

TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Poplar Room
Nashville, TN
May 28-29, 2014

BOARD MEMBERS PRESENT

Nina Smothers, D.Ph., Vice President
Will Bunch, D.Ph.
Kevin Eidson, D.Ph.
R. Michael Dickenson, D.Ph.
Charles Stephens, D.Ph.
Joyce McDaniel, Consumer Member

ABSENT BOARD MEMBER

Jason Kizer, D.Ph., President

STAFF PRESENT

Reginald Dilliard, Executive Director
Stefan Cange, Assistant General Counsel
Terry Grinder, Pharmacy Investigator
Tommy Chrisp, Pharmacy Investigator
Scott Denaburg, Pharmacy Investigator
Rebecca Moak, Pharmacy Investigator
Andrea Miller, Pharmacy Investigator
Robert Shutt, Pharmacy Investigator
Larry Hill, Pharmacy Investigator
Jane Young, Chief General Counsel
Sheila Bush, Administrative Manager

STAFF ABSENT

Richard Hadden, Pharmacy Investigator

The Tennessee Board of Pharmacy convened on Wednesday, May 28, 2014 in the Poplar Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 9:08 a.m.

Minutes

Dr. Eidson made the motion to approve the minutes from the May 12, 2014 board meeting as amended. Ms. McDaniel seconded the motion. The motion carried. Dr. Bunch made the motion to approve the minutes from the March 11-12, 2014 as amended. Ms. McDaniel seconded the motion. The motion carried.

Appearance

Asteres Prescription Pick-Up

Phillip Burgess, D.Ph. and Saura Lake, representatives from Asteres Prescription Pick-Up appeared before the board to request approval for an automated prescription dispenser machine to be placed outside the pharmacy at Memorial Health Care System, Hixson, TN. This automated dispensing machine will be for employees only. Sandra Vredevel, pharmacist in charge for Memorial Hospital, Chattanooga, stated that automated dispensing machine would provide better access to prescription for employees, the employees would have access to pharmacist counseling 24/7, enhance employee safety and care and the pharmacy would maintain one comprehensive record. Dr. Burgess referred the board rule to 1140-4-.15 which states "No prescription drug or

device or related material shall be distributed or issued by the use of any automated dispensing device unless the device and the method of operation have been found by the board to ensure the purity, potency, and integrity of the prescription drug or device or related material, and to protect the prescription drug or device or related material from diversion". Dr. Burgess stated that this rule is the reason why Asteres Prescription Pick-up is appearing before the board to ask for approval of the automated dispensing machine to be used as a prescription pick up for employees of Memorial Health Care System in Hixson, TN. The prescriptions are filled the same way that they are filled by a retail pharmacy and it is not considered to be a dispensing machine but an automated prescription pick up machine. Dr. Burgess also referenced board rule 1140-3-.01 which states "Upon the receipt of a medical or prescription order and following a review of the patient's record, a pharmacist shall personally counsel the patient or caregiver "face-to-face" if the patient or caregiver is present. If the patient or caregiver is not present, a pharmacist shall make a reasonable effort to counsel through alternative means." Dr. Burgess stated that there will be 24/7 telephone access to a pharmacist. During pharmacy hours the employee (patient) can go to the outpatient pharmacy and after hours the inpatient pharmacy will have full access to patient records and will be able to counsel the patients. Ms. Lake explained the process of the automated prescription pick-up and how it works. Dr. Bunch asked how does this process improve patient care other than convenience? Dr. Vredevelde stated that it is just the access and convenience of being able to pick up the prescription at work instead of going to a retail pharmacy. Dr. Bunch asked if the machine is able to interact with the patient. Dr. Burgess stated that it can be programmed to interact with the patient. Dr. Bunch asked if they are expecting the patient to seek counseling. Dr. Vredevelde stated that they are aggressively seeking the patient and counseling them about their medication. Dr. Burgess stated that the machine could be programmed that every new prescription be held until the patient has been counseled. Dr. Eidson stated each prescription would have to be held because counseling is required on refills as well. Ms. McDaniel asked if the counseling will be face to face. Ms. Lake stated that as of right now the counseling is done over the phone but they can add a Skype feature to the device to allow face to face counseling depending on the rules and regulation of the different boards. Dr. Eidson asked how they would implement a refrigerated medication into the machine. Ms. Lake stated that there is locker system that stands next to the kiosk that takes care of refrigerated items. Dr. Eidson asked if this machine is being used in any pharmacy in Tennessee. Ms. Lake stated that she believes that they were approved for a pilot program to put the machines in Walmart several years ago but don't believe that it was ever implemented. Dr. Dilliard stated that he doesn't remember the board approving a pilot program especially since the board does not approve pilot programs. Dr. Stephens stated that one of the issues is that they are dispensing medication outside of a pharmacy. Dr. Burgess stated that it is delivery not dispensing. Dr. Eidson stated that the rules stated that they can delivery medication to a patient's home or business. Dr. Burgess stated that this machine is at their work and deliverable to the employee. Dr. Stephens stated that the documentation submitted states this machine is not for use of hospital patients or outsiders. Ms. Lake stated that they are not asking for that feature today only for dispensing to employees of the hospital. Dr. Dilliard asked if they will be reporting to the controlled substance monitoring database. Dr. Vredevelde stated that the prescription will come from the retail pharmacy and the retail pharmacy reports to the database. Dr. Dilliard referred the board to board rule 1140-03-.01(1)(f) which states "Upon the receipt of a request for a refill of a medical or prescription

order, a pharmacist or a person designated by the pharmacist shall offer for the pharmacist to personally counsel the patient or caregiver. Counseling as described in (e) above is not required unless requested by the patient or deemed necessary in the professional judgment of the pharmacist. Dr. Dilliard stated that one of the things that the board would need to consider is if the person that shows on the screen can be the person to personally counsel the patient or caregiver on a refill. Ms. Lake stated that other states that use the machine and have the rule in place for counseling uses the screen. Dr. Smothers asked if they had a turn-around time study on the response rate of the pharmacist to answer the telephone for counseling. Ms. Lake stated that they did a study in California based on the people at the counter versus the people using the kiosk and did they get the same amount of counseling. Ms. Lake stated that there were no differences between people at the counter and people using the kiosk in terms of access to a pharmacist. Dr. Stephens stated that he has a problem with patient coming in to get their prescription without coming to the pharmacy and the access to drugs outside the pharmacy. Dr. Dilliard asked Dr. Burgess how does the DEA view the kiosk that stores controlled substances since the DEA requires that automated dispensing machines be licensed as a pharmacy because they house controlled substances. Dr. Burgess stated that since the machines are in hospitals they haven't had any issues with the DEA. Dr. Stephens asked if the filling of the machine is done by the hospital pharmacy or the outpatient pharmacy at the hospital. Ms. Lake stated that the kiosk are always filled by an outpatient pharmacy and not always filled in the same building as the kiosk. Dr. Stephens asked how the outpatient pharmacy was licensed. Is it licensed as an institutional or an retail pharmacy. Dr. Vredeveld stated that the outpatient pharmacy is a retail pharmacy located in the hospital. Mr. Cange stated that if it is in a different building it is required to have a different license. Dr. Bunch asked who is counseling the patient the inpatient pharmacy or the outpatient pharmacy. Dr. Vredeveld stated that it is the outpatient pharmacy. Ms. Lake stated the prescriptions are typically dropped off at the kiosk twice a day. Dr. Dilliard asked about the new law that requires that a valid identification be presented at the time of pickup of a controlled substances by the patient or caregiver. Dr. Bunch asked Mr. Cange if what Asteres Prescription Pick-up is proposing fits within the board's rules and regulations. Mr. Cange stated the board needs to think about the intent of the counseling requirement and the show of identification to pick up a controlled substance as it relates to the pharmacist patient relationship and exercising of professional judgment by the pharmacist. After further discussion, Dr. Eidson made the motion to deny the request by Asteres Prescription Pick-Up. Dr. Stephens seconded the motion. The motion carried. Ms. McDaniel voted no.

Complaint Summary

1.

This complaint was presented for discipline at a previous meeting. Respondent technician was alleged to have forged prescriptions for controlled substances. Respondent claimed that they were a victim of identity theft. Subsequent investigation cast doubt on the initial evidence, and investigators do not believe the case is worth pursuing further.

Prior discipline: None.

Recommendation: Dismiss.

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

2.

Complaint alleged misfill. Infant patient was prescribed Zantac syrup, but was dispensed Zyrtec syrup instead. Complainant believes that prescription was dispensed correctly the first time, and that error occurred during refill, but investigation could not verify this. Prescription was entered and dispensed as Zyrtec, bottle was labeled accordingly ("Ceterizine 1mg/ml, Give Patient .75ml BID before meals"). Complainant alleged that patient experienced gastric distress requiring an emergency room visit after the alleged misfill. Based on investigation, it does not appear that adequate counseling was performed during the initial fill, and no counseling was offered or performed during the refill. Complainant also returned to Respondent pharmacy to inform them of the problem, but Respondent PIC did not submit notification of the incident to the Board until a visit from Board investigators related to this complaint.

Prior discipline: No prior discipline.

Recommendation: Letter of Warning to dispensing pharmacist for misfill

\$1000 civil penalty to dispensing pharmacist for failure to counsel; \$1000 to respondent pharmacy; LOI to PIC on counseling

Letter of Warning to PIC on notification of the Board for misfills where patient harm occurs

Dr. Eidson made the motion to issue a **Letter of Warning** to the dispensing pharmacist and the pharmacist in charge for the misfill, a Letter of Warning to the pharmacist in charge for the misfill where patient harm occurs and patient counseling. Dr. Eidson would also like the pharmacy investigator to go back to the pharmacy to make sure that patient counseling is being performed. Dr. Bunch seconded the motion. The motion carried.

Mr. Cange presented complaint numbers 3, 4 and 5 to the board and suggested that the board take the complaints as one since they are similar. Dr. Dilliard suggested to the board that they hear from the Dr. Hill, Dr. Grinder and Dr. Moak. They were the investigators who conducted the investigation. Dr. Bunch asked that Dr. Mitchell Mutter, Director of Special Projects, be present during this type of complaints in order to answer questions concerning the morphine equivalents. Ms. McDaniel stated that she is on the committee for controlled substance monitoring database and she always asked about discipline the prescriber for over prescribing but the board is going to have to address the issue of the dispensing these large quantities of controlled substances. Dr. Dilliard stated that the pharmacist has a correspondence responsibility

with the prescriber to make sure that the patient is receiving adequate care and that the prescription is a valid prescription. Dr. Smothers asked if the prescription were being enter in the database on a regularly basis. Dr. Hill stated that they were looking at the database but not as often as they should. Dr. Eidson asked what the investigators recommend for disciplinary action. Dr. Hill stated that while he doesn't want to speak for the board he thinks some disciplinary action is needed. He also stated that the investigators will do a follow-up inspection with this pharmacy to make sure that they understand the seriousness of the situation. Dr. Bunch asked if a formal disciplinary against the pharmacy and the pharmacist would be enough. Dr. Smothers asked about a monitoring program for the pharmacy and the pharmacist to make sure that they are doing as the board asked. Dr. Dilliard stated that Affiliated Monitors have worked with other boards and are monitoring the individuals by the parameters that the board has placed on the licensee. The licensee will be responsible for payment to this monitoring group. Affiliated Monitors will also send in reports on their findings as often as the board recommends. Dr. Eidson asked if manufacturer/wholesale/distributors are reporting to the database concerning the drugs being sold to pharmacies. Dr. Dilliard stated that they are collecting the data but their system is still being updated. Ms. Andrea Huddleston, Deputy General Counsel, stated that Office of General Counsel has used Affiliate Monitoring Group for about six years to monitoring prescribers that have issues. Ms. Huddleston stated that Affiliate Monitoring Group will find a preceptor license professional to monitoring the licensee and they will make the report to the board based on the requirements put in place by the board's consent order. The reports will be sent to the executive director of the board. Dr. Eidson stated that he would like for Affiliated Monitoring Group to appear before board for discussion. The board decided to invite Affiliated Monitoring Group to appear at the next scheduled meeting. After discussion, Dr. Eidson made the motion to **authorize a formal hearing** for suspension of the pharmacy license with the suspension stayed and the license placed on probation for 2 years, all licensed pharmacists submit 15 live continuing pharmaceutical education hours based on pharmacy practice, ethics and controlled substances within 90 days after consent order has been ratified by the board, quarterly reports and monitoring by an outside agency at the expense of the pharmacy. The continued pharmaceutical education hours must be in person and the curriculum will be based on a course approved by Dr. Dilliard, Dr. Eidson, a pharmacy investigator and TPA. Dr. Dickenson seconded the motion. The motion carried.

3.

Complaint generated due to investigation of prescriber by other boards. Inspection conducted subsequent to receipt of complaint and review of reports from the Controlled Substance monitoring database. Records, both from the CSMD and as reviewed by investigators at the site, indicate that Respondent pharmacy has dispensed inordinate amounts of controlled substances.

Pharmacy also dispensed to patients receiving controlled substance prescriptions from multiple providers, and in at least one instance to a patient that was prescribed the equivalent of 4,000 milligrams of morphine per day. Respondent pharmacy has since decreased its volume of controlled substances dispensed, but investigators believe this is due to the imposition of inventory controls by Respondent's wholesaler.

Prior discipline: none

Recommendation: Discuss.

