

Tennessee Board of Pharmacy
Board Meeting
September 12-13, 2017

TENNESSEE BOARD OF PHARMACY
665 Mainstream Drive, Iris Room
Nashville, TN
September 12-13, 2017

BOARD MEMBER PRESENT

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

STAFF PRESENT

Reginald Dilliard, Executive Director
Matthew Gibbs, Associate General Counsel
Terry Grinder, Pharmacy Investigator
Richard Hadden, Pharmacy Investigator
Scott Denaburg, Pharmacy Investigator
Rebecca Moak, Pharmacy Investigator
Robert Shutt, Pharmacy Investigator
Andrea Miller, Pharmacy Investigator

BOARD MEMBER ABSENT

Debra Wilson, D.Ph.

The Tennessee Board of Pharmacy convened on Tuesday, September 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 9:00 a.m. Dr. Eidson welcomed Dr. Rodgers as the new board member.

Minutes

The minutes from the July 13, 2017 board meeting were presented. After discussion, Dr. Pryse made the motion to approve the minutes as amended. Ms. Tittle seconded the motion. The motion carried.

OGC Report

Mr. Gibbs informed the board that there are 49 cases in the Office of General Counsel with 18 of those cases being contested. Mr. Gibbs also informed the board that the rules for hormonal contraceptives are in the Commissioner's Office for review.

Complaint Summary

Case 1.

Complainant (prescriber DVM) alleged respondent pharmacy asked for an NPI number, which the prescriber does not have. Then, the pharmacy asked for the prescriber's DEA number even though the prescription was not a controlled substance.

BOP Investigator interviewed PIC and pharmacy staff members who said the prescriber was not in the pharmacy's computer system. The pharmacy's normal procedure is to obtain as much information as possible when entering a new prescriber's information. The prescriber became angry and would not give any information so the prescription was not filled.

Recommend: Dismiss

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

Case 2.

BOP office was notified 11/23/16 of a PIC change effective 11/8/16. However, the PIC being replaced had departed 10/30/16. So the pharmacy did not have a PIC for a 9 day period.

Recommend: LOW for 1140-01-.08 (a) (8) and 1140-03-.14 (2) (a).

Dr. Pryse made the motion to accept counsel's recommendation. Dr. Dickenson seconded the motion. After further discussion, Dr. Pryse amended the motion to authorize a formal hearing with a \$50.00 civil penalty for the pharmacy not have a licensed PIC for 9 days. Dr. Dickenson seconded the amended motion. The motion passed.

Case 3.

Respondent failed a pre-employment drug screening by testing positive for oxycodone but was unable to provide a valid medical reason. BOP Investigator has been unsuccessful in contacting the respondent or obtaining a response.

Recommend: Revoke

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

Case 4.

Complainant alleged that on 6/10/17, respondent pharmacy reported to CSMD a duplicate dispensing of 90 Clonazepam 1mg. BOP Investigator visited the pharmacy and reviewed prescriptions, CSMD reports and patient printout. There was no evidence the pharmacy filled twice or reported twice to CSMD.

Recommend: Dismiss

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

Case 5.

Respondent technician admitted in writing to stealing controlled substances.

Recommend: Revoke tech registration

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

Case 6.

Complainant PIC informed BOP Investigator that respondent technician had been forging and filling prescriptions, including controlled substances, for personal use. PIC provided a letter in which the prescriber denied authorizing any prescriptions for the respondent. PIC stated that prescriptions which were documented as transfers from another pharmacy were denied by the transferring pharmacy. Policies prohibiting employees from filling their own prescriptions were not followed and it appears that at least some of the prescriptions were filled and dispensed without pharmacist involvement or verification.

Recommend: Revoke tech registration

Dr. Pryse made the motion to authorize a formal hearing for revocation. Ms. Tittle seconded the motion. The motion carried.

Case 7.

Respondent technician admitted in writing to stealing Alprazolam for personal use.

Recommend: Revoke tech registration

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

Case 8.

