TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Poplar Room
Nashville, TN
September 10-11, 2014

BOARD MEMBER PRESENT
Jason Kizer, D.Ph., President
Nina Smother, D.Ph., Vice President
Kevin Eidson, D.Ph.
R. Michael Dickenson, D.Ph.

STAFF PRESENT
Reginald Dilliard, Executive Director
Stefan Cange, Assistant General Counsel
Terry Grinder, Pharmacist Investigator
Tommy Chrisp, Pharmacist Investigator
Scott Denaburg, Pharmacist Investigator
Rebecca Moak, Pharmacist Investigator
Larry Hill, Pharmacist Investigator
Bob Shutt, Pharmacist Investigator
Andrea Miller, Pharmacist Investigator
Richard Hadden, Pharmacist Investigator
Sheila Bush, Board Administrator
Marc Guilford, Assistant General Counsel
Devin Wells, Deputy General Counsel

BOARD MEMBER ABSENT
Joyce McDaniel, Consumer Member
Debra Wilson, D.Ph.

The Tennessee Board of Pharmacy convened on September 10, 2014 in the Poplar Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:12 a.m.

Rulemaking Hearing

Mr. Cange, Assistant General Counsel served as moderator for the rulemaking hearing. There were no written or verbal comments from the public regarding the proposed changes. The board decided to amend rule 1140-01-.08(b) 2 to accept FDA inspection reports since federal law supersede state law. After discussion, Dr. Eidson made the motion to adopt the rules as amended. Dr. Smothers seconded the motion. A roll call vote was taken.

Department of State
Division of Publications
312 Rosa L. Parks, 8th Floor Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615.741.2650
Fax: 615.741.5133
Email: register.information@tn.gov

For Department of State Use Only
Sequence Number: 09-07-14
Notice ID(s): 2152-2153
File Date: 9/11/14

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: Board of Pharmacy
Division:
Contact Person: Stefan Cange
Address: 665 Mainstream Drive, Nashville, Tennessee 37243
Phone: (615) 741-1611
Email: Stefan.Cange@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, Tennessee
Zip:	37228
Hearing Date :	09/10/2014
Hearing Time:	9:00 a.m. X CST/CDT ___EST/EDT

Additional Hearing Information:

Revision Type (check all that apply):
X Amendment
___ 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**
1140-01	Introductory Rules
Rule Number	**Rule Title**
1140-01-.01	Definitions
1140-01-.04	Pharmacy Internship

1140-01-.08	Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses
1140-01-.10	Fees
1140-01-.12	Sterile Product Registration
1140-01-.13	Standards for Pharmacies and Prescription Department Safety
1140-01-.14	Standards for Manufacturers and Wholesalers/Distributors
1140-01-.15	Prescription Drugs Dispensed by Health Departments

Chapter Number	**Chapter Title**
1140-09	Manufacturers and Wholesalers/Distributors
Rule Number	**Rule Title**
1140-09-.01	Manufacturer and Wholesaler/Distributor Licensing
1140-09-.02	Minimum Information Required
1140-09-.03	Minimum Qualifications
1140-09-.04	Personnel
1140-09-.05	Minimum Requirements for General Operation
1140-09-.06	Minimum Requirements for Sterile Product Operation

(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://state.tn.us/sos/rules/1360/1360.htm)

Chapter
1140-01
Introductory Rules

Amendments

Rule 1140-01-.01 Definitions is amended by adding paragraphs (21) and (22) and renumbering the remaining paragraphs, so that as amended, the new paragraphs (21) and (22) shall read:

(21) "Outsourcing facility" means a facility engaged in the compounding of sterile drugs which has elected to register as an outsourcing facility with the U.S. Food and Drug Administration and which complies with all relevant federal laws and regulations.

(22) "Oxygen supplier" means any person who sells, delivers, distributes or wholesales medical gases which require a prescription or medical order prior to administration, dispensing or delivery and which are considered legend drugs pursuant to the federal Food, Drug, and Cosmetic Act to any person residing in this state.

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301 and 63-10-304.

Rule 1140-01-.04 Pharmacy Internship is amended by deleting the rule in its entirety and substituting instead the following language, so that as amended, the new rule shall read:

(1) An applicant for an initial pharmacist license by examination must show, on affidavit forms prescribed by the board, that the applicant has acquired a minimum of one thousand seven hundred (1,700) hours of pharmacy internship (practical pharmacy experience) under the instruction of a pharmacist in good standing, subject to all of the following conditions.

(a) The one thousand seven hundred (1,700) hours must be acquired after enrollment in a recognized college or school of pharmacy; one thousand seven hundred (1,700) of these hours may be acquired in pharmacy programs or demonstration projects structured by the college or school of pharmacy.

(b) Pharmacy internship may be acquired in another state, provided that the preceptor's qualifications are certified by the appropriate authorities of such state.

(c) Foreign pharmacy graduates shall complete five hundred (500) hours of pharmacy internship in Tennessee within a period of six (6) consecutive months.

Authority: T.C.A. §§ 63-10-101, 63-10-102, 63-10-202, 63-10-404.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses is amended by deleting the rule title and paragraphs (1), (2), and (3) in their entirety and substituting instead the following language, so that as amended, the new rule title and new paragraphs (1), (2), and (3) shall read:

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer, Outsourcing Facility, Oxygen Supplier, and Wholesaler/Distributor Licenses

(1) Application for a license to operate as a pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor within the state of Tennessee shall be submitted to the office of the board at least thirty (30) days prior to the scheduled opening date. No pharmacy practice site, manufacturer, outsourcing facility or wholesaler/distributor may open within the state of Tennessee until a license has been obtained; and such license will not be issued until an inspection by an authorized representative of the board has been made.

(2) An application for an existing pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor physically located within the state of Tennessee must be filed when the

pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor changes name, location or ownership.

(3) No out-of-state pharmacy practice site, manufacturer outsourcing facility, oxygen supplier or wholesaler/distributor shall conduct business in the state of Tennessee until such pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor obtains the required license from the board. In order to obtain a license for a pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor physically located out-of-state the following standards must be met.

Authority: T.C.A. §§ 63-10-204, 63-10-301 and 63-10-304.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/Distributor Licenses is amended by deleting subparagraph (3)(b) and parts (3)(b)1. and (3)(b)2. and substituting instead the following language, so that as amended, the new subparagraph and parts shall read:

(b) Manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor.

1. Submit an application for a license, which shall include the address of the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor, name of owner if a sole proprietorship, names of partners if a partnership or names and titles of all officers if a corporation, together with the appropriate application fee. The director shall be notified in writing within thirty (30) days of any change in the information contained on the original application for a license.

2. Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor is physically located. Thereafter, the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor shall submit to the director a copy of any subsequent inspection report conducted by the regulatory or licensing agency of the state in which the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor is physically located. Inspection reports which are more than one (1) year old at the time of submission shall not satisfy the requirements of this part.

Authority: T.C.A. §§ 63-10-204, 63-10-301 and 63-10-304.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/Distributor Licenses is amended by deleting paragraphs (4) and (5) and substituting instead the following language, so that as amended the new paragraphs (4) and (5) shall read:

(4) Representatives of a manufacturer, outsourcing facility or wholesaler/distributor conducting business in the state of Tennessee and who possesses and distributes controlled substances shall obtain a controlled substance registration from the Board of Pharmacy.

(5) Any entity licensed as or applying for licensure as manufacturer or outsourcing facility conducting business in the state of Tennessee and who manufactures, prepares, propagates, repackages, or processes sterile drug products or biological products using aseptic processing must register and possess a modifier as a sterile manufacturer with the Board of Pharmacy in accordance with this chapter. This section shall not apply to wholesalers/distributors of sterile products.