4.

Complaint generated due to investigation of prescriber by other boards. Inspection conducted subsequent to receipt of complaint and review of reports from the Controlled Substance monitoring database. Records, both from the CSMD and as reviewed by investigators at the site, indicate that Respondent pharmacy has dispensed inordinate amounts of controlled substances. Investigation revealed numerous irregularities in Respondent's CSMD records.

Prescriptions for high dosages of controlled substances were rounded down (e.g., a prescription for hydrocodone 5/500mg #16 that was calculated to last for 1.8 days was listed as a 1 day supply; a prescription for hydrocodone 7.5/325mg #40 was entered as a 3 day supply). There were multiple prescriptions in the database with no specific provider because the pharmacy did not put in the resident 4 digit ID number with the correct hospital DEA number from the local hospital. The pharmacy's own computer system had all the correct information in it, but this information was not being sent to the CSMD.

Numerous other prescriptions were dispensed by this pharmacy that, in the opinion of the investigators, were highly suspicious and/or lacked proper documentation (e.g., a prescription for methadone 10mg #300 that was filled only one time without documentation of the large dose, pharmacist on duty dispensed the prescription because the patient had been getting it regularly at another branch of Respondent pharmacy).

Prior discipline: none

Recommendation: Discuss.

5.

Complaint generated due to investigation of prescriber by other boards. Inspection conducted subsequent to receipt of complaint and review of reports from the Controlled Substance monitoring database. Records, both from the CSMD and as reviewed by investigators at the site, indicate that Respondent pharmacy has dispensed inordinate amounts of controlled substances.

For example, Respondent pharmacy dispensed multiple prescriptions to a Patient A for oxycodone 30mg #500 every 7 to 14 days. Patient A's daily morphine equivalency is calculated by the CSMD as being 4,714 milligrams. Patient A's wife, daughter, and son-in-law, all of whom reside at the same address as Patient A, also receive prescriptions for oxycodone 30mg, morphine, fentanyl, hydrocodone, and alprazolam from Respondent pharmacy.

Respondent PIC told Investigator that they check the CSMD for every patient, but when Investigator asked Respondent to log onto the database, Respondent PIC did not appear to know how to do so. Investigator indicates that technician at Respondent pharmacy used PIC's login information to access and utilize the database.

Prior discipline: none

Recommendation: Discuss.

6.

Complaint generated during opening inspection. Investigator discovered that Respondent M/W/D, a wholesaler of medical devices, had been in operation under current owner (and at that site) since 2003.

Prior discipline: none

Recommendation: \$100/month for each month of unlicensed activity. 137 months of unlicensed activity for a total penalty of \$13,700.

Dr. Dickenson made the motion to **authorize formal hearing** with a \$100.00 per month civil penalty for unlicensed activity for 137 months. Dr. Bunch seconded the motion. The motion carried.

7.

Complainant prescriber alleged that pharmacy refused to follow directions on prescriptions. Complainant prescriber submitted prescriptions to Respondent which called for both legend drugs and OTC items (nicotine patches and gum), accompanied by the instructions to "fill all or none." Respondent pharmacy filled and dispensed the prescriptions for legend drugs, but did not fill the prescriptions for the OTC items. Respondent pharmacy indicated to investigator that they do not fill or dispense prescriptions for OTC items.

Prior discipline: none

Recommendation: Dismiss.

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

8.

Complaint alleged unauthorized early refills of controlled substances at Respondent pharmacy (refilling every 28 days, instead of every 30 days). Investigation of the pharmacy did not

substantiate the complaint.

Prior discipline: none

Recommendation: Dismiss.

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

9.

Complaint alleged misfill. Patient was prescribed Restoril 45mg, but was dispensed mirtazapine. Prescription was dispensed by floating pharmacist, who told investigators that they did not recall counseling on this particular prescription, nor could they recall overriding DUR flags or reviewing the patient's records to see if they had been prescribed the drug before. Misfill was reported to pharmacy by patient, but neither dispensing pharmacist nor PIC was informed of the error (based on investigation, it appears that mistake was corrected and entered as a misfill by district pharmacy manager). Complainant alleges substantial weight gain, water retention, and loss of sleep resulted from misfill.

Prior discipline: none

Recommendation: Letter of Warning to dispensing pharmacist. Discuss if further discipline is warranted.

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

10.

Complaint generated after Investigators noticed advertisement for location while en route to conduct an unrelated inspection during the month of November, 2013. Respondent M/W/D held a pharmacy license for a location in Nashville, but believed that the Nashville license also covered its location in Gallatin, which had been in operation without a license for 17 years. Respondent M/W/D is an oxygen supplier. As of December, 2013, Respondent has obtained a license for its Gallatin location.

Prior discipline: none

Recommendation: Discuss.

Dr. Dickenson made the motion to **authorize a formal hearing** with \$100.00 per month for a total of \$20,400.00 civil penalty for unlicensed activity. Dr. Eidson seconded the motion. The motion carried.

11.

Periodic inspection in March 6, 2014 revealed that technician had been working on an expired registration since October 31, 2013. Respondent technician had sent renewal fee to the Board office on November 26, 2013. Neither Respondent technician nor PIC responded to correspondence from Board staff regarding late fees (sent December 3, 2013). Respondent technician renewed 3/17/14.

Prior discipline: none

Recommendation: \$100 to Technician.

\$100 per month to PIC for expired technician, for a total of \$500.

Dr. Eidson made the motion to **authorize a formal hearing** with a \$10.00 civil penalty to the technician for working on an expired registration and a \$100.00 civil penalty to the pharmacist in charge for a total of \$500.00 for allowing a pharmacy technician to work on an expired registration. Ms. McDaniel seconded the motion. The motion carried.

12.

Complaint alleged impairment and unprofessional conduct by Respondent pharmacist. Investigation did not substantiate complaint.

Prior discipline: None

Recommendation: Dismiss.

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

13.

Respondent pharmacist was terminated from employment for diversion of controlled substances. Law enforcement is involved with this case. There is no specific admission from Respondent as to the amount and type of controlled substances diverted other than the DEA Form 106 submitted by the pharmacy. Respondent has indicated that they intend to check into treatment, and has indicated that they are willing to surrender their license.

Prior discipline: none

Recommendation: Accept voluntary surrender of license.

Ms. McDaniel made the motion to **authorize a formal hearing** to accept the voluntary surrender of the pharmacist license. Dr. Bunch seconded the motion. The motion carried.

14.

Complaint alleges that Respondent technician called in fraudulent prescriptions for controlled and non-controlled substances. Although Respondent technician did not admit to calling in fraudulent prescriptions, prescriber indicated that they were not authorized or called into the pharmacy by any employee in prescriber's office.

Amount and Type of Non-Controlled Substances:

Zofran 8mg, #30

Amount and Type of Controlled Substances:

Xanax 0.5mg, #90

Ambien 10mg, #30

Prior discipline: none

Recommendation: Revoke.

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

15.

Complaint alleges that Respondent technician was suspended from employment due to being suspected of diversion. A large number of alprazolam 2mg tablets were noted as missing from the pharmacy, and technician was suspected of removing the tablets without a prescription or authorization. Investigation showed that technician engaged in some behavior that may have violated pharmacy policies (e.g., took own call-in prescriptions, filled prescriptions for family members), but no evidence linking Respondent technician to theft or diversion of alprazolam could be discovered.

Prior discipline: none

Recommendation: Dismiss.

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

16.

Complaint generated while Investigator was conducting inspection of another facility. Respondent M/W/D, an oxygen supplier, was formerly located under the same roof as a licensed pharmacy (same owner). The pharmacy moved locations in July of 2010, but Respondent's oxygen and DME businesses were left intact and in operation at the original location without ever obtaining additional licensure from the Board of Pharmacy.

Prior discipline: none

Recommendation: \$100 per month of unlicensed operation (45 months) for a total of \$4,500

Ms. McDaniel made the motion to **authorize a formal hearing** with a \$100.00 per month civil penalty for a total of \$4500.00 for unlicensed operation. Dr. Eidson seconded the motion. The motion carried.

17.

Respondent technician was terminated for calling in a fraudulent controlled substance prescription for themselves (phentermine 37.5mg, #30). Respondent's alleged fraud was discovered when pharmacist on-duty contacted prescriber's office to verify prescription.

Prior discipline: none

Recommendation: Revoke

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

18.

Periodic inspection revealed 26 out-of-date drugs still on the shelves alongside unexpired products. Investigator

Prior discipline: none

Recommendation: \$10 per expired product for a total of \$260.

Ms. McDaniel made the motion to **authorize a formal hearing** with \$10.00 civil penalty per expired drugs for a total of \$260.00. Dr. Eidson seconded the motion. The motion carried.

19.

This case was presented for discipline at a prior meeting. Respondent pharmacist became ill

while on duty and left the pharmacy unsupervised. During this time, the pharmacy dispensed a single prescription to a patient. The Board voted to assess discipline against Respondents for counseling violation. Respondent pharmacy feels that discipline against the facility is unwarranted given the circumstances. This incident was self-reported by Respondent pharmacy, and Respondent pharmacy alleges they were misled by pharmacist-employee about employee's absence from the premises during business hours. Respondent also draws a distinction between this incident, where pharmacist was acting completely outside the scope of their employment, and a "normal" counseling violation, where a pharmacist may be on duty inside the pharmacy and neglects their legal obligations. Respondent pharmacist in this case has accepted the discipline imposed by the Board and has returned a signed consent order and paid the associated civil penalties.

Prior discipline: none

Recommendation: Dismiss.

Dr. Stephens made the motion to **accept counsel's recommendation** for dismissal of the complaint against the pharmacy based on the pharmacy's statement. Dr. Bunch seconded the motion. The motion carried. Dr. Eidson recused himself.

20.

Respondent pharmacist has entered treatment for chemical dependency and wishes to surrender their license.

Prior discipline: none

Recommendation: Accept voluntary surrender.

Ms. McDaniel made the motion to **authorize a formal hearing** to accept the voluntary surrender of the pharmacist license. Dr. Eidson seconded the motion. The motion carried.

21.

Respondent pharmacist has entered treatment for chemical dependency and wishes to surrender their license.

Prior discipline: none

Recommendation: Accept voluntary surrender.

Ms. McDaniel made the motion to **authorize a formal hearing** to accept the voluntary surrender of the pharmacist license. Dr. Eidson seconded the motion. The motion carried.

OGC Report

Mr. Cange presented to the board drafted rules that pertain to the collaborative practice agreements. According to the statute the collaborative practice agreement rules have to be promulgated in collaboration with the board of medical examiners and board of osteopathic examiners. Mr. Cange suggested that the board make a recommendation and then he can present them to the other boards. Dr. Eidson stated that he would prefer that the work group be established to promulgate these rules. The work group would consist of Dr. Dickenson, Dr. Dilliard, Mr. Cange and a representative from the Tennessee Pharmacist Association. Mr. Cange stated that he will present the drafted language at the July 30-31, 2014 board meeting.

Proposed New Rules:

1140-02-.03 COLLABORATIVE PRACTICE AGREEMENTS

(a) a collaborative pharmacy practice agreement under this chapter shall be between one (1) or more pharmacists licensed in this state and an individual prescriber licensed in this state, or one (1) or more prescribers licensed in this state in an organized medical group, including but not limited to, staff of a licensed health care facility, clinic, group medical practice, accountable care organization, or patient centered medical home.

1. When a collaborative pharmacy practice agreement is being established between a pharmacist or pharmacists and an organized medical group or one (1) or more members employed or contracted by an organized medical group, the chief medical officer, medical director, or a designated physician in that group shall be required to approve the collaborative pharmacy practice agreement in order to permit the provision of patient care services, as defined in the collaborative practice agreement.

(b) The collaborative pharmacy practice agreement shall define the nature and scope of patient care services to be provided by the pharmacist or pharmacists. The prescriber or prescribers entering into the agreement retain the ultimate authority regarding the scope of services provided by pharmacists in accordance with the collaborative pharmacy practice agreement.

1. The patient care services authorized to be provided by the agreement shall be within the scope of practice of the authorizing prescriber or prescribers.
2. Any patient care services provided by a pharmacist or pharmacists pursuant to a collaborative pharmacy practice agreement shall be documented in a patient record accessible by the pharmacist and the prescriber or communicated to the prescriber or prescribers within three (3) business days in accordance with the provisions of the collaborative pharmacy practice agreement.

(c) No retail pharmacy may employ or contract with a prescriber for the purpose of maintaining, establishing or entering into a collaborative practice agreement with a patient. Nothing shall prohibit a pharmacy or pharmacist or group of pharmacists from employing or entering into a professional contract with a physician or licensed medical practitioner for the purpose of conducting quality assurance review of its pharmacists that are engaged in the practice of collaborative drug therapy.

(d) An individual prescriber licensed in this state or one (1) or more prescribers licensed in this state in an organized medical group may employ pharmacists for the purpose of providing patient care services pursuant to a collaborative pharmacy practice agreement for the benefit of a patient or patients of that prescriber or prescribers in that organized medical group.

(e) If a collaborative practice agreement includes one (1) or more prescribers who are either advanced practice nurses (APN) or physician assistants (PA), the supervising physician who has primary responsibility for supervising the APN or PA must also approve and sign the collaborative pharmacy practice agreement.