BOP performed a joint inspection with DEA due to high quantities of controlled substances being dispensed by respondent pharmacy. Only minor recordkeeping violations were found and education was provided. An audit revealed only a minor variance on two medications. Respondent pharmacy shares a building with a registered pain clinic which has 5 medical doctors and 14 mid-level prescribers. Pharmacy averages 100 prescriptions per day with 60 to 80 percent being controlled substances. Pharmacy only accepts prescriptions from and patients of the pain clinic. CSMD is being utilized correctly. Prescriptions are refused if they are early. Prescriptions are reviewed for red flags and refused or documented appropriately. Pharmacy staff members are in frequent contact with prescribers' staff regarding questions or concerns and those are documented. Pharmacists help coordinate patients' medicine days supply with their next appointment to alleviate patients running out of medicine before their next appointment.

Investigator provided education on site for recordkeeping and DEA requested a written plan of correction instead of discipline.

Recommend: Dismiss

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

Case 9.

Respondent technician admitted in writing to stealing medications. Respondent was terminated and a police report was filed.

Recommend: Revoke tech registration

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

Case 10.

Complaint alleged unprofessional conduct after the patient presented a prescription for Percocet 5/325 on 6/19/17. Patient was told there was no managing pharmacist on site to order C2 medication until September because the PIC who had been there was now working at a different location and no supplies could be ordered until then. Complainant felt disrespected and thought staff should have told her the truth if they simply did not want to fill her prescription.

BOP Investigator did confirm a gap of PIC coverage. The outgoing PIC left 6/4/17 and the incoming PIC started 7/2/17. Investigator also confirmed there were ordering issues for C2's during that time period, however, this particular drug was in-stock the day the complainant attempted to fill the prescription.

Recommend: LOW to pharmacy for no PIC. LOI for unprofessional?

Dr. Dickenson made the motion to authorize a formal hearing with a \$50.00 civil penalty and a Letter of Warning to the pharmacy for not having a license PIC. Dr. Wright seconded the motion. The motion carried.

Case 11.

Respondent was PIC for Case 19 above until 6/4/17 and was not responsible for the incident on 6/19/17.

Recommend: Dismiss

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

Case 12.

Complaint was forwarded to BOP from Division of Consumer Affairs. Complainant is a physician's assistant that alleged problems with multiple patients' medications being received in a timely manner from respondent pharmacy.

BOP Investigator was able to work with pharmacy management and determine the occurrences affecting the patients involved. A lengthy investigation resulted in lots of documentation, however no violations by the pharmacy were found. Delays resulted from several issues involving prior approval attempts. Some delays were caused due to poor communication between patients' representatives, the pharmacy, and the PBM's involved.

Recommend: Dismiss

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

Case 13.

Complaint was generated by BOP staff due to respondent pharmacy operating without a designated PIC.

BOP Investigator received verification from the district manager that the following timeline is correct:

PIC change occurred in February, 2016 but was not reported to BOP. Documentation was never completed.

PIC took LOA starting 2/23/17 and notified BOP on 3/6/17 that he was no longer PIC

A replacement PIC was appointed 3/16/17 and documentation was received at BOP on 3/23/17.

Recommend: Civil penalty \$50 per month X 14 months = \$700

Dr. Pryse made the motion to authorize a formal hearing with a \$50.00 civil penalty for each month that the pharmacy was without a licensed PIC. Dr. Dickenson seconded the motion. The motion carried.

Case 14.

Complaint alleged unprofessional conduct by respondent pharmacist who became loud, rude and unprofessional. Complainant alleged the pharmacist directed the technician to return the patient's prescription and the pharmacist screamed at the patient to fill her prescriptions elsewhere.

Respondent pharmacist provided a typed response indicating the patient was not happy with their service and became loud, used profanity, and refused to calm down. Respondent claims the language was unacceptable and escalated to racial name calling so he told the patient to go somewhere else to get the prescription filled.

Recommend: Dismiss

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

Case 15.

Respondent technician admitted in writing to stealing controlled substances from the pharmacy.

Recommend: Revoke tech registration

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

Case 16.

Respondent technician admitted in writing to stealing controlled substances from her employer.

Recommend: Revoke technician registration

Dr. Pryse made the motion to authorize a formal hearing for revocation. Dr. Wright seconded the motion. The motion carried.

