

Tennessee Board of Pharmacy
Board Meeting
May 11-12, 2015

TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Iris Room
Nashville, TN
May 11-12, 2015

BOARD MEMBERS PRESENT

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

STAFF PRESENT

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

STAFF ABSENT

Terry Grinder, Pharmacy Investigator
Larry Hill, Pharmacy Investigator

The Tennessee Board of Pharmacy convened on Monday, March 11, 2015, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:02 a.m.

Minutes

The minutes from the March 11-12, 2015 board meeting were presented. After discussion, Dr. Eidson made the motion to approve the minutes as amended. Dr. Dickenson seconded the motion. The motion carried.

Legislative Update

Mr. Ben Simpson, Legislative Liason, presented the following legislation to the board.

Public Chapter 82/Senate Bill 45

This act prohibits the sale of products containing dextromethorphan to persons less than 18 years of age.

Public Chapter 293/Senate Bill 87

This act allows the board of pharmacy to regulate and license third party logistics providers with regard to controlled substances. This will require rulemaking from the board.

Senate Bill 98/House Bill 87

This act would allow the Commissioner of Health or his designee to have electronic access to medical records in order to facilitate investigations when responding to an immediate threat to public health. Today the Commissioner of Health or his designee already has this authority but must go to the facility to review the medical records.

Public Chapter 94/Senate Bill 99

This act defines “abuse” and “neglect” for purposes of placing a person on the registry of persons who have abused, neglected, or misappropriated the property of vulnerable individuals specifically within the statutes that govern the Dept. of Health. It does not impact the definitions within the statutes that govern the Dept. of Intellectual and Developmental Disabilities nor the Dept. of Human Services. It also increases the time within which placement on the registry may be appealed from 30 to 60 days.

Public Chapter 59/Senate Bill 111

This act changes the limits and the identification requirements for products that may be sold containing ephedrine or pseudoephedrine. This applies to their salts, isomers and salts of isomers as well.

Public Chapter 26/Senate Bill 157

This legislation deletes the Intractable Pain Act. This becomes effective on July 1, 2015.

Public Chapter 352/ Senate Bill 280

This legislation would decriminalize the possession of cannabis oil as long as all of the following are met:

- The oil contains less than 0.9% of THC and is labeled as such by the manufacturer
- The person in possession retains proof of the legal order or recommendation from the issuing state
- The person in possession retains proof that the person or person’s family member has been diagnosed with intractable seizures or epilepsy by a physician licensed to practice in TN

This legislation does not allow a physician in TN to prescribe, order or recommend the oil.

This act became effective on April 16, 2015.

Public Chapter 40/ Senate Bill 409

This act allows pharmacies to participate in pharmacy drug disposal programs. This act will require rulemaking from the board.

Public Chapter 502/ Senate Bill 467

This act allows the Joint Government Operations Committee (the legislative committee that reviews all rules) to stay a rule up to 75 days instead of 60 days. Present law authorizes the Joint Government Operations Committee to consider the following factors when reviewing rules: authority, clarity, consistency, justification, necessity and reference. This act adds arbitrariness and capriciousness as two new considerations.

Public Chapter 376/ Senate Bill 811

This creates the “Tennessee Right to Try Act.” It authorizes eligible patients to utilize investigational drugs, biological products or devices that have completed phase 1 of a clinical trial, but has not yet been approved for general use by the FDA. The clinical trial must be documented by the National Institutes of Health. An eligible patient is:

- someone with an advanced illness that is attested to by the patient’s treating physician and confirmed by a second physician
- has considered all other FDA-approved treatment options
- has received a recommendation from the patient’s physician for an investigational drug, biological product, or device
- has given written, informed consent for the use of an investigational drug, biological product, or device
- has documentation from such physician that the patient meets all the aforementioned requirements.

All expenses related to the use of investigational treatment will be borne by the patient. Manufacturers are authorized to make investigational products available to patients with or without compensation. This bill specifically prohibits Medicare or any licensing board from taking any adverse action against a licensee based solely on a recommendation for treatment with an investigational product and holds manufacturers and providers harmless if operating in good faith. This act takes effect on July 1, 2015.

Public Chapter 396/ Senate Bill 871

This creates the “Addiction Treatment Act of 2015.” It prevents certain criminal drug charges from being filed against an individual who is experiencing a drug overdose or is in the company of an individual who is experiencing a drug overdose and seeks or is the subject of a request for medical assistance. Any such person is immune to penalties for a violation of a permanent or

temporary protective order or restraining order or sanctions for a violation of a condition of pretrial release, condition of probation, or condition of parole based on a drug violation. This immunity does not provide protection against seizure of any evidence or contraband, limit the admissibility of any evidence in connection with the investigation or prosecution of a crime for an individual who doesn't qualify for the aforementioned exemptions, or limit the authority of a law enforcement officer to detain or take into custody a person in the course of an investigation or to effectuate an arrest for any offense not immune by the aforementioned exemptions. This immunity only applies to the person's first such drug overdose.