1. The supervising physician may only approve a collaborative pharmacy practice agreement of an APN or PA if the services authorized in the agreement are included in the routine services delivered by the supervising physician in the supervising physician's medical practice.
2. Any supervising physician entering into collaborative pharmacy practice agreements shall be available for consultation with the pharmacist or pharmacists as needed.

(f) Pharmacists and authorizing prescribers entering into collaborative pharmacy practice agreements shall maintain a copy of the written collaborative pharmacy practice agreement on file in a readily retrievable location at their places of practice.

Mr. Cange also presented draft rules changes to update board rules 1140-01 and 1140-09. Ms. Young suggested that the board remove collaborative practice definitions due to the work group presenting the changes as the July 30-31, 2014 board meeting. The board agreed. Dr. Eidson made the motion to authorize a rulemaking hearing for board rule 1140-01 and 1140-09 at the September 10-11, 2014. Dr. Bunch seconded the motion.

**RULES
OF
THE TENNESSEE BOARD OF PHARMACY**

**CHAPTER 1140-01
INTRODUCTORY RULES**

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1140-01-.01 DEFINITIONS.

- (1) "ACPE" means the Accreditation Council for Pharmaceutical Education.
- (2) "Alternate or alternative infusion pharmacy practice site" means a pharmacy practice site where parenteral, enteral or respiratory therapies, and ancillary supplies, medications and equipment are provided to patients in a non-institutional setting.
- (3) "Accreditation Council for Pharmacy Education (ACPE)" means the national organization for accreditation of professional degree programs in pharmacy and for accreditation of providers of continuing pharmacy education.
- (4) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.
- (5) "Blood fraction/component" means that part of blood separated by physical or mechanical means.

- (6) "Centralized Prescription Processing" is the filling or refilling of a lawful prescription order written by the patient's authorized prescriber by one (1) pharmacy licensed by the State of Tennessee at the request of another pharmacy licensed by the State of Tennessee for the delivery of the prescription drugs to the patient or patient's agent.
- (7) "Certified pharmacy technician" means an individual who is certified by a national or state agency that offers a certification program that is recognized by the board.
- (8) "Collaborative pharmacy practice" is the practice of pharmacy whereby one (1) or more licensed pharmacists licensed in this state, jointly and voluntarily work with one (1) or more prescribers licensed in this state, under a collaborative pharmacy practice agreement to provide patient care services, to achieve optimal medication use and desired patient outcomes;
- (9) "Collaborative pharmacy practice agreement" is a written and signed agreement entered into voluntarily between one (1) or more licensed pharmacists in this state, and one (1) or more prescribers licensed in this state, each of whom is in active practice in this state providing patient care services in this state, that provides for collaborative pharmacy practice, as defined by law;
- (10) "Commercially available" means any marketed FDA-approved drug or biologic product not currently listed on any official shortage list recognized by the Board of Pharmacy.
- (11) "Component" means any active ingredient, or any added substance, inactive ingredient, excipient or pharmaceutical ingredient, intended for use in the compounding of a drug product, including those that may not appear on the product label.
- (12) "Consultant pharmacist" means a pharmacist retained on a routine basis to consult with organizations, institutional facilities or patients in areas that pertain to the practice of pharmacy.
- (13) "Contact hour" means any hour of completed continuing pharmaceutical education programming which is:
 - (a) accredited by ACPE (including, but not limited to, live programs, independent study courses, home correspondence courses, and audio or video cassettes); or

- (b) approved by the board (including, but not limited to, attendance at state, district, or local pharmacy association meetings).
- (14)“Continuing education unit” means ten (10) hours of participation in an ACPE approved or board-approved continuing pharmaceutical education program under responsible sponsorship, capable direction, and qualified instruction.
- (15)“Drug sample” means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the prescription drug.
- (16) “Electronic medical or prescription order” means a medical or prescription order which is transmitted by computer technology other than by electronic image transmission.
- (17)“Facsimile (FAX) medical or prescription order” means a medical or prescription order which is transmitted by an electronic image transmission.
- (18)“Foreign pharmacy graduate” means a person whose undergraduate pharmacy degree was conferred by any college or school of pharmacy not accredited by the ACPE but which is listed in the World Health Organization World Directory of Colleges and Schools of Pharmacy, or otherwise approved by the Foreign Pharmacy Graduate Examination Committee (FPGEC) certification program as established by the National Association of Boards of Pharmacy.
- (19)“Hazardous product” means any substance that may be cytotoxic, genotoxic, oncogenic, mutagenic, teratogenic, or otherwise pose a potential health hazard.
- (20)“Institutional facility” means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, and where patients spend a majority of their time within the facility, including but not limited to a(n):
- (a) adult care facility;
 - (b) assisted living facility;
 - (c) correctional facility;
 - (d) developmental disability center;
 - (e) hospital;
 - (f) inpatient psychiatric center;
 - (g) intermediate care facility for the mentally retarded;
 - (h) mental health facility;
 - (i) nursing facility;
 - (j) personal care home;
 - (k) rehabilitation center;
 - (l) residential drug or alcohol treatment center;
 - (m) rest home;

- (n) retirement center;
 - (o) sub-acute care facility; and
 - (p) university health center.
- (21) “Institutional pharmacy practice site” means a pharmacy practice site serving patients within an institutional facility.
- (22) “Medication order” means a prescription order for any prescription drug or device or related material issued by an authorized prescriber to authorized healthcare personnel in an institutional facility or institutional pharmacy practice site.
- (23) “National Association of Boards of Pharmacy (NABP)” means the professional organization that represents the individual state boards of pharmacy.
- (24) “Nuclear pharmacy practice site” means a pharmacy practice site providing radiopharmaceutical services.
- (25) “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.
- (26) “Oxygen supplier” means any person who sells, distributes or wholesales medical gases which require a prescription prior to 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.
- (27) “Patient counseling” means communication by the pharmacist of information to the patient or caregiver in order to improve therapeutic outcome.
- (28) “Pharmaceutical care” is the responsible provision of drug therapy through, among other things, pharmacists identifying potential and actual drug-related problems and resolving and preventing drug-related problems, for the purpose of achieving definite outcomes that improve a patient’s quality of life. The outcomes include but are not limited to cure of a disease, elimination or reduction of a patient’s symptomatology, arresting or slowing of a disease process and the preventing of a disease or symptomatology.
- (29) “Pharmacy internship” is a period of practical pharmacy experience under the direct supervision of a licensed pharmacist and pursuant to the rules of the board.
- (30) “Pharmacy practice site” means any place within this state where prescription drugs or prescription devices are dispensed and where pharmaceutical care is provided, and any place outside of the state where prescription drugs or prescription devices are dispensed and pharmaceutical care is provided to persons residing in this state.

- (31)“Preceptor” means an individual who is currently licensed as a pharmacist and who meets the qualifications of a preceptor under the rules of the board and participates in the education of pharmacy interns.
- (32)“Prescription department” means the area of a pharmacy practice site in which prescription drugs and devices and related materials are stocked and medical and prescription orders are compounded and dispensed.
- (33)“Quality assurance” means a system for identifying problems in patient care that are resolved via administrative, clinical, or educational actions to ensure that final products and outcomes meet applicable specifications.
- (34) “Radiopharmaceutical service” means, but is not limited to:
- (a) the compounding, dispensing, labeling, and delivering of radiopharmaceuticals;
 - (b) the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews;
 - (c) the proper and safe storage and distribution of radiopharmaceuticals;
 - (d) the maintenance of radiopharmaceutical quality assurance;
 - (e) the responsibility for advising, where necessary or where regulated, of the diagnostic and therapeutic value, hazards, and use of radiopharmaceuticals; and
 - (f) the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a nuclear pharmacy practice site.
- (35)“Reciprocity” means to issue a license to an applicant who furnishes satisfactory proof of licensing by examination in another state or territory pursuant to the rules of the board.
- (36)“Shall” means that compliance is mandatory.
- (37) “Sterile product” means any dosage form, drug product, or biological product devoid from all living microorganisms, including but not limited to bacteria and fungus.
- (38) “Sterile manufacturing” means the production, propagation, processing, pooling, or repackaging of sterile products for wholesale or any other form of distribution, not pursuant to a prescription or medical order.

- (39)“Third party pharmacy program” means any system of providing for the reimbursement of medical or prescription orders and/or pharmaceutical care services under a contractual arrangement or agreement between a provider of such services and the third party program administrator who is not the consumer of those services.
- (40)“Third party pharmacy program administrator” means, but is not limited to, insurance companies, managed care organizations, health maintenance organizations, preferred provider organizations, pharmacy benefit managers, and pharmacy services administrative organizations.
- (41)“Unit dose packaging” means that packaging which is designed to hold a quantity of a drug product intended for administration as a single dose.
- (42) USP” means the United States Pharmacopeia.
- (43) “USP standards” means any applicable standard or standards published in the most current version of United States Pharmacopeia National Formulary guidelines, to the extent that such guidelines do not conflict with state law, rules, or Board Policy Statements and as those guidelines may, from time to time, be amended.

Authority: T.C.A. §§ 63-10-101, 63-10-102, 6-10-404(5), (6), (14), (22), (26), (28), and (29), 63-10-304, 63-10-304(b)(1), 63-10-504(b)(1), and Chapter 966 of the Public Acts of 2008 §1.
Administrative History: Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009. Amendment filed December 23, 2009; effective March 23, 2010.

1140-01-.02 VIOLATIONS CONSTITUTE UNPROFESSIONAL CONDUCT.

- (1) Any person who violates any rule of the board may be deemed guilty of dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).

Authority: T.C.A. §§ 63-10-101, 63-10-102, 63-10-202, 63-10-504(b)(1), and 63-10-505(6).
Administrative History: Original rule certified June 7, 1974. Amendment filed August 14, 1974; effective September 13, 1974. Repeal filed January 11, 1977; effective February 10, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed January 19, 1988; effective April 27, 1988. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-01-.03 APPLICATION FOR A PHARMACIST LICENSE.

- (1) An applicant for a license to engage in the practice of pharmacy shall submit the following to the Board office at time of application:
 - (a) A completed application on a form approved by the Board;
 - (b) Application and registration fees established in rule 1140-01-.10; and
 - (c) The result of a criminal background check, which the applicant shall pay for and cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's licensure application materials.
 - (d) Any application submitted which lacks required information or reflects a failure to meet any of the requirements for licensure will be returned to the applicant with written notification of the information that is lacking or the reason(s) the application does not meet the requirements for licensure and will be held in "pending" status until satisfactorily completed within a reasonable period of time, not to exceed sixty (60) days from date of written notification.
- (2) For the purpose of *T.C.A. § 63-10-506(d)*, a "recognized" college or school of pharmacy is a college or school of pharmacy which meets the minimum standards of the ACPE and appears in the ACPE "Annual Directory of Accredited Professional Programs of Colleges and Schools of Pharmacy."
- (3) No applicant shall be eligible for a license if the applicant has engaged in conduct or suffers a condition which would constitute grounds for revocation or suspension of a license under *T.C.A. § 63-10-505*, unless the applicant can show cause why a license should be issued.
- (4) No license shall be issued to a reciprocal applicant from a state which denies reciprocal privileges to a pharmacist currently licensed and in good standing in Tennessee.
- (5) It shall be unlawful for any person to procure or attempt to procure a license or certificate of registration for such person or for any other person by making any false representations.
- (6) An applicant initially licensed in another state and who wishes to obtain a Tennessee license may, in the discretion of the board, transfer to Tennessee the applicant's score on NAPLEX taken in another state. Provided, however, if the applicant has been licensed for twelve (12) or more months in another state, then the applicant shall apply for a license in Tennessee by reciprocity. No license shall be issued to a score

transfer applicant from a state which denies score transfer privileges to a pharmacist currently licensed and in good standing in Tennessee.

Authority: T.C.A. §§ 63-10-101, 63-10-102(a), 63-1-116, 63-10-202, 63-10-304, 63-10-306, 63-10-404(2), (13), (17), and (26), 63-10-404(2), (13), (17), and (26), 63-10-504(b)(1), 63-10-506, and 63-10-508. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed December 17, 1984; effective March 16, 1985. Amendment filed October 30, 1991; effective December 14, 1991. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed January 4, 2012; effective April 3, 2012.

1140-01-.04 PHARMACY INTERNSHIP.

- (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(29), and 63-10-504(b)(1). **Administrative History:** Original rule filed June 7, 1974; effective July 7, 1974. Amendment filed September 23, 1975; effective October 23, 1975. Amendment filed January 11, 1977; effective February 10, 1977. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed December 17, 1984; effective March 16, 1985. Amendment filed January 19, 1988; effective April 27, 1988. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-01-.05 LICENSING EXAMINATIONS.

- (1) An applicant for an initial license to engage in the practice of pharmacy in the State of Tennessee shall take the National Association of Boards of Pharmacy (NABP)

Multistate Pharmacy Jurisprudence Examination (MPJE®) and the NABP North American Pharmacy Licensing Examination (NAPLEX®), which shall be administered on the dates scheduled by the NABP. An applicant shall also meet the minimum acceptable passing scores on the NAPLEX® and MPJE® as established and nationally accepted.

