TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Iris Room
Nashville, TN
July 17-18, 2018

BOARD MEMBER PRESENT

R. Michael Dickenson, D.Ph., President
Debra Wilson, D.Ph., Vice President
Kevin Eidson, 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
Terry Grinder, Pharmacy Investigator
Andrea Miller, Pharmacy Investigator
Albert Hill, Pharmacy Investigator
Derek Johnston, Pharmacy Investigator
Scott Denaburg, Pharmacy Investigator
Keshia Evans, Board Administrator

STAFF ABSENT

Sheila Bush-Administrative Director

The Tennessee Board of Pharmacy convened on Tuesday, July 17, 2018, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 8:02 a.m.

Minutes

The minutes from the May 1st and 2nd, 2018 board meeting were presented. After discussion, Dr. Wright made the motion to accept the minutes with correction to the date on the first page and resolution being added to case 20. Dr. Rodgers seconded the motion. The motion carried.

Rule Making Hearing

Mr. Gibbs, Assistant General Counsel served as moderator for the rulemaking hearing. Mr. Gibbs informed the board pursuant to Tennessee Code Annotated section 4-05-204 in the Iris Room, 665 Mainstream Drive, Nashville, TN. The purpose of the rulemaking hearing was to solicit comments on rules proposed by the board in order to amend rules 1140-01-.01, 1140-01-.10, and to create new rule chapter 1140-16 Third Party Logistics Provider. There were written or verbal comments from the public regarding the proposed changes. After discussion, Dr. Pryse made a motion to approve the rules as amended. Ms. Tittle seconded the motion. A roll call vote was taken. The Board acknowledged the Regulatory Flexibility Analysis and the Statement of Economic Impact on Small Businesses.

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For Department of State Use Only

Sequence Number: _____
Rule ID(s): _____
File Date: _____
Effective Date: _____

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

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

Revision Type (check all that apply):

___ Amendment
_X_ New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. 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 as a Repository 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. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). 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 except the drug is only tablet or capsule form, and includes cancer drugs and anti-rejection drugs, but does not include controlled substances and drugs covered by the risk evaluation and mitigation strategy program of the federal food and drug administration

(16) "Repository" means a pharmacy or medical facility that meets the eligibility requirements of Rule 1140-17-.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 Tenn. Code Ann. §§ 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. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

1140-17-.03 Eligibility Criteria for Program Participation as a Repository 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 revenue 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 Tenn. Comp. R. & Regs 1140-17-.03(4).

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

(4) 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.

(5) 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. §§ 63-10-501 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, which includes unit dose packaging created by a licensed pharmacy. 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 expiration date of the drug.

(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, 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.

For purposes of this subparagraph a health care professional is any person licensed in accordance with the provisions of Title 63 by any health related board of the Tennessee Department of Health to perform any profession of the healing arts.

(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 or unit dose packaging created by a licensed pharmacy;

(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, which includes the use of any common carrier. 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. §§ 63-10-501 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, prior to dispensing, 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, returned, or destroyed.

(3) Repositories shall return or destroy donated non-controlled substances that are not suitable for dispensing and make a record of such return or destruction which shall include, at a minimum, the drug name, strength, quantity, method of destruction, and date of 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. Destruction shall be accomplished by either the use of a reverse distributor or by following current DEA regulations regarding destruction of controlled substances.

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].

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 these rules, 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 these rules, 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. Drugs specified in a recall notice shall be considered recalled unless the drug has an affixed lot number which would exclude the drug from a 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. Drugs specified in a recall notice shall be considered recalled unless the drug has an affixed lot number which would exclude the drug from a recall.

(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. §§ 63-10-501 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 is below 200 percent of the FPL;

3. The individual is uninsured and has no prescription coverage for the prescribed drugs;

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 given to the recipient is valid for one year or until the new federal poverty guidelines have been published for all prescriptions and supplies.

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].

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.

(d) Intake collection form. A repository is authorized to make available to a recipient a blank intake collection form.

(2) The identification card shall be given to the recipient by the repository, and the completed intake 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 (5) years by participating pharmacies and medical facilities.

(b) Other 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) 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. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

Rule 1140-17-.09 Handling Fee. A repository may charge the recipient of a donated prescription drug a handling fee, not to exceed a maximum of 200 percent of the applicable tiered reimbursement rate as produced by the Bureau of TennCare, 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. §§ 63-10-501 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.

Any compounded drug which is made into tablet or capsule form, regardless of packaging, shall not be accepted by the prescription drug donation repository program

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].

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. §§ 63-10-501 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. §§ 63-10-501 through 63-10-510. [effective January 1, 2018].

