

MINUTES

UTAH PHARMACY BOARD MEETING

October 26, 2010

Room 474 – 4th Floor – 8:00 A.M.
Heber Wells Building
Salt Lake City, UT 84111

Convened: 8:03 a.m.

Conducting: Dominic DeRose, Chair

Bureau Manager: Laura Poe
Board Secretary: Shirlene Kimball
Compliance Specialist: Connie Call

Division Staff: Neena Bowen, Compliance Specialist
Kent Barnes, Senior Business Analysis

Board Members Present: Derek Garn, R.Ph.
Dominic DeRose, R.Ph.
Kelly Lundberg, PhD public member
Jan Bird, CPhT, pharmacy technician
Andrea Kemper, PharmD D
David C. Young, PharmD D
Gregory Jones, R.Ph.

Guests: Colby Hancock, U of U School of Pharmacy
Kevin Walkenhurst, U of U School of Pharmacy
Greg Jensen, Target Pharmacy
Linda Sandberg, Omnicare
Betty Yamashita, IHC
Jason Braithwaite, University of Hawaii
Josh Newbold, Wal-Mart Pharmacy
Robert Hansen, Wal-Mart Pharmacy
Jaime Peterson, Walgreens Pharmacy
Kelly Hansen, HCA
Richard Ensign, IHC
Missy Duke, IHC

TOPICS FOR DISCUSSION

DECISIONS AND RECOMMENDATIONS

ADMINISTRATIVE BUSINESS:

September 28, 2010 Minutes:

Dr. Lundberg made a Motion to approve the minutes with corrections. Ms. Bird seconded the Motion. All Board members in favor.

Connie Call,
Compliance Report:

Ms. Call reported the following individuals are in compliance with the terms and conditions of their order: Andrea Lowry, Mary Jo Cates, Phuong Sheffer, Zion's Pharmacy, Mark Akagi, Heather Palmer, James Bee, William Cordova and Paul Martz.

Ms. Call reported the following individuals are out of compliance with the terms and conditions of their Orders: Sheryl Ledet and Susan Macon.

Aidee Torres submitted a request for termination of probation. She also submitted a letter explaining what she has learned in the probation process and the changes she has made. Dr. Lundberg made a Motion to terminate Ms. Torres' probation. Mr. Garn seconded the Motion. All Board members in favor.

Zion's Pharmacy
Kurtney Stirland,
Probation interview:

Mr. Stirland reported things are going very well. Board members questioned whether or not the pharmacy has had a recent inspection. Mr. Stirland stated the pharmacy has not had a recent on-site inspection and he has not submitted a self inspection report. Ms. Poe stated the pharmacy needs to have an inspection completed. Board members indicated they would accept a self inspection report. Once the report has been received and reviewed, Mr. Stirland could request early termination of probation for Zion's Pharmacy. Mr. Garn made a Motion that the self inspection report be forwarded to Mr. DeRose for review. If the self inspection report is accepted, the probation on Zion's Pharmacy could be terminated. Dr. Kemper seconded the Motion. All Board members in favor. **Zion's Pharmacy is in compliance with the terms and conditions of probation.**

Phuong Sheffer,
Probation interview:

Mr. Sheffer reported things are going well and he continues to work at the 4th Street Clinic. Mr. Sheffer will be seen again in January, and if he remains in compliance, he can request termination of probation at that time. **Mr. Sheffer is in compliance with the terms and conditions of his Order.**

Sheryl Ledet,
Probation interview:

Ms. Ledet stated she feels she is doing well. She indicated she has problems in her personal life, however, she also indicated she has not felt the need to have a drink or use drugs. Board members indicated she had a urine screen that was out of range and Ms. Poe explained what an out of range urine screen means. Ms. Ledet stated she does not know why it would have been out of range, other than because of a recent health issue. Ms. Poe also explained that one out of range urine screen does not establish a pattern, but if it happens again, it would be a red flag. Ms. Ledet is current on all paperwork with the exception of submitting one prescription. Ms. Ledet will be seen in January. **Ms. Ledet is out of compliance due to the prescription not being submitted.**

Mary Jo Cates,
Probation interview:

Ms. Cates reported things are going well. Board members had a question regarding the supervisor's comments on the employer report. Ms. Cates indicated she feels this is typical of the supervisor and Ms. Cates does not feel she is regressing. Ms. Cates also stated the controlled substance audit was not completed because her supervisor did not think it was necessary after the Order was amended for general supervision. Board members stated that if she is in compliance in January, the Board will move her to meeting with the Board every six months instead of quarterly. **Ms. Cates is out of compliance with the Order and needs to submit the audit report.**

Susan Macon,
Probation interview:

Ms. Macon reported she is doing well. Board members indicated she needs to submit a copy of the prescription she received July 19, 2010. Board members also stated they would like to see a more thoughtful response to the self assessment report. **Ms. Macon will be in compliance with the terms and conditions of her Order when the prescription has been submitted. Her next meeting with the Board will be in January.**

Tom Strebel,
Interview:

Mr. Strebel requested a meeting with the Board after the Division denied his request for termination of probation. Since his request to terminate probation was denied, he would like to request several amendments to his Order. Ms. Poe explained that the

recommendation from the Board last month was reviewed by the Division director. It was felt that due to the seriousness of the action that led to the probation, it was not acceptable to terminate the probation after two years. Mr. Strebel stated he would like to request general supervision and be allowed to work on-call. He also stated he would like the hours required to work to keep the probation going be changed to 16 hours per month.

Dr. Lundberg made a Motion to amend the Order to allow for general supervision with quarterly supervisor reports, allow Mr. Strebel to work alone in the pharmacy, and that working 16 hours per month will be sufficient to continue the probationary period. Dr. Young seconded the Motion. Mr. Strebel's next meeting will be August 2011 and his reports are due quarterly (February, May, August, November). All Board members in favor.

Paul Martz,
Board request:

Mr. Martz submitted all reports and has signed up with CVI for drug screening. He indicated his license remains suspended; however, he has completed all evaluations required and is in compliance with the terms of the suspension. Mr. Martz indicated he has been sober 100 days. He stated he continues to attend 12-step meetings daily, he has completed the outpatient treatment program and attends aftercare twice a week (one meeting with the group, one meeting alone) and meets with the therapist twice a week. He stated he has had a lot of stressors lately, and has had thoughts of relapse, but has not relapsed. He reported he is still considering entering Drug Court. He indicated he speaks with his sponsor daily and has a lot of support from family members and friends. Mr. Martz has met all requirements of the suspension. Dr. Young made a Motion to lift the suspension and place the license on probation with the terms and conditions outlined in the Order. Dr. Lundberg seconded the Motion. All Board members in favor. **Mr. Martz is in compliance with the terms and conditions of his Order and will be seen again in December.**

Diann Millikan,

Diann Millikan met with the Board to request

Request for termination of suspension:
Request to have Board meeting closed:

termination of suspension. Ms. Millikan requested the meeting be closed. Ms. Bird made a Motion to close the meeting in accordance with the Open and Public Meetings Act, section 52-4-205(1)(a) to discuss the character, professional competence, or physical or mental health of an individual. Mr. Jones seconded the Motion. All Board members voted in favor of closing the meeting. The meeting was closed at 10:30 a.m.

Board meeting opened at 11:00 a.m.:

Dr. Lundberg made a Motion to open the meeting. Dr. Kemper seconded the Motion. All Board members in favor. The meeting was opened at 11:00 a.m. Dr. Lundberg stated for the record that before the Board can consider the request to terminate suspension, Ms. Millikan must provide a current psychological and physical evaluation and an updated progress report from her current therapist.

Elena Renteria,
Application review:

Ms. Renteria met with the Board to discuss her pharmacy technician application. Ms. Renteria indicated she had answered yes on the qualifying questionnaire. She also reported she needed to request an extension to the one year requirement because she did not have the money to apply for licensure within the one year (it has been 14 months).

Ms. Renteria stated she wanted to be honest when she submitted the application and answered "yes" to the questions due to her juvenile record. Ms. Poe provided the Board with background information and stated that Ms. Renteria did not need to report the juvenile record information. However, since it was reported, the Board needs to review the information. Ms. Renteria indicated she had been charged with alcohol consumption by a minor. She stated she was between thirteen and sixteen when the drinking occurred. She stated she has paid all fines and completed community service. She indicated she no longer associates with the friends she had when she was younger. Dr. Young made a Motion to accept the two month waiver request and to issue the license unrestricted. Ms. Bird seconded the Motion. Dr. Lundberg stated she does not see any evidence that indicates there will be further problems. All Board members in favor. Board members stressed to Ms.