This bill further mandates that only M.D.'s or D.O.'s are permitted to prescribe buprenorphine for opioid dependence and it may only be prescribed for uses recognized by the FDA unless the patient has a documented opiate addiction, receives treatment from a DEA registered addiction treatment practice, and is counted as one of the total allowable number of patients the provider is allowed to treat. Only pregnant women, nursing mothers, or patients with a hypersensitivity to naloxone may be prescribed buprenorphine mono. These provisions do not apply to perioperative surgery or ventilator sedation performed in a licensed facility, or to inpatients and outpatients of a hospital.

The BME and the BOE are required to promulgate rules establishing requirements for licensees to qualify as addiction specialists.

This act takes effect on July 1, 2015.

Public Chapter 268/ Senate Bill 892

This act makes disclosures of protected healthcare information permissible in medical malpractice lawsuits and became effective on April 24, 2015.

Public Chapter 371/ Senate Bill 984

This act defines biological product and interchangeable biological product and allows their use under all circumstances unless:

- An adverse reaction has previously taken place
- The interchangeable has been previously deemed ineffective
- Any other clinically based prescriber determined need or the interchangeable biologic is not available

When prescriber determines biological is medically necessary he/she must

- Place these instructions on the prescription showing intent in writing
- If orally the prescriber must alert the pharmacist

- An electronic communication between prescriber and pharmacist that only the biological product be communicated

When a biologic is issued a pharmacist must

- Notify the patient of the substitution on the prescription label
- Communication within 5 days to the prescriber by:
 - Add it to the interoperable electronic medical records system
 - Communication can be set forth in collaborative pharmacy agreement
 - That this communication only applies to the original communication and not the refill
- Maintain a record of the biologic dispensed

This does not apply if the product if the product is

- Is directly dispensed to the patient
- Is dispensed in a nursing home or assisted living facility
- Vaccines

The board of pharmacy shall maintain a link on its website to the current list of all biological products determined by the FDA to be interchangeable.

Public Chapter 261/ Senate Bill 1223

The act provides for the practice of telehealth. It outlines the following:

- Defines a healthcare provider
- Establishes a provider-patient relationship by mutual consent and mutual communication
- Specifies that telehealth does not create a new standard care
- Prohibits any board from creating a more restrictive standard of professional practice for telehealth service
- Allows a physician to prescribe by means of telemedicine and follow all prescribing applicable statutes such as checking the Controlled Substance Monitoring Database; however, pain management clinics are not permitted

There is no separate telehealth license required by the Board of Medical Examiners.

Public Chapter 476/ Senate Bill 1287

Currently, the top 50 prescribers of controlled substances in the state are annually identified and sent a letter notifying them of their inclusion on this list and asked to respond with a justification for their prescribing patterns. This legislation expands on this list and requires the top 10 prescribers from all of the combined counties having populations of fewer than 50,000 to also be on this annual list.

Separate from this provision, the bill also specifies that a provider of home medical equipment or services that provides its own company-branded insulin pumps and related supplies does not have to have a physical place of business in the state if the provider maintains an employee presence in the state, is accredited by the Joint Commission on Accreditation of Healthcare Organizations and maintains a 24-7 service telephone number.

This act took effect on April 22, 2015.

Public Chapter 513/Senate Bill 1014

This act clarifies that certified registered nurse anesthetists (CRNA) are not required to obtain authorization to prescribe in order to select, order and administer drugs during services ordered by a physician, dentist, or podiatrist and requires the CRNA to collaborate with those physicians.

Office of General Counsel Report

Mr. Cange informed the board that there are 53 open cases for discipline in the office of general counsel. Seven (7) of those cases are set for hearings. Mr. Cange explained to the board that the rules pertaining to the outsourcing facilities, oxygen suppliers and internship hours will become effective on June 22, 2015. The rule related to drug disposal are undergoing legal review at the Attorney General's office and the rules related to the correction for citations, law enforcement access fee for the CSMD, and other matter are undergoing internal review.

Complaint Summary

1.

BOP received a DEA 106 form indicating employee pilferage caused the following shortages:
1,604 Alprazolam 2mg tablets
1,842 Hydrocodone APAP 10/325

BOP investigator obtained the name of the employee along with a signed confession admitting to diverting "Hydrocodone," "some Lortab," and "Xanax" beginning the middle of December, 2014.

Recommend: Revoke technician registration

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

2.

During a periodic inspection, BOP Investigator pulled, photographed and logged at least 100 out of date products that were intermingled in pharmacy inventory. There was additional stock that

may not have been expired but in bottles with expired dates due to the practice of cutting pills in half and placing into older bottles on the shelf for future use. Staff was educated on handling out of dates and on proper labeling and repackaging.

Recommend: Civil penalty for expired drugs $\$10 \times 100 = \$1,000$. (Costs? Discovered during an inspection but it took a lot of time to photo and log all the out of dates)

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

3.

