

MINUTES

**UTAH
PHARMACY BOARD
MEETING**

May 22, 2012

**Room 474 – 4th Floor – 8:30 a.m.
Heber Wells Building
Salt Lake City, UT 84111**

CONVENED: 8:32 a.m.

ADJOURNED: 2:25 p.m.

Bureau Manager:

Debra Hobbins, DNP, APRN, LSAC

Board Secretary:

Shirlene Kimball

Conducting:

Dominic DeRose, Chair

Board Members Present

Kelly Lundberg, PhD, public member

Andrea Kemper, Pharm D

Dominic DeRose, R.Ph

Greg Jones, R.Ph

Board Members Excused:

Jan Bird, CPhT, pharmacy technician

Derek Garn, R.Ph

David Young, Pharm D

DOPL Staff Present:

Ray Walker, Enforcement Counsel

Mark Steinagel, Division Director

Connie Call, Compliance Specialist

Guests:

Sarah Leavitt

Greg Jensen, Target

Kurt Price, Bowman's Pharmacy, UPhA

Emily Buxton, University of Utah

Cody Jones, Spartan Tactical Inc.

Linda Sandberg, Omnicare

Brad Winter, U of U College of Pharmacy

Jaime Peterson, Walgreen's

Christina Heiner, Regence

Ashley Jensen, Roseman University

Reid Barker, Utah Pharmacists Association

Betty Yamashita, IHC

Paul Allen, University of Utah

Mark Munger, University of Utah

Paige Andersen, BCBS of Utah

Rob Nahoopii, IHC, USHP

Casey Robinson, Roseman University
Andre Lian, Roseman University
Kavish Choudhary
Kirt Wray, Eagle Gate
McKenzie Macfarlane, Eagle Gate
Kelli Marshall, Eagle Gate
Caroline Heyrend, Roseman University
Jeanne Brennan, Law Firm of J.Brennan

TOPICS FOR DISCUSSION

April 24, 2012 Minutes:

Cody Jones,
Request for Canine Handler, non-law
enforcement license:

DECISIONS AND RECOMMENDATIONS

Dr. Lundberg made a motion to approve the minutes with corrections. Dr. Kemper seconded the motion. All Board members voted in favor of the motion.

Dr. Hobbins reported the DEA has issued two licenses for non-law enforcement K-9 Handlers for Utah. Dr. Hobbins also stated there are approximately 100 Controlled Substance Handler licenses issued by the Division. This type of license was issued for researchers and law enforcement agencies. However, there was no Statutory authority to issue this type of license and the Division no longer issues new Controlled Substance Handler licenses.

Mr. Cody Jones is requesting he be licensed as a controlled substance handler in order to obtain marijuana and other drugs for training purposes. Dr. Hobbins stated most police agencies have their own training programs and these agencies use toys that have the smell of the drugs absorbed into the toy. Mr. Cody Jones stated he feels a similar substance does not have the same training benefits that the real substance has. He also stated he feels putting the toy in with the other substances contaminates the process. Dr. Lundberg questioned what type of security measures he would have in place? He indicated he has found the property he wants, but he was waiting to obtain the license before purchasing the property. He indicated the property has a security fence with barb wire across the top. The drugs will be locked in a safe, in a locked room, within a secured building, within a fenced in lot and the Cedar City police have agreed to patrol the area more frequently. Mr. Greg Jones questioned the maximum of drugs he would have on hand at one time. Mr. Cody Jones stated 28

grams would be the maximum on hand at one time. He stated he would have to go to the police department to get the drugs and would be audited by the DEA.

Mr. Walker reported that H.B. 109 gives authority for conducting research with Schedule 1 Controlled Substances but does not provide authority to obtain Schedule 1 Controlled substances for K-9 training. Board members suggested that since the Statute does not currently allow for the non-law enforcement K-9 training license, Mr. Cody Jones thoroughly research the issues, develop language and find a sponsor to make changes at the next Legislative session.