Authority: T.C.A. §§ 63-10-204, 63-10-301 and 63-10-304.

Rule 1140-01-.05 Fees is amended by deleting paragraphs (6), (7), and (10) in their entirety and substituting instead the following language, so that as amended, the new paragraphs (6), (7), and (10) shall read:

(6) All manufacturers, outsourcing facilities, oxygen suppliers and wholesalers/distributors of prescription drugs and devices and related materials doing business in the state of Tennessee must be licensed by the Board of Pharmacy by paying a registration fee of five-hundred twenty-five dollars ($525.00), and thereafter a biennial renewal fee of five-hundred twenty-five dollars ($525.00).

(7) The fee for the Board of Pharmacy's publication of Pharmacy Drug Laws, Rules and Regulations shall be an amount which covers the cost of publication and shipping, as determined by the Board of Pharmacy. The Board may also to publish Pharmacy Drug Laws, Rules and Regulations electronically, and may make an electronic publication freely available on the Board's website.

(10) The fee for any duplicate or revised license, registration, modifier or license wall certificate shall be twenty five dollars ($25.00).

Authority: T.C.A. §§ 63-10-301, 63-10-304, 63-10-306 and 63-10-308.

Rule 1140-01-.14 Standards for Manufacturers and Wholesalers is amended by deleting the rule and rule title in their entirety and substituting instead the following language, so that as amended, the new rule title and new rule shall read.

1140-01-.14 Standards for Manufacturers, Outsourcing Facilities, Oxygen Suppliers and Wholesaler/Distributors.

No license to operate a new or remodeled manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor location within the state of Tennessee, or an existing manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor location which changes location or ownership, will be issued unless the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor meets the standards set forth in Chapter 1140-09 of the rules of the Board of Pharmacy.

Authority: T.C.A. §§ 63-10-301, 63-10-304 and 63-10-306.

New Rule

Chapter 1140-01
Introductory Rules

Rule 1140-01-.12
Sterile Compounding Registration

New Rule: 1140-01-.12 New Table of Contents.

(1) No licensee may compound, manufacture, prepare, propagate, or process any sterile product to be dispensed, sold, traded, or otherwise distributed in or from this state without first obtaining a sterile compounding modifier registration from the Board of Pharmacy.

(2) A registration modifier to compound and dispense sterile products into or from this state may be suspended by the Board of Pharmacy, upon information that the registrant has:

(a) Knowingly furnished false or fraudulent material information in any application filed before the Board of Pharmacy; or

(b) Been convicted of a felony under any state or federal law relating to drugs or to the practice of pharmacy; or

(c) Had any of its licenses, permits, or registrations granted by the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), the Department of Health and Human Services (DHHS), or any other federal agency or subdivision thereof, suspended, revoked, or voluntarily surrendered; or

(d) Been enjoined from operation by the court of any state or a federal court; or

(e) Been identified by the Commissioner of Health or the Commissioner's designee, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), or an investigator of the Board of Pharmacy as a source of adulterated, misbranded, or otherwise unsafe sterile products which have been, or pose an imminent risk of being dispensed, sold, traded, or otherwise distributed.

(3) An order of suspension issued by the Board of Pharmacy may contain additional directives or requirements necessary to protect public health, safety and welfare, including but not limited to:

(a) The quarantine or disposal of any sterile product compounded, manufactured, prepared, propagated or processed at the facility.

(b) The initiation of a recall of any sterile product compounded, manufactured, prepared, propagated or processed at the facility where such products or any label, container, packaging, or dosage form associated with such products may be adulterated, misbranded, contaminated, or otherwise unsafe.

(c) An order of suspension issued by the Board of Pharmacy may contain exceptions or allowances necessary to protect individual patients or the public health.

(4) Any order of suspension issued by the Board of Pharmacy pursuant to this chapter shall follow the procedures required by the Uniform Administrative Procedures Act, including those procedures required by T.C.A. § 4-5-320(d) where appropriate.

Authority: T.C.A. §§ 63-10-301, 63-10-304, 63-10-305 and 63-10-306.

Chapter
1140-09
Manufacturers and Wholesaler/Distributors

Amendments

Chapter 1140-09 Manufacturers and Wholesaler/Distributors is amended by deleting the chapter title in its entirety and substituting the following language, so that as amended, the new chapter title shall read:

Manufacturers, Outsourcing Facilities, Oxygen Suppliers and Wholesaler/Distributors

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.01 Manufacturer and Wholesaler/Distributor Licensing is amended by deleting the rule title and paragraph (1) in their entirety, and substituting instead the following language, so that as amended the new rule title and paragraph (1) shall read:

Rule 1140-09-.01 Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/Distributor

(1) Every manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor, before engaging in the manufacture, sale or distribution of prescription drugs and prescription devices in this state, must be licensed by the Board in accordance with this chapter.

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.02 Minimum Information Required is amended by deleting the rule in its entirety and substituting instead the following language, so that as amended, the new rule shall read:

(1) The board shall require the following minimum information from each manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor applying for a license or any renewal of such license:

(a) The name, full business address, and telephone number of the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor;

(b) All trade or business names used by the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor;

(c) Addresses, telephone numbers, and the names of contact persons for all facilities used by the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor for storage, handling, and distribution;

(d) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(e) The name(s) of the owner and/or operator of the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor, including:

1. If a person, the name of the person;

2. If a partnership, the name of each partner, and the name of the partnership;

3. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;

4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

5. DEA registration number if applicable; and

6. The results of a criminal background check for the owner or manager of the facility seeking licensure, submitted directly to the Board of Pharmacy by the vendor identified in the Board of Pharmacy's licensure application materials.

(2) Applicants seeking to register as manufacturers or outsourcing facilities shall provide the following materials to the Board of Pharmacy:

(a) Proof of registration with the Food and Drug Administration as a manufacturer or outsourcing facility and the most current inspection by that agency, or correspondence or other written proof from the Food and Drug Administration which states that registration with that agency is unnecessary;

(b) The name and contact information of the owner, the owner's agent, or another such individual employed at or contracted by the applicant that can be reached at any time by the Board of Pharmacy, the Department of Health or any agents thereof in the event of a potential or actual public health threat related to the sterility or potency of any drug or biologic product manufactured, wholesaled or distributed by the applicant.

(3) Applicants seeking to purchase a sterile compounding modifier shall provide the following materials to the Board of Pharmacy:

(a) Upon request by the Board of Pharmacy or the executive director, a list of sterile products currently being manufactured, wholesaled and distributed;

(b) The name and contact information for any laboratory, corporation, or other organization that may perform sterility and potency testing, or similar procedures for the purposes of quality assurance on any drug or biologic product produced by the applicant;

(4) Changes in any information in paragraphs (1), (2), or (3) of this rule shall be submitted in writing to the Board of Pharmacy immediately.

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.03 Minimum Qualifications is amended by deleting paragraph (1) in its entirety and substituting instead the following language, so that as amended, the new paragraph (1) shall read:

(1) The board shall consider, at a minimum, the following factors in reviewing an application for a license as a manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor:

Authority: T.C.A. §§ 63-10-404 and 63-10-504.

Rule 1140-09-.04 Personnel is amended by deleting the rule in its entirety and substituting instead the following language, so that as amended, the new rule shall read:

The board shall require that personnel employed by a manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor have appropriate education and/or experience to assume positions of responsibility for compliance with board requirements.

Authority: T.C.A. §§ 63-10-404 and 63-10-504.