BOP was informed of potential violations of counseling rules and improper tech ratios. Investigator visited the pharmacy and observed 1 patient with 2 new prescriptions being asked by cashier/tech if they had any questions but no counseling was given; and observed 1 patient with 2 new prescriptions being allowed to pay and leave without counseling or even being asked if they had questions. Tech ratios were compliant at the time of the visit.

Recommend: Civil penalty (and costs) to pharmacy and dispensing pharmacist (who is also the PIC).

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

4.

Loss prevention provided a copy of respondent's signed statement admitting theft of controlled substances. Admission statement indicated respondent took 10 to 15 Hydrocodone 2 to 3 times per week and roughly 5 Xanax a couple of times per week from November til February. DEA 106 forms filed indicated the following shortages:

Alprazolam 1 mg tab = 357
Hydrocodone/APAP 10/325 = 586
Hydrocodone/APAP 7.5/325 = 180

Recommend: Revoke technician registration

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

5.

Routine periodic inspection revealed 123 expired commercial medications intermingled on shelves with regular drug stock. BOP investigator pulled and inventoried the expired products. Most of the expired products expired in 2012, 2013, 2014, and early 2015, however one product

was found with an expiration of 2006. Respondent PIC claimed that expired products are sent to a reverse distributor 2 or 3 times per year but later provided a typed response that expired products are usually pulled in June. A 4/25/15 email from respondent indicates all expired products have now been sent to a reverse distributor.

Recommend: \$ 1,230 C.P. to pharmacy, maybe LOW to PIC?

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

6.

Routine periodic inspection revealed 32 separate commercial medications for a total of 47 packages that were intermingled with regular drug stock. BOP investigator pulled and inventoried the expired products. Most of the expired products had expired between November 2014 and April 2015. Three products were on the shelf in dispensing vials dated 1/14/14, 2/12/14, and 4/3/14 but did not show the expiration of the contents. Respondent was directed on 4/24/15 to return the expired products and notify BOP investigator when that was completed.

Recommend: \$ 320 C.P. to pharmacy, maybe LOW to PIC?

Dr. Eidson made the motion to **dismiss** the complaint. Dr. Dickenson seconded the motion. The motion carried. Dr. Wilson voted no.

7.

CSMD report indicated narcotic prescriptions filled in a Tennessee pharmacy from Georgia and Florida prescribers for Kentucky patients. BOP investigators found "red flags" including: Patients driving long distances to see prescribers, then long distances to the pharmacy, then long distances back to the patients' homes.

Cash payments for controlled substances.

Lack of documentation on checking for legitimate purposes for controlled substances prescribed. Same prescriber, same drugs, same or similar strengths, same diagnosis and same quantities for multiple patients.

Multiple patients from same area of Kentucky coming to the pharmacy together.

High unexplained volume for promethazine with codeine syrup.

One patient was flagged as trying to pass a fraudulent prescription, but was allowed to continue as a pharmacy patient.

Pharmacy's wholesaler recently ceased business with the pharmacy.

36% of total prescription volume is controlled substance prescriptions.

An audit was conducted for approx. 18 month period and resulted in the following discrepancies:

Endocet 10/325 overage of 37 tablets

Oxycodone 30 mg overage of 150 tablets

Methadone 10 mg shortage of 1 tablet
Tussionex liquid shortage of 4,306 ml
Alprazolam 2mg shortage of 355 tablets
Promethazine Codeine syrup shortage of 9,482 ml

PIC has since provided a typed statement indicating the pharmacy no longer fills for out-of-state patients, only fills for local prescribers within a reasonable distance, the pharmacist has enrolled in "Pharmacy Regulatory Specialist" certification course, more documentation is occurring, staff is watching for red flags, and pharmacists demand from prescribers greater insight and explanation for prescriptions.

Recommend: Revoke pharmacy license

Ms. McDaniel made the motion to **authorize a formal hearing** for revocation. The motion died for lack of second. After discussion, Dr. Dickenson made the motion to authorize a formal hearing for 5 year probation for the pharmacy and the pharmacist with an additional 12 hours of continuing education in pharmacy law and a follow-up visit from the pharmacy investigator within 6 months of the signed consent order. Dr. Kizer seconded the motion. After further discussion, Dr. Kizer rescinded his second and Dr. Dickenson amended the motion to authorize a formal hearing for 5 year probation for the pharmacy, pharmacist in charge, the pharmacist in charge to submit an additional 12 hours of continuing education in pharmacy law, a 6 month follow-up visit by the investigator and case cost. Dr. Kizer seconded the motion. The motion carried.

8.

CSMD report indicated narcotic prescriptions filled in a Tennessee pharmacy from Georgia and Florida prescribers for Kentucky patients. BOP investigators found "red flags" including: Patients driving long distances to see prescribers, then long distances to the pharmacy, then long distances back to the patients' homes.

Cash payments for controlled substances.