- (2) An applicant to obtain a pharmacy license by reciprocity shall successfully complete the MPJE®.
- (3) In addition to completing the requirements in paragraph (1) of this rule, a pharmacy foreign graduate shall successfully complete the foreign pharmacy equivalency examination, the Test of Spoken English (TSE®) examination and any other requirements established by the NABP.
- (4) Any applicant who fails either the NAPLEX® or MPJE® may retake the examinations at any of the next examination dates scheduled by the NABP. If an applicant fails the NAPLEX® or MPJE® three (3) consecutive times, then the Board may require that applicant to take review courses prior to any following reexamination.

Authority: T.C.A. §§ 63-10-304 and 63-10-306. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009.

1140-01-.06 SUMMARY SUSPENSION OF LICENSE.

Pursuant to T.C.A. § 4-5-320, if the board finds that public health, safety or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, summary suspension of a license may be ordered pending proceedings for revocation or other action.

Authority: T.C.A. §§ 4-5-320, 63-10-101, 63-10-102, 63-10-504(b)(1), 63-10-504(b)(2), and 63-10-505. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed November 15, 1989; effective December 30, 1989. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-01-.07 INACTIVE LICENSES AND LICENSE REINSTATEMENT.

- (1) A pharmacist may apply for an inactive license by:
 - (a) Completing the biennial license renewal application form; and
 - (b) Paying the biennial renewal fee for an inactive license.

- (2) A pharmacist maintaining an active license to practice pharmacy in another state or jurisdiction is ineligible for inactive license status in Tennessee.
- (3) A pharmacist seeking active status for an inactive, delinquent, suspended or revoked license must fulfill the following minimum requirements.
 - (a) If the license has been inactive, delinquent, suspended or revoked for less than one (1) year, the pharmacist shall:
 1. Provide written notice to the board requesting an active license;
 2. Satisfy all past due continuing pharmaceutical education as required by the board; and
 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.
 - (b) If the license has been inactive, delinquent, suspended or revoked from one (1) year to not more than five (5) consecutive years, the pharmacist shall:
 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. Successfully complete the jurisprudence examination;
 4. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked; and
 5. Complete a period of pharmacy internship in Tennessee as follows.
 - (i) If the license has been inactive, delinquent, suspended or revoked from one (1) year to not more than three (3) consecutive years, one hundred sixty (160) hours within ninety (90) consecutive days.
 - (ii) If the license has been inactive, delinquent, suspended or revoked for more than three (3) consecutive years but not more than five (5) consecutive years, three hundred twenty (320) hours within one hundred eighty (180) consecutive days.

- (c) If the license has been inactive, delinquent, suspended or revoked for more than five (5) consecutive years, the pharmacist shall:
 - 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. Successfully complete the NAPLEX and jurisprudence examinations;
 - 4. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked; and
 - 5. Complete a period of pharmacy internship of three hundred twenty (320) hours within one hundred eighty (180) consecutive days.
- (d) Fulfill any other requirements which may be contained in any order of the board suspending or revoking the applicant's license.
- (e) The board shall consider a written notice requesting reinstatement of an inactive, delinquent, suspended or revoked license within ninety (90) days of the notice being received by the director.
- (f) The board shall consider a waiver upon request.

Authority: T.C.A. §§ 63-10-101, 63-10-102, 63-10-210, 63-10-404(17), and 63-10-504(b)(1).
Administrative History: Original rule certified June 7, 1974. Amendment filed June 7, 1974; effective July 7, 1974. Amendment filed September 23, 1975; effective October 23, 1975. Amendment filed January 11, 1977; effective February 10, 1977. Amendment filed April 11, 1979; effective July 30, 1979. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed January 26, 1987; effective April 29, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-01-.08 APPLICATION FOR PHARMACY PRACTICE SITE, MANUFACTURER AND WHOLESALE/DISTRIBUTOR LICENSES.

- (1) Application for a license to operate as a pharmacy practice site, manufacturer, outsourcing facility 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 or wholesaler/distributor physically located within the state of Tennessee must be filed when the pharmacy practice site, manufacturer, outsourcing facility or wholesaler/distributor changes name, location or ownership.
 - (a) Transactions constituting a change of ownership include, but are not limited to, the following:
 1. A sole proprietor becomes a member of a partnership or corporation, which succeeds him as the new operator;
 2. A partnership dissolves;
 3. One partnership is replaced by another through the removal, addition or substitution of a partner;
 4. Two (2) or more corporations merge and the originally-licensed corporation does not survive; and
 5. Transfers between levels of government.
 - (b) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 1. Changes in the membership of a corporate board of directors or board of trustees;
 2. Two (2) or more corporations merge and the originally-licensed corporation survives; and
 3. Corporate stock transfers or sales, even when a controlling interest.
- (3) No out-of-state pharmacy practice site, manufacturer outsourcing facility or wholesaler/distributor shall conduct business in the state of Tennessee until such pharmacy practice site, manufacturer, outsourcing facility or wholesaler/distributor obtains the required license from the board. In order to obtain a license for a pharmacy practice site, manufacturer, outsourcing facility or wholesaler/distributor physically located out-of-state the following standards must be met.
 - (a) Pharmacy practice site.
 1. Submit an application for a license, which shall include the address of the pharmacy practice site, name of owner if a sole proprietorship, names of

partners if a partnership or names and titles of all officers if a corporation and names of all pharmacists who practice at the site, 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, including names of pharmacists practicing at the site.

2. Comply with all statutorily authorized directions and requests for information from the board.
 3. Maintain at all times a current permit, license or registration to conduct the pharmacy practice site in compliance with the laws of the state in which the site is physically located.
 4. 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 pharmacy practice site is physically located. Thereafter, the pharmacy practice site 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 site is physically located.
 5. Maintain records of prescription orders dispensed to persons residing in Tennessee.
 6. All records of prescription orders prepared and dispensed to persons residing in Tennessee shall be readily retrievable from other records.
 7. During regular hours of operation, but not less than six (6) days per week nor for a minimum of forty (40) hours per week provide access to a pharmacist by a toll-free telephone service. A toll-free number shall be placed on the label affixed to the dispensing container for each prescription dispensed to a person residing in Tennessee.
 8. Designate a pharmacist in charge who shall be responsible for compliance with the provisions in this section, and who shall hold a current Tennessee pharmacist license.
 9. All out-of-state pharmacy practice sites shall comply with the requirements for patient counseling, patient profiling, drug regimen review and pharmaceutical care as set forth at 1140-03-.01.
- (b) Manufacturer, outsourcing facility or wholesaler/distributor.

1. Submit an application for a license, which shall include the address of the manufacturer, outsourcing facility 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 or wholesaler/distributor is physically located. Thereafter, the manufacturer, outsourcing facility 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 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.
 3. Comply with the requirements contained in Chapter 1140-09 of the rules of the Board of Pharmacy.
- (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.
 - (6) It shall be unlawful for any person to procure or attempt to procure a license or certificate of registration for such person or for any other person by making any false representations.
 - (7) In determining whether to grant a license under this rule, the board shall require from the applicant proof satisfactory to the board that the:
 - (a) Applicant is of good moral character, or, if the applicant is a partnership or corporation, that the managing officers are of good moral character; and

- (b) That the applicant is equipped as to land, buildings and equipment necessary to conduct the business for which the application has been submitted.

Authority: T.C.A. §§ 53-11-301, 53-14-104, 53-14-106, 53-14-107, 56-1-302(b)(1)(2), 63-10-101, 63-10-102(a), 63-10-203, 63-10-204, 63-10-210, 63-10-404(18), (28), and (37), 63-10-504(b)(1), § 63-10-504(b)(2), and 63-10-508. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed September 30, 1985; effective October 30, 1985. Amendment filed January 19, 1988; effective April 27, 1988. Amendment filed August 25, 1989; effective October 9, 1989. Amendment filed October 30, 1991; effective December 14, 1991. Amendment filed November 17, 1994; effective March 30, 1995. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-01-.09 RENEWAL OF LICENSES.

- (1) All licenses and certificates of registration granted by the board shall be for a two (2) year period beginning on the date the license is initially granted. All licenses and certificates of registration shall be renewed on or before the last day of the two (2) year license cycle.
- (2) A pharmacist or pharmacy technician serving in the uniformed services of the United States shall not be required to pay license or registration renewal fees during the period of active duty and the pharmacist shall not be required to complete continuing pharmacy education requirements during the period of active duty.

Authority: T.C.A. §§ 53-11-301, 53-11-302, 56-1-302(b)(1)(2), 63-10-102(a), 63-10-404(17), 63-10-504(1) and (2), 63-10-304(b)(1) and 63-10-508. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed April 12, 1990; effective July 29, 1990. Amendment filed November 17, 1994; effective March 30, 1995. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed December 23, 2009; effective March 23, 2010.

1140-01-.10 FEES.

- (1) An applicant for examination for a license as a pharmacist shall pay a fee of fifty dollars (\$50.00) plus cost of the examination and materials.
- (2) An applicant for a reciprocal license or NAPLEX score transfer shall pay a fee of three hundred dollars (\$300.00).
- (3) Each person becoming licensed as a pharmacist shall pay a registration fee of one-hundred twenty-five dollars (\$125.00). Each person licensed as a pharmacist who

desires to continue in the practice of pharmacy shall biennially, on or before the last day of the month that the person's license shall expire, pay a renewal fee of one-hundred twenty-five dollars (\$125.00). Each person licensed as a pharmacist and who wishes to obtain an inactive license shall biennially, on or before the last day of the month that the person's license shall expire, pay a renewal fee of sixty-three dollars (\$63.00).

- (4) Each person becoming registered as a pharmacy technician shall pay a registration fee of seventy-five dollars (\$75.00). Each person who desires to continue to practice as a pharmacy technician shall biennially, on or before the last day of the month that the person's registration shall expire, pay a renewal fee of seventy-five dollars (\$75.00).
- (5) Any person, partnership, firm, corporation or agency owning or operating a pharmacy practice site or any establishment or institution where prescription drugs and devices and related materials are kept for the purpose of the compounding and dispensing of medical and prescription orders shall pay a registration fee of three-hundred dollars (\$300.00) biennially. Any new pharmacy practice site to be opened or established, or any change in location, name or ownership of any existing pharmacy practice site, shall before active operation obtain a license from the Board of Pharmacy and shall pay a fee of three-hundred dollars (\$300.00)
- (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 publish Pharmacy Drug Laws, Rules and Regulations electronically, and may make an electronic publication freely available on the Board's website.
- (8) The charge for a roster of Tennessee pharmacies, pharmacists and printing of mailing labels of Tennessee pharmacies and pharmacists shall be determined by the administration of the Department of Health.
- (9) The fee for certification of license examination grades shall be twenty five dollars (\$25.00).
- (10) The fee for any duplicate or revised license, registration, modifier or license wall certificate shall be twenty five dollars (\$25.00).

- (11) If any person fails to renew a license, such license may be reinstated upon complying with rule 1140-01-.07 and upon the payment of the appropriate renewal fee plus a penalty fee of ten dollars (\$10.00) for each month or fraction thereof that payment for renewal is delinquent. In the event such renewal is not procured within six (6) months from the date on which the last renewal became delinquent, the board may refuse to issue the renewal.
- (12) If any person fails to renew a license or registration certificate, such license or registration certificate may be reinstated upon complying with rule 1140-01-.07 and upon the payment of the appropriate renewal fee plus a penalty fee of ten dollars (\$10.00) for each month or fraction thereof that payment for renewal is delinquent. In the event such renewal is not procured within six (6) months from the date on which the last renewal became delinquent, the board may refuse to issue the renewal.
- (13) A penalty of fifty dollars (\$50.00) may, in the discretion of the board, attach to each failure of a licensee or registration certificate holder to provide any required notice to the director as may be required by the rules of the board.
- (14) Any licensee who wishes to modify the terms or conditions of a license to manufacture, obtain, possess, administer or dispense a prescription drug or device or controlled substance for the purpose of scientific research, chemical analysis, instruction or training of detection animals shall file those modifications with a non-refundable fee of five dollars (\$5.00).
- (15) Any person who holds a license to manufacture, obtain, possess, administer or dispense a prescription drug or device or controlled substance for the purpose of scientific research, chemical analysis, instruction or training of detection animals shall pay a renewal fee of one-hundred dollars (\$100.00) biennially from the date of issuance.
- (16) Any person, partnership, firm, corporation or agency owning or operating a pharmacy practice site or any other establishment licensed pursuant to this chapter, where sterile products are compounded, manufactured, prepared, propagated, repackaged, processed, stored, or distributed shall pay a registration fee of two-hundred and fifty dollars (\$250.00), and thereafter a biennial renewal fee of two-hundred and fifty dollars (\$250.00).

Authority: T.C.A. §§ 4-5-202, 63-10-102(a), 63-10-216, 63-10-404(17), 63-10-504(b)(1), 63-10-504(b)(2), and 63-10-508. **Administrative History:** Original rule certified June 7, 1974. Amendment filed June 7, 1974; effective July 7, 1974. Amendment filed December 15, 1977; effective January 16, 1978. Amendment filed September 26, 1978; effective December 29, 1978. Repeal and new rule file February 7, 1983; effective March 9, 1983. Amendment filed May 23, 1986; effective August 12, 1986. Amendment filed January 26, 1987; effective April 29, 1987. Amendment filed October 1, 1987; effective January 27, 1988. Amendment filed November 18,

1989; effective February 28, 1989. Amendment filed October 18, 1990; effective January 29, 1991. Amendment filed May 3, 1991; effective August 28, 1991. Amendment filed December 22, 1992; effective March 31, 1993. Amendment filed June 25, 1993; effective September 28, 1993. Amendment filed October 19, 1996; effective February 28, 1996. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002.

