TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Iris Room
Nashville, TN
April 12, 2017

**BOARD MEMBERS PRESENT**
Kevin Eidson, D.Ph., President
Michael Dickenson, D.Ph. Vice President
Katy Wright, D.Ph.
Debra Wilson, D.Ph.
Will Bunch, D.Ph.
Lisa Tittle, Consumer Member

**STAFF PRESENT**
Reginald Dilliard, Executive Director
Matthew Gibbs, Assistant General Counsel
Terry Grinder, Pharmacy Investigator
Andrea Miller, Pharmacy Investigator
Sheila Bush, Administrative Director

**BOARD MEMBER ABSENT**
Rissa Pryse, D. Ph

**STAFF ABSENT**
Richard Hadden, Pharmacy Investigator
Robert Shutt, Pharmacy Investigator
Rebecca Moak, Pharmacy Investigator
Scott Denaburg, Pharmacy Investigator
Albert Hill, Pharmacy Investigator
Tommy Chrisp, Pharmacy Investigator

The Tennessee Board of Pharmacy convened on Tuesday, April 12 2017, in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members being present, the meeting was called to order at 1:05 p.m.

**Contested Cases**
**Deonna Lowery, RT**

Ms. Lowery was not present nor represented by legal counsel. Mr. Gibbs represented the State. Mr. Michael Begley was the Administrative Law Judge. Mr. Gibbs asked to proceed in default. The board granted the motion to proceed in default. Mr. Gibbs passed out the Notice of Charges. Ms. Lowery is charged with violating T.C.A § 63-10-402(a) (g), T.C.A.§ A 63. 10-305 (4), T.C. A § 63-10-305 (6) and T.C.A.§ 63-10-305 (3) Dr. Bunch made the motion to revoke Ms. Lowery's registration as a pharmacy technician and case cost. Dr. Wilson seconded the motion. A roll call vote was taken. The motion carried. Dr. Wilson made the motion that the action taken was to protect, promote and improve the health and prosperity of people in Tennessee. Dr. Dickenson seconded the motion. The motion carried.

## Consent Order

Dr. Wilson made the motion to accept the consent orders and agreed orders as presented. Dr. Dickenson seconded the motion. The motion carried.

VOLUNTARY SURRENDER (same as revocation)
Benjamin Todd Bradford, D.Ph.
Sarah Kathleen Wallace, D.Ph.
Thomas Radford Richardson, D.Ph.
Dallas Trent Hoffman, D.Ph.
Thomas J. O'Donnell, D.Ph.
Corey Bradley, D.Ph.
Lori Beth Murphy, RT

REPRIMAND
Joseph Victor Barone, D.Ph.

REINSTATEMENT
Amanda Clark, D.Ph.

VIOLATED BOARD RULE 1140-2-.02(1)
Amy Perez, RT-$100.00 civil penalty
Charlie Griffy, D.Ph.-$600.00 civil
Linda Conatser, D.Ph. -$600.00 civil

**Rules**
Mr. Dilliard presented a draft of the contraceptive rules for review and asked the board to authorize a rulemaking hearing.

## PURPOSE

A pharmacist, in good faith, is authorized to provide hormonal contraceptives according to a valid collaborative pharmacy practice agreement containing a non-patient-specific prescriptive order and standardized procedures developed and executed by one (1) or more authorized prescribers.

## DEFINITIONS

- Hormonal contraceptive - a self-administered drug, or a transdermal patch applied to the skin of a patient, by the patient or by a practitioner, which releases a drug composed of a combination of hormones that are approved by the United States Food and Drug Administration ("FDA") to prevent pregnancy.

- Total cost - providing the consumer with specific information regarding the price of the hormonal contraceptive and the price of the administrative fee charged

- Pharmacist's agent – (??)

## TRAINING - Must be approved by DOH

- A pharmacist shall complete educational training related to the prescribing of hormonal contraceptives by a pharmacist prior to providing contraceptive therapies to patients through a collaborative pharmacy practice agreement.

- The educational training shall be provided by an Accreditation Council for Pharmacy Education (ACPE) -approved provider.

- The pharmacist shall submit a copy of the certificate of completion of the educational training to the Board within 15 days of completion.

- Pharmacist shall permanently maintain the certificate of completion and make the certificate available upon request.