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PIC has since provided a typed statement indicating the pharmacy no longer fills for out-of-state patients, only fills for local prescribers within a reasonable distance, the pharmacist has enrolled in "Pharmacy Regulatory Specialist" certification course, more documentation is occurring, staff is watching for red flags, and pharmacists demand from prescribers greater insight and explanation for prescriptions.

Recommend: Revoke PIC license

Ms. McDaniel made the motion to **authorize a formal hearing** for revocation. The motion died for lack of second. After discussion, Dr. Dickenson made the motion to authorize a formal hearing for 5 year probation for the pharmacy and the pharmacist with an additional 12 hours of continuing education in pharmacy law and a follow-up visit from the pharmacy investigator within 6 months of the signed consent order. Dr. Kizer seconded the motion. After further discussion, Dr. Kizer rescinded his second and Dr. Dickenson amended the motion to authorize a formal hearing for 5 year probation for the pharmacy, pharmacist in charge, the pharmacist in charge to submit an additional 12 hours of continuing education in pharmacy law, a 6 month follow-up visit by the

9.

Upon opening the pharmacy 8/29/14, floater pharmacist obtained a key from a store associate and became aware that an IT person (who happened to be the store manager's son) had been allowed to enter the pharmacy the previous night to work on a scanner without a pharmacist present. The store associate claims to not have known about the pharmacist requirement even though the associate had resealed the envelope after the IT person turned it back in. Investigator determined from video that the IT person did not go into the drug bays of the pharmacy and Loss prevention began a thorough investigation of the breach of security. Investigator has asked for a copy of their report when finished and noted concerns about who has access to the safe containing the pharmacy key: (manager, 2 assistant managers, 6 front end managers, the head cashier, and the computer room operator.)

Recommend: \$100.00 civil penalty for key violation

Dr. Wilson made the motion to **authorize a formal hearing** with \$100.00 civil penalty and a plan of correction. Dr. Kizer seconded the motion. The motion carried.

10.

Hospital pharmacist reported respondent technician was having "difficulty keeping her eyes open while exchanging the med cart." The complaint filed stated this prompted a UDS which came

back positive for marijuana metabolites and methamphetamine. Investigators have been unable to reach respondent by phone nor by 2 letters sent asking for a response. RBS records indicate respondent's technician registration expired 4/30/15 and place of employment has not been updated.

Recommend: Revoke

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

11.

Loss prevention notified BOP of termination and arrest of respondent technician for diversion of a controlled substance. Respondent has not replied to 2 letters asking for a response. Outcome of charges is not known and police report has not been received. Loss prevention is willing to testify about diversion but details of the internal investigation were not released.

Recommend: Revoke

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

12.

Respondent technician is alleged to have been involved in criminal activity and stealing drugs from a pharmacy. Outcome of charges is not known however respondent has not replied to letters asking for a response.

Recommend: Revoke

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

13.

Loss prevention notified BOP and police when an internal investigation revealed 2 technicians stealing drugs. Outcome of charges is not known, however respondent has not replied to letters asking for a response. The missing drugs reported on DEA 106 are:

- 60 Buprenorphine 8mg
- 62 Alprazolam 1mg
- 256 Alprazolam 2 mg
- 839 Hydrocodone Bitartrate 10 mg
- 846 Hydrocodone Bitartrate 10 mg (different brand)

Recommend: Revoke

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

14.

Loss prevention notified BOP and police when an internal investigation revealed 2 technicians stealing drugs. Outcome of charges is not known, however respondent has not replied to letters asking for a response. The missing drugs reported on DEA 106 are:

60 Buprenorphine 8mg
62 Alprazolam 1mg
256 Alprazolam 2 mg
839 Hydrocodone Bitartrate 10 mg
846 Hydrocodone Bitartrate 10 mg (different brand)

Recommend: Revoke

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

15.

Respondent technician admitted to loss prevention to stealing 300 Buprenorphine 8mg and 64 Modafinil 200 mg. The missing drugs reported on DEA 106 are:

3,516 Buprenorphine 8mg
150 Modafinil 200 mg

Loss prevention policy and procedures have been reviewed but they report that they believe the additional shortages are all attributable to the respondent.

Police were notified but outcome of charges is not known. Respondent has not replied to letters asking for a response.

Recommend: Revoke

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

16.

Loss prevention internal investigation revealed respondent technician passing 2 prescriptions for cough syrup to an acquaintance in the drive thru. Technician was terminated. Technician has not replied to BOP letter asking for a response.

Recommend: Revoke

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

17.

Complaint was referred to BOP from Division of Consumer Affairs. However, the complaint deals with an increased copay and insurance administration issues not within the authority of BOP.

Recommend: Dismiss

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

18.

Anonymous complainant alleged a Mississippi sterile compounder is shipping patient specific controlled substances to prescribers' offices in Tennessee. According to DEA agents, this is allowable if the firm is licensed as a manufacturer. DEA agents confirmed the pharmacy does not hold a manufacturer's license.

