

MINUTES

UTAH PHARMACY BOARD MEETING

October 23, 2012

Room 474 (Fourth Floor) – 8:30 a.m.
Heber Wells Building
Salt Lake City, UT 84111

CONVENED: 8:36 a.m.

ADJOURNED: 4:22 p.m.

Bureau Manager:
Board Secretary:

Debra Hobbins, DNP, APRN
Shirlene Kimball
Hailee Robertson

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
Dominic DeRose, R.Ph

DOPL Staff Present:

Mark Steinagel, Division Director
Ray Walker, Division Enforcement Counsel
Matthew White, DOPL Intern
Connie Call, Compliance Specialist
Jared Memmott, Investigator
Jake Corsi, Investigator
David Furlong, Chief Investigations

Guests:

Greg Jensen, Target
Adya Mishra, University Hospital
Erik Sorenson, U of U COP
Steffanee Wanlass, HCA
Lisa Dimick, PCM
Geoffrey Brediger, PCM
Linda Sandberg, Omnicare
Betty Yamashita, IHC
Jaime Peterson, Walgreens
Reid Barker, UPhA
Kurt Price, UPhA, Bowman's Pharmacy

Jeanne Brennan
Dave Cheney
Carolyn Kowalchik, University Hospital
Erin Johanson, Roseman University
Travis Hunt, PCMC
Aaron Bench, Roseman University
Codi Littlefield, Harding University
Macheala Jacquez, U of U College of Pharmacy
Missy Duke, USHP
Kevin Janes, PCMC
Angie Kilpatrick
Bret Rawson

TOPICS FOR DISCUSSION

September 25, 2012 minutes:

Dr. Hobbins, update on the fungal Meningitis outbreak:

David Furlong, Chief Investigator,
Discussion regarding investigative procedures:

DECISIONS AND RECOMMENDATIONS

The September 25, 2012 minutes were tabled.

Dr. Hobbins reported on a telephone meeting with the Utah Health Department regarding the fungal meningitis outbreak. It was reported that the FDA made available two lists of customers (consignees) who received products that were shipped on or after May 21, 2012 from the New England Compounding Center's (NECC) Massachusetts facility. The first list included customer names and addresses organized by state. The second list contained the same basic information as the first list, organized by customer name, and included the specific products shipped, the quantities of product shipped and the shipping date. Dr. Young stated Utah has been diligent regarding compounding facilities and feels action will happen fairly quickly on a national level to address compounding issues brought to the forefront by NECC.

Mr. Furlong was invited to discuss investigative procedures as they pertain to probationers. He reported DOPL regulates a number of occupations and professions and one-third of DOPL's employees are investigators and support staff. He reported five investigators handle pharmacy issues. Mr. Furlong explained the process of investigations and indicated that once a complaint has been received, he meets with the investigator, the investigator supervisor and the bureau manager to discuss the case and make a collaborative recommendation to the Assistant Attorney General. It is the hope that the individual can be

brought into compliance without the Division having to be punitive. In these cases, a letter of reprimand, a request for additional continuing education or a fine may be issued.

Mr. Furlong reported that in some instances, a licensee may have a number of complaints, but only a few are addressed in the Stipulation and Order, especially if there is an attorney involved and the terms are negotiated. Once an agreement is reached and the Stipulation is signed, Board members monitor the probation. Board members can determine whether or not to recommend early release of probation based on compliance with the terms and conditions of an Order. Mr. Furlong stated that in a recent situation, there was a probationer under investigation by a federal agency, but before that agency finished their investigation, the Board released the individual from probation. Mr. Furlong stated he is requesting that once a probationer requests release from probation, the Board wait at least a month to see if there are any unresolved reasons why the probationer should not be released. He reported that an investigation can not be shared, but the Board could be made aware that an investigation is being conducted. Mr. DeRose questioned whether or not a pharmacist is contacted for expert advice? Mr. Steinagel indicated that the Division can designate a member of the Board for contact; however, that Board member would have to be recused if there were a hearing. He indicated investigations regularly call members of the profession for advice. Mr. Steinagel stated generally the Division will contact a past board member for expert advice. Mr. Steinagel stated it is very important that the Board be comfortable with the direction the Division is going.

