TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Iris Room
Nashville, TN
January 30-31, 2018

BOARD MEMBER PRESENT

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

STAFF PRESENT

Reginald Dilliard, Executive Director
Matthew Gibbs, Associate General Counsel
Richard Hadden, Pharmacy Investigator
Rebecca Moak, Pharmacy Investigator
Robert Shutt, Pharmacy Investigator
Andrea Miller, Pharmacy Investigator
Albert Hill, Pharmacy Investigator
Derek Johnston, Pharmacy Investigator
Sheila Bush, Administrative Director

STAFF ABSENT

Terry Grinder, Pharmacy Investigator
Scott Denaburg, Pharmacy Investigator

The Tennessee Board of Pharmacy convened on Tuesday, January 30, 2018, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:00 a.m. Dr. Eidson welcomed Derek Johnston as the new pharmacist investigator for the board and students for Lipscomb University.

Elections

Dr. Eidson thanked the Board and the Board staff for the cooperation and help during his leadership as president. Dr. Wilson made the motion to nominate Dr. Dickenson as president. Dr. Rodgers seconded the motion. The motion carried. Dr. Pryse made the motion to nominate Dr. Wilson as vice president. Dr. Dickenson seconded the motion. The motion carried.

Rulemaking Hearing

Mr. Gibbs, Assistant General Counsel served as moderator for the rulemaking hearing. There were written or verbal comments from the public regarding the proposed changes. After discussion, Dr. Wilson made the motion to adopt the rules as amended. Ms. Tittle seconded the motion. A roll call vote was taken. The Board acknowledged the impact statement.

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Sequence Number: 11-20-17
Notice ID(s): 2773
File Date: 11/28/17

Notice of Rulemaking Hearing

Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, T.C.A. § 4-5-204. For questions and copies of the notice, contact the person listed below.

Agency/Board/Commission:	Tennessee Board of Pharmacy
Division:	
Contact Person:	Rachel Appelt, Assistant General Counsel
Address:	710 James Robertson Parkway, 5th Floor, Nashville, TN, 37243
Phone:	(615) 532-7924
Email:	Rachel.Appelt@tn.gov

Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:

ADA Contact:	ADA Coordinator
Address:	710 James Robertson Parkway, Andrew Johnson Building, 5th Floor, Nashville, Tennessee 37243
Phone:	(615) 741-6350
Email:	Tina.M.Harris2@tn.gov

Hearing Location(s) (for additional locations, copy and paste table)

Address 1:	Metro Center	
Address 2:	665 Mainstream Drive, Iris Conference Room	
City:	Nashville	
Zip:	37228	
Hearing Date :	01/30/18	
Hearing Time:	9:00 a.m.	X CST/CDT ___EST/EDT

Additional Hearing Information:

Revision Type (check all that apply):

___ Amendment
X New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	**Chapter Title**
1140-17	Drug Donation Repository Program
Rule Number	**Rule Title**
1140-17-.01	Definitions

1140-17-.02	Purpose
1140-17-.03	Eligibility Criteria for Program Participation by Medical Facilities and Pharmacies
1140-17-.04	Standards and Procedures for Accepting Donated Prescription Drugs and Supplies
1140-17-.05	Standards and Procedures for Inspecting and Storing Donated Prescription Drugs and Supplies
1140-17-.06	Standards and Procedures for Dispensing Donated Prescription Drugs and Supplies
1140-17-.07	Eligibility Criteria for Individuals to Receive Donated Prescription Drugs and Supplies
1140-17-.08	Forms and Record Keeping
1140-17-.09	Handling Fee
1140-17-.10	List of Drugs and Supplies Program Will Accept.
1140-17-.11	Exemption From Disciplinary Action, Civil Liability and Criminal Prosecution.
1140-17-.12	Long-term Care Facilities

Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to
http://sos-tn-gov-files.s3.amazonaws.com/forms/Rulemaking%20Guidelines_September2016.pdf.

New Rule Chapter 1140-17
Drug Donation Repository Program

Rule 1140-17-.01 Definitions.

In addition to the definitions contained in T.C.A. 63-10-501, the following definitions are applicable to this chapter:

(1) "Cancer Drug" means a prescription drug that is used to treat any of the following:

(a) Cancer or the side effects of cancer; or

(b) The side effects of any prescription drug that is used to treat cancer or the side effects of cancer.

(2) "Controlled Substance" means the same as defined in T.C.A. § 39-17-402.

(3) "Department" means the Tennessee Department of Health.

(4) "Donor" means a person, pharmacy, or medical facility as well as any drug manufacturer or wholesaler licensed by the Tennessee Board of Pharmacy, who donates prescription drugs to a repository program approved pursuant to these rules.

(5) "Eligible individual" means an indigent person or an uninsured person who meets all other criteria established by these rules.

(6) "Indigent" means a person with an income that is below 200 percent (200%) of the federal poverty level (FPL) as defined by the most recently revised poverty income guidelines published by the United States Department of Health and Human Services.