Rule 1140-09-.05 Minimum Requirements for General Operation is amended by deleting the title paragraph, subparagraphs (5)(c) and (6)(a) but not its parts, paragraph (7) and part (7)(b)2 as well as subparagraphs (7)(c) and (7)(d) in their entirety and substituting instead the following language, and is further amended by deleting paragraphs (8) and (9), subparagraphs (9)(a) and (9)(b), and paragraph (10) in their entirety and substituting instead the following language, so that as amended, the new title paragraph, paragraphs, subparagraphs and part shall read:

The following shall be the minimum requirements for the storage and handling of prescription drugs and prescription devices and for the establishment and maintenance of prescription drug and prescription device distribution records by manufacturers, outsourcing facilities, oxygen suppliers and wholesalers/distributors:

(5) (c) If the conditions under which a prescription drug or prescription device has been returned cast doubt on safety, identity, strength, quality, or purity, then the prescription drug or prescription device shall be destroyed, or returned, unless examination, testing, or other investigation proves that the prescription drug or prescription device meets appropriate standards of safety, identity, strength, quality and purity. In determining whether the conditions under which a prescription drug or prescription device has been returned cast doubt on safety, identity, strength, quality, or purity, the manufacturer, outsourcing facility , oxygen supplier or wholesaler/distributor shall consider, among other things, the conditions under which the prescription drug or prescription device has been held, stored or shipped before or during return and the condition of the prescription drug or device or related material and its container, carton, or labeling, as a result of storage or shipping.

(6) (a) Manufacturers, outsourcing facilities, oxygen suppliers and wholesalers/distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription devices. These records shall include the following information:

(7) Written policies and procedures. Manufacturers, outsourcing facilities, oxygen suppliers and wholesalers/distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs and prescription devices; including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Manufacturers, outsourcing facilities, oxygen suppliers and wholesalers/distributors shall include in written policies and procedures the following:

(b) 2. Any voluntary action by the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor to remove defective or potentially defective prescription drugs and prescription devices from the market; or

(c) A procedure to ensure that manufacturers, outsourcing facilities, oxygen suppliers and wholesalers/distributors prepare for, protect against, and respond to any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(d) A procedure to ensure that any outdated prescription drugs and prescription devices shall be segregated from other prescription drugs and prescription devices and either returned to the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs and prescription devices. This documentation shall be maintained for two (2) years after disposition of the outdated prescription drugs and prescription devices.

(8) Responsible persons. Manufacturers, outsourcing facilities, oxygen suppliers and wholesalers/distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of distribution, storage, and handling, including a description of such persons' duties and a summary of such persons' qualifications.

(9) Compliance with federal, state, and local law. Manufacturers, outsourcing facilities, oxygen suppliers and wholesalers/distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(a) Manufacturers, outsourcing facilities, oxygen suppliers and wholesalers/distributors shall permit the board and authorized federal, state, and local law enforcement officials to enter and inspect premises and delivery vehicles, and to audit records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b) Manufacturers, outsourcing facilities, oxygen suppliers and wholesalers/distributors that handle controlled substances shall register with the board and with the United States Drug Enforcement Administration (DEA) and shall comply with applicable state, local and DEA regulations.

(10) Salvaging and reprocessing. Manufacturers, outsourcing facilities, oxygen suppliers and wholesalers/distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to salvaging or reprocessing of prescription drugs and prescription devices.

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

New Rule
Manufacturers, Outsourcing Facilities, Oxygen Suppliers and Wholesaler/Distributors
Chapter 1140-09

1140-09-.06
Minimum Requirements for Sterile Product Operation.

New Rule: 1140-09-.06 New Table of Contents.

(1) Any manufacturer, outsourcing facility or wholesaler/distributor licensed pursuant to this chapter that also holds an active sterile compounding registration from the Board of Pharmacy and that holds a license or registration from the Federal Food and Drug Administration, shall comply with all applicable federal laws, regulations, and guidelines including, but not limited to:

(a) FDA Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs 21 CFR 210;

(b) FDA Current Good Manufacturing Practice for Finished Pharmaceuticals 21 CFR 211;

(c) DEA regulations relating to controlled substances 21 CFR 1300-99.

(2) Any manufacturer, outsourcing facility or wholesaler/distributor licensed pursuant to this chapter who also holds an active sterile compounding registration from the Board of Pharmacy and who does not hold a license or registration from the federal Food and Drug Administration shall comply with all applicable USP standards.

(3) Any manufacturer, outsourcing facility or wholesaler/distributor licensed pursuant to this chapter who also holds an active sterile compounding registration from the Board of Pharmacy shall comply with all other applicable Board of Pharmacy rules and all other applicable laws of this State.

(4) The Board of Pharmacy may waive any applicable USP standards upon a showing by the applicant that good cause exists and that a waiver would better promote public health, safety, and welfare.

Authority: T.C.A. §§ 63-10-404 and 63-10-504.

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: 6/11/14

Signature:

Name of Officer: Stefan Cange

Title of Officer: Assistant General Counsel
Department of Health

Subscribed and sworn to before me on: 6-11-14

Notary Public Signature: Lynne Mcclanahan

My commission expires on:

Department of State Use Only

...MISSION EXPIRES
...RIL 19, 2017

Filed with the Department of State on: 6/11/14

Tre Hargett
Secretary of State

2014 JUN 11 PM 3:46

Minutes

Dr. Eidson made the motion to approve the minutes from the July 7, 2014 board meeting as amended. Dr. Bunch seconded the motion. The motion carried. Dr. Dickenson made the motion to approve the minutes from the July 29, 2014 board meeting as amended. Dr. Bunch seconded the motion. The motion carried. Dr. Smothers made the motion to approve the minutes from the July 30-31, 2014 board meeting as amended. Dr. Bunch seconded the motion. The motion carried.

Director's Report

Dr. Dilliard informed the board that Andy Holt, director of the controlled substance monitoring database, resigned effective September 29, 2014.

Dr. Dilliard informed the board that we have 104 open complaints, 77 complaints in office of general counsel and 69 are assigned to staff for investigations.

Dr. Dilliard asked the board for approval to attend Maltagon scheduled for October 26-29, 2104 in St. Petersburg, FL. After discussion, Dr. Bunch made the motion to approve travel for the executive director and two board members to attend. Dr. Smothers seconded the motion. The motion carried.

Dr. Dilliard asked the board for approval to attend the National Association of State Board of Pharmacy executive officer forum scheduled for October 15, 2014 in Chicago, IL. After discussion, Dr. Eidson made the motion to approve travel for Dr. Dilliard to attend the NABP executive officer forum. Dr. Bunch seconded the motion. The motion carried.

Dr. Dilliard informed the board that the Department of Health will be streaming live the board meetings. Dr. Dilliard stating that it may happen at the November meeting.

Dr. Dilliard reminded the board that hydrocodone will be listed as a scheduled II controlled substance effective October 6, 2014.

Dr. Dilliard informed the board that the fall updates are scheduled for September 18-19, 2014 in Murfreesboro, TN and October 2-3, 2014 in Chattanooga, TN.

Dr. Dilliard informed the board of the Tennessee Pharmacist Association retreat scheduled for September 22-23, 2014 in Maryville, TN. Dr. Dilliard stated that he will not be able to attend but suggested that a board member attend if they are available.

Contested Cases
Medicap Pharmacy

Lawrence Montgomery, owner and pharmacist in charge, was present and represented by Frank Scanlon, Attorney. The Honorable Michael Begley, Administrative Law Judge, presided. Mr. Stefan Cange represented the State. Mr. Cange handed out the Notice of Charges. Medicap Pharmacy is charged with violating T. C.A. § 63-10-305 (8) and board rule 1140-03-.11. After discussion, Dr. Smothers made the motion to accept the proposed findings of fact. Dr. Bunch seconded the motion. The motion carried. Dr. Eidson made the motion to accept the conclusion of law. Dr. Dickenson seconded the motion. The motion carried. Dr. Smothers made the motion to assess Medicap Pharmacy $10.00 per item for a total of $3260.00 and case costs. Dr. Eidson seconded the motion. The motion carried. Dr. Smothers made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Bunch seconded the motion. The motion carried.