Discussion regarding the Stipulation and Order template:

Mr. Steinagel requested Board members review the template and if they have any changes, let the Division know. Ms. Brennan stated an individual can contact an attorney before signing the document. Mr. Furlong stated Dr. Hobbins brings unusual cases to the Board; however, it may be helpful to know that a pharmacist has been contacted for advice. Mr. Garn stated one of the most common changes to an Order is the number of hours the probationer needs to work to keep the probation going. Mr. Steinagel stated he would prefer the Order read employed full time and indicated he

would rather have someone working under supervision and fixing their problem. Mr. Steinagel stated Mr. Mitchell Jones could draft an Order specifically for pharmacy and leave out the number of hours a pharmacist must work to keep the probation going. Mr. Garn made a motion to leave out the number of hours a pharmacist must work to keep the probation going. Ms. Bird seconded the motion. All Board members voted in favor of the motion.

Adjourn to Rules Hearing at 9:15 a.m.
Reconvened from Rules Hearing at 9:25 a.m.

Ms. Johanson questioned why the intern hour issue was not addressed in these Rules? Dr. Hobbins indicated that after a discussion with Mr. Walker, it was determined that a Statute change would be necessary. Mr. Steinagel stated after a review of the Statute, the intern hours could be changed in Rule. Mr. Walker stated that the Statute anticipated that the education is separate from the intern hours and the original thought when reading the Statute was that we could not define the internship as the education. The Statute anticipates the internship occurs after the education. All other rules regarding the intern will remain the same, but will eliminate the number of intern hours required. Board members indicated R156-17b-303b should be changed and strike (1)(a),(b), (c) and (d). Mr. Steinagel stated we can make the change; however the question is whether or not the change can go on this rule filing and delay the implementation of the rule for two months; or if another rule filing should be done. R156-17b-303b (2) and (3) will still be required. The individual would have to complete 1640 hours to graduate, but most will have completed 2100 hours. Dr. Young stated he does not feel we need to keep (b) or (c) or (d). A motion was made to strike R156-17b-303b(1)(a)(i) and R156-17b-303b(1)(a)(ii). Section (2) and (3) will be retained. The motion was seconded. All Board members voted in favor of the motion.

For the foreign graduate, R156-17b-303a (1), (2) and 303c (5) will still apply.

PIC Change form:

Mr. Memmott indicated a letter will be faxed to the pharmacies indicating the PIC information needs to be updated. Mr. Jones questioned whether or not the change form needs to be filled out if there are no PIC changes. Mr. Memmott stated he could make

a change to the form and create a box that indicates this is the date the PIC changed. Dr. Young stated that he feels only the new PIC information should be gathered and old data would not need to be listed. Board members indicated this form is fine for obtaining the PIC information, but not for gathering the initial e-mail addresses. Mr. Steinagel stated the form will be changed. He stated it is not necessary to go back years to determine each PIC and the date that the PIC began. However, this information must be kept from here on. Mr. Jones requested the forms be brought to the Board for approval prior to being posted on the Division's web site. Mr. Steinagel stated the Division can not bring all forms to the Board for approval, but will bring the PIC change form and the e-mail address form back to the Board.

Hospital Guidelines:

Dr. Hobbins reported she received an e-mail regarding a request that the Board consider eliminating the word "rural" from the document because rural is not defined. This individual would like the document to read: after-hours medications taken from pharmacy when a pharmacy is closed. Dr. Kemper made the motion to strike the word "rural". The motion was seconded. All Board members voted in favor of the motion

Ray Walker, presentation regarding Informal Hearing process:

Mr. Walker indicated the Division just completed the umbrella informal hearing processing document. The informal hearing process reviews violations of probation, actions from other states, denial of renewal of licensure and denial of initial licensure. A petition would be filed, the individual required to submit a written response, the matter placed on the Board agenda and an open meeting held providing the individual the opportunity to be heard. The bureau manager will have reviewed the case and have made a recommendation. If the individual does not appear for the informal hearing process, the matter is determined by the Board. If the individual doesn't file a response, it doesn't even go before the Board. This process may take about 30 minutes on the agenda. If the Board makes the same recommendation as the bureau manager, it is given to the Division Director. This process will provide direct dialogue between the Board and the individual. If the Board does not want to take action, it doesn't have to.

If there is significant factual dispute, the matter will go to a formal hearing. Mr. Walker stated the downside to the informal hearing process would be no discovery and everything would start over if it goes to Appellate Court. Mr. Walker stated either side can make a motion to move to a formal hearing. If this happens, the Division Director makes the determination whether or not to move to a formal hearing.

