

MINUTES

**UTAH
PHARMACY BOARD
MEETING**

November 13, 2012

**Room 210 (second floor) – 8:30 a.m.
Heber Wells Building
Salt Lake City, UT 84111**

CONVENED: 8:34 a.m.

ADJOURNED: 4:00 p.m.

**Bureau Manager:
Board Secretary:**

Debra Hobbins, DNP, APRN,
Shirlene Kimball

Conducting:

David Young, Pharm D, Chair

Board Members Present:

Kelly Lundberg, PhD, public member
Jan Bird, CPhT, pharmacy technician
Derek Garn, R.Ph
David Young, Pharm D
Andrea Kemper, Pharm D
Greg Jones, R.Ph

Board Members Excused:

Dominic DeRose, R.Ph

DOPL Staff Present:

Mark Steinagel, Division Director
Ray Walker, Division Enforcement Counsel
Connie Call, Compliance Specialist
Jake Corsi, Investigator
Jared Memmott, Investigator
Mitchell Jones, Assistant AG

Guests:

James Ruble, University of Utah
Reid Barker, UPhA
Greg Jensen, Target
Linda Sandberg, Omnicare
Jaime Petersen, Walgreen's
Jordan Burger, University of Utah
Kyle Anderson, Med Quest Pharmacy
Lisa Dimick, PMC
Alice Olsen, Obagi
Marge Hebert, IMC Outpatient Pharmacy
Betty Yamashita, IHC

Erin Johanson, Roseman University
Cody Littlefield, Harding University

TOPICS FOR DISCUSSION

September 25, 2012 Minutes:

October 23, 2012 Minutes:

Mr. Steinagel:

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.

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

Mr. Steinagel indicated the Division will be sending out a letter regarding compounding standards, pharmacist-in-charge notifications and email address notification. Mr. Steinagel stated he wants everyone to be comfortable with the direction the Division is moving. He stated the Division would like to educate pharmacists first so that they are in compliance with the Statute and Rules. Mr. Barker questioned how long the Division will wait after the letter is sent out to begin investigating pharmacies. Mr. Steinagel stated the Division would like to make sure all pharmacists receive the letter. He stated he does not feel the Division needs to be heavy handed, we want to get the information out, then after a number of months, we may move from education to enforcement

Mr. Garn stated he would like to add to the letter the offer to counsel. Counseling should happen on every new prescription and at least once a year on refills. Mr. Jones suggested attaching the PIC change and email address forms to the letter. Dr. Young suggested shifting the compounding paragraph to become the first paragraph of the letter. Mr. Jones indicated a statement should be added that reads: "Please review requirements and be sure you comply." A guest indicated a due date would be helpful. Mr. Steinagel stated the form could be modified and a due date added that within 30 days of the PIC change, the form would be due. Dr. Kemper questioned whether or not the email address needs to be submitted if there is no change. Mr. Steinagel stated if the Division has the current information, the information would not need to be submitted again. However, any changes

would have to be sent to the Division. Mr. Steinagel reported the Division's licensure system will only accept one email address. Mr. Jones stated it would be nice if district managers received the notice and alerts sent to one of their pharmacies.

The Compounding Inspection report was reviewed by Board members. Mr. Steinagel stated the Board needs to determine whether or not to leave in bullet numbers six and seven. Mr. Corsi stated the wording in six and seven is taken from the current Rule. He stated he can not add the proposed wording until those Rules are adopted. Board members indicated they would like to take out bullets six and seven and wait until the Rules are amended. Mr. Jones stated bullet numbers three and eighteen should read "for each form." On bullet number 23 add "beyond use date."

Mr. Memmott and Mr. Corsi will make the suggested changes to the form and bring the form back to the Board for review later today. Mr. Steinagel stated he would make the suggested changes to the letter.

Matthew White,
Report on E-Prescribing:

Mr. White met with the Board to provide an update on electronic prescribing (e-prescribing). Mr. White reported that in 2009 the Legislature passed the "Electronic Prescribing Act" that requires all practitioners to provide existing patients with the option of electronic prescriptions. He indicated this Act was to go into effect July 1, 2012. The 2012 Legislature amended the Act to extend the date to July 1, 2013. Mr. White reported that the DEA issued rules detailing standards for transmitting and receiving prescriptions for controlled substances. The Rule did not require the prescribers to e-prescribe, but if the practitioners wanted to issue prescriptions electronically, they have to comply with the Rules to issue an e-prescription for controlled substances. Mr. White reported the DEA rules are only for controlled substances.