Case 17.

Respondent technician admitted in writing to stealing controlled substances from her employer.

Recommend: Revoke technician registration

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

Case 18.

Respondent technician admitted in writing to stealing controlled substances from her employer.

Recommend: Revoke technician registration

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

Case 19.

Respondent technician applicant admitted in writing to stealing controlled substances from his employer. Voluntary statement indicated respondent had been working as a technician for 8 months. Application was received at BOP office 10/24/16. CBC indicated a concern so a letter was sent from BOP office on 11/29/16 requesting more information. A response was never received. Respondent was confronted and provided the written admission on 3/10/17. A DEA 106 dated 3/10/17 was filed.

Recommend: Deny/close and flag application

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

Case 20.

Respondent was PIC for Case 19 above. Respondent allowed an unregistered technician to work beyond the 90 day probationary period.

Recommend: Civil penalty \$100 per month X 3 months beyond probationary period = \$300

Dr. Pryse made the motion to authorize a formal hearing with a \$100.00 civil penalty for each month that the technician worked passed the 90 day probationary period. Dr. Wright seconded the motion. The motion carried.

Case 21.

Respondent technician was terminated for theft of controlled substances. Audits by PIC revealed losses and computer records showed respondent was changing on-hands of the missing drugs. Respondent did not admit to the losses. Respondent's technician registration expired 3/31/17.

Recommend: Close and flag against renewal/reapplication

Dr. Pryse made the motion to authorize a formal hearing for revocation. Dr. Wright seconded the motion. The motion carried.

Case 22.

Anonymous complaint alleged respondent out-of-state pharmacy is shipping compounded products into Tennessee which are on the FDA “Do Not Compound list.” It also alleged that the products are approved only for research purposes.

Respondent replied that there is no current “Do Not Compound List” from FDA and that FDA guidance documents are not enforceable. BOP Investigator contacted FDA who requested they be allowed to address the complaint.

Recommend: Close and refer to FDA

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

Case 23.

Anonymous complaint alleged respondent out-of-state pharmacy is shipping compounded products into Tennessee which are on the FDA “Do Not Compound list.” It also alleged that the products are approved only for research purposes.

Respondent replied that the products are not on the FDA list prohibiting compounding. BOP Investigator contacted FDA who requested they be allowed to address the complaint.

Recommend: Close and refer to FDA

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

Case 24.

Anonymous complaint alleged respondent out-of-state pharmacy is shipping compounded products into Tennessee which are on the FDA “Do Not Compound list.” It also alleged that the products are approved only for research purposes.

Respondent denied ever possessing one of the alleged products, and that they are aware the other product is on the FDA Category 3 list and for that reason they have begun to phase that product out of their practice. BOP Investigator contacted FDA who requested they be allowed to address the complaint.

Recommend: Close and refer to FDA

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

Case 25.

Anonymous complaint alleged respondent pharmacy is shipping compounded products which are on the FDA "Do Not Compound list." It also alleged that the products are approved only for research purposes.

Respondent replied that the products are not on the FDA "Do Not Compound " list and believes there is confusion between that list and the FDA "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act," which respondent believes is a non-binding document.

BOP Investigator contacted FDA who requested they be allowed to address the complaint.

Recommend: Close and refer to FDA

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

Case 26.

Anonymous complaint alleged respondent pharmacy is shipping compounded products which are on the FDA "Do Not Compound list." It also alleged that the products are approved only for research purposes.

Respondent replied that they are in compliance with FDA's "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry" dated January 2017.

BOP Investigator contacted FDA who requested they be allowed to address the complaint.

Recommend: Close and refer to FDA

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

Appearance

Vanderbilt University Medical Center

Dr. Rusty Caitlin, Dr. Manfred and Mr. Paul Patel appeared before the board requesting to use the Scriptcenter kiosk at their One Hundred Oaks and Vanderbilt Children's hospital locations.

They are also requesting that they be allowed to add new prescription to all the Scriptcenter kiosks. The board had previously granted approval for refills only. After discussion, Dr. Wright made the motion to approve the Scriptcenter kiosk for One Hundred Oaks and Vanderbilt Children's Hospital locations as well as allow them to be stocked with new prescriptions. Dr. Dickenson seconded the motion. The motion carried. Dr. Pryse voted no.