Marvin Sims
Report on NABP Interconnect:

Mr. Sims reported that the Justice Department is concerned with security issues and the Interconnect system. Utah has signed a MOU with NABP, but the overall NABP inter structure may have to be redone. Mr. Sims reported the Division is looking to see whether or not Utah's system meets Federal guidelines. Mr. Sims stated we feel our security meets the federal guidelines, there are separate logins; however, may need to have double or triple logins according to the Federal guidelines. States will need to adopt the Federal security guidelines and each state will have a porthole to obtain access. Based on the rules, practitioners in other states will have access to the database.

Marvin Sims, DOPL
Christopher Rice, Utah Interactive,
Report on real time database:

Mr. Sims stated the Division is working with 26 pharmacies that are reporting real time and approximately one-half are Harmon's Pharmacies. Mr. Rice reported the system is working very well. Mr. Rice reported there are 22,000 transactions per month and the new system takes 2.5 seconds to complete a transaction. He reported the transaction occurs at the point of sale. Mr. Rice reported we are currently working with only one software vendor; a lot of vendors are reluctant to give up control of their firewall.

Missy Duke:

Ms. Duke submitted proposed rule language for documentation of disclosure to patients. This would allow the patient to choose a pharmacy to obtain the medications if they wish. She indicated she is not sure how to word rule so that it addresses whether or not physicians are making a profit. Ms. Duke also indicated that there will be a stakeholder meeting on October 25, 2012 and then a meeting with Health and Human Services Interim Committee on November 14, 2012 with Dr. Munger. Mr. Jones stated he agrees with writing proposed language for documentation of disclosure to patients that they can use a pharmacy of

their choice. However, he stated he does not know how we would address the issue of physicians making a profit. Mr. Corsi stated the division may be able to subpoena the records, but is not sure if that is the direction we should be going. Dr. Young stated we could put this action in the “bucket” list for writing the next set of rules. Mr. DeRose stated that if there are codes being used for insurance purposes, the pharmacy benefit manager may want to be involved. Ms. Brennan stated there are laws that prohibit bundling; the provider can not charge more for the service.

NABP “Electronic Mailbag” – letter from the American Veterinary Medical Association and NABP’s response:

The document was reviewed. Informational only.

Mr. Jones, question regarding verifying continuing education through NABP:

Mr. Barker stated the Utah Pharmacist Association will start reporting continuing education to NABP. He stated that ACPE is pushing for this reporting. Dr. Young stated that the certificate is entered into the NABP system and when the pharmacist needs the information, all he/she has to do is print off the report regarding the number of credit hours earned and the certificates. If the pharmacist has not attended an ACPE-approved course, it is not entered into the system. Mr. Barker stated there is a large national group that is not reporting to NABP. He also indicated there are other organizations that will not begin reporting until January 2013.

Mr. Jones, discussion regarding USP Chapter 17 language regarding prescription counseling:

Mr. Jones questioned what happened with the issue that Rep. Poulson brought before the Board for requiring all pharmacists to provide consultation with all prescriptions. It was reported there is still opposition to having to provide consultation for every prescription. A guest indicated that a motion regarding this issue was made at an UPhA Board meeting; however there was not a quorum of the Board and it will be placed on their agenda in the future. He reported if the motion passes, the UPhA will not be pursuing the issue. Dr. Young reported that those states that have mandatory counseling had inspectors go out, and the rates of pharmacists offering consulting went up. There appears to be a number of pharmacists that are not offering counseling on new prescriptions, let alone on refills.

Mr. Garn stated that the language is in the Rule, there is a fine for not consulting under unprofessional conduct. Mr. Jones stated the key is public safety and there is a need to communicate with the pharmacists and review with them on what is expected in the law and that counseling on a day-to-day basis is a critical function of the pharmacist. Mr. Garn stated he agrees that education must take place and then step up to enforcement. At that point, if the pharmacist is not providing consulting, a fine could be issued. Mr. Jones feels a fine schedule should be posted so that the pharmacists will know what to expect. Mr. Jones made the motion to communicate and educate pharmacists regarding counseling; and then move to issuing fines if the behavior continues. The fine schedule needs to be posted. Mr. Garn seconded the motion. All Board members voted in favor of the motion.