1140-01-.11 CONTROLLED SUBSTANCE REGISTRATION.

No licensee may obtain, possess, administer, dispense, distribute, or manufacture any controlled substance in this state, and no representative of a manufacturer or wholesaler/distributor may distribute any controlled substance in this state, without obtaining a controlled substance registration from the board. Application for such registration shall be submitted on a form prescribed by the board, and shall be accompanied by a fee of forty dollars (\$40.00) and thereafter a biennial renewal fee of forty dollars (\$40.00).

Authority: *T.C.A. §§ 53-10-303, 63-10-102(a), 63-10-404(6), 63-10-504(b)(1), 63-10-504(b)(1) and (2), and 63-10-508. Administrative History:* *Original rule filed October 30, 1991; effective December 14, 1991. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-01-.12 STERILE COMPOUNDING REGISTRATION

- (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.

1140-01-.13 STANDARDS FOR PHARMACIES AND PRESCRIPTION DEPARTMENT SECURITY.

A license to operate a new or remodeled pharmacy practice site, or an existing pharmacy practice site which changes location or ownership, will not be issued unless the pharmacy practice site meets the following standards.

- (1) The pharmacy practice site and equipment therein shall be maintained in a clean, sanitary, orderly and well-lighted condition, and all persons working in the pharmacy practice site shall be required to keep themselves and their apparel in a clean and sanitary condition.
- (2) All new or relocated pharmacies opening after July 1, 1998 shall provide a consultation area which offers sufficient privacy to the patient before a license will be

issued. All existing pharmacies shall be in compliance with this requirement on or before January 1, 2000.

- (3) The prescription department at the pharmacy practice site shall meet the following standards.
 - (a) The department shall have necessary counters and storage space.
 - (b) The department shall have a representative stock of prescription drugs and devices and related materials sufficient to compound and dispense medical and prescription orders as indicated by experience.
 - (c) The department shall have the apparatus and equipment needed to compound and dispense medical and prescription orders properly.
 - (d) The department shall occupy a space of not less than one hundred eighty (180) square feet.
 - (e) The department shall have hot and cold running water and immediate area refrigeration.
 - (f) The department shall have a physical barrier sufficient to protect against unauthorized entry and pilferage of prescription drugs and devices and related materials.
 - (g) Keys or other access devices to the physical barriers shall be subject to the following standards.
 1. Only pharmacists practicing at the pharmacy and pharmacists authorized by the pharmacist in charge shall be in possession of any keys or other access devices.
 2. The pharmacist in charge shall place a key or other access device in a sealed envelope bearing the signature of the pharmacist in charge affixed across the seal and placed in a safe or vault in a secured place outside of the department. The key or access device may be used to allow emergency entrance to the department.
 - (h) Access to the department is restricted to pharmacists, pharmacy interns and pharmacy technicians who are practicing at the pharmacy. Other persons designated by the pharmacist in charge may be allowed access but only during hours that a pharmacist is on duty.

- (i) Notwithstanding any rule or regulation to the contrary, a pharmacy which was established before June 6, 1945, and which serves food, and which has continuously had a soda fountain, may allow a customer to go through the pharmacy area to the restroom, and not be required to have a gate or door to separate the pharmacy from the restroom or other parts of the establishment.
- (4) All licenses and certificates of registration for a pharmacy practice site shall at all times be conspicuously displayed at the practice site.
- (5) If a pharmacy practice site is located in a mercantile establishment (such as a discount store, grocery store, department store, or other similar establishment), then such pharmacy practice site shall be:
 - (a) open for business during the same hours as the mercantile establishment, unless the pharmacy practice site is capable of being closed-off by physical barrier from floor to ceiling; and
 - (b) under the supervision of a pharmacist at all times; except as provided in rule 1140-03-.07.
- (6) The pharmacist shall not at any time be denied access to the prescription department of a pharmacy practice site located in a mercantile establishment; provided, however, that entry of the pharmacist at times when the pharmacy is closed to the public may be subject to reasonable and prudent conditions.
- (7) A pharmacy practice site where prescription drugs and devices and related materials are received, stored, compounded and dispensed shall not be opened for business or any other reason unless a licensed pharmacist is present. Furthermore, no medical or prescription order shall be dispensed except during the presence and under the direct supervision of a pharmacist.
- (8) Nothing in this rule applies to a pharmacy practice site or prescription department operating in an institutional facility.
- (9) In cases of practical difficulty or undue hardship, the board may permit exceptions to the standards specified in this rule.

Authority: T.C.A. §§ 63-10-404(28), 63-10-504(b)(1), and 63-10-504(b)(1) and (2).
Administrative History: Original rule filed May 11, 1998; effective July 25, 1998.

~~1140-01-.14—1140-01-~~ STANDARDS FOR MANUFACTURERS, OUTSOURCING FACILITIES, OXYGEN SUPPLIERS AND WHOLESALE/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. §§ 63-10-204(18) and (37), and 63-10-304(b)(1). Administrative History: Original rule filed May 11, 1998; effective July 25, 1998.*

1140-01-.15 PRESCRIPTION DRUGS DISPENSED BY HEALTH DEPARTMENTS.

For purposes of *T.C.A. § 63-10-405*, the following drugs are hereby approved as not subject to abuse:

- (1) Tuberculosis Control Agents:
 - (a) Capreomycin Injection
 - (b) Cycloserine Capsules
 - (c) Ethambutol Tablets
 - (d) Ethionamide Tablets
 - (e) Isoniazid Tablets
 - (f) Para-Aminosalicyclate Tablets
 - (g) Pyrazinamide Tablets
 - (h) Rifampin Capsules
 - (i) Streptomycin Injection
 - (j) Tuberculin Skin Test (Mantoux only)
 - (k) Rifampin/Isoniazid
 - (l) Ofloxacin
 - (m) Rifampin-isoniazid-pyrazinamide

- (2) Venereal Disease Control Agents:
 - (a) Ampicillin Capsules
 - (b) Doxycycline Capsules
 - (c) Erythromycin Tablets
 - (d) Penicillin
 1. Benzathine Penicillin G Injection
 2. Procaine Penicillin G Injection
 - (e) Probenecid Tablets
 - (f) Spectinomycin Injection
 - (g) Tetracycline Capsules
 - (h) Ceftriaxone
 - (i) Ciprofloxacin

- (j) Lidocaine Injection
 - (k) Azithromycin
 - (l) Acyclovir Tablets, Ointments
 - (m) Trichloroacetic Acid
 - (n) Salicylic Acid
 - (o) Podophyllin/Salicylic Acid
 - (p) Aldara (Imiquimod)
- (3) Biologicals/Immunizations:
- (a) Antiserums
 - (b) Antitoxins
 - (c) Immune Serum Globulin
 - (d) Toxoids
 - (e) Vaccines
 - (f) Antigens
- (4) Reproductive Health Agents:
- (a) Metronidazole Tablets
 - (b) Oral Contraceptives
 - (c) Podophyllin
 - (d) Prenatal Vitamins
 - (e) Triple Sulfa Vaginal Cream/Tabs
 - (f) Vaginal Antifungal Cream/Tabs
 - 1. Clotrimazole
 - 2. Miconazole
 - 3. Nystatin
 - 4. Terconazole (Terazole)
 - (g) Amino-Cerv
 - (h) Nitrofurantoin
 - (i) Ibuprofen, 600 mg Tablets
 - (j) Metronidazole (vaginal jell)
 - (k) Fluconazole Tablets
 - (l) Clindamycin Vaginal Cream
 - (m) Premarin Tablets (for use in estrogen trials for the evaluation of atypical cells in certain inflammatory atrophic pap smears)
 - (n) Medroxyprogesterone Acetate Injectable (Depo Provera®)
 - (o) Norelgestromin/ethinyl estradiol transdermal system (Ortho Evra®)
 - (p) Etonogestrel/ethinyl estradiol vaginal ring (Nuvaring®)
- (5) Child Health Agents:

- (a) Fluoride Tablets and Drops
 - (b) Lindane Cream, Lotion, Shampoo
 - (c) Mebendazole Tablets
 - (d) Pyrantel Pamoate Liquid
 - (e) Sulfadiazine Tablets
 - (f) Trimethoprim and Sulfamethoxazole
 - (g) Permethrin
 - (h) Crothamiton
 - (i) Nystatin Oral Suspension
 - (j) Nystatin Triamcinolone Cream
 - (k) Ibuprofen, Suspension Liquid
- (6) Emergency Agents:
- (a) Aminophylline Injection
 - (b) Benztropine Injection
 - (c) Diphenhydramine Injection
 - (d) Epinephrine Injection
 - (e) Glucagon Injection
 - (f) Hydralazine Injection
 - (g) Hydrocortisone Sodium Succinate
 - (h) Insulin, Regular
 - (i) Intravenous Fluids
 - (j) Oxygen
 - (k) Phenylephrine Injection
 - (l) Sodium Bicarbonate Injection
 - (m) Atropine Injection
 - (n) Nitroglycerin Sublingual Tablets
 - (o) Dexamethasone Injection
 - (p) Norepinephrine
- (7) Antihypertensive Agents:
- (a) Methyldopa
 - (b) Reserpine
 - (c) Hydrochlorothiazide
 - (d) Hydralazine
 - (e) Propranolol
 - (f) Potassium Supplements
 - (g) Nicotine Patches

Authority: T.C.A. §§ 63-10-404(14), 63-10-205, 63-10-304, 63-10-304(b)(1), 63-10-405, 63-10-504(b), 63-10-504(b)(1), and 63-10-504(b)(2). **Administrative History:** Original rule filed May

11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002. Amendment filed November 24, 2008; effective February 7, 2009. Amendment filed December 23, 2009; effective March 23, 2010.

**RULES
OF
THE TENNESSEE BOARD OF PHARMACY**

**CHAPTER 1140-09
MANUFACTURERS, OUTSOURCING FACILITIES, OXYGEN SUPPLIERS AND
WHOLESALE/DISTRIBUTORS**

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1140-09-.01 MANUFACTURER, OUTSOURCING FACILITY, OXYGEN SUPPLIER AND WHOLESALE/DISTRIBUTOR LICENSING.

- (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.
- (2) An applicant with physical facilities in this state must obtain and display prominently a separate license for each principal place of business where the applicant manufactures or distributes prescription drugs and prescription devices.
- (3) The requirement of a license shall not apply to the following types of distributions:
 - (a) Intracompany sales;
 - (b) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug

for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

- (c) The sale, purchase or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- (d) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control; for purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership of stock, voting rights, by contract or otherwise;
- (e) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons; for purpose of this subparagraph, "emergency medical reasons" includes transfers of prescription drugs by a pharmacy practice site to alleviate a temporary shortage.
- (f) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase or trade a prescription drug, or the dispensing of a prescription drug pursuant to a medical or prescription order;
- (g) The distribution of prescription drug samples by manufacturers' representatives; or
- (h) The sale, purchase, or trade of blood and blood components intended for transfusion.
 - 1. The sale, purchase, or trade of a prescription drug, or an offer to sell, purchase or trade of a prescription drug by a pharmacy practice site to another pharmacy practice site or to authorized prescribing practitioners, except that the total gross dollar volume of such transfers shall not exceed five percent (5%) of the total medical and prescription orders sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period.

Authority: T.C.A. § 63-10-404(2),(8),(14),(18),(37), § 63-10-504(b)(1), § 63-10-506(f).
Administrative History: Original rule filed January 7, 1992; effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-09-.02 MINIMUM INFORMATION REQUIRED.

- (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; ~~and~~
 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 register as sterile manufacturers 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. § 63-10-404(2),(18),(37), § 63-10-504(b)(1), § 63-10-506(f). **Administrative History:** Original rule filed January 7, 1992; effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-9-.03 MINIMUM QUALIFICATIONS.

- (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](#):
 - (a) Any convictions of the applicant under any federal, state, or local laws relating to drug samples or distribution of controlled substances;
 - (b) Any felony convictions of the applicant under federal, state, or local laws;

- (c) The applicant's past experience in the manufacturing or distribution of prescription drugs and prescription devices, including controlled substances;
 - (d) The furnishing by the applicant of false or fraudulent material in any application made in connection with manufacturing or distribution;
 - (e) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances, prescription drugs and prescription devices;
 - (f) Compliance with licensing requirements under previously granted licenses, if any;
 - (g) Compliance with requirements to maintain and/or make available to the board or to federal, state, or local law enforcement officials those records required federal, state or local laws; and
 - (h) Any other factors or qualifications the board considers relevant to and consistent with the public health and safety.
- (2) The board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

Authority: T.C.A. § 63-10-404(2),(6),(8),(14),(18),(37), § 63-10-504(b)(1). **Administrative History:** Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1999, effective July 25, 1998.

1140-9-.04 PERSONNEL.

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(2),(18),(37), § 63-10-504(b)(1). **Administrative History:** Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-09-.05 MINIMUM REQUIREMENTS FOR GENERAL OPERATION.