Anna Ellis, RT

Ms. Ellis was not present nor represented by an attorney. The Honorable Michael Begley, Administrative Law Judge, presided. Mr. Cange represented the Stated. Mr. Cange asked for a motion to proceed in default. After discussion, Dr. Eidson made the motion to proceed in default. Dr. Smothers seconded the motion. The motion carried. Mr. Cange handed out the Notice of Charges. Ms. Ellis is charged with violating T.C.A §63-10-104(a), (b) and 63-10-305(4). Mr. Steve Burd, Regional Loss Prevention Manager with CVS, was a witness for the State. After discussion, Dr. Bunch made the motion to accept the findings of facts as presented. Dr. Smothers seconded the motion. The motion carried. Dr. Smothers made the motion to accept the conclusion of law. Dr. Bunch seconded the motion. The motion carried. Dr. Eidson made the motion to revoke Ms. Ellis' registration as a pharmacy technician. Dr. Dickenson seconded the motion. The motion carried. Dr. Eidson made the motion to assess case costs to Ms. Ellis. Dr. Dickenson seconded the motion. The motion carried. Dr. Dickenson made the motion to assess Ms. Ellis a $3000.00 civil penalty. The motion died for lack of second. Dr. Eidson made the motion to conclude the disciplinary phase of the hearing. Dr. Smothers seconded the motion. The motion carried. Dr. Eidson made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Bunch seconded the motion. The motion carried.

Summary Suspension
Wellness Store Compounding Pharmacy
Robin Terrero, D.Ph.

Robin Terrero, owner and pharmacist in charge of Wellness Store Compounding Pharmacy, was not present but was represented by Frank Scanlon, Attorney. Mr. Guilford informed the board summary suspension of Wellness Store Compounding Pharmacy and Robin Terrero is pursuant to T.C.A. 4-5-320(c) and can take place when an agency finds that the public health, safety, or welfare imperatively requires emergency action. Mr. Guilford explained to the board that this is a temporary measure and that Wellness Store Compounding Pharmacy and Ms. Terrero can

request a hearing within seven (7) business days. Wellness Store Compounding Pharmacy is charged with violating T.C.A. §63-10-305(4), (6), (8), T.C.A. §63-10-305(b) and T.C.A. §53-11-306. After discussion, Dr. Eidson made the motion to adopt the draft order of suspension for Wellness Store Compounding Pharmacy. Dr. Smothers seconded the motion. The motion carried. Ms. Terrero is charged with violating T.C.A. §63-10-305(4), (6) & (8). After discussion, Dr. Eidson made the motion to adopt the draft order of suspension for Robin Terrero. Dr. Smothers seconded the motion. The motion carried.

Mr. Guilford asked the board to consider meeting on September 18, 2014 for a full hearing concerning the summary suspension of Wellness Store Compounding Pharmacy and Robin Terrero. After discussion, the board decided to meet on September 18, 2014 at 11:00 a.m for a full hearing concerning the summary suspension of Wellness Store Compounding Pharmacy and Robin Terrero.

Appearance
Fresenius

Fresenius appeared before the board to ask permission to deliver the patient's medication to the dialysis clinic instead of the patient's home. After discussion, Dr. Eidson made the motion to accept this business model as presented and if there is any changes to the business model then they would need to come back before the board. Dr. Bunch seconded the motion. The motion carried. Dr. Dickenson recused himself.

Waivers
Board rule 1140-1-.04

Dr. Eidson made the motion to approve the request for **Erin Todd** and accept the 400 non-traditional internship hours accrued under the direct supervision of Dr. Elisa Greene at Siloam Family Health Center. Dr. Smothers seconded the motion. The motion carried.

USP 797 Compliance

Dr. Smothers made the motion to approve the request from **United Regional Medical Center** to extend the waiver that will expire on September 15, 2014 to December 13, 2014. Dr. Eidson seconded the motion. The motion carried.

Dr. Smothers made the motion to approve the request from **Maury Regional** to grant a 180 day waiver beginning on October 9, 2014 to become compliant with UPS 797. Dr. Dickenson seconded the motion. The motion carried.

Board rule 1140-03-.14(12)

Dr. Eidson made the motion to authorize **Stephen Turski, D.Ph**. to be pharmacist in charge at Physician Regional Medical Center and St. Mary's Ambulatory Surgery Center. Dr. Bunch seconded the motion. The motion carried.

Dr. Eidson made the motion to authorize **Diane Drake, D.Ph**. to be pharmacist in charge at The Place, Red Boiling Springs, TN, and Church Hill Health Care and Rehab, Church Hill, TN automated dispensing machines. Dr. Bunch seconded the motion. The motion carried.

Dr. Eidson made the motion to authorize **Stephen Turski, D.Ph**. to be pharmacist in charge at Physician Regional Medical Center and St. Mary's Ambulatory Surgery Center. Dr. Bunch seconded the motion. The motion carried.

Dr. Smothers made the motion to authorize **Marci Wayman, D.Ph**. to be pharmacist in charge at Boulevard Terrace, Murfreesboro, TN, Crestview #1 and #2, Nashville, TN, Glen Oaks, Shelbyville, TN and Manchester health Care Center, Manchester, TN automated dispensing machines. Dr. Dickenson seconded the motion. The motion carried.

Dr. Smothers made the motion to authorize **Michael Gronas, D.Ph**. to be pharmacist in charge at Baxter Healthcare, LaVergne, TN and Spring Pharmacy, Smyrna, TN. Dr. Bunch seconded the motion. The motion carried.

Board rule 1140-01-.12(3)(d) & (e)

Dr. Dickenson made the motion to approve the request from **CareMax Extended Care Pharmacy** to waive the requirement for the pharmacy to have hot and cold running water and refrigerations. Dr. Bunch seconded the motion. The motion carried

Board rule 1140-01-.12(3) (c) (d) & (e)

Dr. Smothers made the motion to approve the request from **St. Mary's Ambulatory Surgery Center** to waive the requirement for the pharmacy to have hot and cold running water, space less than 180 square feet and apparatus and equipment need to compound and dispense medical and prescription order. Dr. Dickenson seconded the motion. The motion carried

Board rule 1140-01-.14(13)

Dr. Eidson made the motion to approve the request from **St. Mary's Ambulatory Surgery Center** to allow the pharmacist in charge to be on site less than 50% of the hours of operation. The pharmacy will only be opened approximately 4 hours per day. Dr. Bunch seconded the motion. The motion carried.

Consent Orders

Mr. Cange presented to the board for approval a consent order for East TN Discount Drugs. East TN Discount Drugs violated T.C.A. 63-10-305 (8) and has agreed to the following: a $5000.00 civil penalty, the pharmacist in charge must submit proof that all dispensing pharmacist employed by East TN Discount Drugs complete 15 hours of continuing education regarding pharmacy practice relating to the dispensing of controlled substances and ethics within 180 days

of the approval of this order and within 90 days of the approval of this order East TN Discount Drugs must obtain practice monitoring provided by an organization approved in advance by the board. After discussion, Dr. Eidson made the motion to accept the consent order as presented. Dr. Smothers seconded the motion. The motion carried.

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

VIOLATED BOARD RULE 1140-3-.01(1)(a) & (f)
Gary Worley, D.Ph.-$1000.00 civil penalty

REVOCATION
Jennifer Lee White, RT
David Lenard, D.Ph.

VIOLATED BOARD RULE 1140-03-.11
Village Pharmacy-$190.00 civil penalty

Agreed Orders

Dr. Smothers made the motion to accept the agreed orders as presented. Dr. Eidson seconded the motion. The motion carried.