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Debra Wilson, D.Ph	X				
Rissa H. Pryse D.Ph	X				
Katy Wright, D.Ph.	X				
Lisa Tittle	X				
Adams Rodgers, D.Ph.	X				
Kevin K. Eidson, Pharm. D.		X			

R. Michael Dickenson, D.Ph.	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Board of Pharmacy (board/commission/ other authority) on 01/30/2018 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: *11/28/17 (mm/dd/yy)*

Rulemaking Hearing(s) Conducted on: (add more dates). *01/30/2018 (mm/dd/yy)*

Date: _____

Signature: _____

Name of Officer: Matthew Gibbs

Title of Officer: Assistant General Counsel
Department of Health

Subscribed and sworn to before me on: _____

Notary Public Signature: _____

My commission expires on: _____

Agency/Board/Commission: Tennessee Board of Pharmacy

Rule Chapter Number(s): 1140-17

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

_____
Herbert H. Slatery III
Attorney General and Reporter

_____
Date

Department of State Use Only

Filed with the Department of State on: _____

Effective on: _____

_____
Tre Hargett
Secretary of State

General Discussion

Defining Preventative Care- Dr. Kevin Eidson presented the board with a document asking to adopt a policy on Preventative Care. The document defines and aids in guidance on what preventative care is. Dr. Eidson asked the board to adopt the definition of preventative care as outlined pending legal review and review by government operations. The Board agreed to review the document presented.

Legislation

Mr. Patrick Powell presented the board with a legislative update as follows:

Public Chapter 611
Requires an agency holding a public hearing as part of its rulemaking process, to make copies of the rule available in "redline form" to people attending the hearing.
This takes effect July 1, 2018.

Public Chapter 615
Allows pharmacists in Tennessee to dispense a prescription without proper authorization or valid prescription to a patient from another state who was displaced by a disaster. This must be done in good faith and the prescription information may be obtained from a prescription label, verbal order, or any other means determined to be legitimate in the professional judgment of the pharmacist. The prescription may be for the number of dosages necessary to allow the patient to secure a valid prescription but no more than a 20 day supply.
This act takes effect on July 1, 2018.

Public Chapter 638
Prohibits healthcare prescribers and their employees, agents, or independent contractors from in-person solicitation, telemarketing, or telephonic solicitation of victims within 30 days of an accident or disaster for the purpose of marketing services of the healing arts related to the accident or disaster. There are specific exceptions laid out in the chapter.
This act takes effect July 1, 2018.

Public Chapter 675
Requires the department of health to accept allegations of opioid abuse or diversion and for the department to publicize a means of reporting allegations.
Any entity that prescribes, dispenses, OR handles opioids is required to provide information to employees about reporting suspected opioid abuse/diversion. That notice is to either be provided individually to the employee in writing and documented by the employer OR by posting a sign in a conspicuous, non-public area of minimum height and width stating: "NOTICE: PLEASE

REPORT ANY SUSPECTED ABUSE OR DIVERSION OF OPIOIDS, OR ANY OTHER IMPROPER BEHAVIOR WITH RESPECT TO OPIOIDS, TO THE DEPARTMENT OF HEALTH'S COMPLAINT INTAKE LINE: 800-852-2187."
Whistleblower protections are also established. An individual who makes a report in good faith may not be terminated or suffer adverse licensure action solely based on the report. The individual also is immune from any civil liability related to a good faith report.
This act takes effect January 1, 2019.

Public Chapter 744
Allows a licensing entity the discretion to not suspend/deny/revoke a license in cases where the licensee has defaulted or become delinquent on student loans IF a medical hardship significantly contributed to the default or delinquency.
This act took effect January 1, 2019.

Public Chapter 745 and Public Chapter 793
These public chapters work together to create and implement the "Fresh Start Act." Licensing authorities are prohibited from denying an application or renewal for a license/certificate/registration due to a prior criminal conviction that does not directly relate to the applicable occupation. Lays out the requirements on the licensing authorities as well as the exceptions to the law (ex: rebuttable presumption regarding A and B level felonies).
These acts take effect July 1, 2018.

Public Chapter 754
Prevents any board, commission, committee, etc. created by statute from promulgating rules, issuing statements, or issuing intra-agency memoranda that infringe on an entity member's freedom of speech.
Freedom of speech includes, but is not limited to, a member's freedom to express an opinion concerning any matter relating to that governmental entity, excluding matters deemed to be confidential under TCA 10-7-504.
Violations as determined by a joint evaluation committee may result in recommendations to the general assembly concerning the entity's sunset status, rulemaking authority and funding.
This act took effect April 18, 2018.

Public Chapter 883
Lays the framework for e-prescribing practices in the state and the exceptions from electronic prescriptions. Requires that all Schedule II prescriptions be e-prescribed by January 1, 2020 except under certain circumstances. Any health-related board under TCA 68-1-101(a)(8) that is affected by this act shall report to the general assembly by January 1, 2019 on issues related to the implementation of this section. The commissioner of health is authorized to promulgate rules to effectuate the purposes of this act.
This act took effect May 3, 2018 for rule purposes.
The act takes effect January 1, 2019 for all other purposes.