## DELIVERY OF CARE

**AGE**
- A pharmacist may provide hormonal contraceptives to individuals who are:

(1) Eighteen (18) years of age or older; Or

(2) Under eighteen (18) years of age, if the individual is an emancipated minor as defined in T.C.A. § 39-11-106.

## PROCEDURAL MANDATES

- For each new patient requesting a hormonal contraceptive, and, at a minimum of every twelve months for each returning patient, the prescribing pharmacist shall:

(1) Ask the patient to use and complete the approved self-screening risk assessment tool

(2) Review the self-screening risk assessments answers and clarify responses with the patient as needed before providing any hormonal contraceptive

(3) Provide, as soon as practical if the pharmacist determines the patient should receive the medication, hormonal contraceptives to the individual or refer the patient to a pharmacy that may dispense the hormonal contraceptive

(4) The pharmacist shall counsel the patient on matters contained in 1140-03-.01(1)(e)(1-8) (patient counseling rule)

(5) The pharmacist shall provide the patient with the FDA-required patient product information document that is included with the hormonal contraceptive and a standardized factsheet which includes, but is not limited to, the indications and contraindications for the use of the drug, the appropriate method for using the drug, the importance of a medical follow-up, and other appropriate information

(6) Advise the patient to consult with the patient's primary care practitioner or women's health practitioner

(7) At the time the contraceptive is dispensed, a pharmacist shall provide the patient with a list of local primary care practitioners or local women's health practitioners

- If a pharmacist cannot provide the patient with a local list of providers at the time the contraceptive is dispensed, the pharmacist shall provide this information within seventy-two (72) hours after the contraceptive is dispensed

## PROHIBITED PRACTICES

- A pharmacist shall not:

(1) Require the patient to schedule an appointment with the pharmacist for the provision or dispensing of hormonal contraceptives

## RECORDS

- A pharmacist must document the encounter and the prescription, and maintain records of drug dispensing

- A pharmacy shall maintain records of the encounter, including, but not limited to the completed self-screening risk assessment tool, for a minimum of five (5) years and maintain records of the medication dispensed for a minimum of three years

## FEES

- A pharmacist, pharmacist's employer, or pharmacist's agent may charge an annual administrative fee for services provided pursuant to this section in addition to any costs associated with the dispensing of the drug and paid by the pharmacy benefit.

- Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total cost that a consumer would pay for pharmacist-provided hormonal contraceptives.

- Total cost is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health

> insurance plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of hormonal contraceptives shall not be required to pay an administrative fee. These patients shall be required to pay co-payments pursuant to the terms and conditions of their coverage.

Dr. Eidson asked what is a pharmacy agent? Mr. Gibbs stated that it is listed in the statute under Section 1(f)(1) which states "A pharmacist, pharmacist employer or pharmacist agent may charge an annual administrative fee for services provided pursuant to this section in addition to any cost associated with the dispensing of the drug and paid by the pharmacy benefit". Mr. Gibbs stated that he was hoping that the board could tell him what it meant since it is not listed in any statute or rule that pertains to the board of pharmacy. Dr. Dilliard stated that some pharmacies have a individual not licensed to do their billing and they could be considered the agent.

Dr. Eidson asked why the Department of Health will be approving the training and not the board of pharmacy. Mr. Gibbs stated that that is the way it is written in the statute Section 1 (d) (1) which states "Complete a training program approved by the Department of Health related to the provision of hormonal contraceptives". Ms. Tittle stated she did not see in the statute where the department could appoint a designee so it would have to be the Department of Health. Dr. Dilliard stated that since this is a collaborative effort by several boards that it may be an overall approval. Dr. Eidson asked who in the division would formulate the training program. Dr. Dilliard stated that the program has already been developed and he will send it to the board. Dr. Eidson asked about minimum standards? Dr. Dilliard stated he didn't know if the board wanted anything in the rules since programs and training may change. Dr. Eidson stated that he doesn't know how you would define the standard without it being in the rules.

Dr. Eidson asked if the approved self-screening risk assessment tool has been developed. Dr. Dilliard stated that it has been approved by the committee and is being developed as a work product. Mr. Gibbs stated that the self-screening risk assessment tool will be approved by the Department of Health per statute.