H.B. 161:

H.B. 161 permits dispensing of cancer drug treatment regimens by a prescribing practitioner who is certified or eligible to be certified by the American Board of Internal Medicine in Medical Oncology (58-17b-309.5(2)(b)(vii). The practitioner must follow various standards that include notifying the Division if he/she intends to dispense; following all labeling, record keeping, patient counseling, storage and other requirements applicable to pharmacies; and permitting the Division to conduct inspections of the office. Dr. Hobbins indicated the Division will develop a process to track practitioners dispensing from their offices. Mr. Steinagel reported the Division is in the process of sending out a letter to all prescribing practitioners informing practitioners of their responsibility to meet the requirements in the Statute.

Controlled Substance Database:

Mr. Walker and Mr. Marvin Sims met with the Board to present proposed Rule changes to the Controlled Substance Database and review policies and procedures and the process for the Database operation.

Mr. Steinagel stated with the Health Department Data breach and the police officer accused of misusing the Database, the Database has become high profile. Mr. Steinagel indicated Division staff members have spent significant time on the policies and procedures and on the re-write of the Rules. Ms. Steinagel stated any individual using the Database unlawfully could be charged with a felony

Mr. Steinagel stated each Legislative session in the last few years has allowed additional individuals to have access to the Database. This last Legislative session granted an employee of the prescribing practitioner access to the Database with the practitioner's consent. The employee has to register with the Database.

Mr. Sims also indicated there are some pharmacies not reporting to the Database because they have nothing to report. However, these pharmacies should be sending in a report indicating they have nothing to report. There is a proposed exemption for these pharmacies; a form would have to be submitted on an annual basis requesting the exemption. Mr. Sims also reported on real-time reporting and indicated one entire county and one chain pharmacy is currently real-time reporting. Mr. Sims stated the real-time reporting pilot is going very well.

Mr. Walker reviewed with the Controlled Substance Database proposed Rule with Board members. The policies and procedures are for internal use for the Division. An e-mail address will be required for all pharmacies as a method of Division information dissemination.

Mr. Jones questioned if there were any flags indicating that the Database is being used unlawfully, such as in the instance of the police officer. Mr. Walker stated we don't have a way to determine unlawful use from the Division's end. From the Division's perspective, nothing went wrong with the system in the recent case, it was the user using the Database illegally. Mr. Sims stated we know who accesses the Database and when the Database was accessed, but we don't know how the information is being used. Dr. Lundberg made a motion to move forward with the proposed Controlled Substance Database Rule changes. Dr. Kemper seconded the motion. All Board members voted in favor of the motion.

Review of Pharmacy Practice Act proposed Rule changes:

Dr. Hobbins reported the Guidelines for Hospital Pharmacies and Emergency Department treatment adopted by the Board January 24, 2012 was revised May 21, 2012. Board members suggested several

changes. Board members suggested adding to the guidelines: the pharmacist may delegate the task and is accountable for the outcome. Also added was the inpatient pharmacy is responsible for submitting prescription data to the Controlled Substance Database for the controlled substances dispensed from the ER. Dr. Lundberg made a motion to approve the Guidelines with the above changes. Mr. Jones seconded the motion. All Board members voted in favor of the motion. The Guidelines will be posted to the Division's web site.

R156-17b-102 Definitions. Added number (24) Medical Supplies. Mr. Walker stated he understands that this definition was added to be consistent with Medicare's definition. However, he expressed concern that it is too restrictive and questioned what happens in a setting other than the home? Will it exclude medical supplies used in facilities? Mr. Walker suggested including language that reads: used in a health care facility or the in the home. Board members agree with this addition.

R156-17b-105 Licensure: Added section (4) to require a secure e-mail address for the PIC and responsible party for the pharmacy for use for self-audits or pharmacy alerts initiated by the Division. Mr. Jones stated he would like to be able to require more than one e-mail address and requested eliminating the sentence that reads "Only one email address shall be used for each pharmacy." It was suggested that the addition would be to list one or more email addresses. Board members agree with the changes.

R156-17b-302 Licensure – Examinations. Dr. Lundberg questioned what happens if an individual meets with the Board to request an additional authorization to test for the NAPLEX or MPJE examinations. Mr. Walker suggested adding that the Board may require additional training as a condition prior to approving additional authorizations to test. Board members agree with the recommendation.