Vanderbilt University Medical Center also requested to expand the Meds to Beds services at their Psychiatric Hospital to include a prescription discharge kiosk. The prescription discharge kiosk will allow them to deliver medications to a central location that the patients can utilize prior to leaving the hospital. After discussion, the board denied this request.

General Discussion

Dr. Dilliard asked the board to consider changes to the qualification for registered pharmacy technicians,

After discussion, the board made a motion to send a consent order to a registered pharmacy technician who admits to diversion from the pharmacy. The motion carried.

The Peer Assistant Grant was awarded to the Tennessee Pharmacy Recovery Network effective September 15, 2017.

Dr. Dilliard stated that Ad Hoc Task force to address the opioid epidemic.

Reinstatement Benjamin Todd Bradford

Dr. Bradford requested to have his licensed reinstated. Dr. Bradford's license was revoked on 04/12/2017. After discussion, Dr. Wright made the motion to reinstate Dr. Bradford's license. Dr. Bradford's license will be on five (5) year probation once he has completed all the necessary requirements for reinstatement with the following conditions. Dr. Pryse 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);

(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. Upon ratification of this order, the Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary care physician. The Respondent shall immediately notify the Board office in writing of the name of the Respondent's primary physician each time the Respondent changes primary physicians;

(c) The Respondent shall not obtain or attempt to obtain any prescriptions in the Respondent's name for any legend drugs, controlled substances or devices containing same from a physician

other than the Respondent's primary physician or from any other health care provider, such as a nurse practitioner, physician's assistant or psychiatrist;

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

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

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

(g) The Respondent shall comply with all of the terms and conditions of the extended aftercare contract he entered into with the Tennessee Pharmacist Recovery Network. Respondent shall return a copy of said contract with this consent order to the Board Office.

(h) The Respondent shall not serve as pharmacist-in-charge for a period of three (3) years from the start date of probation; however, after a period of two (2) years' probation the respondent may petition the Board for a modification of this Consent Order to remove the restrictions upon show of good causes. The Respondent shall not work as a "floater" for a period of three (3) years, meaning that the Respondent shall not work at more than one (1) pharmacy location at the same time without permission of the Board;

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

1. Provide written notice to the board requesting an active license;
2. Satisfy all past due continuing pharmaceutical education as required by the board;
3. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked;

Application Review

Jilbear Hatch, D.Ph.

Dr. Hatch is applying for license as a pharmacist by reciprocity. He marked "yes" to the question that ask "Have 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?" "Have you ever been charged or convicted

(including a nolo contendere pleas or guilty plea) of a felony or misdemeanor (other than a minor traffic offenses) whether or not sentence was imposed, suspended, expunged or whether you were pardoned from any such offense?” Dr. Hatch has been convicted of 2 misdemeanor impaired driving and 1 misdemeanor DUI within 4 years. On September 12, 2016, Dr. Hatch’s UT pharmacist license was placed on probation for 5 years. After discussion, Dr. Wright made the motion to approve Dr. Hatch’s application for license as a pharmacist by reciprocity once all the requirements have been met. His Tennessee pharmacist license will be placed on probation to run concurrent with his Utah pharmacist license. Dr. Dickenson seconded the motion. The motion carried.

Lonnie Turner, RT

Mr. Turner is applying for registration as a pharmacy technician. He marked “yes” to the question that asked “Have you ever been convicted (including nolo contendere plea or guilty plea) of a felony or misdemeanor (other than a minor traffic offense) whether or not sentence was imposed or suspended?” Documentation submitted indicated that Mr. Turner was found guilty on March 3, 2013 for possession of controlled substance with the intent to manufacture/distribute/sell. He was given diversion. After discussion, Dr. Dickenson made the motion approve Mr. Turner’s application for registration as a pharmacy technician once all the requirements have been met. Dr. Pryse seconded the motion. The motion carried.