REVOCATION
Mitzi Pratt, RT
Michael Randolph. D.Ph.

Complaint Summary

1.

Complainant alleged unprofessional conduct on four separate dates by the pharmacist that questioned her about a high dose of medication for an at-risk pregnancy, again when questioned about being prescribed hydrocodone on 2 separate occasions, and lastly when the pharmacist refused to give a price quote for a medication that might be prescribed later. Board investigators determined that the alleged incidents had occurred, but that there was no violation of law or rules.

Prior discipline: None.

Recommendation: **Dismiss.**

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

2.

Complaint alleges medication shipment of Sabril (vigabatrin) was not received in a timely manner resulting in the patient missing doses of medication from 12/15/13 until 12/19/13.

Investigation revealed that the pharmacy does not ship medication until contact with the patient is made. Contact with the patient's mother occurred on 12/10/13 with plans to ship medication on 12/12/13 for delivery on 12/13/13.

Respondent admits the individual responsible for submitting the adjudication of the claim did not complete the task until 7:29pm on 12/12/13, too late for shipment as promised. Respondent contacted patient's mother to set up shipment on 12/13/13 for delivery on 12/16/13. Respondent admits that again on 12/13/13, the adjudication of the claim was not completed in enough time to make delivery deadlines.

On 12/14/13, patient's mother made contact with an unlicensed PBM employee that informed her that the medication did not ship on 12/13/13 but would ship on 12/14/13. Respondent admits that this information was incorrect and stated the miscommunication occurred because the mother was speaking to a customer service representative at another call center that was responsible for managing the patient's benefits but not their prescription. Respondent contacted the mother on 12/17/13 to reschedule the shipment date on 12/18/13 and the medication was delivered on 12/19/13. Respondent admits and estimates that the patient was without medication for 3 days.

Prior discipline: 2006 complaint for out of date drugs, civil penalty $250.00.

Recommendation: Letter of Warning. The board staff have received multiple complaints about this Respondent that allege similar issues.

Dr. Smothers made the motion to issue a **Letter of Warning** to the pharmacy. Dr. Dickenson seconded the motion. The motion carried. Dr. Eidson voted no.

3.

Complaint alleges pharmacist refilled a 30 day supply of Lithium for a bipolar patient with schizophrenia, depression, PTSD, personality disorder and mild MR without authorization. Patient lives in a group home where medications supplied by a pharmacy are administered by staff of the home. Pharmacist employed by Respondent pharmacy was caring for a patient that was being seen by a physician not employed by the home. Prescription refills ran out and pharmacist and technician were unable to contact physician. Nurse practitioner employed by home instructed pharmacist to continue patient's therapy. Instead of creating a new prescription order under the nurse practitioner's name, pharmacist refilled the old order under outside prescriber's name.

Prior discipline: None.

Recommendation: Dismiss.

Dr. Dickenson made the motion to issue a **Letter of Instruction** to the pharmacist. Dr. Smothers seconded the motion. The motion carried.

4.

After being confronted about suspicious behavior observed on CCTV and performing numerous on-hand changes, pharmacy technician admitted by written statement to stealing "about 1,200 tablets of Hydrocodone 10mg" for her own personal use. DEA 106 Form alleges losses of several other drugs including:

2,511 carisoprodol 350mg

608 hydrocodone 7.5/325mg,

387 hydrocodone 7.5/500mg,

and smaller amounts of other products (<100 tablets missing of hydrocodone 5/325, hydrocodone 5/500; tramadol 50mg; alprazolam 1mg).

A criminal investigation in this case is ongoing and board investigators are working with law enforcement. Board investigators also discussed inventory control with management at the pharmacy.

Prior discipline: None.

Recommendation: Revoke.

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

5.

Anonymous complainant alleged respondent pharmacy is delivering patient specific pain medications to the prescriber's office for administration contrary to federal law.

Respondent pharmacist admitted to this action and stated he was not aware this is not allowed.

Prior discipline: 2008 Complaint regarding patient counseling. June 6/2009 BM, Consent Order/ Civil Penalty $1,000. Respondent has received several letters of warning over the past few years.

Recommendation: Letter of Warning, refer to DEA.

Dr. Eidson made the motion to issue a **Letter of Warning** and 10 hours of continuing education in pharmacy law to the responding pharmacist and to refer this complaint to the DEA. Dr. Bunch seconded the motion. The motion carried.

6.

Complainant prescriber alleges that 2 prescriptions for short acting pain medications were filled on the same day even though 1 prescription was clearly labeled "Do not fill for 30 days."

Respondent pharmacist admitted to the error but claimed to have been confused by the intent of the note since the prescriber usually puts an exact date of when to fill. Based upon the patient's refill history the pharmacist interpreted the note to mean 30 days from the last fill date.

BOP investigators obtained printouts, prescriptions and records and also interviewed the patient who has COPD and is on oxygen 24 hours per day. Patient stated she had taken all medications together and that it had affected her breathing so she had cut back on dosages herself.

Prior discipline: 2012 Complaint regarding unprofessional conduct, paid a $1000 civil penalty.

Recommendation: Letter of Warning for failure to perform adequate DUR.

Dr. Dickenson made the motion to issue a **Letter of Instruction** for failure to perform adequate DUR. Dr. Smothers seconded the motion. The motion carried.

7.

Complainant informed BOP investigator about a pharmacy shipping large quantities of non-patient-specific compounded products into Tennessee for use in prescribers' offices.

Investigation did not indicate that amounts shipped into Tennessee violated current state law. Respondent pharmacy is in the process of registering with FDA as an outsourcing facility.

Prior discipline: None.

Recommendation: Dismiss.

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

8.

Employer notified Board investigators of a technician termination due to theft of general merchandise and diversion of legend drugs without prescriber authorization.

Respondent technician replied via e-mail message claiming remorse for bad decisions made during financial demise, but admitting theft of food from the deli, taking ibuprofen frequently and most recently for taking "a couple of pseudoephedrine and a promethazine for a headache."

Prior discipline: None.

Recommendation: **Letter of Warning.**

Dr. Smothers made the motion to issue a **Letter of Warning** to the pharmacy technician. Dr. Bunch seconded the motion. The motion carried.

9.

Information was given to Board investigator that a Canadian pharmacy had contacted a Tennessee pharmacy requesting copies of prescriptions.

Respondent Canadian pharmacy replied by fax, denying that they conducted business in Tennessee but did not specifically address the complaint. A search of their website did reveal a statement that "Manitoba pharmacists are not permitted to fill US physicians' prescriptions. They can only fill prescriptions issued by a physician licensed in a province or territory of Canada."

Prior discipline: None.

Recommendation: Dismiss.

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

10.

Complainant (mother of patient) alleged the pharmacy misfilled a prescription because it dispensed ophthalmic drops instead of optic drops to be placed in the patient's ear.

Respondent provided sworn statement that the change was authorized verbally and that using ophthalmic drops in the ear is acceptable. It is unknown if the pharmacist informed the complainant of the change, however policy dictates counseling on all new prescriptions and BOP investigator observed 100% counseling compliance just before and during the visit.

Prior discipline: None.

Recommendation: Dismiss.

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

Dr. Eidson left the meeting at 4:30 p.m.

11.

Complainant filed complaint with the Board and other organizations and also supplied copies of letters from her attorney alleging respondent pharmacist shouted and disclosed personal information about the patient; refused to fill a prescription and marked through the patient's prescription making it void.