Recommend: Close and refer to DEA

Dr. Eidson made the motion to issue a **cease and desist letter** to the compounder until the proper license has been obtained. Dr. Bunch seconded the motion. The motion carried.

19.

Respondent pharmacist is currently on probation with BOP and was reported by employer as being suspect for multiple missing drugs and altered records. Respondent has since voluntarily entered Cornerstone and sent a letter surrendering his pharmacist license.

Recommend: Accept surrender

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

20.

Respondent pharmacy was inspected by FDA resulting in a recall of compounded medications. Pharmacy has already been disciplined by BOP. Case was opened so BOP investigators could work concurrently with FDA inspectors and learn cGMP. Pharmacy voluntarily closed 8/29/14.

Recommend: Accept retirement of pharmacy license.

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

21.

BOP was copied on a letter from a hospital to respondent infusion pharmacy alleging a 10-fold increase of sodium chloride was added to a patient's home parenteral nutrition. BOP investigator determined a mistake did occur due to a data entry error. 110mEq was entered as 1100mEq of NaCl. Investigator was told that the pharmacy discovered the mistake when the pharmacist spoke to the patient's mother while in transit to the E.R. Patient was having severe headache, burning at the central line catheter site and abdominal pain. Pharmacist informed E.R. of the error. Patient was admitted to the hospital and has since been discharged with no long term effects. At least 6 pharmacy staff members worked on the solution and staff admits that at least 5 of them had a potential opportunity to prevent the error. The pharmacy has implemented safeguards and new procedures to prevent such errors. The software vendor has been asked to develop a stop that would detect a dose outside of therapeutic range. 1 pharmacist will now perform calculations and another pharmacist will check them and perform data entry. Certified techs are now empowered to ask questions about anything that could be inaccurate. One CPhT will now perform primary compounding and another CPhT will verify and sign-off on the work that accurate amounts of electrolytes are drawn prior to compounding. Pharmacy has also asked for a software update for the TPN compounder device to detect doses potentially outside therapeutic range. Final pharmacist review will now be a more thorough process with review of every component of TPN.

Recommend: LOW

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

Reinstatement

Kimberly Hawkins, D.Ph.

Dr. Hawkins requested to have her licensed reinstated. Dr. Hawkins's license was revoked on 07/31/2014. After discussion, Dr. Eidson made the motion to reinstate Dr. Hawkins's license. Dr. Hawkins's license will be on five (5) year probation once she has completed all the necessary requirements for reinstatement with the following conditions. Dr. Bunch 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.

(h) The Respondent shall not serve as pharmacist-in-charge for a period of three (3) years from the start date of probation; however, after a period of two (2) years' probation the respondent may petition the Board for a modification of this Consent Order to remove the restrictions upon show of good causes. The Respondent shall not work as a "floater" for a period of three (3) years, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without permission of the Board;

(i) Respondent shall complete all provisions required for the reinstatement of her license listed in Board Rule 1140-01-.07 (3)(a):

1. Provide written notice to the board requesting an active license;
2. Satisfy all past due continuing pharmaceutical education as required by the board;
3. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked;

General Discussion

Dr. Eidson asked the board about funding the Tennessee Pharmacy Recovery Network (TPRN) in order that they may be able to help impaired pharmacy technicians. Dr. Black stated that TPRN would need to have a director and administrative person as she is working in that capacity in the interim. After discussion, Dr. Eidson made the motion to draft rules to increase the licensing fees by \$10.00 for the purpose of helping impaired licensees and requested that the draft rules be presented at the September 2015 board meeting. Dr. Bunch seconded the motion. The motion carried.

Consent Orders

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

VIOLATED T. C. A. § 63-10-305 (6)
Deal Drugs-2yr probation

REVOCATION

Terry S. Moore, D.Ph. (voluntary surrender)
Lois Hoppstein, D.Ph.
Jason C. McKewen, D.Ph. (voluntary surrender)
Jordan Glenn, RT
Cindy Lou Wilson, RT
Angelica Carlisle, RT
Alexander Alderman, RT
Summer Holland, RT

VIOLATED BOARD RULE 1140-03-.11
The Medicine Shoppe, license #739

VIOLATED BOARD RULE 1140-09-02 (1)(a) & (2)
Medical Necessities & Services, LLC
Oxygen & Sleep Associates, Inc.

LETTER OF REPRIMAND

Melodie Leigh Goodwin, D.Ph.

VIOLATED BOARD RULE 1140-01-.08
Recover Care, LLC

Appearance

Sara Bond, RT

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

traffic offenses) whether or not sentence was imposed, suspended, expunged, or whether you were pardoned from any such offense? Ms. Bond was convicted of DUI 2nd offense on 2/13/2013 (charged 8/21/12 Sullivan County) and 4/30/13 (charged 11/9/12 Washington County) and DUI 1st offense 1/30/2006. On 12/12/2014, Ms. Bond was charged with public intoxication. Ms. McDaniel made the motion to approved Ms. Bond's application for registration as a pharmacy technician. The motion died for a lack of second. After discussion, Dr. Kizer made the motion to approve Ms. Bond's application for registration as a pharmacy technician with the requirement that she must submit quarterly reports from her counselor. Dr. Bunch seconded the motion. The motion carried. Dr. Dickenson voted no.