Erica Williams, RT

Ms. Williams is applying for registration as a registered pharmacy technician. She marked “yes” to the question that asked “Have you ever been convicted (including non contendere plea or guilty plea) of a felony or misdemeanor (other than a minor traffic offense) whether or not sentence was imposed or suspended? Documentation submitted that Ms. Williams was found guilty on 2/27/2017 for possession of drug paraphernalia and controlled substance scheduled VI. After discussion, Dr. Dickenson made the motion to deny Ms. Williams’ application for registration as a pharmacy technician. Dr. Rodgers seconded the motion. The motion carried.

**Order Modification
Valerie Dunn, D.Ph.**

Dr. Dunn appeared before the board to request that she be allowed to be float at Munsey Pharmacy located in Oak Ridge and Loudon, TN. Dr. Dunn signed a consent order on 11/5/2014 placing her pharmacist license on 5 year probation and she would not be allowed to be float for 3 years of probation. After discussion, Dr. Dickenson made the motion to amend Dr. Dunn’s consent order and allow her float at Munsey Pharmacy located in Oak Ridge and Loudon, TN. Dr. Pryse seconded the motion. The motion carried.

Christian Onuh, D.Ph.

Dr. Onuh appeared before the board with his attorney, Dan Warlick, to request that the probation status be lifted from his pharmacist license. Dr. Onuh signed a consent order on 07/29/2016

placing his pharmacist license on 5 year probation. After discussion, Dr. Wright made the motion to deny Dr. Oahu's request. Dr. Pryse seconded the motion. The motion carried.

Director's Report

Dr. Dilliard informed the board that the Buprenorphine Treatment Guideline Committee meeting is working on guidelines for the use of Buprenorphine. The recommendations will be presented to the TDMHSAS Commissioner for her approval.

Dr. Dilliard informed the board that he will be attending the Food and Drug Administration (FDA) meeting scheduled for September 26-27, 2017 in Silver Springs, MD.

Dr. Eidson asked the board if they would consider completing a fact sheet concerning USP 800 with the board's response. The board decided that the board will accept USP 800 as standard.

Waivers

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

Dr. Wright made the motion to approve the request from **J. Michelle Settles, Pharm. D.** to waive the one hundred and sixty (160) internship hours but she must successfully take and pass the MPJE. Dr. Dickenson seconded the motion. The motion carried.

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

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

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

The meeting adjourned at 4:00 p.m.

September 13, 2017

The Tennessee Board of Pharmacy reconvened on Wednesday, September 13, 2017 in the Iris Room, 665 Mainstream Drive, Nashville, TN. A quorum of the members were present, the meeting was called to order at 9:00 a.m., by Dr. Eidson, president.

General Discussion

Dr. Eidson stated that he would like for it to be clear to Colleges of Pharmacy the importance of criminal background checks and drug screens. The Board has seen an increase in the number of licensees who admit to having issues with impairment while attending pharmacy school.

Dr. Eidson suggested that Dr. Dilliard send a letter to ACPE requesting their help in establishing and developing standards for accredited programs for pharmacy technicians. Dr. Dickenson stated that the board needs to raise the bar for standards of technician and to look at the submitted applications more carefully.

Complaint Summary

Case 27.

On April 9, 2017, an APRN prescribed, to patient D.H., Roxanol 20mg/ml, 0.25 mg per tube to be administered every 30-60 minutes for pain or dyspnea, and to be dispensed in a quantity of 30 ml. Also on April 9, 2017, Respondent, the pharmacist on duty where the aforementioned prescription was sent to be filled, entered the prescription into the pharmacy's software, but transposed 0.25 ml per tube instead of 0.25 mg per tube. As written by the prescriber, the amount of liquid to be administered per dose was 0.0125 ml. Respondent instructed D.H.'s parent to administer 0.25 ml per dose (during patient counseling) which caused D.H. to receive 5 mg of Roxanol per dose versus 0.25 mg, as prescribed. D.H. received two incorrect doses on April 9, 2017.

D.H., an infant patient (i.e. 50 weeks), was terminally ill due to mitochondrial disease. D.H. was born at 29 weeks and had profound hypotonia. D.H. required a nasal tube for feeding and medication administration. D.H. spent every day of its life in the NICU prior to April 6, 2017. On April 6, 2017, D.H. was discharged from the NICU to home-based Hospice care. D.H. died on April 9, 2017.