Mr. White stated the Utah Law covers all prescriptions and is mandatory. In order to be approved for e-prescribing the software must go through an audit or qualification. There is an audit completed by a certified system auditor. If the software provider goes

through a certification process, it has to be approved by the DEA. Mr. White stated currently there are no software providers certified.

Mr. White stated most practitioners have not converted their systems for e-prescribing; however most pharmacies are ready. Mr. Garn questioned why the DEA does not require e-prescribing, but Utah makes it mandatory. Mr. Steinagel stated the DEA wanted to get a handle on e-prescribing of controlled substances and the State wants everyone to offer e-prescribing.

Mr. Steinagel indicated there is a federal standard and the Board could write a rule that basically adopts the DEA standards. An exemption could be granted if it can be shown the requirement would be a financial hardship. The Division would be willing to help people/pharmacies come into compliance and would grant an exemption for a year or two and then the process would be tightened up. Mr. Jones made a motion to accept a Rule that adopts the federal standard. Mr. Garn seconded the motion. All Board members voted in favor of the motion.

Discussion regarding opening and closing inventories:

Mr. Walker indicated he recently conducted a Citation Hearing in which a pharmacy acquired pharmacy xyz and conducted a combined inventory. The pharmacy investigator wrote a citation for not conducting a new opening inventory and a closing inventory. The pharmacist appearing at the hearing indicated a combined inventory has been the standard in the past if a pharmacy simultaneously moves the inventory from one pharmacy to the new pharmacy in one day. Mr. Walker stated the Pharmacy Practice Act has a Rule for opening and a Rule for closing a pharmacy. He stated if there is a different standard, the standard must be clarified. Mr. Memmott stated if a new opening inventory is not conducted, no one knows if the closing inventory made it to the new pharmacy. Dr. Young stated he agrees there needs to be a closing and a reopening inventory completed.

Dr. Hobbins requested Board members review the Pharmacy Practice Act Rule, section R156-17b-605 to make sure the inventory requirements are clear. Mr.

Jones stated that the confusion in Mr. Walker's instance was the combining of two pharmacies and moving to a new location. He indicated a section in Rule may need to be created to clarify what needs to happen in this instance. Dr. Hobbins stated the Pharmacy Practice Act Rule, section R156-17b-604 refers to closing a pharmacy. Section R156-17b-605 is general standards. Opening a pharmacy is referenced in section R156-17b-605(2) and reads: an initial inventory shall not be combined with closing inventory except as allowed in (4) (change in ownership). Section R156-17b-605(2)(b) reads: when combining two pharmacies, there must be a closing inventory at the old pharmacy and initial inventory at the new pharmacy. Mr. Garn suggested taking out R156-17b-605(6) and reference section 605(5) in R156-17b-604. Then add to R156-17b-605(2)(b) when combining pharmacies, present standards apply to each pharmacy. Dr. Hobbins will reword the inventory section.

Citations for non-compliance to USP Chapter 797:

Mr. Corsi reviewed with Board members an article on media testing and sterile compounding. He reported the article indicates that everyone compounding should undergo a media field test once a year and go through appropriate training. Mr. Corsi questioned what would the Board consider appropriate training and how serious is it if a media field test has not been completed. Mr. Jones stated the compounding pharmacy should be following USP 797 and we do not need to introduce standards outside that. Dr. Hobbins questioned whether or not the Board has citation authority for non-compliance. Mr. Walker stated yes, the Statute allows up to \$10,000 for a violation. Mr. Barker questioned whether or not prescribers would be subject to the same fines if they violate the law. Mr. Walker stated yes, however, a fine for practicing without a license would be different.

Break at 10:18 a.m.
Reconvened at 10:34 a.m.

Pharmacy Rules discussion:

Dr. Hobbins indicated she placed the Cancer Regimen exemptions in the same section as the Cosmetic Drug exemption. Mr. Jones requested Dr. Hobbins add to the Rule Ms. Duke's suggestion that a practitioner

who chooses to dispense must disclose to the patient that they can have the medications filled anywhere they choose. Dr. Hobbins reported eighteen oncologists have registered with the Division and the online notification should be ready within the next several weeks. She indicated Mr. Memmott will print off a monthly report for the Board.