Public Chapter 893
Allows for pharmaceutical manufacturers or their representatives to engage in truthful promotion

of off-label uses. The act also prohibits action against pharmaceutical manufacturer's, pharmaceutical representative's, healthcare institution's or physician's license solely for such activity.
This act takes effect July 1, 2018

Public Chapter 901
Requires that prior to prescribing more than a three day supply of an opioid or an opioid dosage that exceeds at total of 180 MME to a woman of childbearing age (15-44yo), a prescriber must do the following:
1. Advise of risks associated with opioid use during pregnancy;
2. Counsel patient on effective forms of birth control; and
3. Offer information on availability of free or reduced cost birth control

Doesn't apply if previously informed by prescriber in previous three months or prescriber reasonably believes patient is incapable of becoming pregnant. Requirements may be met with a patient under 18 years of age by informing parent of the patient.
The department of health is to publish guidance to assist prescribers in complying with this act.
This act takes effect July 1, 2018.

Public Chapter 929
Redefines policy and rule and requires each agency to submit a list of all policies, with certain exceptions, that have been adopted or changed in the previous year to the chairs of the government operations committees on July 1 of each year. The submission shall include a summary of the policy and the justification for adopting a policy instead of a rule.
This act also prohibits any policy or rule by any agency that infringes upon an agency member's freedom of speech.
Finally, this act establishes that an agency's appointing authority shall have the sole power to remove a member from a board, committee, etc.
This act takes effect July 1, 2018 and applies to policies adopted on or after that date.

Public Chapter 954
Requires the initial licensure fee for low-income persons to be waived. Low income individuals per the statute are defined as persons who are enrolled in a state or federal public assistance program including but not limited to TANF, Medicaid, and SNAP. All licensing authorities are required to promulgate rules to effectuate the purposes of this act.
This act takes effect January 1, 2019.

Public Chapter 978
Makes a number of revisions to opioid treatment regulations. The definition of "nonresidential office-based opiate treatment facility" (OBOT) has been changed to encompass more facilities.
The commissioner of mental health is required to revise the rules of OBOTs to be consistent with state and federal law for such facilities to establish certain new protocols.
Rules regarding OBOTs are to be reviewed each even-numbered year and the department of mental health and substance abuse services shall submit the rules for OBOTs to each health related board that licenses any practitioner authorized by the state to prescribe products for treatment of an opioid use disorder. Each board is required to enforce the rules. Each board is required to post the rules

on the board's website. Violation of a rule is grounds for disciplinary action by the board.
The act also makes revisions to the licensing fees of OBOTs and revision of the buprenorphine treatment guidelines.
The legislation also requires (subject to 42 CFR part 2) that dispensing of buprenorphine be subject to the Controlled Substance Monitoring Database (CSMD) requirements.
The act prohibits dispensing of buprenorphine except by certain individuals/facilities and requires pharmacies/distributors to report to the department of health (TDH) the quantities of buprenorphine that are delivered to OBOTs in the state.
The act also makes revisions to the high-volume prescriber list compiled by TDH.
The act requires the comptroller to complete a study of statistically abnormal prescribing patterns. After the study, TDH shall identify prescribers and shall inquire with the boards of action taken against the prescribers and the board is required to respond within 30 days. Each board is required to report the total number of prescribers disciplined each year, as well as other information. TDH shall report a summary of the data and of the disciplinary actions to the chairs of the health committees.
The act also comprises a task force to create minimum disciplinary actions for prescribing practices that are a significant deviation from sound medical judgment. The board of medical examiners, osteopathic examination, dentistry, podiatric medical examiners, optometry, nursing and medical examiner's committee on physician assistants shall select one member each for the task force before September 1, 2018.
This act took effect for rulemaking on May 21, 2018 and takes effect July 1, 2018 for all other purposes.

Public Chapter 1007
Allows for a prescription for a controlled substance to be partial filled if requested by the patient or the practitioner who wrote the prescription AND the total quantity dispensed through partial fills does not exceed the total quantity prescribed for the original prescription. The act lays out the requirements on the pharmacists and gives details regarding payments.
This act takes effect January 1, 2019.

Public Chapter 1015
Lays out the specific requirements of hospitals to notify law enforcement of involuntary commitments as well as the possible penalties for failure to comply. Inspections of hospitals by the department of mental health and the department of health shall include a determination of the hospital's compliance with the reporting requirements of this act.
The act also allows a pharmacist the right to provide information to an insured regarding the amount of the insured's cost share for a prescription drug. Neither a pharmacy nor a pharmacist shall be penalized by a pharmacy benefits manager for discussing such information or selling a lower priced drug if one is available.
This act takes effect July 1, 2018.

Public Chapter 1021
Allows for appeals of contested case hearings to be in the chancery court nearest the residence of the person contesting the agency action or at that person's discretion, in the chancery court nearest the place the action arose, or in the chancery court of Davidson County. Petitions seeking review

must be filed within 60 days after entry of the agency's final order.
This act takes effect July 1, 2018.

Public Chapter 1029
This act requires the board of pharmacy to promulgate rules regarding the board's oversight of facilities that manufacture, warehouse, and distribute medical devices. Rulemaking shall begin no later than September 1, 2018. The rulemaking process shall include the formation of an advisory committee composed of medical device industry representatives and a representative of the department of economic and community development. Rules promulgated shall be reviewed every three years for purposes of reviewing advancements of new medical device technologies.
This act takes effect July 1, 2018.