Weszleia Price, RT

Ms. Price answered yes to the question that asked "Have you ever been charged or convicted (including a nolo contendere plea or guilty plea) of a felony or misdemeanor (other than a minor traffic offenses) whether or not sentence was imposed, suspended, expunged, or whether you were pardoned from any such offense? Documentation submitted shows that Ms. Price pled guilty to driving on revoked license 2nd offense on 7/7/2014, driving on revoked license 11/26/2013, driving on suspended license 2nd offense 9/19/2012, driving on suspended license 5/16/2012, driving on suspended license 2nd offense 1/8/2012. Ms. Price has been charged with assault, domestic fear of bodily injury on 5/14/2014, failure to appear 5/10/2012, driving on suspended license 11/30/2011, 11/14/2011 and 8/9/2011 and failure to appear 1/7/2011. Ms. McDaniel made the motion to approve Ms. Price application for registration as a pharmacy technician. Dr. Kizer seconded the motion. The motion failed with Dr. Bunch, Eidson, Dickenson and Wilson voting no. Ms. McDaniel and Dr. Kizer voted yes.

Monica Covington, RT

Ms. Covington appeared before the board to request that she be allowed to reinstate her pharmacy technician certification. Ms. Covington registration as a pharmacy technician was revoked on January 23, 2014. After discussion, Dr. Dickenson made the motion to deny Ms. Covington's request to reinstate her pharmacy technician registration. Dr. Eidson seconded the motion. The motion carried. Dr. Kizer and Ms. McDaniel voted no.

Bedcovet Pharmacy

Carlyle Johnson, D.Ph., owner of Bedcovet Pharmacy, appeared before the board to request that a pharmacy that specializes in veterinary prescriptions only should be licensed and regulated by the Tennessee Board of Veterinary Medical Examiners and not the Board of Pharmacy. The board did not make a decision.

USP 797 Extensions Erlanger Hospital

Allen Broome, D.Ph., pharmacy manager Erlanger Hospital appeared before the board to inform them that he has received USP 797 certification for the main IV room. They are still working on

bringing the rest of the IV rooms into compliance and only do low to medium risk compounding. Dr. Broome also asked for a 90 day extension of the USP 797 compliance for the Children's Pharmacy. After discussion, Dr. Dickenson made the motion to grant a 90 day extension of USP 797 compliance to Erlanger's Hospital Children's Pharmacy and to notify the board if problems or delays occur. Dr. Wilson seconded the motion. The motion carried. Dr. Broome asked the board's opinion about surgery pharmacies and if they would need to be in compliance with USP 797 since the product compounded is for immediate use only. Mr. Cange stated that this may have wider implications than just Erlanger Hospital and asked the board not to make a decision at this time. He would like to be able research the matter and bring it up to the board at a later time.

Waivers

Board rule 1140-3-.05 Kroger Pharmacy

Ms. Laura Ramey, D.Ph., Pharmacy Merchandiser for Kroger, appeared before the board to discuss Kroger Company purchasing the Harris Teeter stores located in Nashville, TN. Dr. Ramey stated that three of the stores will be converted to Kroger stores and will be closed and remodeled. The store located at 2201 21st Avenue South is going to close in mid-June to be remodeled and will open as a Kroger store in early 2016. They would like to keep the pharmacy open due to the volume of neighborhood traffic that the pharmacy receive but the pharmacy is located on the 2nd floor and would not lend itself to remaining open during the remodel. Kroger would like to operate the pharmacy from a trailer specially designed for temporary relocations due to disaster or remodel. The trailer will be stationary and have security. After discussion, Dr. Eidson made the motion to approve the waiver and stated that counseling must occur, the trailer to be non-mobile in nature and have a private area for immunization. Dr. Wilson seconded the motion. The motion carried.

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

Dr. Wilson made the motion to approve the request from **Newport Health & Rehabilitation** for two automated dispensing machine that the pharmacy to be 180 square feet and the requirement for hot and cold running water and to notify the board if the business model changes. Dr. Eidson seconded the motion. The motion carried.

Dr. Wilson made the motion to approve the request from **TSVH Knoxville** for two automated dispensing machine that the pharmacy to be 180 square feet and the requirement for hot and cold running water and to notify the board if the business model changes. Dr. Eidson seconded the motion. The motion carried.

Dr. Wilson made the motion to approve the request from **Huntsville Manor** for the automated dispensing machine that the pharmacy to be 180 square feet and the requirement for hot and cold running water and to notify the board if the business model changes. Dr. Eidson seconded the motion. The motion carried.