Mr. Jones also indicated that the final vote for the USHP will take place in November. This may become a national standard and the Board needs to add it to the "bucket" list for addition to the Rule.

Adjourn to lunch at 12:01 p.m.
Reconvened at 1:01 p.m.

Connie Call,
Compliance report:

Ms. Call reported the following individuals are out of compliance with the terms and conditions of their Order:
-Kyle Rootsart submitted his paper work late.
-Colton Dale did not submit his employer report.

Lincare,
New Order:

The interview for Lincare was conducted by telephone. Mr. Paul Gabos and Jeanne Reese reported that Lincare DME and Oxygen was placed on probation in Missouri for sending products before they were licensed in Missouri. When applying for the Utah license, they disclosed the Missouri probation and Utah placed them on probation with the same terms and conditions listed in the Missouri Order. Ms. Reese stated that the Missouri probation is scheduled to end June 1, 2013. Board members indicated that if they comply with the terms and conditions of the Missouri Order, they will also be in compliance with Utah's Order. Board members requested documentation from the Missouri Board regarding their compliance. They will need to have Missouri provide documentation of completion

of the probation in June 2013 and the Utah probation will be terminated. **Lincare is in compliance with the terms and conditions of probation.** A telephone interview will be scheduled for February 26, 2013.

Layne Kilpatrick,
Quarterly interview:

Mr. Kilpatrick submitted his employer report and self-assessment report. The employer report was excellent. Mr. Kilpatrick stated business is good. Ms. Bird questioned whether or not Board members would like to move Mr. Kilpatrick to meeting with the Board every six months instead of quarterly. Mr. Kilpatrick stated he would agree with meeting with the Board every six months. Mr. Kilpatrick submitted all required continuing education. He will be scheduled to meet in January and July. Dr. Young commented on Mr. Kilpatrick's demeanor and Mr. Kilpatrick stated he feels much better and has been putting things into perspective. **Mr. Kilpatrick is in compliance with the terms and conditions of his Order.** He will be seen again January 22, 2013, then again in July 2013.

James Ammon,
New Order:

Mr. Ammon explained the circumstances that brought him before the Board. Mr. Ammon stated he understands the terms and conditions of the Order and will submit self-assessment and employer reports monthly for the first six months and will meet with the Board quarterly. Mr. Ammon indicated he has submitted paperwork to the 4th Street Clinic for volunteer hours. He indicated he will be able to request termination off the OIG list by December 21, 2012. Dr. Kemper recommended he attend a thinking errors course. Dr. Kemper clarified that he would not need to submit audits; the Division will conduct random audits. Mr. Ammon stated he will notify the Division when he obtains work and will sign up for the thinking errors course. **Mr. Ammon is in compliance with the terms and conditions of his Order.** He will be seen again February 2013.

Sheryl Ledet,
Quarterly interview:

Ms. Ledet expressed gratitude to the Board for allowing her to stop calling into Affinity during time she was out-of-state attending her mother's funeral. Ms. Ledet reported her own surgery went well and she returned to work two weeks ago. **Ms. Ledet has been in complete compliance with the terms and conditions of her Order for ten months.** Ms. Ledet will be seen

Kohler Food Stores Pharmacy,
Rick Willie, PIC
New Order:

again January 22, 2013.

Mr. Willie, PIC for Kohler Food Stores Pharmacy, met with the Board due to violations found during an inspection. The pharmacy was not documenting the offer to counsel and the wrong patient information had been entered into the computer. Mr. Willie stated he was not aware that the pharmacy technician had entered the information incorrectly. He also indicated he was not aware he needed to keep track of the refrigerator temperatures or that he needed to have separate refrigerators for medications and food. Other issues included medications without an expiration date on the label. Mr. Willie stated he has been the PIC since November 1999 and had forgotten parts of the Pharmacy Practice Act and Rule requirements. Dr. Lundberg indicated that the Pharmacy Practice Act and related Rules are located on the Division's web site and readily available for review. Dr. Lundberg questioned whether or not he provides training to employees and whether or not he had a policy and procedure manual? Mr. Willie stated he will make sure all new employees and all employees receive appropriate training and there is a policy and procedures manual. Mr. Willie stated he understands the terms and conditions of the Order. **He is in compliance with the terms and conditions of his Order** and will be seen again January 22, 2013.