Respondent pharmacist provided sworn statements and other documentation to Board investigator stating the prescription in question was too early to fill but that the pharmacist quietly discussed it with the patient. Patient demanded the return of the prescription which already had a filling sticker attached. Pharmacist wrote on the sticker on the back of the RX "do not fill until" and put the date it was due. Other documentation provided showed that the lawsuit filed against the pharmacist was voluntarily dismissed by the plaintiff. Board investigator does not see any violations of laws or rules.

Recommendation: Dismiss.

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

12.

Complainant alleged he received medication (Epogen), he had not been prescribed and that it was left by his garage door in extreme heat for an unknown period of time without notification or a signature. Complainant also alleged he received very poor customer service when he tried to report to the pharmacy that the medication was not his.

Respondent pharmacists provided sworn statements to Board investigator stating that an oversight allowed a 4 line address label to be shipped with only 3 lines readable and those 3 lines did not include a street name or number. The shipping company delivered the package to a person with the same name in the same city, however, since the street address did not show on the shipping label, the shipping company dropped off the package at the incorrect person's home.

Respondents hold a license as a pharmacy and also as an MWD. Invoices contain the names and addresses of both businesses. Respondents stated they believe the complainant called the MWD at night on a weekend when very limited staff is present. Respondents maintain that if complainant had called the pharmacy number they would have been connected to an on-call pharmacist. Respondent also states that they have put processes in place to prevent another occurrence of this nature.

Prior discipline: None.

Recommendation: Letter of Warning.

Dr. Smothers made the motion to issue a **Letter of Warning** to the shipper and the pharmacy. Dr. Bunch seconded the motion. The motion carried.

13.

Allegation of technician diversion of controlled substances resulting in job termination.

Respondent did not reply to a BOP request for a response. BOP investigators obtained a copy of a signed and witnessed voluntary statement in which the respondent admitted to taking Hydrocodone APAP in the following quantities:
10/325…..500 tablets
5/325……213 tablets
7.5/325….588 tablets

Respondent noted in the statement that "I did not consume the pills."

A DEA 106 was filed indicating the same quantities missing except the 10/325 strength shows 1,686 tablets missing, which is over 3 times more than the quantity admitted to. Investigation of other employees is ongoing.

Prior discipline: None.

Recommendation: Revoke.

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

14.

Complainant alleged out-of-state pharmacy is shipping into Tennessee without being properly licensed.

Respondent was contacted by telephone and stated verbally to Board investigator that no product had been sent to Tennessee prior to the facility becoming licensed in May 2014 and that prescriptions are compounded to be patient specific and are not being mass produced. Respondent followed-up with a written statement providing the pharmacy license number and attesting that they are in full compliance with Tennessee Pharmacy Rules.

Pharmacy is now properly licensed and allegations were not substantiated.

Prior discipline: None.

Recommendation: Dismiss.

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

15.

Complainant alleged 2 misfills on different dates at the same pharmacy. The first alleged misfill occurred because the pharmacist gave generic Concerta even though the presciber signed on the brand name line. Patient's mother alleges the child developed behavior problems as a result of not receiving the brand name. The second alleged misfill occurred when the pharmacist labeled the medicine for a child as "Take 2 tablets" instead of "Take ½ tablet."

Board investigator visited respondent pharmacy and interviewed staff. The Concerta prescription was signed by the prescriber underneath "DISPENSE AS WRITTEN" however, there was no handwritten notation or circling as required by law to clearly convey the intent that a brand name was necessary. Respondent pharmacist also stated that the same manufacturer makes the brand and generic and that they are identical.

The second misfill allegation was proven. The prescription was scanned into the computer system and filled from the scanned image. However, the scanner did not detect the "1/" above the "2" so the scanned image appeared to say "2." Respondents indicated that there were usually clues if the prescription does not scan correctly, but in this case, nobody noticed or questioned the high dosage.

Prior discipline: None.

Recommendation: **Letter of Warning for misfill. Counseling violation to dispensing D.Ph and pharmacy.**

Dr. Bunch made the motion to **authorize a formal hearing** with a $1000.00 civil penalty to the dispensing pharmacist and the pharmacy a Letter of Warning to the dispensing pharmacist for the misfill. Dr. Dickenson seconded the motion. The motion carried.

16.

Complaint was forwarded from Virginia Department of Health Professions. Complainant had provided a chronological list of events that resulted in patient being told several times that medication would be shipped but it was not. Respondent is a specialty pharmacy located in several states, however upon investigation, Board investigator determined that the issues with the pharmacy actually occurred at an Indiana location and the patient lives in Virginia.

Prior discipline: None.

Recommendation: Refer to Indiana Board of Pharmacy.

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

17.

Complainant made numerous allegations against pharmacist and pharmacy regarding improper billing, re-dispensing, accepting returned medication, selling samples, and improperly obtaining power of attorney over a patient.

Board investigator conducted interviews, reviewed records, conducted a search of the pharmacy and could not substantiate any of the allegations.

Prior discipline: None.

Recommendation: Dismiss.

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

18.

Complainant made numerous allegations against pharmacy regarding improper billing, re-dispensing, accepting returned medication, and selling samples.

BOP investigator conducted interviews, reviewed records, conducted a search of the pharmacy and could not substantiate any of the allegations.

Prior discipline: None.

Recommendation: Dismiss.

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

19.

Complainant sent letters to multiple states alleging the pharmacy was mass producing compounded product, providing "office use only" drugs, and providing "patient starter doses." Complainant alleges that these practices are not ethical or legal be the standards of most states.

Respondent claims the complaint was filed in all 50 states by a competitor using a fictitious name. Respondent admitted that for a short period in 2012, some creams were compounded for office administration in order to check for efficacy and allergic reactions. Respondent claims that once made aware that some prescribers were giving the products away as samples and patients were taking them home, the practice was discontinued.

Respondent claims that practice was stopped about 2 years ago and was only done for a short time. Respondent claims it currently on does "office use" compounding for its in-state prescribers (Arizona.) Pharmacy currently appears in good standing with all states where it is licensed and also provided a copy of a recent visit by two Arizona Board of Pharmacy compliance officers and no violations were noted.

Prior discipline: None.

Recommendation: Dismiss.

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

20.

Complainant reported compounding pharmacy was being investigated by the Colorado Board of Pharmacy due to a pharmacy representative advertising and soliciting business directly from prescribers. Respondent pharmacy/pharmacist denied any wrongdoing and denied ever having authorized or contracted with the person mentioned to act as a representative for the pharmacy. Respondent also stated the pharmacy does not participate in manufacturing, providing office use samples, or mass production.

Respondent claims complainant also notified Colorado and Wisconsin and provided letters from those boards dismissing those cases. Respondent also provided a copy of NABP VPP report in which the pharmacy was found to be substantially compliant. (Categories are "substantially compliant", "somewhat compliant" and "substantially non-compliant.")

Prior discipline: None.

Recommendation: Dismiss.

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

21.

Complainant reported compounding pharmacy is shipping product for office use, is mass producing, and is not licensed as an FDA outsourcer. Respondent pharmacy replied by quoting TCA 63-10-204 (4). Respondent did not address the new Federal legislation.

Prior discipline: Board voted to discipline Respondent at the last meeting. OGC is in negotiations with counsel for Respondent.

Recommendation: Refer to FDA.

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

22.

Complainant alleged the pharmacist was rude, confrontational, threatened to withhold medication, forced the complainant to receive counseling, and acted in a "bullying fashion." Respondent pharmacist replied that the patient had "huffy behavior" and treated staff with "complete and utter disrespect." Respondent stated the issue escalated far beyond reasonable bounds and he has learned a great deal from it. Respondent stated he makes no apologies for defending staff and other patients, but does apologize for not being as tactful as he could have been.

Prior discipline: None.

Recommendation: Dismiss.

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

23.

