2019

VIOLATED BOARD RULE 1140-03-.01 (1) (a)

Amanda Matney, D.Ph
Walgreens Pharmacy #09429
Martha Warriner Powers, D.Ph.
Walgreens Pharmacy #12448
Lindsey N Snyder, D.Ph.

VIOLATED BOARD RULE 1140-01-.08 (2)

Hospice Source, LLC

VIOLATED T.C.A, § 63-10-305 (a)

Jimmy Gean, D.Ph.
Todd's Discount Pharmacy

REPRIMAND

Kathryn Nolan, RT

Director's Report

Dr. Dilliard asked for volunteers for NABP District III meeting scheduled for August 11-14, 2019 in Chattanooga, TN. Ms. Tittle and Dr. McCall volunteered to assist with the meeting.

Dr. Dilliard informed the board of Tennessee Pharmacist Recovery Network (TPRN) contract with the Department of Health.

Dr. Dilliard informed the board that the recipient of the Kendall Lynch Award is Dr. Terry Grinder. This award will be presented at the TPA 2019 Summer Meeting.

Dr. Rodgers made the motion to adjourn. Dr. McCall seconded the motion. The motion carried.

The minutes were approved as presented at the July 16, 2019 board meeting.

Tennessee Board of Pharmacy
Board Meeting
May 8, 2019