Renteria the importance of making the right decisions in the future.

Missy Duke,
Collaborative Practice:

Ms. Duke met with the Board to discuss collaborative practice in a hospital setting. Ms. Duke indicated that outside the hospital, the collaborative practice agreements have been very successful. However, a number of different challenges exist in the inpatient hospital setting. She reported the most challenging is the number of physicians who have been granted practice privileges in each hospital. There is significant burden to maintain collaborative practice agreements for participating physicians. The benefit of collaborative pharmacy practice in the hospital is that pharmacists can write orders which would result in the enhanced efficiency of patient care. Ms. Duke explained collaborative pharmacy practice is different from institutional protocols. Collaborative pharmacy practice allows pharmacists to exercise professional judgment and clinical decision-making within the parameters defined in the collaborative practice protocols, policies, and procedures. The institutional protocols do not allow for professional judgment or clinical decision-making.

The proposal is to have the collaborative practice agreement approved by the institution's pharmacy and therapeutics committee, medical executive committee and the department of pharmacy. The agreement will define appropriate patient population, scope of pharmacist practice and transition of care between pharmacists and physician. There will be comprehensive training for all pharmacists. Physicians will receive education on protocols, policies and procedures of the collaborative practice agreements with clear articulation of their role and the role of the pharmacist. The director of pharmacy and the appointed medical director will assume responsibility for the safe implementation of the collaborative practice agreement.

The primary clarification requested is that when a physician writes an order in the chart for pharmacists to manage medications by collaborative practice, this indicates the physician's agreement to the collaborative practice. Upfront documentation of the

physician's agreement each time an order is written would be eliminated. In order for a pharmacist to write orders based on physician request, there must be an approved collaborative agreement at the facility for the medications and service in question. The physician retains the responsibility for placing all orders.

Ms. Poe questioned whether or not this type of agreement meets the letter of the law, or will the Rule need to be changed. The pharmacist documents in the patient records and the physician co-signs. Pharmacists practicing under the collaborative agreement would have been invited to participate by IHC and would have completed the training and competency assessment. The physician is educated on their responsibility and the pharmacist has to have a collaborative practice agreement in place. Ms. Poe stated the wording "to be managed by the pharmacist" would need to be in place because this is how the current rule is written. She indicated the Rule could be clarified to include the collaborative agreement on a facility level between physicians and pharmacist, and when ordered, it is considered the consent of the physician.

Mr. Garn indicated this is already covered in Rule R156-17b-611 and in the Pharmacy Practice Act, 58-17b-102(16). As long as the physician signs the order, it is acceptable.

Adjourned for lunch at 1:00 p.m.
Reconvened at 1:30 p.m.

Tom Harper,
Update on the Controlled Substance Database:

Mr. Harper presented the Board with an update on the Controlled Substance Database. Mr. Harper stated he is currently looking at pharmacies that report to the Controlled Substance Database. He indicated the only exemptions from reporting are the inpatient pharmacies. Mr. Harper stated he would like to see the inpatient pharmacies report, however, Dr. Young indicated that inpatient pharmacies provide pain medications for reasons other than pain (such as placing a PIC line, etc). Mr. Harper indicated he would like to have emergency rooms also report. Dr. Lundberg stated one avenue to look at may be to

Review e-mails received regarding pharmacy issues:

contact the addictionologist's in the area.

Ms. Poe stated she received an e-mail regarding Allen Memorial Hospital. She indicated they are changing their name to Moab Hospital. They will be adding a hospice unit and providing hospice care. Their question is whether or not the medications for chemotherapy can be prepared at the Moab Hospital and sent to San Juan and/or Blue Mountain for administration to patients. This would prevent patients having to travel from San Juan to Moab to obtain chemotherapy. The procedure will fall under medications prepared in one facility to be administered in another facility. The Statute and Rules do not allow one pharmacy to dispense to another pharmacy unless they have a manufacturer license. However, this is a different situation, there is a contract with an infusion administration facility and the medication is prepared patient specific. The current Statute and Rules do not prohibit a contractual agreement to prepare the medications to be administered at another site. Dr. Young stated this would be similar to home care, the pharmacy prepares the medications and sends out to the home. Board members indicated it would be acceptable if the hospitals are willing to provide the infusion. An additional license is not necessary as long as the medications are prepared patient specific from the original pharmacy and given in another hospital.