Respondent pharmacist was PIC of a pharmacy where a large volume of controlled substances went missing without explanation. Investigation revealed Respondent had allowed unlicensed personnel to have access to the pharmacy and had failed to keep required records regarding controlled substance inventory and prescriptions.

Prior discipline: None.

Recommendation: Revoke.

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

24.

Complainant alleged that an unauthorized person picked up a controlled substance prescription issued to them from Respondent pharmacy. Investigation revealed that 15 prescribers in the pharmacy database were assigned the pharmacy's DEA number, rather than the prescribers'. PIC of Respondent pharmacy acknowledged the error during visit by investigator, but stated they were unaware of it prior to then. PIC believed that a technician no longer employed by the pharmacy may have been responsible for this, but admitted they should have kept better track of what their employees were doing.

Prior discipline: None.

Recommendation: Letter of Warning.

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

25.

Complaint alleged that Respondent pharmacy dispensed prescriptions while pharmacist-employee was practicing on an expired license. Respondent was later able to provide information that indicated that pharmacist's license was not expired at the time complaint was made.

Prior discipline: None.

Recommendation: Dismiss.

Dr. Bunch made the motion to **accept counseling recommendation**. Dr. Smothers seconded the motion. The motion carried.

26.

Allegation of technician diversion of controlled substances resulting in job termination. Video surveillance provided by employer showed technician diverting controlled substances. DEA 106 indicates that 90 alprazolam ER 0.5mg, 268 hydrocodone 10/650mg, 496 hydrocodone 10/500mg, and 1,200 alprazolam 1mg tablets were missing from the pharmacy.

Prior discipline: None.

Recommendation: Revoke.

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

27.

Technician worked without registration from July 2013 until February 20, 2014 (date application was received by the Board—granted March 25, 2014). Interview of Respondent PIC indicates that PIC assisted technician with paperwork and believed that technician had obtained registration. At the time, technician did not have the money to pay for the background check. Respondent PIC offered to pay the fee for technician, but technician refused to accept.

Prior discipline: None.

Recommendation: $100 per month to PIC, less the 90 day grace period, for a

total civil penalty of $500.

Dr. Bunch made the motion to **authorize a formal hearing** with a $100.00 per month civil penalty to the PIC for allowing a technician to work unregistered. Dr. Dickenson seconded the motion. The motion carried**.**

28.

Complainant alleged that protected information was released by the pharmacy to someone outside the facility because the patient was getting harassing phone calls from a drug seeker trying to buy medication. Complainant is not the patient but complainant wants both the complainant and patient to remain anonymous.

BOP investigator visited pharmacy and spoke to PIC. However, without a specific patient name it was difficult to research what might have happened. PIC provided a sworn statement about HIPAA policy and training and was not aware of anyone alleging a breach up to that point. PIC stated that all staff will be reminded about compliance.

Prior discipline: None.

Recommendation: Dismiss.

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

29.

Complainant prescriber alleged that the CSMD showed a prescription for alprazolam filled which the prescriber did not authorize.

BOP investigator visited pharmacy and spoke to PIC. PIC explained and provided a sworn statement that a verbal order for a 20 day supply was obtained because a fax had not been sent from the prescriber. 17 days later, a fax was received and filled at the pharmacy, however the patient never picked it up. When the prescriber called the pharmacy to inquire, it was determined that the faxed prescription was to cover the initial prescription which had been verbally authorized. The second RX has been reversed and voided.

Prior discipline: None.

Recommendation: Dismiss.

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

30.

Complaint filed by BOP investigator based upon information received regarding technician theft of controlled substances from employer. DEA 106 indicated a loss of 1,200 Oxycodone 30 mg tablets. Court documents were obtained showing a guilty plea to Class C felony 39-17-417, Possession of a controlled substance (Oxycodone) with intent to sell.

Prior discipline: None.

Recommendation: Revoke.

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

31.

Complainant alleged that a batch of compounded medication ABHR gel was not effective and contained mostly air pockets. Caregiver returned the product to pharmacy.

BOP investigator visited pharmacy and spoke to the pharmacist. Pharmacist provided a sworn statement that the caregiver did return the product to the pharmacy and pharmacist noted the air pockets/bubbles. Pharmacist apologized for the air bubbles and prepared a new batch. Pharmacist followed up with patient 3 days later and stated the patient is doing well. Patient continues to have the medication compounded at this pharmacy.

Investigators followed up with the pharmacist since a misfill was neither admitted nor denied. Pharmacist stated via telephone that all the ingredients were correct in the original batch but that it did have air bubbles. Pharmacist stated the original batch was made and dispensed on a Friday afternoon and returned to the pharmacy on a Saturday morning.

Aside from the air bubbles, the medication appears to have been correct. Pharmacist stated that topical gels often have bubbles but they burst upon application so the correct amount of medication gets applied either way. Pharmacist made a new batch for customer satisfaction, not because she thought it was wrong.

Prior discipline: None.

Recommendation: Dismiss.

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

32.

Complainant alleged rude and unprofessional behavior occurred when respondent refused to sell complainant pseudoephedrine because complainant did not have a driver's license but did have a government issued photo I.D.

BOP investigator visited the pharmacy and obtained a sworn statement. Respondent contacted patient and apologized and reassured him that appropriate steps have been taken to prevent a reoccurrence. Respondent also provided a copy of a letter from the complainant stating he was satisfied with the outcome

Prior discipline: None.

Recommendation: Dismiss.

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

33.

Complainant alleged unprofessional conduct by charging for prescriptions that should have been free.

BOP investigator visited the pharmacy and obtained a sworn statement from the pharmacist. Once the pharmacist became aware that the patient had an additional benefit card, the claims were adjudicated and the patient was refunded.

Prior discipline: None.

Recommendation: Dismiss.

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

34.

Complaint alleges a misfill by dispensing Fentanyl 75mcg/hr instead of Fentanyl 25mcg/hr.

BOP investigator visited the pharmacy and obtained a sworn statement from PIC. PIC was not aware of misfill however when records were pulled, the misfill allegation was confirmed. PIC stated that the RX was written as Duragesic Patch 72 hours 25mcg/hr. PIC believes the input tech misread the strength and PIC (who is also the dispensing pharmacist) did not catch the error.

Prior discipline: 2010 complaint, professional conduct & responsibilities, paid a civil penalty of $1,500.

Recommendation: Letter of Warning.

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

35.

Complaint was opened based upon DEA concerns of respondent being a possible link in a case DEA was working.

BOP investigator and DEA agents visited the pharmacy, interviewed staff and performed an audit. Nothing suspicious was found.

Prior discipline: none

Recommendation: Dismiss.

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

36.

Complaint was opened based upon notification from employer that respondent pharmacy tech was terminated for theft of non-pharmacy merchandise.

Respondent provided a copy of restitution agreement for $30.62 along with proof of payment and a typed statement explaining that there was a glitch with a credit card machine and another employee handed him a receipt and stated the credit card had finally gone through. Respondent claims he glanced at the receipt but did not look at the bottom part which showed that the card did not go through. Respondent stated he left the store thinking that everything had been handled.

Prior discipline: none

Recommendation: Dismiss.

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

37.

Complainant informed BOP of pharmacist termination for theft of controlled substances. Pharmacist self-reported to BOP and stated he was voluntarily entering a treatment program for

addiction. Pharmacist wrote a letter offering to voluntarily surrender his pharmacist license.

Prior discipline: none

Recommendation: Accept voluntary surrender.

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

38.

Complaint alleges the pharmacist refused to fill patient's prescriptions. BOP investigator visited the pharmacy. Patient printouts and pharmacy documentation were reviewed showing that the prescriber was contacted and declined to authorize early refills. Patient was later discharged from the prescriber's care.

Prior discipline: none

Recommendation: Dismiss.