D.H.'s health deteriorated rapidly on April 9, 2017, prior to the order for Roxanol. D.H.'s heart rate was near 200 prior to the order for Roxanol and multiple calls to a nurse and a Hospice-employed pediatrician were made on account of D.H.'s failing health both before and after the first dose of the incorrect medication was administered.

For the prescription, Respondent performed the following acts:

- Data entry of the prescription
- Data verification
- Product verification
- DUR overrides for the prescription
- Compounding of the medication
- Counseling
- Dispensing

Factors contributing to the event:

- Severe illness of the child and the prognosis
- Patient and prescriber were unknown to the pharmacist / pharmacy
- Communication barrier (parents of D.H. have limited English proficiency)
- Counseling occurred via the patient's 12 y.o. sister serving as a translator between the pharmacist and the patient's father

- Difficult dosage (0.0125 ml) considering the standard concentration
- Staffing issues at the pharmacy – lack of pharmacy / technician hours during a busy weekend time period which caused an increased workload and stress for the pharmacist Pharmacist trying to serve the family as quick as possible
- Pharmacist performing the aforementioned acts without performing additional checks on the prescription

Dr. Wright made the motion to issue a Letter of Warning for the misfill to the PIC and 2 hours of continuing education hours on misfills. Dr. Rodgers seconded the motion. The motion carried. Ms. Tittle made the motion to issue a Letter of Warning to the pharmacy. The pharmacy must also submit a root cause analysis with a copy to the board. Dr. Pryse seconded the motion. The motion carried. Dr. Rodgers amended the motion to ask for a corrective action plan. Dr. Wright seconded the amended motion. The motion carried.

Case 28.

Complaint alleges an anti-rejection suspension for Tacrolimus was compounded incorrectly and labeled incorrectly. Complainant stated the patient is a very complex post stem cell transplant patient. A photo of a dispensing label was provided which shows “TACROLIMUS 0.5 MG/ML SUSP.” The directions read “TAKE 4 ML VIA TUBE TWICE DAILY,” however the “4 ML” had been crossed through and “40 ML” had been hand written on the label. According to the complaint, when a nurse from the hematology/oncology clinic contacted the respondent pharmacy, she was told that the drug had been compounded as 0.05 mg/ml because the correct strength was not in stock. Instead of typing a corrected label showing a 40 ml dose of the 0.05 mg/ml concentration, pharmacy staff left the label showing a concentration of 0.5 mg/ml and simply marked through the 4 ml dosage and hand-wrote 40 ml. This made it appear that the patient was taking 20 mg instead of the prescribed 2 mg. However, the patient did receive the correct dose and a Tacrolimus blood level was within therapeutic range.

BOP Investigator visited the pharmacy and interviewed staff. Investigator followed the work flow of the prescription in question. It was as follows:

1. Original prescription was a verbal order but was not initialed as to who took the order.
2. Rx scanned into the system by a tech.
3. Data entry was performed by a different tech.
4. Rx was reviewed by remote verification, however the pharmacist performing the verification was not licensed in Tennessee. (This will be dealt with separately since the pharmacy’s computer system is not supposed to allow out-of-state pharmacists to perform remote verification unless they are licensed in Tennessee.)
5. Product was compounded by a compounding technician.
6. DUR was performed by an on-site pharmacist.
7. Product verification was performed by a different on-site pharmacist. A compounding worksheet could not be located for the Investigator. This pharmacist told Investigator that she was only involved because she noticed an empty bottle of Tacrolimus was the wrong strength for the compound but the prescription had already been dispensed. After

Investigator pointed out that the workflow history showed that this pharmacist actually performed product verification, the pharmacist acknowledged she had checked the prescription but “did not really look at it.” She also told Investigator she “thinks” she contacted the patient and the nurse. Pharmacist said she instructed the technician to remake the suspension correctly but is not sure what happened because she was off the next day.