Mr. Jones questioned what is happening with the intern hour discussion. Dr. Young stated he thought we would incorporate the ACPE guidelines. Mr. Jones questioned if it is necessary to add these guidelines or just say the individual must graduate from an ACPE accredited program. Mr. Garn stated the hours may change and he would like the Rule to state that an individual could be licensed as a pharmacist if they are a graduate from an ACPE accredited pharmacy education program. Dr. Hobbins stated Internship notification requirement will be the title of this section of the Rule.

Dr. Hobbins will review the changes and make sure the numbering is correct.

Open and Public Meetings Act training:

Dr. Hobbins conducted the Open and Public Meetings Act training.

Review changes to the compounding report:

Mr. Memmott stated he took out the email address for the PIC. Dr. Kemper made a motion to accept the compounding report with the changes. Ms. Bird seconded the motion. All Board members voted in favor of the motion.

NECC compounding issues update,
Dr. Jim Ruble:

Dr. Jim Ruble presented an update on the NECC compounding pharmacy and meningitis cases. Dr. Ruble provided a map regarding the spread of the cases as of Friday, November 9, 2012. He indicated there are currently 438 meningitis cases in 19 states with 32 fatalities. Dr. Ruble stated Massachusetts does not have any reported cases because the wholesaler is located in that state and ships to out-of-state pharmacies. Dr. Ruble reported that the meningitis is non-contagious and those with compromised immune systems are more inclined to be the most affected. He reported the onset can be very rapid or at least within a six-week period. If

symptoms have not developed within six weeks, the individual is not likely to be infected and is not treated. Dr. Ruble stated there are three principle owners of two pharmacies and all products from those pharmacies have been quarantined. He stated that three lots accounted for 17,676 doses of the medication. Dr. Ruble reported the CDC and FDA are trying to give out as much information as possible, but NCEE has legal counsel and it is hard to get the information. Dr. Ruble reported this is not the first event for this pharmacy. In 1999 the FDA concluded there were substantial violations, but the FDA didn't have the power to do anything at that time. Dr. Ruble stated the USP 797 guidelines were released in 2004 and did not become mandatory until 2008. On July 23, 2012 Colorado conducted an inspection and found vials supplied by NCEE without prescriptions. Colorado notified the Massachusetts Board chairman and requested further information. Massachusetts did not respond. The Massachusetts Board chairman has been released from his position and the administrator of the Board has been put on a leave of absence.

Dr. Ruble reported FDA revised standards in 2007 but the bill was never filled due to a challenge and a court ruling that the FDA has zero authority for compounding or manufacturing.

Dr. Young reported on a telephone conference call with Senator Hatch's office. The NABP was on the conference call and NABP is putting together a statement. Dr. Young reported Rep. Vickers has also been in contact with Senator Hatch. Mr. Jones stated the fear in the community is that the FDA will regulate all compounding. Dr. Young stated he feels our Board is on the right track. Board members thanked Dr. Ruble for the update on this issue.

Adjourned to lunch at 12:10 p.m.
Reconvened at 1:00 p.m.

Connie Call, compliance report:

Ms. Call reported the following individuals are out of compliance:

-Suresh Boodram was late submitting his employer report. He is requesting early termination of his probation. Dr. Lundberg made a motion to deny the

request. Ms. Bird seconded the motion. All Board members voted in favor of the motion.

-David Barrow was late submitting copies of his prescriptions.

-Paul Martz was late submitting copies of prescriptions and has not paid his therapist.

-Scott Williams submitted a practice plan which was reviewed and accepted by Board members.

-James Ammon requested he be allowed to complete an online thinking errors course. Dr. Lundberg indicated Mr. Ammon would need to complete a face-to-face thinking errors course and made a motion to deny the request. Mr. Jones seconded the motion. All Board members voted in favor of the motion.