Ms. Poe stated that based on the discussion last month regarding positive ID, a driving privilege card would be accepted. However, there are a number of pharmacists wanting clarification regarding positive ID and the driving privilege card clearly states it is not to be used for ID. The callers are also questioning whether or not the ID has to be current. The pharmacists are concerned that if a law enforcement agency prosecutes an individual regarding controlled substances obtained at the pharmacy, the pharmacy will need to provide records that they received positive ID. Dr. Young stated that in the 2010 Pharmacist Manual, Office of Diversion Control, DEA Federal Regulations page 58 lists ID requirements. Positive ID is only required for Controlled Substances. The purpose of the ID is to identify who picked up the

controlled substance. Ms. Poe stated she is hearing that the Board does not want to define positive ID in Rule because it has already been defined by the DEA.

Ms. Poe reported there is a company that sells legend products to wholesalers only. The manufacturing plant will be in Connecticut and they will use a third party logistic company to deliver the product. Board members stated if they manufacture, warehouse, and use a third party logistic company in Utah, they will need a Utah Class C license. If the third party logistic company, such as Fed Ex, is delivering, that company does not need a license. If the manufacturing plant is not licensed in the state where they are located and they are selling products to Utah customers, they would need a Utah license. If warehousing in Utah, a Utah license is necessary.

Continued discussion regarding possible rule changes:

Ms. Poe presented a Rule draft for the Remote Order and Remote Fill Pharmacy.

Section R156-17b-622(5). Operating Standards – Remote Order Processing reads: a pharmacy using remote order processing services is responsible for maintaining records of all orders entered into their information system including orders entered from a remote location.

Section R156-17b-623, Operating Standards – Remote Fill Processing. Number (6)(b): if the prescription is delivered to the patient directly by the central fill pharmacy, the pharmacist employed by the central fill pharmacy shall ensure that the patient receives written notice of available counseling.

Number (7): The Remote Order pharmacy is responsible for placing the label on the prescription with the address of the dispensing pharmacy.

Number (13) A prescribing practitioner cannot place a verbal order with a remote fill pharmacy. The verbal order shall be received by the dispensing pharmacy. The hard copy of the prescription should be kept with the pharmacy that dispenses the medications.

Number (14) add: Bulk compounding of drugs that

are not patient specific can not be sold to another pharmacy.

Discussion regarding (15), (16) and (17). Number (15) is already covered and can be eliminated. This reads that a remote fill pharmacy shall not dispense compounded drugs. Ms. Poe stated she feels if the compounded drug is patient specific, the remote fill pharmacy should be allowed to fill the prescription as long as they follow the 795 Rule. The remote fill pharmacy should be allowed to provide the compounded drug to the patient. Ms. Yamashita stated it was put in the Rule so that the compounded drug could not be wholesaled out. (16). If the drugs are sent to a patient, it is not a remote fill but mail order pharmacy. This section may not be necessary and could be eliminated if the dispensing pharmacy address is on the label. This would allow a tracking system back to the dispensing pharmacy and remote fill pharmacy. Number (16) will be eliminated. (17) Add patient specific to the 90 day supply. Mr. Garn questioned why we would want to limit the number of day's supplies. Ms. Poe stated this would make sure bulk shipment was not being sent out and most insurance only allow up to a three month supply. Mr. Garn stated the pharmacy may be given authorization to provide up to a year supply. Requiring it to be patient specific gets around the bulk issue. Dr. Young and Mr. Garn agree that number (17) could be taken out. Ms. Poe stated she feels it needs clarification because she would look at the Rule and say, I can only supply what your immediate needs are. If a dispensing pharmacy can receive more than the amount dispensed, the remote fill could supply 4 months of medications, and the dispensing pharmacy dispense one month at a time. Mr. Garn stated he does not believe a pharmacy would do this, but it could be done. Ms. Poe questioned whether or not a dispensing pharmacy can hold on to a portion of the medication. Dr. Young stated it would have to be kept separate from those on the shelf since it is patient specific. Ms. Sandberg questioned what happens if the pharmacy has the three months supply, the patient has paid for the medications, but doesn't pick them up. Ms. Poe stated it must be clear that flexibility is allowed. Board members indicated number (17) can

be eliminated.