R156-17b-304(3)(e)(i) add if an individual applies for technician-in-training status more than twice in a two

year period, the Division in collaboration with the Board may require the individual meet with the Board and additional training may be required. Board members agreed with the recommendation.

R156-17b-304(3)(e)(iii). The wording added in the last sentence of this paragraph should be a new section (iv). Board members agreed to the change.

R156-17b-305 (2)(d) – Temporary license. Change the word from may to shall meet with the Board prior to additional authorizations to test. Add: the Division in collaboration with the Board may require the individual to meet with the Board and additional training may be required. Board members agree with this addition.

R156-17b-307. Licensure – Background Check. Make section (2) clearer by changing the order in which it is written. Board members agree with this suggestion.

R156-17b-402. Administrative Penalties. Section (63) was added. Board members agree with the addition.

R156-17b-502. Unprofessional Conduct. Added section (20) failing to update the Division within seven days of any email address change. Board members agree with this addition.

Board members suggested developing a PIC notification form with the email change notification on the same form and posting it on the web site. Mr. Jones requested a space for at least two e-mail addresses and to include the email address of the pharmacy owner.

R156-17b-601: Operating Standards – Pharmacy Technician. (1)(k) pharmacy technician accepting new prescription drug orders. Eliminated the wording telephonically or electronically submitted and add: left on voicemail for a pharmacist to review. Board members agree with this change.

Dr. Hobbins indicated the Vaccine Protocol will be posted and a link to the web-site regarding reporting

requirements will be added to the Divisions web site.

Dr. Lundberg made a motion to approve the proposed Pharmacy Practice Act Rule with the suggested changes. Dr. Kemper seconded the motion. All Board members voted in favor of the motion.

Break at 10:35 a.m.
Reconvened at 10:50 a.m.

Discussion regarding S.B. 161:

Mr. Barker indicated he would like to discuss S.B. 161 further. He indicated that the bill allows stakeholders to be involved in the study regarding prescribing practitioner safety and requested the Pharmacist Association be included. Mr. Steinagel stated that the Division posted a RFP and no submissions were received. The process was opened for an additional week and closes tomorrow. He indicated there are two candidates at this time. The individual chosen would do the research and that is why stakeholders have not been contacted. Ms. Brennan stated the RFP did not require the researcher to work with stakeholders. She indicated the RFP deals with studies and research. Mr. Steinagel questioned whether or not there is a feeling the Division does not want to work with stakeholders? Ms. Brennan stated no, but all these stakeholders want to work together and the RFP will not provide enough time for this involvement. Mr. Steinagel stated he will involve as many stakeholders who want to be involved. He stated there was no intention of excluding the stakeholders. Ms. Brennan questioned whether or not the Division will be looking at the physician for compliance? Mr. Steinagel stated the RFP did not include compliance, but the Division addresses compliance. He indicated there may not be a lot of information from this year, but there should be enough information from the bill that passed two years ago regarding cosmetic medications. Ms. Brennan stated the RFP was online and it was difficult to address the all language in the bill. She stated she requested clarification, however, didn't receive the clarification. By that time, the web site indicated the application process had closed two weeks prior.

Review E-Mail received by the Divisions:

Dr. Hobbins indicated she received an e-mail from a

Class C Pharmacy requesting clarification whether or not a pedigree is required if drugs do not leave, or have ever left, the normal distribution channel. Dr. Hobbins indicated she is concerned with increase in grey market pharmacies and would like the Board's opinion regarding the pedigree requirements. Dr. Hobbins reported that Dr. Young indicated the only instances of a drug leaving the normal distribution channel would be in emergency situations where medications are stock piled, not to be dispensed to patients unless there is a declared pandemic; or if a drug is in short supply and the medication comes from outside the US or from a pharmacy that specializes in hard-to-obtain medications. Mr. Jones stated he has concerns with this issue and the issue of shell pharmacies. Mr. Jones stated the Rules need to be made clearer regarding Class C Pharmacies.

Dr. Hobbins also indicated an e-mail was received regarding an individual wanting to have an automated kiosk system outside physician offices or other public places to dispense unit doses or pre-packed stock medications. Board members indicated this would require a Statute change and currently could not be done.