Investigator obtained a written statement from the compounding tech admitting the mistake of using 0.5 mg capsules instead of 5 mg, but the compound had already been sold when the pharmacist noticed the mistake. This conflicts with other statements that the weaker suspension had intentionally been filled and the dose changed on the label. According to the compounding tech’s statement, the nurse was called and advised of the correct dose and the correct compound was then made. This would indicate that the wrong dose and directions were dispensed and that pharmacy staff did not hand-write “40 ml” which would have corrected the dosage.

Investigator followed up with the complainant via telephone and complainant stated that although the patient received the correct dosage, the mislabeling and hand-written notation could confuse the patient and provide obstacles to the patient’s care.

Recommend:

Dr. Pryse made the motion to issue a Letter of Warning and for the pharmacy to submit a root cause analysis with a corrective action plan. Dr. Rodgers seconded the motion. The motion carried.

Case 29.

Respondent is the pharmacist that performed final verification for Case 29 above.

Recommend:

Dr. Pryse made the motion to issue a Letter of Warning and for the pharmacist to submit a root cause analysis with a corrective action plan. Dr. Rodgers seconded the motion. The motion carried.

Case 30.

Respondent is the compounding technician for Case 29 above.

Recommend:

Dr. Pryse made the motion to issue a Letter of Warning and for the technician to submit a root cause analysis with a corrective action plan. Dr. Rodgers seconded the motion. The motion carried.

Case 31.

During a periodic inspection, BOP Investigators noted the respondent pharmacy only had 1 pharmacist on duty. That pharmacist (who is also the PIC) had many customers waiting. Some were waiting for immunizations, prescriptions to be filled, to drop off prescriptions and for counseling. Investigators noted that the pharmacist was visibly upset with the workload she was trying to complete. Respondent pharmacy had recently acquired prescription files from a competitor that closed. According to the PIC, she did not have enough help and confirmed to Investigators that she felt she was working in an unsafe work environment. Investigators noted on the inspection form that the pharmacy appeared to be grossly understaffed. PIC requested more help but reported later to Investigators that conditions had not improved and she felt that patient safety was being sacrificed. PIC provided a written statement indicating she had a meeting with her supervisor who proposed further cuts in technician hours from 120 down to 79 hours per week. She informed her supervisor that she would not comply with such a drastic cut and that she intended to use her professional judgment in making schedules so that patient safety would not be sacrificed. Her statement says she expects the company will soon take measures to force those cuts but she intends to be resolute in her belief she is operating in the best interest of the patients.

Recommend: Discuss

Dr. Wright made the motion to issue a Letter of Warning requiring the district manager to meet with the staff and submit a plan of correction. Dr. Dickenson seconded the motion. The motion carried.

Case 32.

Complaint alleged multiple early refills and listed specific prescription numbers as proof.

BOP Investigators reviewed dispensing history of the prescriptions listed. Respondent pharmacy functions as a retail pharmacy. There is another pharmacy at this site, inside the same area, that functions as a LTC pharmacy. The pharmacies share staff, inventories and recordkeeping, but each has its own PIC. Investigators reviewed patient records and interviewed staff. Investigators were told the refills appear to be early because of LTC billing cycles but the medications are not shipped until the proper time.

During the investigation several other violations were noted:

A non-pharmacist possessed a key that can access both pharmacies;

Prescriptions are randomly assigned to either license without any logical explanation;

Inventories are not separated;

Prescriptions for each pharmacy are not separated;

Investigators were told all prescriptions are processed under the LTC license, however, this was proven to be incorrect;

Investigators were told the retail pharmacy did not have controlled substances, however, this was proven to be incorrect;

Investigators discovered bags of unlabeled tablets and capsules in the retail pharmacy drawers. Investigators were told they were bagged to be destroyed but no destruction records were found and staff did not remember the last date of destruction;

Retail pharmacy did not have a biennial inventory of controlled substances;

Investigators attempted an audit, however the intermingled inventories and records made it difficult to arrive at definite counts;

Neither PIC was familiar with PIC responsibilities.

Recommend: Reprimand and costs to pharmacy owner for recordkeeping

Dr. Dickenson made the motion to authorize a formal hearing for a Reprimand with case cost for recordkeeping to the pharmacy. Dr. Wright seconded the motion. The motion carried.

Case 33.