Public Chapter 1039
Places limits and requirements on the amount of opioids prescribed and dispensed. It limits opioid prescriptions to up to a three day supply with a total of 180 MME (morphine milligram equivalents) for those three days. This limitation is subject to a number of exceptions under certain circumstances. These exceptions include up to a ten day supply with a total of 500 MME, up to a twenty day supply with a total of 850 MME for a procedure that is more than minimally invasive, and up to a thirty day supply with a total of 1200 MME when other reasonable and appropriate non-opioid treatments have been attempted and failed and the risk of adverse effects from the pain exceeds the risk of the patient developing an addiction or overdose. Prescribing under these exceptions requires the prescriber to check the controlled substance monitoring database, personally conduct a physical exam of the patient, consider non-opioid alternatives, obtain informed consent including counseling about neonatal abstinence syndrome and contraception for women of childbearing age, and document the ICD-10 code for the patient's primary disease (as well as the term "medical necessity" on thirty day prescriptions). These ten, twenty, and thirty day opioid prescriptions will only be filled by dispensers in an amount that is half of the full prescription at a time, requiring patients and pharmacists to consider whether the patient requires the full amount prescribed. There are still further exceptions for those patients undergoing active or palliative cancer treatment, receiving hospice care, diagnosed with sickle cell disease, administered to in a hospital, being treated by a pain management specialist or collaborating provider in a pain management clinic, who have received ninety days or more in the year prior to April 2018 or subsequently do so under one of the exceptions, receiving treatment for medication-assisted treatment, or suffering severe burns or major physical trauma.
This act took effect for rule purposes on May 21, 2018, and for all other purposes shall take effect July 1, 2018.

Public Chapter 1040
Revises various provisions of the law regarding controlled substances and their analogues and derivatives, including updating identifications of drugs categorized in Schedules I - V. The act also creates an offense for the sale or offer to sell Kratom, unless it is labeled and in its natural form. It is also an offense to distribute, sell, or offer for sale, kratom to a person under 21 years of age. It is also an offense to purchase or possess kratom if under 21 years of age.
This act takes effect July 1, 2018.

Office of General Counsel Report

Litigation:

Mr. Gibbs informed the board that there are currently 67 cases open for discipline within the Office of General Counsel. Of those 67 cases, 9 are eligible for a contested hearing.

Rules:

Drs. Dilliard, Dickenson, Rodgers and Attorney Gibbs appeared before the General Assembly's Joint Government Operations Committee meeting on June 20, 2018. After a very brief discussion by the committee members, the rule packet was given a positive recommendation (by the committee) for inclusion within the General Assembly's omnibus bill. The "hormonal contraceptive" rule packet will take effect on Wednesday, July 18, 2018.

On July 25, 2018, the "drug repository" rule packet is scheduled as an agenda item for the General Assembly's Joint Government Operations Committee. The "drug repository" rule packet is scheduled to take effect on August 29, 2018.

Complaint Summary

1.

Complaint alleged Respondent pharmacy had over dispensed controlled substances to a patient being seen by different prescribers.

BOP Investigator reviewed the pharmacy's records and discovered the patient in question had been in hospice care and during that time all prescriptions were issued by one prescriber, usually for a 7 day supply. In January 2018, the patient was released from hospice. On January 26, the patient was dispensed #120 Oxycodone APAP 10-325 for a 30 day supply. On January 29, the patient was dispensed #21 Oxycodone 20 mg for a 7 day supply from the hospice provider. The same pharmacist dispensed both prescriptions and was unable to recall if he had checked with the prescriber or whether he had performed a DUR. CSMD report for the patient showed nobody accessed the patient's record on either of those days.

Prior discipline - $1,000 civil penalty for a counseling violation in 2012.

Recommend: Dismiss against the pharmacy and open against the dispensing pharmacist.

Dr. Eidson made the motion to dismiss against pharmacy and open against the dispensing pharmacist. Dr. Wright seconded the motion. The motion carried.

2.

Respondent is the dispensing pharmacist in Case 1 above.

No prior discipline.

Recommend: LOW for failure to perform DUR

Dr. Wright made the motion to issue a Letter of Warning to the dispensing pharmacist for failure to perform DUR with the inclusion of educational materials. Dr. Pryse seconded the motion. The motion carried.

3.

Complainant alleged the respondent pharmacy uses unprofessional and aggressive tactics to try to lure patients into having prescriptions transferred to the respondent pharmacy. Complainant asked BOP Investigator not to contact patients since they had all refused to allow the respondent pharmacy to transfer their prescriptions and complainant feared BOP contact would disturb them. BOP Investigator did contact the respondent pharmacy but was not able to speak to any pharmacists, only customer service representatives. Investigator explained patients' right to choose and the CSRs' denied using any pressure tactics to attract business.

Although the allegations could not be substantiated, the Investigator has concerns about the message being passed along to the pharmacists.