Dr. Wright asked if this rule "A pharmacist shall complete educational training related to the prescribing of hormonal contraceptives by a pharmacist prior to providing contraceptive therapies to patients through a collaborative pharmacy practice agreement", will require a pharmacist to train other pharmacist on prescribing hormonal contraceptives. Mr. Gibbs stated that the training should be geared toward pharmacist dispensing and administering hormonal contraceptives and he will change the language to where it reads better.

Dr. Eidson asked about the list of primary care practitioner or local women's health practitioners that a pharmacist is to provide to the patient at the time that the contraceptive is dispensed. He stated that the best source of this type of information should come from the Board of Medical Examiners and/or the Board of Osteopathic Examiners and not the pharmacist or pharmacies. Dr. Dilliard stated that there was concerned about the patients being steered to a certain practitioner

and thought a list would provide a better options on where they can receive care. Dr. Eidson asked if there was any liability to the pharmacist if they provide the list and something goes wrong. Mr. Gibbs stated that there is a provision in the statutes that provides immunity to the pharmacist and the prescriber Mr. Gibbs also stated that the under the statute Section (2) (5) states "Provide the patient with the contact information of a primary care practitioner or women's healthcare practitioner within a reasonable period of time after provision of the hormonal contraceptive". Dr. Wright asked if there is a penalty to the pharmacist if the list is not updated and a new practitioner is not included on the list. Dr. Dilliard stated that this question did not come up in the committee meeting but it is something that could be added to the training stating that pharmacies should try to keep an updated list of primary care practitioners and/or women's healthcare practitioner. Ms. Tittle asked why not just limited the list to the county health departments. Dr. Dilliard stated that the committee felt that just using the county health department was not a complete list of providers. Mr. Gibbs asked if the board wanted to add the county health departments to the list as well. The board decided that the county health department should be added to the list

Dr. Eidson asked about the rule that states "- For each new patient requesting a hormonal contraceptive, and, at a minimum of every twelve months for each returning patient, the prescribing pharmacist shall (3) Provide, as soon as practical if the pharmacist determines the patient should receive the medication, hormonal contraceptives to the individual or refer the patient to a pharmacy that may dispense the hormonal contraceptive". Dr. Eidson asked who the rule applies to if the pharmacist is not working under this agreement. Dr. Dilliard stated that it could be that a pharmacy could set up a practice and go through the assessment process and send the patient to a different pharmacy, because that pharmacy would not be dispensing.

Dr. Eidson asked if the pharmacist or pharmacy should maintain records. Mr. Gibbs stated that he believes that the pharmacy should maintain the records since a pharmacist could potentially leave. Dr. Dilliard stated that if the pharmacist working in a clinic and dispensing the contraceptive, they will need to keep the records. Dr. Eidson asked about the prescription records being kept in a pharmacy for two (2) years but the risk assessment tool being kept for a minimum of five (5) years. Mr. Gibbs stated that the risk assessment is the vital piece of this rule. Dr. Wright asked if the risk assessment rule could be separate for the rule that pharmacy maintain prescription records for two (2) years. Mr. Gibbs stated that he will change it. Dr. Wright asked if the record keeping should be keep along the same lines as the collaborative practice agreement rules. Mr. Gibbs state that the hormonal contraceptive collaborative is non-patient specific and it the collaborative practice agreement rule does not apply.

After discussion, Dr. Bunch made the motion to give Dr. Wright the authority to work with Mr. Gibbs to finalize these rules. Dr. Dickenson seconded the motion. The motion carried. Once Dr. Wright has given final approval of these rules, Mr. Gibbs will schedule a rulemaking hearing. The motion carried.

**Disciplinary Guidelines**

Dr. Dilliard passed out a draft of disciplinary guidelines to the board. Dr. Dilliard stated that this is based on last year audit and we need to have adopted as policy. After discussion Dr. Bunch made the motion to accept the policy statement as amended. Dr. Wright seconded the motion. The motion carried. The policy statement will be placed on the board's website.