Dr. Wilson made the motion to approve the request from **Claiborne & Hughes Nursing Home** for the automated dispensing machine that the pharmacy to be 180 square feet and the requirement for hot and cold running water and to notify the board if the business model changes. Dr. Eidson seconded the motion. The motion carried.

Dr. Wilson made the motion to approve the request from **TSVH Murfreesboro** for two automated dispensing machine that the pharmacy to be 180 square feet and the requirement for hot and cold running water and to notify the board if the business model changes. Dr. Eidson seconded the motion. The motion carried.

Dr. Wilson made the motion to approve the request from **Countryside Health & Rehabilitation Center** for the automated dispensing machine that the pharmacy to be 180 square feet and the requirement for hot and cold running water and to notify the board if the business model changes. Dr. Eidson seconded the motion. The motion carried.

Board rule 1140-03-.14 (12)

Dr. Wilson made the motion to approve the request from **Ope Adeiya, D.Ph.** to be the pharmacist in charge of the automated dispensing machines located at TSVH Knoxville, Newport Health & Rehabilitation and Huntsville Manor. Dr. Edison seconded the motion. The motion carried.

Dr. Wilson made the motion to approve the request from **Ezekiel Baker, D.Ph.** to be the pharmacist in charge of the automated dispensing machines located at TSVH Murfreesboro and Countryside Health & Rehabilitation. Dr. Edison seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Tim Albonetti, D.Ph.** to be the pharmacist in charge at Pharmacy Care of Tennessee independent pharmacy and Pharmacy Care of Tennessee specialty pharmacy. Dr. Wilson seconded the motion. The motion carried.

Dr. Wilson made the motion to approve the request from **Kasey Graham, D.Ph.** to be the pharmacist in at LeConte Medical Center Infusion Services Pharmacy and the automated dispensing machine. Dr. Edison seconded the motion. The motion carried.

Dr. Kizer made the motion to approve the request from **Phillip J. Baker, D.Ph.** to be the pharmacist in charge at Good Shepherd Health in Memphis, TN and Good Shepherd Medication Management in Millington, TN. Dr. Edison seconded the motion. The motion carried.

USP 797 Waivers

Dr. Eidson made the motion to deny the request from **Cardinal Health 414, LLC, Nashville, TN** to waive the requirement that they are in compliance with USP 797 and that they must comply with USP 797 and that includes nuclear pharmacy. Dr. Dickenson seconded the motion. The motion carried.

Application Review

David Henderson, D.Ph.

Dr. Henderson answered yes to the question that asked “Have you ever voluntarily surrendered your pharmacist license or pharmacist registration issued by a federal or state controlled substance authority?, Has your pharmacist license in any state or jurisdiction ever been revoked, suspended, restricted, terminated or otherwise been subject to disciplinary action (public or private) by any board or pharmacy or other state authority?, “Have you ever been charged or convicted (including a nolo contendere plea or guilty plea) of a felony or misdemeanor (other than a minor traffic offenses) whether or not sentence was imposed, suspended, expunged, or whether you were pardoned from any such offense?” and “ Are you presently or have you within the past five years ever participated in a chemical substance rehabilitation program?”

Dr. Henderson stated that his Alabama pharmacist license was suspended in July 2013 for substance abuse and reinstated December 2013. Documentation submitted indicates that Dr. Henderson was charged with Hallucinogen possess-possession of controlled substance on 11/7/2012 (2), 4/8/2013(2), 5/4/2013, 5/3/2012 and 6/4/2013. Dr. Bunch made the motion to have Dr. Henderson appear before the board at the next scheduled meeting. Dr. Eidson seconded the motion. The motion carried.

Austin Weaver, D.Ph.

Dr. Weaver is applying for license as a pharmacist by reciprocity. Dr. Weaver submitted a request to the board to waive the requirement that requires a licensee to be licensed in another state for one year or more before they can apply for license as a pharmacist in Tennessee by reciprocity. Dr. Weaver received his pharmacist license in the state of Indiana on June 17, 2014. After discussion, Ms. McDaniel made the motion to approve Dr. Weaver’s request. Dr. Bunch seconded the motion. After further discussion, Ms. McDaniel withdrew her motion. Mr. Cange stated that he would not recommend waiving this requirement. The board did not waive this requirement.

Director’s Report

Dr. Dilliard passed out the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products between states and the U. S. Food and Drug Administration for the board to review and asked the board for comments. The comments will need to be submitted by June 19, 2015.

Dr. Dilliard informed the board that the Safe Med program will lose their funding by June 30, 2015. Safe Med presented their pilot program to the board at the November 13-14, 2013 board meeting.

Dr. Dilliard asked the board for travel authorization to attend the NABP District III meeting scheduled for August 15-18, 2015 in St. Augustine, FL. After Discussion, Ms. McDaniel made the motion to approve the board members and the executive director to attend the NABP District III meeting. Dr. Kizer seconded the motion. The motion carried.