Application Review,
Family Provo:

Dr. Hobbins stated the Division received an application from Family Provo, applying for a Class C, Pharmaceutical Wholesaler/Distributor license. The current Rule requires the designated representative be at least 21 years of age and document at least 3 years experience in the manufacture or distribution of prescription drugs/devices. The designative representative worked in a California pharmacy as a cashier. She indicated they will sell generic medications to pharmacies and hospitals and will receive the medications from AmerisourceBerger Drug Corporation and Anda Pharmaceuticals, Inc. Dr. Hobbins indicated the Division has questions regarding the application and most pharmacies buy directly from Anda Pharmaceuticals and is not sure why this company would want to be an intermediary. Mr. Jones stated the Board needs to do a better job of defining standards; however, it appears that the individual meets the requirements of the current Rule.

Review Department of Commerce Rule regarding recusal of Board Members:

Mr. Walker stated the Department of Commerce Rule has been filed. The Rule states that any Board member can only be recused if they personally decide they should be recused.

Surescripts E-Mail update regarding electronic prescribing of controlled substances:

Surescripts provided an update on electronic prescribing. Nine states are now currently e-prescribing. Mr. Walker stated a Rule could be written to incorporate the Federal Code by reference. There would be a waiver if the pharmacy does not have the capability to meet the requirement. Dr. Hobbins stated that it was her understanding that no software vendors meet the requirements and that is what we are waiting for. Mr. Walker stated the Board could put the Rule in place, and then when it comes to fruition, the Board and Division would be ready to implement the Rule. Mr. Jones made a motion to adopt the Federal Standards into Rule. Dr. Kemper seconded the motion. All Board members voted in favor of the motion. Dr. Hobbins indicated she would add those standards to the proposed Rule.

E-Mail regarding multidose medication dispensing at discharge for inhalers, eye/ear drops and creams/ointments used during inpatient stay:

An inpatient pharmacy can not dispense medications for a patient going home. There was a question whether or not a patient could take home the inhaler, creams/ointments, etc. Dr. Hobbins stated it seems like the medications already belong to the patient. Dr. Kemper stated that most inpatient pharmacies dispense hospital size inhalers and creams/ointments, and they are not full size. Mr. Jones stated that the patient can not take the medications home. The medications need to be labeled correctly and there is no language in Rule to allow the patient to take them home. The prescription would have to be written, and filled at the Outpatient Pharmacy or pharmacy of choice.

E-Mail question regarding dispensing for office use:

There is nothing in Statute that allows for a pharmacy to dispense to a physician for office use. The medications must be invoiced between the pharmacy and the practitioner and should be in minimum quantities. There are exceptions that allow a physician to dispense out of the office, but these are limited and covered in Statute and Rule.

The question also included the compounding of drugs

for office use. Mr. Jones stated that a pharmacy can not compound medications for the physician use unless it is patient specific. The physician can not obtain the medications under his name. If a pharmacy were to supply medications not used for administering purposes and used by the practitioner for dispensing, the pharmacy could be aiding in the unlicensed practice of pharmacy. Supplying sterile products to a practitioner is the same. The practitioner would have to abide by USP for 795 or 797 and the pharmacy could be aiding and abetting the practitioner to violate these guidelines. The practitioner can purchase the compounded medication for a specific patient, but the medications have to be maintained in a sterile environment.

Pharmacy Intern Hours:

The discussion regarding pharmacy intern hours was tabled until next month.

Adjourned for lunch at 12:00 noon
Reconvened at 1:03 p.m.

Mark Steinagel:

Mr. Steinagel answered questions regarding e-prescribing. Mr. Jones stated that the bigger chains are already e-prescribing in other states and as soon as the law allows it in Utah, these chains will be able to make the change quickly. However, there is concern for the smaller pharmacy and for the cost of purchasing the software. Mr. Steinagel stated the DEA established Rule and States needed to determine state requirements. He indicated the sponsor for the Utah bill was approached for an extension and the sponsor agreed to postpone the implementation date. Mr. Steinagel stated he will have Karl Perry, assistant attorney general review the Statute to see what is currently allowed and will have Mr. Perry report back to the Board next month.

Connie Call,
Compliance Report:

Connie Call reported she has had no contact with James Bee and doesn't know if he will be available to interview by telephone. All other probationers are in compliance.