**General Discussion**
**Automated Dispensing Machines**

Dr. Dilliard passed out copies of the rule where he feels as though there is still a conflict and still need clarification. Dr. Dilliard stated that the definition of automated dispensing system refers to the machine and it seems to be the standard. In part of the rules the word "systems" refer to a group of machines as well. Dr. Dilliard stated that he believes that this is where the problem begins with who should be registered and pay the fee. He stated that he and Mr. Gibbs thought to use the word network could be used if facilities have multiple machines. Dr. Dilliard asked the board to clarify what is a system and he thought that the system was the machine. Dr. Eidson asked if there was anyone in the audience who would like to speak on this issued. Dr. Mark Sullivan, pharmacist at Vanderbilt Medical Center, stated that he looks at them as an institution system. He stated that his wish would be for the hospital pharmacy to register one machine and maintain a list of the other machines. Dr. Bunch asked Dr. Grinder to explain the process of how they inspection the machines. Dr. Grinder stated that when they inspect a hospital pharmacy they will inspect the pharmacy itself not the machines because the machines are not licensed and they don't know where all the machines are located in a hospital. In a long-term care facility the investigator inspect the room where the machine is located because it is licensed as a pharmacy. The rule change was to stop the waiver request for space and hot and cold running water since it is just a room the is actual registered as a pharmacy not the machine. Dr. Eidson asked do they ever run into problems inspecting the machines. Dr. Grinder stated that the only problem that the investigator have it locating the paperwork. Dr. Dilliard stated that he has spoken to several people that were on the committee to write the rules and that the intent was that all the machines would be register but not as pharmacies. The machines would all be under the central fill pharmacies authority. Dr. Julie Frazier stated that the intent was to be recognized as like hospital and that the machine would be registered at each facility and the paperwork would be maintain at the pharmacy own the machines. Dr. Wright asked for clarify the hospital with different locations. Dr. Dilliard stated that if they have separate physical address each address will need to register. Dr. Dilliard ask for a definition for system. Dr. Wilson define the machine is a system and a system may have multiple machines but we are registering the location.

After discussion, Dr. Wilson made a motion to rescind the prior motions made by the board in reference to the automated dispensing machines, correct the system definition to state that the system refers to the machine and a location may have multiple machines but register as one system, and add a policy statement to the board's website site stating that each system will be registered as a location. Dr. Dickenson stated the he would like to use the word device instead of

system have the definition states that the system is a series of interconnected devices within a confined address. Dr. Wilson amended her motion to accept Dr. Dickenson definition. Dr. Wright seconded the motion. The motion carried. Dr. Wright asked about board rule 1140-04-.15 (7) 1 (ii) (iv) All drugs to be stocked in the automated dispensing system shall be delivered to the off-campus site by the institutional pharmacy. She asked if the wording could be change stating that a carrier could be used to delivery. Dr. Dilliard stated that intent was that pharmacist and/or a pharmacy technician deliver the drugs. Dr. Eidson stated that he thought it meant the the pharmacy was responsible for the drugs but not the pharmacist or an employee of the pharmacy would have to deliver the drugs. Dr. Wilson stated that she read it as the pharmacist had to deliver the drugs. Dr. Wright stated the some intuition use a delivery services and the drugs are dropped shipped by the wholesaler and that officer of the facility would load the machine. Dr. Dilliard stated he is comfortable with the pharmacy using a carrier service but not the drop-shipping by the wholesaler. Dr. Dilliard asked the board to reconsider the items in emergency kits because the patient use in long-term care has changed. Dr. Frazier stated that long-term facilities are no longer used for acute care but for rehabilitation purposes. Most facilities are using are using automated dispensing machines instead of emergency kits to provide better patient care. Dr. Frazier asked that the limit supply of controlled substances in an emergency kit used as an automated dispensing machine be lifted and that the pharmacist in charge will be responsible for the recordkeeping record. After discussion, Dr. Wilson made the motion to issue a policy statement that at each facility the pharmacist in charge and manager of the facility will make the determination on the limits of controlled substance to be added to an automated dispensing machine used a an emergency kit. Dr. Wright seconded the motion. The motion carried.

Dr. Dilliard presented a request from Dr. Pat Rowan to be PIC for six weeks at ETSU charitable pharmacy during the summer. The board has previously granted this request. After discussion, Dr. Wilson made the motion to allow Dr. Rowan to be the PIC for six weeks at ETSU charitable pharmacy Dr. Dickenson seconded the motion. The motion carried.

Dr. Bunch made the motion to adjourn. Dr. Wilson seconded the motion. The motion carried.

**The minutes were approved and ratified at the June 13, 2017 board meeting**.