Respondent is the LTC pharmacy referenced in Case 32 above.

Recommend: Reprimand to pharmacy owner for recordkeeping

Dr. Dickenson made the motion to authorize a formal hearing for a Reprimand with case cost for recordkeeping to the pharmacy. Dr. Wright seconded the motion. The motion carried.

Case 34.

Respondent is PIC for respondent pharmacy in Case 32 above.

Recommend: \$1,000 civil penalty for key violation for unknown length of time;

Reprimand for recordkeeping violations

Dr. Rodgers made the motion to authorize a formal hearing with a \$1000.00 civil penalty for key violation to the PIC along with a Reprimand for recordkeeping. Dr. Wright seconded the motion. The motion carried.

Case 35.

Respondent is PIC for respondent pharmacy in Case 33 above.

Recommend: \$1,000 civil penalty for key violation for unknown length of time;

Reprimand for recordkeeping violations

Dr. Rodgers made the motion to authorize a formal hearing with a \$1000.00 civil penalty for key violation to the pharmacy along with a Reprimand for recordkeeping. Dr. Wright seconded the motion. The motion carried

Contested Case
Arthur Collins, RT

Mr. Collins was not present nor represented by legal counsel. Mr. Gibbs represented the State. Ms. Kim Summers was the Administrative Law Judge. Mr. Gibbs asked to proceed in default. R. Dickenson made the motion to proceed in default. Dr. Rodgers seconded the motion. The motion carried. Mr. Gibbs passed out the Notice of Charges. Mr. Collins is charged with violating T. C. A. §53-10-104(a), (b), §53-10-105 (a). Dr. Pryse made the motion to revoke Mr. Collins' registration and to assess case cost. Dr. Rodgers seconded the motion. The motion carried. Dr. Pryse made the motion to allow 90 days for case cost to be paid. Ms. Tittle seconded the motion. The motion carried. Ms. Tittle 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.

Ms. Tittle left at 2:22 p.m.

Pilot Program
Technician Product Verification

Dr. Micah Cost, Executive Director of Tennessee Pharmacy Association, appeared before the board to request approval for a temporary pilot program for Technician Product Verification. This pilot program will allow a certified pharmacy technician to verify contents of unit dose carts and automated dispensing systems prepared by other register technicians and when an additional verification by use of bar code technology or a licensed health care professional is performed prior to administration to the patient. This process will not include controlled substances or compounded products. Dr. Cost stated that they will be recording the modules in October and expect to have live training in place by November. An affidavit must be signed by the pharmacist stating that they would accept the responsibility for this pilot program. Kate Gainer, Vice President and CEO of the Iowa Pharmacy Association, stated that they have approved this program. Ms. Gainer stated that there is no reduction in staffing but the pharmacy must have full commitment from all staff. Ms. Gainer also state that the pharmacy is require to submit quarterly reports. After discussion, Dr. Pryse made the motion to approve the pilot program. Dr. Wright seconded the motion. Dr. Rodger amended the motion to as for quarterly reports and with the board's involvement in the training program. Dr. Pryse seconded the motion. The motion carried.

Consent Orders

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

VIOLATED BOARD RULE 1140-01-.09 (1)
Julie H. Brown, D.Ph.

VOLUNTEER SURRENDER
Kelley R. Ledet, D.Ph.

Tennessee Board of Pharmacy
Board Meeting
September 12-13, 2017

Rachel Johnson, RT
Selina Reynolds, RT

VIOLATED BOARD RULE 1140-03-.01 (1) 9(a) & (f)

Alice K. Farr, D.Ph.

Walgreens Pharmacy #9945

Walgreens Pharmacy #5053

Danny Law, D.Ph.

VIOLATED BOARD RULE 1140-2-.02 (1)

Martha Ann Butler, RT

REPRIMANDED

Omnicare of Memphis

Norman J. Noffsinger, Jr., D.Ph.

Bradley Drug Center

PROBATION

Larry D. Stephens, D.Ph.

Dr. Pryse made the motion to adjourn at 2:29. Dr. Dickenson seconded the motion. The motion carried.

The minutes were approved and ratified at the November 14-15, 2017 board meeting.