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

September 11, 2014

The Tennessee Board of Pharmacy reconvened on Thursday, September, 11, 2014 in the Poplar Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members were present, the meeting was called to order at 8:07 a.m., by Dr. Kizer, president.

Appearance
Medicine Shoppe

Terry Cole, pharmacist and owner of the Medicine Shoppe, appeared before the board to request an extension of his pharmacy being in USP 797 compliance. Dr. Cole stated that his business partner has passed away and he is in the process of trying to get acquire the necessary financing to complete the construction of the pharmacy and he is also in the process of trying to sell the business. Dr. Cole also stated that the pharmacy is no longer doing sterile compounding at this time. After discussion, Dr. Smothers made the motion grant the waiver of USP 797 extension for six months and the business practice to be sterile to sterile only until the pharmacy is in compliance with USP 797. Dr. Eidson seconded the motion. The motion carried.

Collaborative Practice Rules

Dr. Dilliard presented to the board a draft of the collaborative practice rules for review and explained the board that the rules have to be in collaboration with the board of medical

examiners and the board of osteopathic examiners. Dr. Baeteena Black, executive director of Tennessee Pharmacy Association, informed the board that this rule is modifying the board of pharmacy practice act and that the board develop the rules but collaborate with the board of medical examiners and board of osteopathic examiners. Dr. Black stated that she has met with the Tennessee Medical Association and they help draft the rules. After discussion, Dr. Eidson made the motion to authorize a rulemaking hearing to be held at the November 5-6, 2014 board meeting. Dr. Bunch seconded the motion. The motion carried.

Dr. Dilliard informed the board that he has received a letter from Jim Dunn, chairperson of the Tennessee Society of Long Term Care Pharmacist, requesting that the board look at the policy statement on E-Kits which allows up to 40 units of medication in scheduled II thru V and they are anticipation that more medication may be needed since hydrocodone is going to be classified as a scheduled II drug. After discussion, Dr. Eidson made the motion to amend the policy statement that relates to an the contents of an emergency kit be specifically limited to up 40 total units of medication in scheduled II thru V and each unit in oral liquid formulation shall not exceed 30 milliliters. Dr. Smothers seconded the motion. The motion carried.

Dr. Dilliard stated that on September 9, 2014 the federal register released the final rules for take back of controlled substances. Dr. Dilliard stated that the board may need to incorporate this rule into the board rules to authorize pharmacies to take back drugs since the board of pharmacy does not allow for take back drugs. Dr. Eidson stated that the take back rule already listed in the purposed long term care rules. Mr. Guilford stated that this is a federal rule it supersedes the pharmacy rules and therefore the board shouldn't take any disciplinary action against a pharmacy if they decide to have a receptacle. The board decided to table this discussion until the September 18, 2014 meeting.

Appearance
Virgina Hopkins, RT

Ms. Hopkins appeared before the board because she answered yes to the question that asked "Have your ever been charged or convicted (including a nolo contendere plea or guilty plea) of a felony or misdemeanor (other than a minor traffic offenses) whether or not sentence was imposed, suspended, expunged, or whether you were pardoned form any such offenses?" In the documentation submitted, Ms. Hopkins was found guilty of three counts of child abuse on 02/12/2004-sentence to 120 days and court cost; found guilty of theft of property-$500 or less on 07/20/1999; guilty of DUI 09/14/2006 served 7 days in jail; found guilty of driving on suspended license on 10/16/2006. After discussion, Dr. Dickenson made the motion to approve Ms. Hopkins' application for registration as a pharmacy technician. Dr. Bunch seconded the motion. The motion carried.

Zachary Storer, D.Ph.

Dr. Storer appeared before the board because he answered yes to the question that asked "Have you ever voluntarily surrendered your pharmacist license or any pharmacy registration issued by

a federal or state controlled substance authority? And "Are you presently or have you within the past five years ever participated in a chemical substance rehabilitation program:" In the documentation submitted, Dr. Storer pled guilty to DUI September 2005, May 2009 and August 2010. He stated that he voluntarily surrendered his KY pharmacist license and entered a 5 year contract with the Kentucky Professional Recovery Network. After discussion, Dr. Smother made the motion to approve Dr. Storer's application for license by reciprocity. Dr. Bunch seconded the motion. The motion carried.

Order Modification
Linda Cayce

Dr. Cayce appeared before the board to request that she be allowed to be PIC. Dr. Cayce signed a consent order on 4/03/2013 placing her pharmacist license on 5 year probation and she would not be allowed to be PIC for 3 years of probation. After discussion, Dr. Smothers made the motion to amend Dr. Cayce's consent order and allow her to be PIC at Town & Country, Clarksville, TN. Dr. Bunch seconded the motion. The motion carried.

General Discussion

Mr. Guilford informed the board that the Department of Health will be releasing a statement to the media concerning the summary suspension of Wellness Store Compounding Pharmacy and Robin Terrero licenses. Mr. Guilford ask the board that if they receive any request from the media about the case to refer them to the Office of Media Affairs for the department.

USP 797
Physicians Regional Medical Center

Allen Welch, director of pharmacy and Steve Turski, operation manager for Physician Regional Medical Center, appeared before the board to ask for an extension of the UPS 797 waiver. Physician Regional Medical Center is in the process of filing paperwork to build a new hospital with the completion date to be roughly 3 years from now. Dr. Welch stated that the problem that they are having in the present hospital is an air extension problem. After discussion, Dr. Eidson made the motion to grant the extension for 6 months and that the pharmacy not any high risk sterile compounding products. Dr. Smothers seconded the motion. The motion carried. The board also recommended that Physician Regional Medical Center seek other options.

Bedside Delivery
Mountain States Outpatient Pharmacy

Trish Tanner, appeared before the board to ask for clarification of the attestation for bedside delivery. The problem that they are having is that the attestation states that the chain of custody for the medication must be direct from the pharmacy to patient and some patients are discharged after the outpatient pharmacy is closed. The hospital policy states that patient specific medication is stored in the inpatient pharmacy and not with the patient at bedside. The other problem is that they offer concierge services where patient delivery is at the physic site and they have a clinical

physic pharmacist who does all discharge counseling. They would like to have an exception for this facility where they will deliver the patient specific medication. Dr. Moak spoke to the board concerning the changings in the bedside delivery at Johnson City Medical Center retail pharmacy. Dr. Moak stated that when she went to visit the pharmacy and asked about the bedside delivery she was told that the pharmacist was delivery the medication and doing face to face counseling because the hospital did not allow them to use the IPads but they have now changed their policies and only have one pharmacist on staff. That pharmacist cannot leave the pharmacy so they are now having telephoning the patient's room which does not meet the requirements for face to face counseling. Dr. Moak stated that she explained to the pharmacist that the use of the telephone for face to face counseling was not acceptable and that they would have to use the IPads. Dr. Moak asked Dr. Tanner if the hospital will now allow them to use the IPads. Dr. Tanner stated that must patient are just coming by the pharmacy to pick up their prescriptions. The board reiterated that counseling for bedside delivery must be done by using the IPads and the use of telephones is not allowed. Dr. Moak asked Dr. Tanner who takes delivery of the drugs once they're delivered to the Woodbridge Psychiatric Hospital. Dr. Tanner stated that the pharmacist at the clinic takes receipt of the medication and then counsel's the patients. After discussion, Dr. Smothers made the motion to allow the clinical pharmacist to do counsel patients at Woodbridge Psychiatric Hospital. Dr. Bunch seconded the motion. The motion carried.

Dr. Bunch made the motion to adjourned at 10:35 a.m. Dr. Eidson seconded the motion. The motion carried.

The minutes were approved and ratified at the November 5-6, 2014 board meeting.