No prior discipline.

Recommend: LOI

Dr. Pryse made the motion to issue a Letter of Instruction to the pharmacist in charge and pharmacy. Notify the home state BOP to investigate for further action. Dr. Eidson seconded the motion. The motion carried.

4.

Respondent pharmacist was terminated from employment after the employer conducted an internal investigation and found that the respondent filled, checked and picked up three prescriptions (including one for Alprazolam) which the prescriber denied authorizing. A copy of the internal investigation was given to BOP Investigators.

BOP Investigator interviewed the respondent who stated the prescriptions were for a friend, who handed her some prescriptions to have filled. Later the prescriptions could not be located. Respondent indicated she filled the prescriptions from memory.

BOP Investigator also contacted the prescriber who provided a signed statement denying authorizing the prescriptions.

No prior discipline.

Recommend: period of probation

Dr. Eidson made the motion to table the complaint pending TPRN evaluation. Dr. Wright seconded the motion. The motion carried.

5.

Complaint was filed alleging that the respondent pharmacist had accessed the complainant's medical records without consent.

BOP Investigator obtained a sworn statement from the respondent stating the only encounter with the complainant occurred at a wedding in 2011. The complainant is not Respondent's patient. Respondent denies ever looking at the patient's profile and a check of computer records shows that the patient has never had any prescriptions filled at the respondent's pharmacy and does not have a medication history.

No prior discipline.

Recommend: Dismiss

Dr. Eidson made the motion to dismiss. Mrs. Tittle seconded the motion. The motion carried.

6.

Complaint was filed against the respondent pharmacy for failure to note (in a patient profile) that a particular generic caused the patient to encounter side effects. The side effects went away after the pharmacy exchanged a different manufacturer's generic. About 2 months later, the pharmacy dispensed the generic which caused problems to the patient. The patient returned to the pharmacy and the tablets were again exchanged for a different manufacturer's generic.

BOP Investigator obtained a sworn statement from the PIC of the respondent pharmacy. PIC agreed the events occurred but noted that the patient's insurance would only cover the cost of the generic that reportedly caused the side effects. PIC stated he was trying to save the patient from having to pay for the medication and had forgotten the incident by the time the next prescription was filled about 2 months later.

No prior discipline.

Recommend: LOW to the pharmacy for lack of DUR, mixing of NDC's and probable lack of counseling

Dr. Eidson made the motion to issue a Letter of Instruction to the pharmacy. Ms. Tittle seconded the motion. The motion carried.

7.

Complaint alleged the respondent pharmacy filled a prescription for oxymorphone with Opana but the bottle was still labeled as oxymorphone. Complainant stated the Opana was disposed of by the complainant's doctor who told the patient not to go back to the respondent pharmacy. Complainant alleged the respondent pharmacy refused to transfer the patient's prescriptions and also allegedly instructed other pharmacies in the area to not accept her as a patient.

BOP Investigator interviewed the patient and verified she is now receiving medications at another pharmacy. Investigator interviewed staff at the respondent pharmacy and verified the prescription in question was partially filled with oxymorphone and finished with Opana. Respondent pharmacy is subject to wholesaler restrictions. PIC told the Investigator that the prescriber had authorized the switch and the patient was aware of it. No violation could be determined.

Prior discipline - $1,000 civil penalty for a counseling violation in 2012.

Recommend: Dismiss

Dr. Wilson made the motion to dismiss. Dr. Rodgers seconded the motion. The motion carried.

8.

Complaint alleged the respondent pharmacist violated the Health Care Consumer Right to Know Act of 1998 by failing to update the Mandatory Practitioner Profile and also failed to update the pharmacist's practice site with the BOP.

BOP Investigator met with the respondent pharmacist who provided proof of primary practice site is a military base in Ohio. All information is correct and up to date.

No prior discipline.

Recommend: Dismiss

Dr. Pryse made the motion to dismiss. Dr. Wilson seconded the motion. The motion carried.

9.

Complaint was filed alleging a misfill when Levetiracetam 100mg/ml with directions to take 1.5ml twice daily was incorrectly dispensed with a label stating to take 7.5ml twice daily.

BOP Investigator spoke to the complainant who stated the child was given the incorrect dose for 6 days and was very lethargic but there does not appear to be any lasting harm. The complainant told the Investigator there was no interaction with the pharmacist when the medication was picked up at the drive-thru window.

Investigator interviewed the respondent pharmacy's staff, verified the misfill occurred and identified the dispensing pharmacist. Two new prescriptions were dispensed (Levetiracetam and Cephalexin). The dispensing pharmacist's case will be filed separately.

No prior discipline

Recommend: $2,000 civil penalty to the pharmacy for counseling violations.

Dr. Wilson made the motion to authorize a formal hearing with a $2,000 civil penalty to the pharmacy for counseling violations. Dr. Wright seconded the motion. The motion carried.

10.

Respondent pharmacist is PIC for Case 9 above.

No prior discipline.

Recommend: Suggest root cause analysis for misfill be submitted to BOP; LOI as PIC for counseling violation.