Dr. Dilliard asked the board for travel authorization to attend NADSCA meeting scheduled for October 20-23, 2015 in Scottsdale, AZ. Ms. McDaniel made the motion to approve the executive director to attend NADSCA. Dr. Bunch seconded the motion. The motion carried.

The meeting adjourned at 4:30 p.m.

May 12, 2015

The Tennessee Board of Pharmacy reconvened on Tuesday, May 12, 2015 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members were present, the meeting was called to order at 8:04 a.m., by Dr. Smothers, president.

Appearance

Med/SN Support Network

David Lee, president of Med/SN, appeared before the board to waivers of board rules 1140-01-.13 (3)(d) & (e) for 3 pharmacies and 1140-03-.14 (2). Mr. Lee stated that Med/SN Support Network is pharmacy consulting company that consults on various pharmacy topics including physician-owned pharmacies, central-fill pharmacy and DME distribution. Med/SN Support Network is working with three physician groups to help open a new independently-owned retail pharmacy and three separate closed door pharmacies. Mr. Lee stated that this group has a total of 25 practicing physicians. After discussion, Dr. Eidson made the motion to approve the waiver that the pharmacy be 180 square feet for Geriatric Consulting Group pharmacy to be 175 square feet, Skyline Women's Health, PC pharmacy to be 172 square feet and Riverside Family Medicine, Inc. pharmacy to be 103 square feet, waive the hot and cold running water requirement for the 3 closed door pharmacies and that the pharmacist in charge be able to be PIC at the retail pharmacy and one of the closed door pharmacy. The remaining two closed door pharmacy will each have a pharmacist in charge. The approval of the waivers will be based on a passing inspection by the pharmacy investigator. Dr. Dickenson seconded the motion. The motion carried. Dr. Eidson stated that the central fill pharmacy must be in compliance with the board's rules and regulations and to submit that information to Dr. Dilliard.

Financial Report

Dr. Dilliard presented the financial report to the board. Dr. Eidson asked that Dr. Dilliard for a wish list and to use the board's surplus to order law books. Dr. Kizer made the motion to accept the financial report. Dr. Dickenson seconded the motion. The motion carried.

Reinstatement/Consent Order

Enoch "Trey" Hartman, D.Ph.

Mr. Cange presented a consent order signed by Dr. Hartman to place his pharmacist license on probation for 5 years due to impairment. Dr. Hartman was present. After discussion, Dr. Kizer approved the consent order as presented. Dr. Eidson 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 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 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.
- (h) The Respondent shall not serve as pharmacist-in-charge the respondent's pharmacist-in-charge from the start date of probation; however, after a period of two (2) years' probation the respondent may petition the Board for a modification of this Consent Order to remove the restrictions upon show of good causes. The Respondent shall not work as a "floater" for a period of three (3) years, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without permission of the Board;

Agreed Orders

Mr. Wells presented a signed agreed order in the name of Food City Pharmacy, #616 to the board. Mr. Gary Asher, Attorney for Food City was presented. Food City Pharmacy #616 has

agreed to a 2 year probation, the pharmacist in charge and all the dispensing pharmacist that work in the pharmacy must complete 15 live (in person) hours of continuing pharmaceutical education in dispensing of controlled substances, quarterly monitoring report of controlled substance dispensing, drug review and case cost. Dr. Eidson made the motion to accept the agreed order as presented. Dr. Dickenson seconded the motion. The motion carried.

Mr. Wells presented a signed agreed order in the name of Food City Pharmacy, #694 to the board. Mr. Gary Asher, Attorney for Food City was presented. Food City Pharmacy #694 has agreed to a 2 year probation, the pharmacist in charge and all the dispensing pharmacist that work in the pharmacy must complete 15 live (in person) hours of continuing pharmaceutical education in dispensing of controlled substances, quarterly monitoring report of controlled substance dispensing, drug review and case cost. Dr. Eidson made the motion to accept the agreed order as presented. Dr. Dickenson seconded the motion. The motion carried.

Contested Cases

Philip G. Yardley, RT

Mr. Yardley was not present nor represented by legal counsel. Mr. Wells represented the State. Ms. Rachel Waterhouse was the Administrative Law Judge. Mr. Wells asked to proceed in default. Dr. Dickenson made the motion to proceed in default. Dr. Eidson seconded the motion. The motion carried. Mr. Wells passed out the Notice of Charges. Mr. Yardley is charged with violating T.C.A. 53-10-104 (a) and (b). After discussion, Dr. Kizer made the motion to revoked Mr. Yardley registration as a pharmacy technician and case cost. Dr. Bunch seconded the motion. The motion carried. Dr. Bunch made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Dickenson seconded the motion. The motion carried.

Dr. Kizer made the motion to adjourn. Dr. Eidson seconded the motion. The motion carried.

The minutes were approved at the July 29-30, 2015 board meeting as amended.