Diann Millikan,
Probation interview:

Ms. Millikan reported her sobriety date has been seven months. She reported she is focusing on herself, attending meetings and understands she needs the

support of others to help her in her recovery process. She indicated her counseling also includes relationship issues. Ms. Millikan stated she continues to volunteer and has not missed calling Affinity. Ms. Millikan stated she is feeling much better. Board members indicated it was good to see her here as her own support, without needing others to come with her. Ms. Millikan questioned whether or not she could work as a pharmacy intern. Board members indicated she could explore the issue and if she finds an opportunity, to contact Ms. Call. **Ms. Millikan is in compliance with the terms and conditions of her Order.** She will be seen in August 2012.

Suresh Boodram,
Quarterly probation interview:

Mr. Boodram indicated he is having a difficult time finding a pharmacist position and stated finding employment is not feasible with the conditions placed on his license. Mr. Boodram reported he has been working a few hours, but doesn't think he will be employed much longer because his position is a temporary position. Dr. Lundberg reviewed his essay on the Critical Thinking course. Dr. Lundberg stated the essay submitted continues to be unacceptable. She questioned Mr. Boodram's understanding of what should be on the essay. Mr. Boodram stated he thought the essay should include what he got out of the class and how the class taught him to rethink decisions. Dr. Lundberg stated she would like Mr. Boodram to think about his actions, why he was brought before the Board and apply what he has learned to his situation. Mr. Boodram's essay is the same one he submitted last time with the addition of six sentences. Mr. Boodram stated he thought the reason the essay was not accepted was due to the way it was written. Dr. Lundberg reminded Mr. Boodram that he has been present each time the Board discussed why the essay was not accepted. Dr. Lundberg again indicated he should think about his actions, what has changed and what he has learned. He stated he understands and will rewrite the essay. Mr. Boodram submitted a letter requesting changes to supervision. Dr. Lundberg stated Mr. Boodram continues to have difficulty taking responsibility for his actions and stated amending the Order would not be considered at this time. **Mr. Boodram is in compliance with the Order because the Order does not require him to**

submit the Thinking Errors essay. However, Board members consider him out of compliance because he has not completed the requirements requested by the Board. He will be seen again August 2012.

Dennis White,
Quarterly probation interview:

Mr. White reported things are going well. He is current on all reports and his employer report is excellent. He stated he thought about taking the Thinking Errors course as suggested by Board members, but he is planning on retiring in October 2012 and decided not to take the course. **Mr. White is in compliance with the terms and conditions of his Order** and will be seen in November 2012.

James Bee,
Telephone probation interview:

Mr. Bee could not be reached by telephone. Dr. Lundberg questioned whether or not a fine should be issued for non-compliance for not submitting a current telephone number where he could be reached. Mr. Bee was placed on probation for two years and has been out of compliance for one year. He has not taken the MPJE examination and the Order indicates he should have completed the examination within one year. Dr. Lundberg made a motion to impose a \$100.00 fine for non compliance. Mr. Jones seconded the motion. All Board members voted in favor of the motion.

Mr. Bee contacted the Division and indicated he had left a new phone number on voice mail. The letter was sent to the correct address. He indicated he has registered for the MPJE and is waiting for the Division to approve him to sit for the examination. After further review it was determined that Mr. Bee had contacted the Division with a new phone number and called the Division when he did not receive a phone call from the Board. Mr. Jones made a motion to dismiss the vote to issue the \$100.00 fine. Dr. Lundberg seconded the motion. All Board members voted in favor of the motion.

Pharmacy Technician University:

A motion was made to approve the Pharmacy Technician University program. The motion was seconded. All Board members voted in favor of the motion.

Lenny's Richfield Pharmacy Technician

More information is required before approval can be

Program: granted. The program must submit a copy of the final exam, submit additional details regarding the practical training at IHC and submit the link to the textbooks referenced, or submit the textbook for review.

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.

July 28, 2012
Date Approved (ss) Dominic DeRose
Dominic DeRose, chair,
Pharmacy Licensing Board

July 28, 2012
Date Approved (ss) Debra Hobbins
Debra Hobbins, Bureau Manager,
Division of Occupational & Professional Licensing