Dr. Rodgers made the motion to accept council's recommendation. Dr. Pryse seconded the motion. The motion carried.

11.

Respondent pharmacist is dispensing pharmacist for Case 9 above.

No prior discipline.

Recommend: $1,000 civil penalty for failure to counsel; LOW for misfill

Mrs. Tittle made the motion to authorize a formal hearing with a $1,000 civil penalty for failure to counsel; and a Letter of Warning for misfill. Dr. Eidson seconded the motion. The motion carried.

12.

BOP Investigator performed an inspection on 6/4/18 for change of ownership and change of location for respondent MWD. Investigator discovered the respondent had ignored his instructions to apply for the changes in October, 2017. Respondent changed owners and location on 10/19/18 but did not file application with BOP until 4/19/18.

Recommend: $700 civil penalty for 7 months @ 100.00 per month, unlicensed activity for drug wholesaler.

Dr. Wilson made the motion to authorize a formal hearing with a $700 civil penalty ($100.00 per month) for unlicensed activity for drug wholesaler. Mrs. Tittle seconded the motion. The motion carried.

13.

Complaint alleged a misfill causing side effects for the complainant and also alleged the same pharmacy refills early and requires the patients to pay cash.

Complainant provided BOP Investigator with a labeled vial for Topiramate 50mg which contained Quetiapine 50mg. Patient reported feeling lethargic, anxious and moody while taking the incorrect medication. Pharmacy PIC could not provide any explanation as to how this occurred, however the tablets provided by the patient did match a generic Quetiapine on the pharmacy's shelf. An audit was attempted, however it was inconclusive without a known starting inventory of Quetiapine. Pharmacy files and records were in disarray and 56 expired products were located on shelves. PIC/owner had been warned on previous visits to create a policy which would allow staff to pull expired drugs from shelves before expiring. Other allegations made in the complaint involving complainant's family members receiving refills early were not substantiated as being consistently or repeatedly early.

No prior discipline.

Recommend: $560 civil penalty for expired drugs on shelves. Open a complaint on dispensing pharmacist for misfill.

Dr. Eidson made the motion to authorize a formal hearing with a $560 civil penalty for expired drugs on shelves. Open a complaint on dispensing pharmacist for misfill. Dr. Pryse seconded the motion. The motion carried.

14.

Respondent is the dispensing pharmacist for Case 13 misfill.

No prior discipline.

Recommend: LOW

Dr. Rodgers made the motion to issue a Letter of Warning to the dispensing pharmacist. Dr. Wright seconded the motion. The motion carried.

15.

Original complaint alleged the Respondent pharmacy performs incorrect calculations when preparing sterile products, fails to log reported errors, and engaged in unprofessional conduct in regards to an investigational drug study.

BOP Investigator interviewed staff and PIC. Multiple deficiencies, which were created by the Respondent pharmacy, were noted within the investigational drug study which would severely compromise the results of the drug study because of labeling, testing, potency, and expiration / BUD dating.

No prior discipline.

Recommend: Reprimand and costs; monitoring; notify drug study investigators; notify FDA

Dr. Wilson made the motion to issue a reprimand and access costs of the investigation; monitoring; notify drug study investigators and notify FDA. Dr. Wright seconded the motion. The motion carried.

16.

Respondent is PIC for Case 15 above.

No prior discipline.

Recommend: Reprimand; notify drug study investigators; notify FDA

Dr. Eidson made the motion to authorize a formal hearing to reprimand the pharmacist; notify drug study investigators IRB and notify FDA. Dr. Pryse seconded the motion. The motion carried.

17.

Complainant alleged unauthorized access to CSMD records by staff at the respondent pharmacy. Complainant is employed by the Respondent pharmacy. Supporting documentation showed the complainant's CSMD records were accessed on 2 of his off days by using his access code. Records were also accessed using another pharmacist's access code on days when the complainant did not have any prescriptions filled. Complainant alleged the CSMD information,

which showed that the complainant has medications filled at other pharmacies, was then used by the employer to claim disloyalty which created a hostile work environment. Complainant also stated that access was without permission and without his knowledge.

BOP Investigator spoke to the pharmacist that took over as PIC after the complainant resigned. PIC told the Investigator that only pharmacists have access to CSMD, but admitted that she has codes written down and that she "signs on for the technicians to check." The pharmacy owner told the Investigator that only pharmacists have access to CSMD and that the complainant must have allowed others to have his access information.

No prior discipline.

Recommend: LOW to pharmacy for proper CSMD access.

Dr. Eidson made a motion to issue a Letter of Warning to the pharmacy for proper CSMD access. Dr. Wilson seconded the motion. The motion carried.

Case 18.

Respondent is the pharmacist and PIC for Case 17 above.

No prior discipline.

Recommend: LOW for proper access to CSMD

Dr. Eidson made a motion to accept council's recommendation to issue a Letter of Warning to the pharmacy for proper CSMD access. Dr. Wilson seconded the motion. The motion carried.

19.