(7) "Medical facility" means any of the following:

(a) A physician's office;

(b) A hospital;

(c) A health clinic;

(d) A nonprofit health clinic, including a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B); a rural health clinic as defined in 42 U.S.C. § 1396d(l)(1); and a nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured;

(e) A free clinic as defined in T.C.A. § 63-6-703;

(f) A charitable organization as defined in T.C.A. § 48-101-501; or

(g) A nursing home as defined in T.C.A. § 68-11-201.

(8) "Legend Drug" means the same as defined in T.C.A. § 53-10-101.

(9) "NDC #" means the unique national drug code number that identifies a specific approved drug, its manufacturer and its package presentation.

(10) "Nurse practitioner" means an advanced practice nurse as defined in T.C.A. § 63-7-126.

(11) "Pharmacist" means a pharmacist as defined in T.C.A. § 63-10-204.

(12) "Pharmacy" means a pharmacy as defined in T.C.A. § 63-10-204.

(13) "Physician" means an individual licensed under T.C.A. § 63-6-201 or § 63-9-104.

(14) "Physician's Assistant" means an individual licensed under T.C.A. § 63-19-105.

(15) "Prescription drug" means the same as defined in T.C.A. § 63-10-204.

(16) "Repository" means a pharmacy or medical facility that meets the eligibility requirements of Rule 1140-15-.03.

(17) "Reverse Distributor" means an establishment that dispositions or otherwise processes saleable or nonsaleable legend drugs and controlled substances received from a pharmacy such that the legend drugs and controlled substances may be processed for credit to the purchaser, Manufacturer, or seller and disposed of for no further distribution.

(18) "Supplies" means the supplies necessary to administer the prescription drugs donated.

(19) "USP" means United States Pharmacopoeia.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

1140-17-.02 Purpose. The overall purpose of this chapter is to establish administrative rules in accordance with T.C.A. § 63-10-501 *et seq.* relative to the following:

(1) Requirements for medical facilities and pharmacies to accept and dispense donated prescription drugs and supplies;

(2) Additional eligibility criteria for indigent or uninsured persons;

(3) Necessary forms for administration of the prescription drug donation repository program, including forms for use by individuals who donate, accept, distribute, or dispense the prescription drugs or supplies under the program;

(4) A means by which an individual who is eligible to receive donated prescription drugs and supplies may indicate eligibility;

(5) The maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated prescription drugs and supplies under the program; and

(6) A list of prescription drugs that the prescription drug donation repository program will accept.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§63-10-503 through 63-10-510. [effective January 1, 2018].

1140-17-.03 Eligibility Criteria for Program Participation by Medical Facilities and Pharmacies.

(1) To be eligible for participation in the prescription drug donation repository program, a medical facility or pharmacy shall be in compliance with all applicable federal and state laws, including laws applicable to the storage and distribution of drugs and the appropriate licensure standards, and shall hold active, unencumbered, state-issued licenses or registrations in good standing. In the case of a physician's office, the physician(s) and other medical staff shall be duly licensed.

(2) A medical facility or pharmacy which intends to operate as a repository within the prescription drug donation repository program shall receive a determination of exemption from the United States internal review service pursuant to 26 U.S.C. § 501(c)(3) prior to making application to the Board to act as a repository. The medical facility or pharmacy shall present the exemption along with the form prescribed by the department and available on the program's web page as outlined in Rule 1140-17-.03(3).

(12) "Pharmacy" means a pharmacy as defined in T.C.A. § 63-10-204.

(13) "Physician" means an individual licensed under T.C.A. § 63-6-201 or § 63-9-104.

(14) "Physician's Assistant" means an individual licensed under T.C.A. § 63-19-105.

(2) Participation in the prescription drug donation repository program is voluntary.

(3) A pharmacy or medical facility may elect to participate in the prescription drug donation repository program by providing, on a form prescribed by the department and available on the program's web page, written notification to the department of all of the following:

(a) The name, street address, and telephone number of the pharmacy or medical facility, and any state-issued license or registration number issued to the pharmacy or medical facility, including the name of the issuing agency;

(b) The name and telephone number of the responsible pharmacist, physician, physician's assistant or nurse practitioner who is employed by or under contract with the pharmacy or medical facility; and

(c) A statement, signed and dated by the responsible pharmacist, physician, physician's assistant or nurse practitioner, indicating that the pharmacy or medical facility meets the eligibility requirements under this rule and shall comply with the requirements of this chapter.

(4) Withdrawal from participation. A pharmacy or medical facility may withdraw from participation in the prescription drug donation repository program at any time by providing written notice to the department on a form prescribed by the department and available on the program's web page.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§63-10-503 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.04 Standards and Procedures for Accepting Donated Prescription Drugs and Supplies.