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:

- (1) Facilities. All facilities at which prescription drugs and prescription devices are stored, warehoused, handled, held, offered, marketed, or displayed shall:
 - (a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
 - (b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
 - (c) Have a quarantine area for storage of prescription drugs and prescription devices that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
 - (d) Be maintained in a clean and orderly condition, and
 - (e) Be free from infestation by insects, rodents, birds, or vermin of any kind.
- (2) Security.
 - (a) All facilities shall be secure from unauthorized entry.
 1. Access from outside the premises shall be kept to a minimum and be well-controlled.
 2. The outside perimeter of the premises shall be well-lighted.
 3. Entry into areas where prescription drugs and prescription devices are held shall be limited to authorized personnel.
 - (b) All facilities shall be equipped with an alarm system to detect entry after hours.
 - (c) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- (3) Storage. All prescription drugs and prescription devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with

requirements, if any, in the labeling of such drugs and devices, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

- (a) If no storage requirements are established for a prescription drug or prescription device it may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that identity, strength, quality, and purity are not adversely affected.
 - (b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs and prescription devices.
 - (c) The record keeping requirements in paragraph (6) of this section shall be followed for all prescription drugs and prescription devices.
- (4) Examination of materials.
- (a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
 - (b) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
 - (c) The record keeping requirements in paragraph (6) of this section shall be followed for all incoming and outgoing prescription drugs.
- (5) Returned, damaged, and outdated prescription drugs and prescription devices.
- (a) Prescription drugs and prescription devices that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs and prescription devices until destroyed or returned.
 - (b) Any prescription drugs and prescription devices whose immediate or sealed outer or sealed secondary containers have been opened or used shall be quarantined and physically separated from other prescription drugs and prescription devices until either destroyed or returned.

- (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.
 - (d) The record keeping requirements in paragraph (6) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs and prescription devices.
- (6) Record keeping.
- (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:
 - 1. The source of the prescription drugs and prescription devices including the name and principal address of the seller or transferor, and the address of the location from which the prescription drugs and prescription devices were shipped;
 - 2. The identity and quantity of the prescription drugs and prescription devices received and distributed or disposed of; and
 - 3. The dates of receipt and distribution or other disposition of the prescription drugs and prescription devices.
 - (b) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the prescription drugs and prescription devices.

- (c) Records described in this paragraph that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.
- (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:
- (a) A procedure whereby the older approved stock of a prescription drug or prescription device is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.
 - (b) A procedure to be followed for handling recalls and withdrawals of prescription drugs and prescription devices. Such procedures shall be adequate to respond to recalls and withdrawals due to:
 - 1. Any action initiated at the request of the United States Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board;
 - 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
 - 3. Any action undertaken to promote public health and safety by replacing of an existing product with an improved product or new package design.
 - (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. § 63-10-404(8),(18),(33),(37), § 63-10-504(b)(1). **Administrative History:** Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-09 .-06 MINIMUM REQUIREMENTS FOR STERILE PRODUCT OPERATION

- (1) Any manufacturer , outsourcing facility, 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 1301.01.

- (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(8),(18),(33),(37), § 63-10-504(b)(1). Administrative History: Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

Legislative Update

Valerie Nagoshiner, Assistant Commissioner, Department of Health, Administrative Affairs, informed the board of the following administrative bills that affect the board.

Public Chapter 949- will allow application for licensure to be accepted online and annual inspections of facilities and pharmacies to be online. The effective date of this bill is July 1, 2014.

Public Chapter 763- authorizes the commissioner to compile and transmit, on a monthly basis, to the appropriate licensing board or agency a list of taxpayers who are delinquent 90 days or more from the due date of the tax and have either not pursued a remedy or remain liable for such tax at the conclusion of such remedy; provided, however, that such list will not include any taxpayer who has made all installment payments due and payable under an agreement with the department to pay the tax liability in installments over an extended period. The appropriate licensing board or agency will not process and will hold in abeyance the application for renewal of the license or registration of any taxpayer appearing on the list.

Public Chapter 906- adds authorization for a pharmacist or pharmacy intern to override the stop sale alert, after counseling with a person seeking to purchase the products as to the reasons for needing the product. When overriding the stop alert the pharmacist or pharmacy intern may sell to the individual products containing up to 2.4 additional grams of the products, during the same 30-day period referred to above; provided, however the total sale of products must not exceed 4.8 grams during such period. This limit applies whether one form of identification required under present law is used to make the purchase or two or more are used to purchase the products. The pharmacist or pharmacy intern will have an affirmative defense from any civil or criminal liability for directing the override of the stop sale alert. The pharmacist, pharmacy intern, or person directed to override the stop sale alert will have an affirmative defense from any civil or criminal liability for overriding the stop sale alert.

Public Chapter 623-authorizes a health care practitioner to prescribe an opioid antagonist in the following circumstances: (1) The practitioner is licensed to do so; (2) The practitioner is acting in good faith; and (3) The prescription is for a person at risk of experiencing an opiate-related overdose, or for a family member, friend, or a person who is in a position to assist a person at risk of experiencing an opiate-related overdose

Public Chapter 585- allows the commissioner of health to provide consultation to the department regarding drugs to be issued by the department or by a local health clinic

Mr. Jeremy Davis, Legislative Liaison for the Department of Health, informed the board of the following senate bills that affect the board.

Senate Bill 1630 -Allows healthcare providers to place a copy of a patient's CSMD profile in that patient's medical records and allows the Department of Health, the CSMD Committee, or other designees to release aggregate, de-identified information from the database to the public.

Senate Bill 1663-Limits who can prescribe and dispense medication, requires that a prescriber notifies their licensing board if they go to work for or leave employment at a pain clinic, manufacturer/wholesale/distributors to report to the pharmacy board unusual quantities of controlled substance requested, manufacturer/wholesale/distributors to report to the CSMD if they have had lost or stolen drugs. This bill goes into effect on January 1, 2015

Senate Bill 1832- This bill requires that prior to dispensing a prescription for any Schedule II-IV opioid, benzodiazepine, barbiturate, or carisoprodol for greater than a seven-day supply, a pharmacist, technician, intern, or clerk must require the person taking possession of the prescription to present a valid government issued ID containing that person's photograph unless that person is personally known to the individual working at the pharmacy. The pharmacy will be required to record the name, address, identification type, identification number, prescription number and initials or code of the individual working at the pharmacy. The information must be noted on the back of the original prescription, electronically, or through use of a log book or photocopied identification. This information must be retrievable within 24 hours. These requirements will apply to all authorized dispensers who dispense the above-described drugs for greater than a seven-day supply.

Senate Bill 1904 (Public Chapter 828) - adds that on learning of a data entry error in which a transaction was submitted to NPLeX when it should not have been, the pharmacy must submit a data entry error correction to NPLeX to remedy the error and prevent an inappropriate stop sale alert from being generated for a person who may seek to purchase an over-the-counter product containing pseudoephedrine or ephedrine. In instances where a data entry correction has been submitted to the NPLeX concerning a purchaser in accordance with this bill, the NPLeX must not generate a stop sale alert in cases where the quantity limit is exceeded due to the data entry error for which the correction was submitted.

Public Chapter 857-a pharmacy benefits manager may not place a drug on the maximum allowable cost list, unless the manager or covered entity finds that there are at least three generically equivalent versions of that drug available for purchase by all pharmacies in the state from national regional wholesalers and the drug is not obsolete or temporarily unavailable or listed on the drug shortage list.

Senate Bill 1992 (Public Chapter 832)- Collaborative Practice Act

Senate Bill 2547- Submission to the database must be made for each business day but no later than the close of business on the following business day instead of at least once every seven days. Also effective July 1, 2016, a pharmacy dispenser that uses a computerized system to record information concerning the dispensing of controlled substances listed in Schedule II, III, or IV, and Schedule V controlled substance identified by the controlled substance database advisory committee as demonstrating a potential for abuse, must submit the required information to the committee or its agent utilizing nationally recognized pharmacy telecommunications format standards.

Public Chapter 575- clarifies that a health care professional voluntarily providing health care services to a patient at a clinic that does not charge the patient or a third party receives the same immunity from liability as a health care professional providing services for a sponsoring organization that charges the patient based on a sliding income scale

Financial Report

Lisa Title gave the board the financial projections for fiscal year ending June 30, 2013. The projected current year net is a negative \$216,364.94. Ms. Title explained to the board that the even years is the low year in collected renewal fees so the fiscal year of 2014 will more than likely closed in a negative. The board does have cumulative carryover of \$1,009,854.63.

Appearance

Board rule 1140-04-.15

Carissa Lynch, Pharmacy Manager for Network Healthcare, appeared before the board requesting CareFusion Pyxis first dose system as their emergency kit. The CareFusion Pyxis will give pharmacists the ability to verify medications and program CUBIEs with medication data at the pharmacy. After discussion, Dr. Stephens made the motion to approve Network Healthcare's request to use the CareFusion Pyxis first dose system as their emergency kit. Dr. Eidson seconded the motion. The motion carried.

Opioid Treatment Program

Tennessee Department of Mental Health

Jason Carter, Chief Pharmacist, Tennessee Department of Mental Health and Substance Abuse Services, and serves as the State Opioid Treatment Authority for Tennessee(formerly Methadone Clinics Authority), appeared before the board to ask if State Opioid Treatment Authority can place a patient's methadone treatment in a Ziploc bag as take home doses. Dr. Carter stated that when a patient first starts coming to the methadone clinic they are required to come to the clinic every day for treatment. The longer the patient is in treatment that will be able to participate in a program of taking home one dose of medication a week. The first 90 days they are eligible to take home on dose per week the rest of the time they are required to come to the clinic to receive the medication. Once a patient has been in the program for 9 months they come to the clinic once a week and will get six take home doses per week. Dr. Carter stated that the clinics have been putting the medication in a Ziploc bag which is heat-sealed and then placed in a prescription bottle. The clinics would like to just send the medication out in the heat-sealed Ziploc baggies and not use the prescription bottles. Dr. Carter stated that the prescription bottles have a pharmacist name listed on them as dispensed by but the clinics do not employ pharmacist only license practical nurses. Dr. Stephens stated that he has asked on several occasions why a pharmacist was not on duty when they were dispensing the take home doses. Dr. Stephens stated that the clinics are dispensing under a physician's supervision. Dr. Carter stated that most location do not have physician onsite. Dr. Eidson asked if they have had a loss of medication in the facilities. Dr. Carter stated that they have had 2 loses that has been reported to the DEA before it was reported to him. Dr. Dilliard stated that the clinics are not required to report to the database per federal law and asked how are they evaluating if the patient are going to different doctors getting different medication. Dr. Stephens stated that they have no way of monitoring the treatment of the patient. Dr. Carter stated that the nurse is dispensing the medication to the patient and verify the medication. Dr. Carter stated that the nurse will print out

a label and mark how much the dose is and give the prescription bottle with the medication in it to the patient. Before a patient can receive the medication they have to present a lock box before they can receive their take home dose. Dr. Stephens stated that the issue is who is doing the dispensing and repackaging of the medication. Dr. Smothers asked who is assessing the patient and helping them to come off the medication. Dr. Dilliard stated that the questions before the board is, is the take home doses considered dispensing and can you use a Ziploc bag for dispensing and/or administering medication. Mr. Cange stated that under federal regulations that State Treatment Authority is able to set rules and regulations as far as the take home doses is concern. Dr. Eidson stated that the reason for Dr. Carter's appearance is using the use of Ziploc bags for dispensing of take home doses and asked if they have been in contact with the Consumer Product Safety Commission because the Ziploc bags are not child proof. Mr. Cange stated that the board has labeling requirements but not packaging requirements. Ms. McDaniel asked if the board is discussing dispensing medication in a Ziploc bag by a person that cannot dispense medication. Dr. Stephens stated that the nurse can administer the medication at the clinic, it is the dispensing of the take home doses that's the problem. Dr. Bunch asked if the board has any control over this process. Dr. Stephens stated that the board regulations all medication dispensed except for what is dispensed by the health department. Mr. Cange stated that the methadone clinics are regulated by the Tennessee Department of Mental Health and Substance Abuse Services. Dr. Dilliard suggested forming a task force with Dr. Mutter and Dr. Carter to deal with the issue drug overdose and the long term use of the drug. Dr. Stephens made a motion that the board form a task force with Dr. Mutter, Dr. Eidson, Dr. Carter and others as needed to come to a decision on how the this program will go forward and anything dispensed beyond a 3 day supply requires that it be dispensed in the presence and under the supervision of a licensed pharmacist. Mr. Cange stated that the board cannot make that decision because the clinic is regulated by Tennessee Department of Mental Health and Substance Abuse Services and the specific regulation take precedence over a general one. The board of pharmacy regulates the dispensing of medication but Mental Health regulates methadone clinics. After discussion, Dr. Eidson seconded the motion. The motion carried. Mr. Devin Wells, Assistant General Counsel volunteered to participate on the task force. Dr. Stephens made the motion to require the methadone clinics to have a licensed pharmacy. Ms. McDaniel asked if the board regulates the dispensing of methadone. Ms. Andrea Huddleston, Deputy General Counsel, stated that the board does not have the authority to regulate the dispensing of methadone in a methadone clinic. Ms. Huddleston stated that the methadone clinic is regulated by the federal government and mental health. Dr. Stephens withdrew his motion. Ms. McDaniel made the motion to deny the use of the Ziploc bag instead of the tamper resistant prescription bottle. Dr. Stephens seconded the motion. The motion carried. Dr. Stephens references T.C.A. § 63-10-202 "The practice of pharmacy within the state is declared to be a professional practice affecting public health, safety and welfare and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in § 63-10-204, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy". Mr. Cange stated that the board can issue an opinion on the dispensing of medication but they cannot force the issue to the methadone. Dr. Dilliard stated that the task force can share the board's opinion with the Department of Mental Health and Substance Abuse Services and try to find a solution.