Ms. Poe stated she will include branch pharmacy additions and will mail the Rule draft to Board members for review and comment.

A guest questioned whether or not the remote fill pharmacy should be classified as a Class E pharmacy. He indicated there is conflicting language and the Class E pharmacy does not require a pharmacist in charge. It may fall more under a Class B, closed system or Class D non resident license. If located in Utah and licensed as either a Class A or B pharmacy, they can offer the services. If it is a new pharmacy located in Utah and the pharmacy will only be doing the remote fill, a Class B license would be required and the pharmacy would need to have a PIC. The guest also questioned if the pharmacist is working from home, could he provide the service under a pharmacist license, or would a pharmacy license be required? The pharmacist should be licensed for discipline purposes. The guest stated if the pharmacist is only entering an order into a computer system that is shared with the facility, the pharmacy should be licensed. But why license the pharmacist if Utah doesn't require the mail order pharmacist to be licensed in Utah. Ms. Poe indicated that the contract between the two pharmacies might be the controlling factor.

Navajo Mountain – Branch Pharmacy
Formulary and application:

Jared Memmott was present for the discussion. Ms. Poe explained that Navajo Mountain submitted an application and formulary as a Branch pharmacy. Ms. Poe questioned whether or not the physician, APRN or PA would be appropriate staff for a Branch pharmacy. Dr. Young stated protocol allows the physician, APRN and PA to log in, fill and hand out prescriptions to the patient at the branch pharmacy. However, an RN can not log in, fill or hand out the prescription.

Ms. Poe also indicated there were questions regarding who can write directions on the label. Mr. Memmott stated he feels the intent of the Rule is that the prescribing practitioner at the branch pharmacy is the only individual who can write directions on the label. Board members stated that only the prescribing

practitioner can write directions on the label.

Ms. Poe reported the delivery of drugs is in question at Navajo Mountain. She indicated a courier from the Navajo Nation receives the medications in Arizona and transports them to the clinic pharmacy. Mr. Memmott stated that the medications are transferred from point A to point B until a person at point B is going to point C. Ms. Poe questioned whether or not supportive personnel can deliver the drugs and whether or not supportive personnel of the parent pharmacy can accept the drugs? Board members stated the PIC of the parent pharmacy would be responsible to designate the personnel for delivery from the parent pharmacy to the branch pharmacy. The drugs need to be accounted for each time and the storage of the medications has to be in a controlled environment.

Ms. Poe stated that the Branch pharmacy has a limited group of people who do all the processes and questioned whether or not there are parts of the process that others can be involved in as an agent of the pharmacist. Dr. Young stated the agent of the pharmacist should be able to do most things, but they can not dispense. Mr. Jones stated support staff can't write the prescription number.

Ms. Poe questioned how often the pharmacist from the parent pharmacy needs to be on site and complete a full inventory of the branch pharmacy. Board members indicated there should be at least a quarterly reconciliation inventory of controlled substances and spot checks of non-controlled substances. A full inventory must be completed annually.

Mr. Memmott stated the Branch pharmacy doesn't have a controlled substance license or DEA registration. He indicated the DEA is working to address this issue.

Ms. Poe also indicated another issue is whether a branch pharmacy can dispense medications not part of their formulary, but available from the parent pharmacy. Mr. Garn stated yes, on an as needed basis.

Dr. Garn made a Motion to accept Navajo Mountain Branch Formulary. Dr. Kemper seconded the Motion. All Board members in favor.

Review Wayne community Health Center – Branch Pharmacy Formulary:

Ms. Bird made a Motion to approve the formulary. Mr. Jones seconded the Motion. All Board members in favor.

Environmental Scan:

Ms. Poe reported the Pharmacy Practice Act Rule regarding physician's dispensing Latisse and injectable HCG went into effect October 22, 2010.

Adjourned:

2:35 p.m.

Note: These minutes are not intended to be a verbatim transcript but are intended to record the significant features of the business conducted in this meeting. Discussed items are not necessarily shown in the chronological order they occurred.

December 14, 2010
Date Approved

(ss) Dominic DeRose
Dominic DeRose, Chairperson, Utah Pharmacy
Licensing Board

December 14, 2010
Date Approved

(ss) Laura Poe
Laura Poe, Bureau Manager, Division of Occupational
& Professional Licensing