(1) A person, pharmacy, or medical facility as well as any drug manufacturer or wholesaler licensed by the Tennessee Board of Pharmacy may donate drugs or supplies to the repository program. Any individual may donate legally obtained prescription drugs or supplies to a repository if the drugs or supplies meet the requirements of this rule, as determined by a pharmacist who is employed by or under contract with a repository.

(2) No drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or USP shall be donated or accepted as part of the prescription drug donation repository program. Drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or USP shall not be donated or accepted because of the increased potential for these drugs to become adulterated. Excluded from this restriction are drugs donated directly from a drug manufacturer.

(3) Controlled substances shall not be donated or accepted. Pursuant to federal and state laws, a controlled substance cannot be returned or reused once the drug has been dispensed to a patient.

(4) A repository may accept a prescription drug only if all of the following requirements are met:

(a) The drug is in its original sealed and tamper-evident packaging. However, a prescription drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit-dose packaging is undisturbed;

(b) The drug has been stored according to manufacturer or USP storage requirements;

(c) The packaging contains the lot number and expiration date of the drug. In the event the lot number is not visible on the packaging, the medication shall not be accepted by a repository.

(d) The drug does not have any physical signs of tampering or adulteration, and there is no reason to believe that the drug is adulterated;

(e) The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity or adulteration; and

(f) All drugs shall be inventoried at the repository. The inventory shall include the name of the drug, strength of the drug, NDC number, quantity of the drug, lot number of the drug, expiration date of the drug, and the date of donation if the drug has been continually under the control of a health care professional. If the drug has not been continually under the control of a health care professional, the repository shall collect a donation form provided by the prescription drug donation repository program that is signed by the person making the donation or that person's authorized representative.

(5) A repository may accept supplies necessary to administer the prescription drugs donated only if all of the following requirements are met: a. The supplies are in their original, unopened, sealed packaging; b. The supplies are not adulterated or misbranded; and c. All supplies shall be inventoried at the repository. The inventory shall include a description of the supplies, expiration date of the supplies, and the date of donation. Such inventory shall be recorded on a form provided by the department.

(6) Drugs and supplies may be donated on the premises of a repository to a person designated by the repository. Donations of prescription drugs and supplies may be made by mail. A drop box may not be used to deliver or accept donations.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§63-10-503 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.05 Standards and Procedures for Inspecting and Storing Donated Prescription Drugs and Supplies.

(1) A licensed pharmacist employed by or under contract with a repository shall inspect donated prescription drugs and supplies to determine, to the extent reasonably possible in the judgment of the pharmacist, that the drugs and supplies are not adulterated or misbranded, are safe and suitable for dispensing, and are not ineligible drugs or supplies. The pharmacist who inspects the drugs shall sign an inspection record stating the above and attach it to the copy of the inventory or donor record provided with the drugs.

(2) A repository shall store donated drugs and supplies in a secure storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies may not be stored with non-donated inventory. When donated drugs are not inspected immediately upon receipt, a repository shall quarantine the donated drugs separately from all dispensing stock until the donated drugs have been inspected and approved for dispensing under the program.

(3) Repositories shall destroy donated non-controlled substances that are not suitable for dispensing and make a record of such destruction. A reverse distributor may be used for destruction.

(4) Controlled substances shall not be accepted for donation. Controlled substances submitted for donation shall be disposed of pursuant to DEA regulations. A reverse distributor shall be used for destruction.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§63-10-503 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.06 Standards and Procedures for Dispensing Donated Prescription Drugs and Supplies.

(1) Donated drugs and supplies may be dispensed only if the drugs or supplies are prescribed by a health care practitioner for use by an eligible individual and are dispensed by a licensed pharmacist, physician, physician's assistant or nurse practitioner. A Tennessee licensed pharmacist shall inspect the prescription drugs and supplies to determine the prescription drugs and supplies are not adulterated or misbranded prior to dispensing.

(2) A repository shall prioritize dispensing to an individual requesting drugs through the program as follows: a. First, to an indigent individual; and b. Second, to an individual who has no active third-party prescription drug reimbursement coverage for the drug prescribed.

(3) A repository shall dispense donated prescription drugs in compliance with applicable federal and state laws and regulations for dispensing prescription drugs, including all requirements relating to packaging, labeling, record keeping, drug utilization review, and patient counseling. A medical facility or pharmacy

may not dispense a prescription drug after the expiration date of the drug.

(4) The repository shall remove the original donor's identification and the name of the donor's dispensing pharmacy from the package prior to dispensing the drugs or supplies.

(5) If a donor receives official notice of a recall of a prescription drug donated pursuant to this part, the donor shall make every effort to notify the repository to whom the drugs were donated of the recall.

(6) If an organization who is administering a drug repository program receives official notice of a recall of a prescription drug donated pursuant to this part, the organization shall make every effort to notify the pharmacy, medical facility, or patient, if known, to whom such donated drugs were dispensed, of the recall.