Phoenix Long Term Care Medication Carts

Mark Steiz, representative of Phoenix LTC, appeared before the board requesting the use of their automated e-med box to be used as 1st dose and stat use only in a long term care facility. Dr. Stephens asked if it is a tackle box or a drug dispensary. Mr. Steiz stated that it is not a drug dispensary and won't be used as a med cart but as a 1st dose or stat use. Dr. Dickenson asked if he is asking for permission from the board to authorize the automated e-med box. Dr. Stephens stated that anyone that is using a machine like this in Tennessee has been licensed by the board as a pharmacy, eligible to be licensed by the DEA and must have a licensed pharmacist to stock the machine. If it is a tackle box it must be sealed at the pharmacy by a pharmacist. Mr. Cange explained that once an emergency kit is open the facility must contact the pharmacy to restock and reseal the emergency kit. Dr. Julie Frazier, Omnicare, asked the board if they are starting to allow a nurse to load the tackle box. She stated that in the past they board did not allow a nurse to load the machine. After discussion, Ms. McDaniel made the motion to defer a decision until the review of the purposed long term rules. Dr. Dickenson seconded the motion. The motion carried.

Kroger Pharmacy Call Center

Amber Kayse, R.Ph., representing Kroger Pharmacy Call Center, appeared before the board requesting approval to allow calls placed to Kroger pharmacies in Tennessee to be routed to their pharmacy call center in Ohio. The pharmacy call center is currently a pilot program with Kroger pharmacies located in Ohio. All patient calls are routed to the call center any calls from the prescriber will route to the pharmacy. The associates working in the call center are not licensed as pharmacist or pharmacy technicians. After discussion, Dr. Eidson made the motion to send correspondence stating what is required of Kroger Pharmacy to have a call center for Tennessee patients. Dr. Stephens seconded the motion. The motion carried.

Dr. Kayse is asking the board for approval of a remote prescription process where the pharmacist are doing pre-verification and DUR at the Center Excellence Center located in Hamilton, OH. Dr. Kayse is asking the board approve this center to a non-resident pharmacy. The pharmacists working in the center will be completing DUR and pre-verification for Kroger pharmacies in Tennessee. They will not perform pre-verification on controlled substances at this location. Dr. Dilliard stated what they are proposing is actually being done by another company but the pharmacists are licensed in Tennessee working for pharmacies in Tennessee and they don't go across state lines. After discussion, Dr. Dickenson made the motion to approve the process Center Excellence Center as long as they are licensed in Tennessee as a non-resident pharmacy and all the pharmacists and pharmacy technicians that work in the center are licensed in Tennessee. Ms. McDaniel seconded the motion. The motion carried.

Dr. Kayse is asking the board for approval of technology pilot (Hard Copy Storage) that will allow for the reduction of printing electronic prescribed hard copies as well as a new way of bundling written hard copies at the end of the day. Dr. Kayse stated that electronic transmitted prescription orders will not be printed but will be filed by date rather than numerically. Dr.

Dilliard stated that this process is already being done but the DEA has recommended that controlled substance prescription be printed and filed. Dr. Eidson referred the board to board rule 1140-03-.04 (2)(b) which states “a hard copy of exact image of the transmitted order shall be maintained in the pharmacy and shall be deemed the original prescription or medical order meeting all requirements of rule 1140-03-.03 of the rules of the board” and asked if the board is saying that electronic prescription meets the exact image of the prescription. Dr. Kayse stated that they keep the original order that is sent to them. Ms. McDaniel made the motion to approve their electronic method of storage with the recommendation that the controlled substance prescription which must be printed. Dr. Dickenson seconded the motion. The motion carried.

May 29, 2014

The Tennessee Board of Pharmacy reconvened on Thursday, May 29, 2014 in the Poplar Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members were present, the meeting was called to order at 8:04 a.m., by Dr. Kizer, president.

Reinstatement Susan Brooks, D.Ph.

Dr. Brooks requested to have her licensed reinstated. Dr. Brooks’ license was revoked on 05/15/2013. After discussion, Dr. Eidson made the motion to reinstate Dr. Brooks’ license. Dr. Brooks’ license will be on five (5) year probation once she has completed all the necessary requirements for reinstatement with the following conditions. Dr. Bunch seconded the motion. The motion carried.

- (a) The Respondent shall completely abstain from the consumption of alcohol or any other drugs, except as specified in;
- (b) 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 Dr. William Wadsworth. The Respondent shall immediately notify the Board office in writing of the name of the Respondent’s primary physician each time the Respondent changes primary physicians;
- (c) The Respondent shall not obtain or attempt to obtain any prescriptions in the Respondent’s name for any legend drugs, controlled substances or devices containing same from the physician other than the Respondent’s primary physician or from any other health care provider, such as a nurse practitioner, physician’s assistant or psychiatrist;
- (d) The Respondent shall destroy any unused controlled substances prescribed under the provisions of subsection (b) no later than thirty (30) days following the completion of the prescribed course of treatment;

- (e) The Respondent shall report to the Board, in writing, the ingestion of any and all legend drugs or controlled substances (a copy of the prescription will satisfy the requirement);
- (f) The Respondent shall submit to random sampling of urine, blood or bodily tissues for the presence of drugs and alcohol, at the Respondent's own expense, by agents of the Board, such as the Tennessee Pharmacist Recovery Network for as long as the Respondent has an active license. In the event that the sampling indicates the presence of drugs for which the Respondent does not have a valid prescription or the sampling indicates the presence of alcohol, then formal disciplinary charges may be brought against the Respondent which could result in the revocation of the Respondent's remaining term of probation or the suspension or revocation of the Respondent's license to engage in the practice of pharmacy. Prior to such disciplinary charges being heard by the Board, the Respondent's license may be summarily suspended;
- (g) The Respondent shall successfully complete the Multistate Pharmacy Jurisprudence Examination
- (h) The Respondent shall not serve as pharmacist-in-charge the respondent's pharmacist-in-charge shall submit to the Board quarterly reports detailing Respondent's work performance for a period of three (3) years from the state date of Probation; the Respondent may not work more than 40 hours over a 5 day period, however, the Respondent may petition the Board for a modification of this time limitation after (2) years from the start date of Probation;
- (i) Respondent shall not work as a "floater" for a period of three (3) years from the start of Probation, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without permission of the Board;
- (j) Respondent shall complete a period of pharmacy internship for a minimum of one hundred and sixty (160) hours and must be completed within ninety (90) consecutive days.

Sean Harrison, D.Ph.

Dr. Harrison requested to have his license reinstated. Dr. Harrison's license was revoked on April 3, 2013. After discussion, Ms. McDaniel made the motion to reinstate Dr. Harrison's license once he has completed the necessary requirements for reinstatement. Dr. Bunch seconded the motion. A roll call vote was taken. Dr. Bunch, Ms. McDaniel and Dr. Smothers voted yes. Dr. Eidson and Dr. Dickenson voted no. The motion carried.

Appearance

Robert Broyles, D.Ph.

Dr. Broyles answered yes to the questions that asked “Have you ever voluntarily surrendered your pharmacist license or any pharmacist registration issued by a federal or state controlled substance authority?”, “Has your pharmacist license in any jurisdiction ever been revoked, suspended, restricted, terminated or otherwise been subject to disciplinary action (public or private) by any board of pharmacy or other state authority?” and “Have you ever been charged or convicted (including nolo contendere plea or guilty plea) of a felony or misdemeanor (other than minor traffic offenses) whether or not sentence was imposed, suspended, expunged, or whether you were pardoned from any such offense?” Dr. Broyles’ North Carolina pharmacist license was restricted on 8/8/1992 because he was convicted twice for driving while intoxicated. On 3/17/1997, his North Carolina license was suspended because he violated the previous order by diverting controlled substances from the pharmacy for his own use. On 11/20/1997 his North Carolina license was reinstated. 10/15/1999, the North Carolina license was suspended until January 29, 2000 once that time period is up Dr. Broyles license was reinstated under the consent order. On 8/5/2008 Dr. Broyles voluntarily surrendered his license due to action that would cause the board to discipline his license. On 9/15/2009, he appeared before the NC BoP to request reinstatement, it was denied. He could not be asked for reinstatement again until after 7/1/2011. On 9/20/2011 Dr. Broyles license was reinstated with the following conditions: No PIC or own a pharmacy, can’t be preceptor and must maintain NCPRN. Dr. Broyles was convicted on 11/28/1998 DUI, 1/31/1991 DUI, 7/13/1999 DUI, 8/5/2002 DUI and 4/8/2009 embezzlement of controlled substances scheduled III. After discussion, Dr. Eidson made the motion to approve Dr. Broyles’ application for reciprocity once he has signed a contract with TPRN. Dr. Dickenson seconded the motion. The motion carried.

Karlton Fields, RT

Mr. Fields answered yes to the questions that asked “Have you ever been charged or convicted (including a nolo contendere plea or guilty plea) of a felony or misdemeanor (other than minor traffic offenses) whether or not sentence was imposed, suspended, expunged or whether you were pardoned from any such offense?” Documentation submitted indicates that Mr. Fields was given a nolle prosequi on January 24, 2013 for filing a false offense report; May 29, 2013 found guilty for crime/att-retaliation past action and received 11 months and 29 days suspended, and nolle prosequi for possession of controlled substance marijuana; he pled guilty of filing false offense report on January 9, 2013. After discussion, Ms. McDaniel made the motion to approve Ms. Field’s application for registration as a pharmacy technician. Dr. Bunch seconded the motion. The motion carried.

Betty Ayers, RT

Ms. Ayers answered no to the questions that asked “Have you ever been charged or convicted (including a nolo contendere plea or guilty plea) of a felony or misdemeanor (other than minor traffic offenses) whether or not sentence was imposed, suspended, expunged or whether you

were pardoned from any such offense?" Documentation submitted shows charges dismissed but Dr. Dilliard felt as though she need to appear before the board for approval. After discussion, Ms. McDaniel made the motion to approve Ms. Ayers' application for registration as a pharmacy technician. Dr. Dickenson seconded the motion. The motion carried.

Damitea Johnson, RT

Ms. Johnson answered yes to the question that asked "Are there any criminal charges pending against you in this state or any other state? Documentation submitted indicates that Ms. Johnson was charged with simple possession of scheduled VI, driving on revoked, suspended, expired license on December 12, 2013. She was found guilty and given judicial diversion for the simple possession of scheduled VI until December 10, 2014. . After discussion, Ms. McDaniel made the motion to approve Ms. Johnson's application for registration as a pharmacy technician. Dr. Dickenson seconded the motion. The motion carried.

Order of Compliance Michael Hornick, RT

Mr. Hornick appeared before the board to request that his probation be lifted. Mr. Hornick's pharmacy technician registration was placed on 3 year probation on March 15, 2011. After discussion, Dr. Eidson made the motion to lift the probation on Mr. Hornick's pharmacy technician registration. Dr. Dickenson seconded the motion. The motion carried.

Waivers

Board rule 1140-01-.13(3) (d)

Dr. Eidson made the motion to approve the request from **Complete Care Compounding** to waive the requirement that the pharmacy to be one hundred and eighty (180) square feet. Ms. McDaniel seconded the motion. The motion carried. They must notify the board if there are any changes to the business model.

Dr. Eidson made the motion to approve the request from **Neurology Clinic** to waive the requirement that the pharmacy to be one hundred and eighty (180) square feet. The pharmacy will be eighty (80) square feet. Dr. Bunch seconded the motion. The motion carried.

Board rule 1140-01-.13(3) (d) & (e)

Dr. Bunch made the motion to approve the request from **LeConte Medical Center (automated dispensing machine)** to waive the requirement that the pharmacy to be one hundred and eighty (180) square feet and the use of hot and cold running water. Dr. Eidson seconded the motion. The motion carried.

Ms. McDaniel made the motion to defer the request from **Bill Groce Animal Services, LLC** to waive the requirement that the pharmacy to be one hundred and eighty (180) square feet and the use of hot and cold running water until the pharmacist in charge and owner can appear before the board. Dr. Bunch seconded the motion. The motion carried.

Ms. McDaniel made the motion to approve the request from **Eastside Pharmacy** to waive the requirement that the pharmacy to be one hundred and eighty (180) square feet and the use of hot and cold running water. Dr. Bunch seconded the motion. A roll call vote was taken. Ms. McDaniel, Dr. Bunch and Dr. Smothers voted yes. Dr. Eidson and Dr. Dickenson voted no. The motion carried.

Board rule 1140-3-.14(12)

Dr. Eidson made the motion to approve the request from **Kevin McClung, D.Ph.**, to be pharmacist in charge at Dickson Medical Pharmacy and Complete Care Compounding. Ms. McDaniel seconded the motion. The motion carried.

Dr. Bunch made the motion to approve the request from **Charles Wall, D.Ph.**, to be pharmacist in charge at Advance Specialty Pharmacy and Heartland Infusion for six (6) months. Dr. Eidson seconded the motion. The motion carried.