Complaint was opened after a DEA audit/inspection of the respondent pharmacy due to C/S purchase history. DEA issued an MOA which outlines several areas of CS violations including shortages, improper record keeping, CSOS violations, filling CS prescriptions that were stamped instead of signed, and failure to file a DEA 106 as required. TBOP Investigators accompanying DEA were able to obtain a copy of the audit performed on-site of 10 C/Ss, 8 which revealed shortages.

Shortage percentages were as follows:

Amphetamine 20mg -0.02% or 1 tablet
Embeda 30/1.2mg -0.09% or 4 tablets
OxycodoneAPAP 10/325 -1.07% or 4,541 tablets
Hydrocodone APAP 5/325 -1.80% or 687 tablets
Oxycodone 10mg -3.53% or 2,121 tablets
Oxycodone 15mg -3.81% or 4,026 tablets
Morphine IR 30mg -26.38% or 910 tablets
Morphine IR 15mg -39.62% or 210 tablets

No prior discipline.

Recommend: Probation with monitoring for 3 years the MOA is in effect; costs

Dr. Wright made the motion to authorize a formal hearing to reprimand with costs; 5 year probation with monitoring for 3 years the MOA is in effect with a corrective action plan being submitted to the board; notify drug study investigators and notify FDA. Dr. Pryse seconded the motion. The motion carried.

20.

Respondent is PIC for Case 19 above.

No prior discipline.

Recommend: Reprimand

Dr. Wilson made the motion to accept the motion to reprimand. After further discussion Dr. Wilson withdrew the aforesaid motion. After further discussion. Dr. Wright made the motion to authorize a formal hearing to PIC license, reprimand with 5 year probation Dr. Rodgers seconded the motion. The motion carried.

Order Modification

Terry Moore, Pharm.D.

Dr. Moore appeared before the board to request that the he be allowed to float for Riddle Drug. After discussion, Dr. Eidson made the motion to approve the request for Dr. Moore's request to float for Riddle Drug only. Dr. Wilson seconded the motion. The motion carried

Reinstatement

James Catron

Dr. Catron requested to have his licensed reinstated. Dr. Catron's license was suspended on 01/28/2015. After discussion, Dr. Eidson made the motion to reinstate Dr. Catron's license. Dr. Catron's license will be on lifetime probation once he has completed all the necessary requirements for reinstatement with the following conditions. Dr. Catron's will receive lifetime revocation if he failed to complete the probation and no PIC status until further notice. Dr. Wilson seconded the motion. Dr. Rodgers opposed the motion. The motion carried.

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

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

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

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

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

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

(g) The Respondent shall comply with all of the terms and conditions of the extended aftercare contract he 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 until further notice.

(i) Respondent shall not work as a "floater" for a period of three (3) years from the start of Probation, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without permission of the Board;

(j) Respondent shall complete all provisions required for the reinstatement of his license listed in Board rule 1140-01-.07(3)(b):

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;
4. Successfully complete the Multi-State Pharmacy Jurisprudence Examination (MPJE)

5. Complete one hundred and sixty (160) pharmacy internship hours within ninety (90) consecutive days.

Application Review

Jessica Montez

Ms. Montez answered "no" to the question that asked "Have you ever applied for or held a state or federal controlled substance certificate that was ever denied, revoked, suspended, restricted, voluntarily surrendered or otherwise disciplined or surrendered under threat of restriction or disciplinary action?" Documentation submitted indicates that Ms. Montez pled guilty of theft of property June 23, 2015. Ms. Montez was given diversion with cost. It ended on June 23, 2016. After discussion, Dr. Wright made the motion to approve Ms. Montez's application for registration as a pharmacy technician. Mrs. Tittle seconded the motion. The motion carried.

Presentation

James Sharp, Indivior Solutions, Inc

Mr. Sharp appeared before the board in regard to a new product that is on the market and issues he is having with the delivery of the particular drug to physician offices, he would like to request a waiver for it to be delivered as such. Dr. Eidson made a motion to table the waiver pending Mr. Gibbs and Dr. Dilliard endeavor to work together and formulate a more concise understanding, then convey such as quickly as possible to the board. Dr. Wright seconded the motion. The motion carried.

Waivers
Board rule 1140-01-.13 (3)(e)
Dr. Wilson made the motion to approve the waiver request from Baptist Memorial Hospital requirement for hot and cold running water. Mrs. Tittle seconded the motion. The motion carried.

Board rule 1140-03-.14 (12)
Dr. Wright made the motion to approve the waiver request for Tritia Townsend, D.Ph. to be PIC at two pharmacy locations pending the licensing of the pharmacy. Dr. Pryse seconded the motion. The motion carried.

Kimberly Hawks, Pharm.D.
Dr. Wright made the motion to approve the waiver request to be PIC at two pharmacy locations pending the licensing of the pharmacy. Dr. Rodgers seconded the motion. The motion carried.

John Prichard, D.Ph.
Dr. Wilson made the motion to approve the waiver request to be PIC at two pharmacy locations, one with non- sterile compounding pending the licensing of the pharmacy. Mrs. Tittle seconded the motion. The motion carried.