(7) Any donor or drug repository program who receives notice of a recall shall dispose of all recalled prescription drugs pursuant to the Tennessee Board of Pharmacy rules.

(8) Prescription drugs or supplies donated under this program shall not be resold.

(9) Repositories may distribute drugs and supplies donated under this program to other repositories for use pursuant to the program. The repository distributing the drugs or supplies shall complete a transfer form containing the inventory information on file in accordance with Rule 1140-17-.04(4)(f).

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§63-10-503 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.07 Eligibility Criteria for Individuals to Receive Donated Prescription Drugs and Supplies.

(1) An individual who requests drugs from the prescription drug donation repository program shall certify to the repository that the individual is a resident of Tennessee and meets one or both of the following criteria:

(a) Is indigent.

(b) Has no active third-party prescription drug reimbursement coverage for the drug prescribed.

(2) A repository shall collect from each individual recipient a signed intake collection form provided by the department.

(a) The intake collection form shall attest that:

1. The individual is a resident of the state of Tennessee;

2. The individual's income does not exceed 200 percent of the FPL;

3. The individual is uninsured and has no prescription coverage or is underinsured and has no prescription coverage;

4. The individual acknowledges that the drugs may have been donated; and

5. The individual consents to a waiver of the requirement for child resistant packaging of the Poison Prevention Packaging Act (16 C.F.R. §1700-1702).

(b) The intake collection form will include an identification card to be given to the recipient for continued use for one year.

(3) The identification card is valid for one year or until the new federal poverty guidelines have been published for all prescriptions and supplies.

(4) A summary of data taken from the intake collection form is to be sent via regular mail, E-mail or facsimile to the department for data collection annually.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§63-10-503 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.08 Forms and Record Keeping.

(1) The following forms developed for the administration of this program shall be utilized by participants of the program and are available on the program's web page.

(a) Prescription drug donation repository program notice of participation or withdrawal.

(b) Prescription drug donation repository program donation, transfer, inventory or destruction record.

(c) A record of medications dispensed.

(2) The prescription drug donation repository program recipient data collection form and identification card shall be given to the recipient by the repository, and the completed data collection form shall be collected from the recipient by the repository.

(3) Record-keeping requirements.

(a) All records required to be maintained as a part of the prescription drug donation repository program shall be maintained for a minimum of five years by participating pharmacies and medical facilities.

(b) Records required as part of this program shall be maintained pursuant to all current applicable practice acts.

(c) Data collected by the prescription drug donation repository program from all repositories shall be submitted quarterly or upon request to the department. The data will consist of the information collected in accordance with (1) and (2) above.

(d) A repository shall submit reports to the department yearly and upon request of the department. Such reports shall include the following data:

1. Number of donors during the reporting year;

2. Number of donations during the reporting year;

3. List of prescription drugs and supplies donated during the reporting year;

4. Number of people who received donations of prescription drugs or supplies during the reporting year;

5. Total number of prescription drugs and supplies dispensed during the reporting year; and

6. Total cost to eligible individuals who received donations during the reporting year.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§63-10-503 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.09 Handling Fee. A repository may charge the recipient of a donated drug a handling fee, not to exceed a maximum of 200 percent of the Medicaid professional dispensing fee as established by rule of the department of human services, to cover stocking and dispensing costs. A prescription drug dispensed through the prescription drug donation repository program shall not be eligible for reimbursement under the medical assistance program.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§63-10-503 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.10 List of Drugs and Supplies Program Will Accept. All prescription drugs, excluding controlled substances, that have been approved for medical use in the United States, that are listed in the USP or National Formulary (USP/NF), and that meet the criteria for donation established by these rules may be accepted for donation under the prescription drug donation repository program.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§63-10-503 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.11 Exemption From Disciplinary Action, Civil Liability and Criminal Prosecution.

(1) Except for gross negligence, willful misconduct, or bad faith, a drug manufacturer is not civilly liable or subject to criminal prosecution for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the drug manufacturer that is donated under this part, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

(2) Except as provided in subsection (4), a medical facility or another person who is not a drug manufacturer subject to subsection (1) is not civilly liable or subject to criminal prosecution for injury to or the death of an individual to whom a donated prescription drug is dispensed under this part except due to its own gross negligence, willful misconduct, or bad faith. The medical facility or other person who is not a drug manufacturer subject to subsection (1) is also exempt from disciplinary action related to the facility's or person's acts or omissions related to the donation, acceptance, distribution, or dispensing of a donated prescription drug under this part.

(3) Except for gross negligence, willful misconduct, or bad faith, the department of health or the board of pharmacy shall not be civilly liable or subject to criminal prosecution for injury, death, or loss to a person or property resulting from matters related to the donation, acceptance, distribution, or dispensing of a prescription drug donated pursuant to this part.