Dr. Bunch made the motion to approve the request from **T. Melvin Mays, D.Ph.** to be pharmacist in charge at West Tennessee State Prison Site 1 & 2, Northwest Correctional Main and Annex, Turney Center Industrial Complex Main and Annex, Charles Bass Correctional, Riverbend Maximum Security, Deberry Special Needs Facility, Tennessee Prison for Women and TDOC Mark Luttrell Prison for Women. Dr. Dickenson seconded the motion. The motion carried.

Dr. Dickenson made the motion to approve the request from **Rick Gallaher, D.Ph.** to be pharmacist in charge at Signal Mountain Pharmacy, LLC and Signal Compounding Lab, LLC., for one (1) year. Dr. Eidson seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Dennis Woods, D.Ph.** to be pharmacist in charge at LeConte Medical Center and automated dispensing machine upon receipt of a letter from Dr. Woods stating that he is willing to be responsible for the automated dispensing machine. Dr. Bunch seconded the motion. The motion carried.

Dr. Bunch made the motion to approve the request from **Terry Brimer, D.Ph.** to be pharmacist in charge at Doctor's Hospital Pharmacy and Midtown Drug Company for one (1) year. Dr. Dickenson seconded the motion. The motion carried.

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

Dr. Bunch made the motion to approve the request from **Evelyn Allen Johnson, D.Ph.**, to waive the three hundred and twenty (320) internship hours and the NAPLEX but she must successfully take and pass the MPJE. Ms. McDaniel seconded the motion. The motion carried.

Dr. Bunch made the motion to approve the request from **Amber L. Bradford, D.Ph.**, to waive the three hundred and twenty (320) internship hours and the NAPLEX but she must successfully take and pass the MPJE. Dr. Bunch seconded the motion. The motion carried.

USP 797 Compliance

Dr. Eidson made the motion to approve the request from **Select Specialty Hospital, Memphis, TN** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Advance Homecare, Kingsport, TN** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Parkridge Health System, Chattanooga, TN** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Wayne Medical Center Pharmacy** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Erlanger Health System East** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Fort Loudoun Medical Center, Lenoir City, TN** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Claiborne County Hospital and Nursing Home** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Cookeville Regional Medical Center**, to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Marshall Medical Center** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Oak Ridge Health Center Pharmacy** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Holston Valley Medical Center** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Lebanon HMA, LLC dba University Medical Center** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Bradley Extended Care, Inc.** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Coram Alternate Site Services, Inc.** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **TriStar Stonecrest Medical Center** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Saint Thomas West Hospital** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Methodist Medical Center, Oak Ridge, TN** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Livingston Regional Hospital** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Horizon Medical Center Pharmacy** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Sycamore Shoals Hospital, Elizabethton, TN** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Summit Medical Center** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **TriStar Centennial Medical Center Pharmacy** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Fort Sanders Regional Medical Center** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Morristown Hamblen Medical Center** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Cumberland County Medical Center** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Parkwest Medical Center** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Claiborne County Hospital** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Nashville General Hospital at Meharry** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Grandview Medical Center** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Perry Community Hospital** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Houston County Community Hospital** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **TriStar Skyline Medical Center** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Holston Valley Medical Center** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Precision Healthcare** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **DCA Pharmacy** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Lowe's Drug, Inc.** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Cocke County HMA dba Tennova, Newport, TN** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Metro Knoxville HMA dba Tennova, Knoxville, TN** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Medical Center of Manchester** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Regional One Health Newborn Center Pharmacy** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Saint Frances Hospital, Memphis, TN** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Care Solutions, Inc.** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Baptist Memorial Hospital, Collierville, TN** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Ampharm, Inc.** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Network Healthcare** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Cardinal Health 414, LLC** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Erlanger Health Systems** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Tulahoma HMA, LLC dba Harton Regional Medical Center** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Baptist Memorial Hospital, Memphis, TN** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Infusion Partners, Memphis, TN** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Sweetwater Hospital Association Pharmacy** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Metro Knoxville HMA dba Tenny, Turkey Creek** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Erlanger Baroness Campus** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Dr. Eidson made the motion to approve the request from **Metro Knoxville HMA, Powell, TN** to grant a 180 day waiver to become compliant with UPS 797. Ms. McDaniel seconded the motion. The motion carried.

Ms. McDaniel made the motion to rescind the approval request from **John Hollis Pharmacy** for a 180 day waiver to become compliant with UPS 797. Dr. Bunch seconded the motion. The motion carried.

Order Modification

Kevin Lyles

Dr. Lyles appeared before the board to request that he be allowed to be PIC. Dr. Lyles signed a consent order on 06/07/2013 placing his pharmacist license on 5 year probation and he would not be allowed to be PIC for the 3 years of probation. After discussion, Dr. Eidson made the motion to amend Dr. Lyles's consent order and allow him to be PIC at Prohealth Rural Healthservices in Franklin, TN. Dr. Dickenson seconded the motion. The motion carried.

Appearance

Lakoya Williams, RT

Ms. Williams answered no the question that asked "Have you ever been convicted of a misdemeanor (except minor traffic offenses) including alcohol or drug related offenses (including marijuana or hallucinogens)" Documentation submitted indicates that Ms. Williams pled guilty to assault, domestic fear of bodily injury on November 21, 2002 and received 11 months and 29 days probation. After discussion, Ms. McDaniel made the motion to approve Ms. Williams' application for registration as a pharmacy technician. Dr. Bunch seconded the motion. The motion carried.

Director's Report

Dr. Dilliard asked the board to approve travel to the Tennessee Pharmacy Association 127th Annual Convention in Hilton Head, SC on July 21-24, 2014 for pharmacy investigators, the executive director and any board member that want to attend. Ms. McDaniel made the motion to approve travel for ten (10) persons (pharmacy investigators, executive director and board members) to attend the Tennessee Pharmacist Association Annual Convention in Hilton Head, SC, July 21-24, 2014. Dr. Bunch seconded the motion. The motion carried.

Dr. Dilliard asked the board to approve travel to the NABP/AACP District III meeting in Charleston, SC on August 2-5, 2014. Ms. McDaniel made the motion to approve travel for any

board member and the executive director to attend the NABP/AACP District III meeting in Charleston, SC, August 2-5, 2014. Dr. Bunch seconded the motion. The motion carried.

Dr. Dilliard presented a request from Odilia Ayanama, D.Ph. requesting permission to take the NAPLEX. Dr. Ayanama has taken and failed the NAPLEX seven (7) times. After discussion, Dr. Eidson made the motion to deny Dr. Ayanama request to retake the NAPLEX. Dr. Dickenson seconded the motion. The motion carried.

Consent Orders

Dr. Eidson made the motion to accept the following consent orders. Ms. McDaniel seconded the motion. The motion carried.

VIOLATED BOARD RULE 1140-3-.01(1) (a) & (f)
William Hobbs, D.Ph. -\$1000.00 civil penalty
Super Discount Drugs, LLC, lic #417-\$1000.00 civil penalty
Four Way Prescription Shop, Inc.-\$1000.00 civil penalty
Ben C. Lott, D.Ph.-\$1000.00 civil penalty
Ryan Long, D.Ph.-\$1000.00 civil penalty
Rite Aid Pharmacy, #1309-\$1000.00 civil penalty

VIOLATED BOARD RULE 1140-9-01(2)
Protech Medical, LLC-\$4700.00 civil penalty
Riverside Medical, Inc.-\$300.00 civil penalty
Larco Medical, Inc.-\$300.00 civil penalty
Lincare, Inc.-\$300.00 civil penalty

VIOLATED BOARD RULE 1140-02-.02(1)
Andrea Cluck, RT-\$100.00 civil penalty
Leonard Lubin, RT-\$100.00 civil penalty
Shawna Hicks, RT-\$100.00 civil penalty
Sandra Elrod, RT-\$100.00 civil penalty
Chasity Bingham, RT-\$100.00 civil penalty
Jamie Carey, RT-\$100.00 civil penalty
Jessica Hayes, RT-\$100.00 civil penalty
Barbara Blackmore, RT-\$100.00 civil penalty
William Gray, RT-\$100.00 civil penalty
Vickie Wiggins, RT-\$100.00 civil penalty
Tonya Middleton, RT-\$100.00 civil penalty

REVOCATION
Kendria Johnson, RT
Shanelle Sutton, RT
Derek Leach, RT

Tyler Zazzi, RT

VIOLATED BOARD RULE 1140-2-.02(1) & (2)
Debbie Pancake, D.Ph.-\$1400.00 civil penalty
Larry C. Worley, D.Ph.-\$3100.00 civil penalty
Donald W. Sullivan, D.Ph.-\$2500.00 civil penalty
David E. Berry, D.Ph.-\$3500.00 civil penalty
Bradley Cross, D.Ph.-\$300.00 civil penalty
Paige Overton, D.Ph.-\$1400.00 civil penalty
Franklin Crigger, D.Ph.-\$7400.00 civil penalty
Jeffrey Pettis, D.Ph.-\$2300.00 civil penalty
Amy Barton, D.Ph.-\$1000.00 civil penalty
Lowell Grizzle, D.Ph.-\$2700.00 civil penalty
Lowell Grizzle, D.Ph.-\$1000.00 civil penalty
Shannon Toland, D.Ph.- \$300.00 civil penalty
Amy Dudney, D.Ph.-\$1100.00 civil penalty
Everett Whitson, D.Ph. -\$1000.00 civil penalty
Amy Fasbinder, D.Ph.-\$300.00 civil penalty
Kevin Evetts, D.Ph.-\$7000.00 civil penalty

VIOLATED BOARD RULE 1140-03-.03(6)(a)
William David Kearney, D.Ph.

VIOLATED BOARD RULE 1140-01-.09(1)
Gary Worley, D.Ph.-\$2000.00 civil penalty
Larry Worley, D.Ph.-\$2000.00 civil penalty
Gary Thomas, D.Ph.-\$1000.00 civil penalty

VIOLATED BOARD RULE 1140-03-.03(6) (a)
Vaughn Pharmacy-\$6000.00 civil penalty

VIOLATED BOARD RULE 1140-9-.01(1)
Phoenix Meds, Inc.-\$1000.00 civil penalty

Mr. Cange presented the consent order for Cindy Page, RT to the board. Ms. Page violated board rule 1140-2-.02(1) and was assessed a \$100.00 civil penalty. Ms. Page submitted the \$100.00 civil penalty but asked the board rescind the civil penalty due to financial hardship. After discussion, Ms. McDaniel made the motion deny Ms. Page's request and approve the consent order with the civil penalty paid. Dr. Dickenson seconded the motion. The motion carried.

Reinstatement

Jessie Thompson, D.Ph.

Dr. Thompson appeared before the board and was represented by Ben Mezer, Attorney. Dr. Thompson was sent a consent order asking him to surrender his pharmacist license due to impairment. Dr. Thompson admits that he received the consent order asking him to surrender his license but he didn't sign it and instead self-reported to Cornerstone on the advice of Mr. Mezer. After discussion, Dr. Eidson made the motion to place Dr. Thompson license on five (5) year probation once he has completed all the necessary requirements for reinstatement with the following conditions. Ms. McDaniel seconded the motion. The motion carried.

- (a) The Respondent shall completely abstain from the consumption of alcohol or any other drugs, except as specified in;
- (b) The Respondent shall be able to consume legend drugs or controlled substances prescribed by the Respondent's primary physician, except in the case of an emergency or upon proper referral from the Respondent's primary physician Dr. Robert Beck. The Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary physician each time the Respondent changes primary physicians;
- (c) The Respondent shall not obtain or attempt to obtain any prescriptions in the Respondent's name for any legend drugs, controlled substances or devices containing same from the physician other than the Respondent's primary physician or from any other health care provider, such as a nurse practitioner, physician's assistant or psychiatrist;
- (d) The Respondent shall destroy any unused controlled substances prescribed under the provisions of subsection (b) no later than thirty (30) days following the completion of the prescribed course of treatment;
- (e) The Respondent shall report to the Board, in writing, the ingestion of any and all legend drugs or controlled substances (a copy of the prescription will satisfy the requirement);
- (f) The Respondent shall submit to random sampling of urine, blood or bodily tissues for the presence of drugs and alcohol, at the Respondent's own expense, by agents of the Board, such as the Tennessee Pharmacist Recovery Network for as long as the Respondent has an active license. In the event that the sampling indicates the presence of drugs for which the Respondent does not have a valid prescription or the sampling indicates the presence of alcohol, then formal disciplinary charges may be brought against the Respondent which could result in the revocation of the Respondent's remaining term of probation or the suspension or revocation of the Respondent's license to engage in the practice of pharmacy. Prior to such disciplinary charges being heard by the Board, the Respondent's license may be summarily suspended;

- (g) The Respondent shall successfully complete the Multistate Pharmacy Jurisprudence Examination
- (h) The Respondent shall not serve as pharmacist-in-charge the respondent's pharmacist-in-charge shall submit to the Board quarterly reports detailing Respondent's work performance for a period of three (3) years from the state date of Probation; the Respondent may not work more than 40 hours over a 5 day period, however, the Respondent may petition the Board for a modification of this time limitation after (2) years from the start date of Probation;
- (i) Respondent shall not work as a "floater" for a period of three (3) years from the start of Probation, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without permission of the Board;
- (j) Respondent shall complete a period of pharmacy internship for a minimum of one hundred and sixty (160) hours and must be completed within ninety (90) consecutive days.

The meeting adjourned at 2:50 p.m.

These minutes were approved and ratified as amended at the July 30-31, 2014 board meeting.