Kirtland Wray,
New Order:

Mr. Wray explained the circumstances that brought him before the Board. He indicated he has been in recovery for eight years. Mr. Wray stated he has been teaching pharmacy technicians since April 2006. He stated he will continue to teach and doesn't think he will work in a traditional pharmacy setting. Mr. Wray stated his drug of choice was Lortab. Dr. Lundberg questioned whether or not he continues to take Lortab? Mr. Wray stated he has only taken Ultram. Mr. Wray then stated he was last prescribed Lortab one year ago at Thanksgiving after shoulder surgery. He also indicated prior to that date he was prescribed Lortab for kidney stones. Dr. Lundberg questioned how many times he has taken Lortab in the last eight years? He stated he thinks he has been prescribed Lortab two, possibly three times in the last several years. Dr. Lundberg questioned how often he takes the Diazepam. He stated two or three times a week. Dr. Lundberg questioned how can the Board evaluate his progress when he is still receiving the medication that he is addicted to? Mr. Wray stated he lets his physicians know he has a substance addiction. Mr. Wray stated he understands the terms and conditions of the Order. He indicated he has completed the evaluations with the exception of the physical. Mr. Wray stated he is not working as a pharmacist. Board members reviewed the evaluation submitted and indicated it was not acceptable as an evaluation. Mr. Wray had submitted a form filled out by a therapist he last saw two years ago. Board members indicated he needs to submit a new evaluation and the evaluator

should review the Controlled Substance Database. Mr. Wray also indicated he does not want to provide urine screens because they are too expensive. He also questioned whether or not teaching pharmacy technicians could count toward his probation. Board members indicated if Mr. Wray wants to count teaching toward the probation, he would need to have the supervisor at the program submit employer reports and the director of the program will have to review the Order and sign the form indicating the Order has been seen and read. Mr. Wray stated he will not let the school know about the Stipulation because he would lose his job. The Order includes the felony information and he stated he can not work at the school with a felony. He indicated he began his job before the felony conviction and he will not inform his employer. He indicated they may know that action was taken on his license, but not about the felony. Mr. Wray indicated he is eligible to have the felony expunged in 2013. Dr. Lundberg stated Mr. Wray may want to reconsider the Order since he continues to be prescribed his drug of choice and he does not want to inform his employer about the Order.

Mr. Mitchell Jones joined the meeting. Mr. Mitchell Jones stated that a felony can not be expunged for seven years. He also indicated that if Mr. Wray had a misdemeanor expunged, he would not be eligible to have the felony expunged. Mr. Mitchell Jones stated the Order does not require Mr. Wray to notify his employer if he is not working as a pharmacist. His current position doesn't require him to be a pharmacist. Mr. Mitchell Jones stated that if it is determined Mr. Wray is practicing as a pharmacist he would be out of compliance if he doesn't notify the employer. Dr. Lundberg stated it is an issue that Mr. Wray has not informed his employer regarding the felony. Mr. Wray stated it is not an issue for him because he was hired prior to the felony charge. Dr. Young questioned whether or not Mr. Wray discusses ethics and law with the students? Mr. Wray stated he does teach ethics and pharmacy law. Dr. Young stated teaching the law and ethics of pharmacy is the practice of pharmacy. Mr. Mitchell Jones stated the Order could be amended if the Board makes a recommendation for an amendment and Mr. Wray

agrees to the amendment. Dr. Lundberg stated she is very uncomfortable changing the Order. Mr. Greg Jones stated he agrees and indicated it is Mr. Wray's choice if he does not want to follow the Stipulation and Order. However, if he doesn't follow the Order, he would lose the license. Mr. Mitchell Jones stated Mr. Wray could sign a non-disciplinary surrender until he wants the license returned. Board members indicated Mr. Wray must make a decision by Friday to either surrender the license or submit a letter from the employer.

William Cordova,
Bi-annual interview:

Mr. Cordova indicated he still has not found employment as a pharmacist. **Mr. Cordova is in compliance with the terms and conditions of his Order.** He will be seen again in June 2013.

Diann Millikan,
Probation interview:

Ms. Millikan reported she is currently working at the State Hospital and things are going well. She indicated she submitted her practice plan and started training on October 1, 2012. Ms. Millikan stated she will be working 38-39 hours per week and indicated she is happy to be working as a pharmacist. Mr. Jones made a motion to approve her practice plan. Mr. Garn seconded the motion. All Board members voted in favor of the motion.

Ms. Millikan stated she continues with counseling and is working on thinking errors. Ms. Millikan reported the employer completed an inventory just prior to her starting and controlled substances are kept in a separate locked box. She reported her employer is aware of her problem and she has a great support system. Ms. Millikan stated her probation ends January 2013 and she is requesting early termination of probation. Board members indicated her clock stopped for a period of time because she took a leave of absence and was not working as a pharmacist. Board members indicated the Division will review the file to determine when her probation should be terminated. Board members indicated her probation may be extended to April 20, 2013.