(4) The immunity and exemption provided in subsections (2) and (3) do not extend to the following:

(a) The donation, acceptance, distribution, or dispensing of a donated prescription drug under this part by a person if the person's acts or omissions are not performed reasonably and in good faith; or

(b) Acts or omissions outside the scope of the program

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§63-10-503 through 63-10-510. [effective January 1, 2018].

1140-17-.12 Long-Term Care Facilities. A long term-care facility licensed under title 68 may donate prescription drugs to the repository program.

Authority: Chapter 392 of the Public Acts of 2017, § 1 and T.C.A. §§63-10-503 through 63-10-510. [effective January 1, 2018].

I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: November 28, 2017

Signature: Rachel Appelt

Name of Officer: Rachel Appelt

Title of Officer: Assistant General Counsel, Department of Health

STATE OF TENNESSEE NOTARY PUBLIC DAVIDSON COUNTY MY COMMISSION EXPIRES 1-6-2020

Subscribed and sworn to before me on: 11/28/17

Notary Public Signature: Amber Ricks

My commission expires on: 1/6/2020

Department of State Use Only

Filed with the Department of State on: 11/29/17

Tre Hargett
Secretary of State

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RULEMAKINGS

Minutes

Dr. Wilson made the motion to accept the minutes as presented. Dr. Eidson seconded the motion. The motion carried.

Appearance

Sara Foster, RT

Ms. Foster answered "yes" 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 offense) whether or not sentence was imposed of suspended" On March 18, 2017, Ms. Foster was charged with possession of controlled substances and drug paraphernalia. After discussion, Dr. Wright made the motion to deny Ms. Foster's application for registration as a pharmacy technician. Dr. Eidson seconded the motion. The motion carried.

Reinstatement
Kellie Ledet, D.Ph.

Dr. Ledet requested to have her licensed reinstated. Dr. Ledet's license was revoked on 09/13/2017. After discussion, Dr. Rodgers made the motion to deny Dr. Ledet's request to reinstate her pharmacist license. Dr. Pryse seconded the motion. The motion carried.

Appearance

TN Department of Mental Health and Substance Abuse Services (TDMHSAS)

Dr. Wesley Gemmin presented the Buprenorphine Treatment Guidelines to the board for review. After discussion, Dr. Eidson made the motion to adopt the Buprenorphine Treatment Guidelines as policy and to post them to the board's website and newsletter. Dr. Wright seconded the motion. The motion carried.

Ampharm

Dr. Richard Coleman appeared before the board to request approval of pharmacy technician being able to stock electronic drug carts. Dr. Coleman stated that verification process will be a three step process between a pharmacy technician and the nurse at the facility. After discussion, Dr. Wilson made the motion to approve this request as presented. Dr. Wright seconded the motion. The motion carried.

Healthcare Associated Infections and Antimicrobial Resistant Program

Dr. Pamela Tally, Deputy Director, appeared before the board to present information about the Healthcare Associated Infections and Antimicrobial Resistant Program

Waivers

Board rule 1140-03-.14 (2)

Dr. Wilson made the motion to approve **Brantely Wescott, Pharm. D.** to be the pharmacist in charge at RARx, LP and RARx II closed door pharmacies. Dr. Pryse seconded the motion. The motion carried.

Dr. Eidson made the motion to approve **T. Melvin Mays. D.Ph**. to be the pharmacist in charge at Tennessee Department of Correction facilities located in Whiteville and Clifton, TN. Ms. Tittle seconded the motion. The motion carried.

Board rule 1140-01-.05 (4)

Dr. Pryse made the motion to approve **Lavesh Patel, Pharm. D**. to take the NAPLEX. The National Association Board of Pharmacy has a rule that candidates must have the board's permission to take the NAPLEX after three failed attempts. Dr. Wright seconded the motion. The motion carried.

Board rule 1140-01-.07(3) (b) 5(ii) & (iii)

Dr. Eidson made the motion to approve the request from **Laura Stiles, Pharm. D.**. to waive the one hundred and sixty (160) internship hours but she must successfully take and pass the MPJE. Dr. Wilson seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Dan Carpenter, D**. **Ph**. to waive the three hundred and twenty (320) internship hours but he must successfully take and pass the MPJE. Dr. Wright seconded the motion. The motion carried.

Dr. Wright made the motion to approve the request from **Michael McDonald, D**.**Ph.** to waive the one hundred and sixty (160) internship hours but he must successfully take and pass the MPJE. Dr. Eidson seconded the motion. The motion carried.

Dr. Wright made the motion to approve the request from **Melissa T. Robinson, D**.**Ph.** to waive the one hundred and sixty (160) internship hours but she must successfully take and pass the MPJE. Dr. Pryse seconded the motion. The motion carried.

Dr. Eidson made the motion to adjourn at 3:55 p.m. Dr. Pryse seconded the motion. The motion carried.

January 31, 2018

The Tennessee Board of Pharmacy reconvened on Wednesday, January 31, 2018 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members were present, the meeting was called to order at 9:00 a.m., by Dr. Dickenson, president.