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

Jessica Liska, D.Ph.- Dr. Rodgers made a motion to waive 160 internship hours but not the MPJE. Dr. Wright seconded the motion. The motion carried.

Timothy Mickel, Pharm.D.- Dr. Eidson made a motion to waive 320 internship hours and the Naplex exam. Dr. Wright seconded the motion. The motion carried.

Maggie Kavanaugh, Pharm.D.- Rodgers made a motion to waive 320 internship hours but not the MPJE. Dr. Wright seconded the motion. The motion carried.

Nicholas Nowak, D.Ph. - Dr. Eidson made a motion to waive internship hours and the NPJE. Dr. Wright seconded the motion. The motion carried. Dr. Pryse recused herself.

Karen Samaan, Pharm.D.- Mrs. Tittle made a motion to waive internship hours and the NAPLEX, but Dr. Kavanaugh must take the MPJE. Dr. Wilson seconded the motion. The motion carried.

Jill Ryan, Pharm.D.- Dr. Wilson made a motion to pay all back fees prior to reinstatement of license. Dr. Wright seconded the motion. The motion carried.

Board rule 1140-03-.01(1)

Crystal Ezell, Pharm.D.-, Dr. Ezell is with PCA New Script appeared before the board to request a waiver in effort to service medications at Buffalo Valley without any face to face interaction. After further discussion the decision was made to withdraw the request for waiver.

Dr. Holley-Discussion of Drug Shortages

Dr. Holley present the board with a proposal to request to authorize the use of expired medication. After further discussion amongst members of the board and the board's attorney, Dr. Holley decided to proceed with his request at the governor's office for more direction in authorization.

July 18, 2018

The Tennessee Board of Pharmacy convened on Tuesday, July 18, 2018, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 8:00 a.m. Dr. Rebecca Moak was absent.

Board rule 1140-03-.14 (12)

Diana Drake, D.Ph. appeared before the board to request a waiver to be PIC at an additional complex in Trousdale pharmacy locations.

After discussion, Dr. Wilson made the motion to approve the waiver request. Dr. Wright seconded the motion. The motion carried.

Director's Report

Dr. Dilliard informed the board of the government opps meeting which is upcoming that Dr. Rodgers and Dr. Dickenson volunteered to participate in.

Dr. Dilliard engaged the board in discussion of District 3 in Asheville was discussed, as a reminder District 3 will be held next year in Tennessee. The board was presented with the request for a few of the investigators to be in attendance of the upcoming meeting in Asheville. After discussion, Dr. Pryse made the motion to approve the request for investigators to travel to Asheville. Dr. Rodgers seconded the motion. The motion carried.

Dr. Dilliard informed the board of MALTAGON a very informative meeting in Kansas City, MO being held October 11th-14th, approval for travel was requested. Dr. Wilson made a motion to approve travel for board members or staff interested in going. The motion carried.

Dr. Dilliard informed the board of the need for volunteers to conduct the item review for MPJE. The review will be conducted by Dr. Hadden from Chicago, Dr. Wright and Dr. Miller will do it remotely.

Dr. Dilliard informed the board of the burprenorphine meeting in Nashville on the evening of July 19th.

Dr. Dilliard informed the board that the budget was approved to hire 2 more investigators.

Consent Orders

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

Voluntary Surrender (same as revocation)

Princess Tipton, RT
Shae L Walker, RT
Veronica Williams, RT
Tiffany Roach, RT
Melissa Blankenship, RT
Samuel Jones, RT
Theresa Mikron, RT
Stephanie Rodgers, RT

Probation
Dr. Jason Miley, D.PH.

Reprimand

Wells Pharmacy Network

Violated Board Rule 1140.03-.02

P and S Pharmacy

Contested Case

Loren Kirby, RT

Ms. Kirby was not present nor represented by legal counsel. Mr. Gibbs represented the State. Mr. Thomas Stovall was the Administrative Law Judge. Mr. Gibbs asked to proceed in default. Dr. Eidson made the motion to proceed in default. Dr. Wilson seconded the motion. The motion carried. Mr. Gibbs passed out the Notice of Hearing in which Ms. Kirby is charged with violating T.C.A § 53-10-104(a), T.C.A. § 53-10-104 (b), T.C. A § 53-10-105 (a) and T.C.A. § 53-11-402 (a) (3), T.C.A § 53-11-416(a), T.C.A § 63-10-305(4), T.C.A § 63-10-305(6). Dr. Wilson made the motion to revoke Ms. Kirby's registration as a pharmacy technician and assess case cost. Dr. Wright seconded the motion. A roll call vote was taken. The motion carried. Dr. Wilson made a motion to accept the policy statement as read and presented in section four of the contested case. Ms. Tittle seconded the motion. The motion carried.

Adjournment

Dr. Eidson made a motion to adjourn the meeting at 9:37. Dr. Pryse seconded the motion. The motion carried.

The minutes were approved and ratified at the September 11-12, 2018 board meeting.