Ms. Millikan stated since the Board can not act on her request for termination of probation, she would like to request a change in supervision and be allowed to

work alone in the pharmacy. Dr. Lundberg questioned whether or not the employer thinks the supervision will be changed at this meeting? Ms. Millikan stated she is hoping the change will be made so she can help out over the holidays. Dr. Lundberg stated she does not want to change the Order at this time because Ms. Millikan recently started a new job.

Ms. Millikan is in compliance with the terms and conditions of her probation. She will be seen in January 22, 2013 if her probation is not terminated by that date.

Cynthia Asher,
Probation interview:

Board members indicated that the physical and psychological evaluations have not been received. Ms. Asher indicated she has completed the chemical evaluation and has received a recommendation that she is safe to return to work. Ms. Asher's license will continue to be suspended until the evaluation are received and reviewed. **Ms. Asher is in compliance with the terms of her Order.** She will be seen February 2013.

Michael Wright,
Probation interview:

Mr. Wright reported things are going well and he is doing great in school. Mr. Wright was reminded to submit his paperwork on time. Board members reviewed the evaluation. Dr. Lundberg questioned how he chose this provider to do the evaluation? Mr. Wright stated it was one of the names suggested to him. Dr. Lundberg stated the evaluation is less than a page long and only seven or eight lines. It is not helpful to the Board. The purpose of an evaluation is to help the Board get an idea what is happening and to set reasonable requirements. Mr. Wright stated the evaluation took six hours and the fee was \$700.00. He indicated he provided the Stipulation to the evaluator. Dr. Lundberg suggested Mr. Wright contact the evaluator and request a refund. This evaluation will not be accepted. Dr. Lundberg questioned Dr. Hobbins whether or not the Division could put pressure on the evaluator for a refund for Mr. Wright. Dr. Hobbins indicated she would write a letter indicating the Board did not find the evaluation helpful and ask for a refund of Mr. Wright's fee. Dr. Hobbins suggested Mr. Wright contact Ms. Call for a recommendation of an acceptable evaluator. Dr.

Lundberg stated she would like to see included in the evaluation information from the Controlled Substance Database and information from the police report. Board members indicated they would extend the due date to submit an appropriate evaluation until January 27, 2013. **Mr. Wright is out of compliance with the terms and conditions of his Order for submitting late paperwork.** He will be seen March 2013.

Jensen Drug,
Probation interview:

Mr. Jensen stated he continues to think about selling the pharmacy. Ms. Call needs to check with the pharmacy inspectors to find out if a recent inspection has been completed. **Mr. Jensen is in compliance with the terms and conditions of his Order.** He will be seen again March 2013.

Clell Fowles,
Telephone interview:

Mr. Fowles stated things are going well. He indicated he is working as a pharmacist 16 hours per month and is currently studying for the NAPLEX. **Mr. Fowles is in compliance with the terms and conditions of his Order.** He will be seen in February 2013.

David Barrow,
Telephone interview:

Mr. Barrow stated things are going well. He stated he places recovery first and continues to see his therapist. He stated he is attending a new support group. **Mr. Barrow is out of compliance for late paperwork and Board members reminded him to submit the paperwork by the 1st of the month.** He will be seen again March 26, 2013.

Paul Martz,
Telephone interview:

Mr. Martz reported things are going well. He indicated he has not paid the therapist and was late submitting copies of prescriptions. **Board members indicated he will be out of compliance until the evaluation report is received.** Mr. Martz will be seen again March 26, 2013.

Colton Dale,
Probation interview:

Mr. Dale was contacted by telephone. He indicated he thought his interview was scheduled for tomorrow and was going to bring in his November employer report. Mr. Dale was reminded that all reports are due by the 1st of the month. However, he submitted an evaluation report and the Board accepted the report as meeting the requirements for the employer report. Board members indicated his essay was written very well. **Mr. Dale is in compliance with the terms and**

conditions of his Order. He will be seen again
February 2013.

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.

January 22, 2013
Date Approved

(ss) David Young
David Young, chair,
Pharmacy Licensing Board

January 22, 2013
Date Approved

(ss) Debra Hobbins
Debra Hobbins, Bureau Manager,
Division of Occupational & Professional Licensing