Waivers

Board rule 1140-03-.14 (2)

Dr. Wright made the motion to approve **Shawn Pruitt, Pharm. D.** to be the pharmacist in charge at Pruitt's Discount Pharmacy, LLC and Pruitts Pharmacy at Neighborhood Health for six (6) months. Dr. Pryse seconded the motion. The motion carried.

OGC Report

Mr. Gibbs informed the board that there are 63 open cases for discipline at the Office of General Counsel and 18 of those cases are eligible for contested cases.

Mr. Gibbs also informed the board that on May 11, 2017, the governor signed into law a bill that requires TennCare to develop and implement a medication therapy management (MTM) pilot program. TennCare is responsible for establishing standards and eligibility criteria for the pilot program. MTM services shall be delivered by a TN-licensed pharmacist. However, nothing in the bill modifies or expands the scope of pharmacy practice. A pharmacist providing MTM, as outlined in the TennCare pilot program, "shall meet the standards for MTM established by rule by the BOP." Dr. Cost has provided language used as "standards" by the American Pharmacists Association. This language outlines nine criteria a pharmacist must observe when engaging in MTM. The rule language consist of one page which contains the nine criteria.

Mr. Gibbs presented the following legislation that pertain to the board:

SB1520/HB1614 (Senator Bell and Reps. Faison and Ragan) - As introduced, extends the board of pharmacy for five years to June 30, 2023.

> Update – Dr. Dilliard and I attended the Senate Government Operations committee meeting on Wednesday, January 24, 2018, wherein the committee accepted the 5-year recommendation.

SB1915/HB1883 (Sen. Niceley and Rep. Kane) - As introduced, clarifies that the present law that exempts certain oils containing cannabidiol and used for research or treatment of seizures or epilepsy will not be repealed on June 30, 2018; and removes DEA certification as an eligibility condition for the research exemption.

SB1659 (Sen. Dickerson) - As introduced, specifically makes the use of generic drugs pursuant to the Tennessee Affordable Drug Act of 2005 applicable to the TennCare program as a cost-saving measure.

SB1670/HB1695 (Sen. Green and Rep. Pitts) - As introduced, permits a pharmacist to honor a valid prescription written by a physician in another state or territory for a person displaced by a disaster who is present in this state.

SJR0528 (Sen. Kelsey) - General Assembly, Statement of Intent or Position - Recognizes the challenges faced by medical professionals and facilities.

SB1774/HB1874 (Sen. Crowe and Rep. Kumar) - As introduced, specifies that a medication therapy management program involves pharmacist-provided services.

SB1710/HB1749 (Sen. Dickerson and Rep. Faison) - As introduced, enacts the "Medical Cannabis Act"; establishes medical cannabis commission for regulation of cannabis-related health care.

Compliant Summary

1.

Complaint was opened after BOP Investigator was given information by a source that wishes to remain anonymous. The information alleged the respondent pharmacy is compounding with an unapproved product, Ipamorelin. Ipamorelin is classified as a small molecule oligopeptide hormone with a mechanism of action of growth hormone releasing factor agonist. It was once in phase IIb trials for treatment of postoperative ileus in the U.S. but was discontinued due to lack of efficacy. It has not been approved for

human use in the U.S. Investigator found that Ipamorelin was being used in combination with Sermorelin, GHRP-2 and GHRP-6("GHRP" stands for Growth Hormone Releasing Peptides). Sermorelin is FDA approved as a diagnostic tool for measuring growth hormone in the body and was used to treat GH deficiency in children. The manufacturer discontinued production of the brand because there was a better treatment for children by using recombinant DNA Growth Hormone. However, the chemical is still available for purchase from chemical suppliers. GHRP-2 and GHRP-6 are in the same class and there are conflicting interpretations of whether FDA allows use of these chemicals (and whether FDA can enforce their interpretation.) Most of the prescriptions found for these products were from prescribers that have performance, weight-loss, or anti-aging clinics.

Another complaint was combined with this one after Board Investigators discovered a sterile product from respondent pharmacy at a clinic located inside another pharmacy. That product appears to have been used as "office use" since it was not labeled with a patient's name and is believed to have been used to promote weight loss. The clinic had been closed prior to Investigators' visit but the vial of medication had been left behind. Investigators believe FDA will view this as manufacturing rather than pharmacy compounding.

Recommend: Forward to FDA

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

2.

Respondent is owner and pharmacist for Case 18 above.

Recommend:

Dr. Wilson made the motion to issue a **Letter of Warning** to the pharmacist concerning office use compounding. Dr. Eidson seconded the motion. The motion carried.

3.

Complaint alleged respondent pharmacist working in a clinic setting was violating multiple pharmacy rules. After a lengthy investigation BOP Investigator determined the respondent was performing clinical pharmacist duties in a clinic setting, including medication counseling and performing medication record review. There is no licensed pharmacy on-site and patients have to obtain medications from the pharmacy of their choice.

Although some of the allegations would be violations of pharmacy rules, the facility is not a licensee of BOP and the respondent pharmacist was not responsible for the areas in question.

Recommend: Close BOP case and refer to HCF and BME for follow-up

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

4.

Complaint was opened based upon a third party insurance audit that allegedly revealed multiple billing discrepancies. BOP Investigators discovered a practice in which an out of state referral company sent prescriptions to the respondent pharmacy to be filled and mailed to patients. Patients may be located in other states. Although it operated under the respondent pharmacy's license, the referral prescriptions were received, filled and packaged to mail in a separate room and supervised by a separate pharmacist that did not work in the main pharmacy. Due to the audit and disagreements between the respondent pharmacy owners and the referral company's owners, the practice had been discontinued prior to BOP Investigators arriving. The referral company did not share any info with the dispensing pharmacy other than the prescriptions and addresses. Investigators obtained statements from staff of the pharmacy, however, due to the lack of documentation on hand, no violations of BOP laws or rules could be determined. It does not appear that the respondent had any control over billing practices.

After the BOP Investigation, the whole pharmacy voluntarily closed.

Recommend: Close BOP case and refer to OIG/TBI

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

5.

Respondent pharmacist was PIC for Case 4 above, however was not involved in the operation or agreements with the referral company. BOP Investigators educated him about PIC responsibilities and he now understands he was ultimately responsible even though he felt he was not allowed to supervise the operation involving the referrals.

Recommend: Dismiss

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

6.

Complaint alleged respondent pharmacy sent unsolicited compounds to a patient, even though the patient's prescriber did not authorize the medications. Upon arrival at the respondent pharmacy, BOP Investigators discovered a practice in which an out of state referral company sent prescriptions to the respondent pharmacy to be filled and mailed to patients. Patients may be located in other states. Although it operated under the respondent pharmacy's license, the referral prescriptions were received, filled and packaged to mail in a separate room and supervised by a separate pharmacist that did not work in the main pharmacy. There was no documentation available at the practice site to determine if the patient and/or the prescriber had authorized the prescriptions. It does not appear the respondent pharmacy had any control over billing practices.

Respondent pharmacy has since voluntarily closed.

Recommend: Close BOP case and refer to OIG/TBI

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

7.

Respondent pharmacist was PIC for Case 6 above, however was not involved in the operation or agreements with the referral company. BOP Investigators educated about PIC responsibilities and he now understands he was ultimately responsible even though he felt he was not allowed to supervise the operation involving the referrals.

Recommend: Dismiss

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

8.

Respondent pharmacist owned the pharmacy in cases 4 and 6 above.

Recommend:

Dr. Eidson made the motion to **authorize a formal hearing** with a $1000.00 civil penalty per prescription to the pharmacy owner. Dr. Wilson seconded the motion. The motion carried.

9.

Complaint alleged unprofessional conduct by respondent pharmacist by way of the pharmacist asking too many questions and making the complainant wait too long before deciding whether to fill complainant's prescriptions. Complainant also alleged being shorted medication but admitted the pharmacist was never informed of the alleged shortage.

BOP Investigator visited the pharmacy where the respondent is employed. Investigator determined the complainant only had one medication filled at that pharmacy and had it filled 4 times. Complainant now uses a different pharmacy. Investigator did not find anything that substantiated the allegations.

Recommend: Dismiss

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

10.

Pharmacy supervisor reported that respondent hospital pharmacist failed to counsel discharge patients multiple times in the month of July, 2017. The complainant explained that 2 other pharmacists were designated to perform this service but one was on maternity leave and the other pharmacist was pulled to cover for another FMLA issue.

BOP Investigator interviewed the respondent. Respondent explained the process as follows:

If a patient is scheduled to be discharged, they have the option to receive free or lower priced discharge medications. Prescriptions are filled, the pharmacist takes them to the floor and counsels the patient. Then the prescriptions are locked in a cabinet until the patient leaves, at which time the floor nurse retrieves the medications and gives them to the patient. If the patient is not available for counseling, the pharmacist returns to the floor later to counsel. However, if the patient is discharged before the pharmacist returns, there is nothing preventing the nurse from giving the patient the medication. Respondent stated he makes several trips to the floor each day to conduct counseling but during July, 2017, two pharmacists were out

on leave so he could not make as many trips as usual so some patients may have left the facility without being counseled by a pharmacist.

Investigator questioned the process as there was no way of preventing drugs being released without verification that a pharmacist had provided counseling. There was also no policy in place addressing alternative means of counseling if the patient or caregiver are not present, even though established procedure was that a nurse would perform discharge counseling if the patient was being discharged prior to being counseled by a pharmacist.

At a follow-up discussion with the pharmacy supervisor, the Investigator was told that the procedure has now been changed so that if the patient was not available for counseling, the prescriptions are taken back to the pharmacy until the patient becomes available. This should prevent the problem in the future. The Investigator concluded that due to the workload and a lack of policy and procedures at the facility, the counseling failures should not be attributed to the respondent.

Recommend: Dismiss

Dr. Eidson made the motion to **authorize a formal hearing** with a $47,000.00 civil penalty ($1000.00 per violation) with $1000.00 stayed with an acceptable plan of correction to the pharmacy and a Letter of Warning to the dispensing pharmacist. Dr. Wilson seconded the motion. The motion carried. Dr. Wright was recused.

11.

Complaint alleges a misfill and unprofessional conduct. Allegedly, 1 pill was short in a bottle of Dexilant so the complainant called the pharmacy and was told they would give the 1 pill as a replacement. When the pill was obtained, it was different in appearance but the patient took it anyway after being told it was the same medicine but from a different manufacturer. The patient became sick and later found out the 1 replacement pill was actually an anti-depressant (possibly Duloxetine.) Complainant alleges unprofessional conduct because of the lack of concern and the refusal to release a copy of the pharmacy's internal incident report.

BOP Investigator interviewed both the complainant and the respondent. Investigator also interviewed other staff members regarding their knowledge of the facts. The respondent did not believe that the patient was shorted because the medication comes in sealed 30 count bottles and no counting is involved. However, the respondent did admit to caving under pressure as the complainant's representative became loud and used abusive language. Respondent admitted it was likely that 1 capsule of Duloxetine was dispensed instead of Dexilant, which sits beside it. Respondent denied that anyone questioned the different appearance. Respondent also denied telling anyone that it was the same thing from a different manufacturer. The PIC was on vacation at the time of the incident, but upon returning, filed a QA report and informed the patient's physician about the error. Company policy it that the QA reports are internal documents and cannot be released.

Recommend: LOW to dispensing pharmacist for misfill

Dr. Rodgers made the motion to issue a **Letter of Warning** to the dispensing pharmacist for the misfill. Dr. Eidson seconded the motion. The motion carried.

12.

Respondent is the pharmacy involved in Case 11 above. No violations by the pharmacy could be confirmed.

Recommend: Dismiss against the pharmacy

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

Consent Orders

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

PROBATION
Boatwright Drug Company
Steven Boatwright, D.Ph.

REPRIMAND
Martha Bryant, D.Ph.

REVOCATON
Aubrey Cain, RT

Director's Report

Dr. Dilliard ask the board to authorize travel and to elect a delegate to the National Association of Boards of Pharmacy Annual Meeting (NABP) in Denver, Co scheduled on May 5-8, 2018. Dr. Eidson made the motion to authorize travel for the executive director and board members to attend the National Association of Board of Pharmacy (NABP) Annual Meeting scheduled for May 5-8, 2018 in Denver, Co and Dr. Rodgers to be the board's delegate. Dr. Wright seconded the motion. The motion carried.

Dr. Dilliard informed the board that he met with the Deans of the College of Pharmacy from Belmont University, University of Tennessee, Union University and East Tennessee State University, to discuss licensing pharmacist interns.

Dr. Dilliard asked the board to authorize travel to attend the NABP multistate pharmacy jurisprudence exam (MPJE) item writing workshop scheduled for March 6-8, 2018. Dr. Wilson made the motion to authorize travel to the NABP multistate pharmacy jurisprudence exam (MPJE) item writing workshop. Dr. Pryse seconded the motion.

Dr. Dilliard informed the board the Accreditation Council for Pharmacy Education (ACPE) will be conducting a review of the college of pharmacy at Belmont University, Lipscomb University and Union University. Dr. Dilliard asked if board members would like to attend. Dr. Dickenson will attend the review of Belmont University on March 20-22, 2018, Dr. Wright will attend the review at Lipscomb University of April 10-12, 2018 and Dr. Dilliard will attend the review at Union University on April 17-19, 2018.

Dr. Dilliard informed the board of the pharmacy updates and asked the board to consider attending as well. The pharmacy updates are scheduled for the following dates and locations: February 10-11, 2018,

Jackson, TN; February 18, 2016, Memphis, TN; March 3-4, 2018, Franklin, TN; March 10, 2018, Cookeville, TN; March 24, 2018, Chattanooga, TN; April 8, 2018, Knoxville, TN; April 28, 2018, Murfreesboro, TN.

Dr. Dilliard asked the board to authorize travel for the pharmacy investigators, executive director and board members to attend the Tennessee Pharmacist Association (TPA) Winter Meeting scheduled for February 24-27, 2018 at the Doubletree Hotel, Nashville, TN. Dr. Eidson made the motion to authorize travel for the pharmacist investigators, executive director and board members to attend the TPA Winter Meeting. Ms. Tittle seconded the motion. The motion carried.

Dr. Eidson made the motion to adjourn at 11:40 a.m. Dr. Wright seconded the motion. The motion carried.

The minutes were approved and ratified at the March 13-14, 2018 board meeting.