Danny Carter,
Probation interview:

Mr. Carter stated he continues to work at a substance abuse treatment center. He submitted a business plan for the Board's review regarding contracting out to other detox centers providing medication consultation. Mr. Carter stated he is pursuing substance abuse treatment centers to provide himself a different employment avenue other than working in a pharmacy. Board members questioned who would supervise him at the other centers? Mr. Garn stated he does not see an issue with the plan that he has submitted. He stated if Mr. Carter is working as a consultant, he does not need a supervisor if it is a position that anyone could do without a pharmacy license. If the consultation is pharmacy specific, he would need to be supervised by a pharmacist and the pharmacy supervisor would need to sign off on the report. He needs to submit a specific practice plan for each facility and the job description of the individual supervising and submitting Mr. Carter's

reports. **Mr. Carter is in compliance with the terms and conditions of his Order.** He will be seen January 22, 2013.

Kyle Rootsart,
Interview:

Mr. Rootsart reported he continues to remain unemployed which is a large financial strain. He indicated he completed the continuing education for Ethics. Mr. Rootsart stated he does not have a criminal background or any action currently pending; however, the Stipulation and Order impacts his ability to find a job. Dr. Lundberg suggested Mr. Rootsart go to the Bureau of Criminal Identification to review his information and obtain a copy to provide to prospective employers.

Board members reviewed the October 16, 2012 letter requesting early termination of probation. Dr. Lundberg stated the Board would only consider early termination if the individual is in compliance with all terms and conditions of the Order and based on the individual's actions. Board members suggest Mr. Rootsart provide the definition of general supervision to each potential employer. Mr. Rootsart also questioned whether or not he could be the PIC of a pharmacy. Board members indicated that the Pharmacy Practice Act requires a PIC to have an active license in good standing.

Mr. Rootsart questioned whether or not hours worked in California would count toward his Utah probation? Board members stated the California Board would have to place his license on probation with equivalent or more stringent terms and conditions and he would have to document compliance. **Mr. Rootsart is out of compliance with the terms and conditions of his Order.**

Scott Williams,
Probation interview:

Mr. Williams stated he is not currently working. Ms. Call indicated that the employer report from September indicates he is working in Grantsville. Mr. Williams stated the pharmacy is closed; however, the store is open. Mr. Williams stated he may have a job at a pharmacy in West Valley with Carl Swenson. **Mr. Williams is in compliance with the terms and conditions of his Order.** He will be seen January 22, 2013.

Cynthia Asher,
Probation interview:

Ms. Asher did not appear for her scheduled interview.

Maribel England,
Request for Intern license:

Ms. England graduated from a foreign pharmacy school and has the FPGC certificate. She has passed the MPJE examination; however, still needs to pass the NAPLEX examination. Ms. England stated she is currently working as a pharmacy technician and feels that if her intern license could be re-issued, it would help her pass the NAPLEX examination. She received the intern license initially in March 2008 and it expired in March 2009. Ms. England stated she feels it would help her pass the exam if she was practicing as a pharmacy intern. She reported her last attempt to pass the NAPLEX was January 2010. She stated she has been a pharmacy technician for thirteen years. Board members indicated pursuant to the Pharmacy Practice Act she does not meet the requirement for an intern license. A motion was made to deny her request for a pharmacy intern license in accordance with R156-17b-302. The motion was seconded. All Board members voted in favor of the motion. The Board denied her request for an extension so that she could study for the NAPLEX. Ms. England was reminded that she had until December 1, 2012 to take the NAPLEX.

David Abrams,
Probation interview:

Mr. Abrams stated he continues to do well. He is volunteering ten hours per week at Mt. Olympus Pharmacy. Dr. Young made a motion to have Mr. Abrams meet with the Board every six months; in January and July. Dr. Lundberg seconded the motion. All Board members voted in favor of the motion. Ms. Call reminded Mr. Abrams that all his paperwork will still be due quarterly.

Dennis White,
Request for termination of probation:

Mr. White submitted a request for early termination of probation. Dr. Lundberg made a motion to approve the request for early termination. Ms. Bird seconded the motion. All Board members voted in favor of the motion.

E-Mail:

Dr. Hobbins reported she received an e-mail inquiring whether or not the pharmacy could fill a prescription from a deceased prescribing practitioner. Board members indicated the prescription can be filled until it expires as long as the prescription is a valid prescription.

It was suggested that the pharmacist let the patient know that the physician is deceased and to find another prescribing practitioner.

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.

November 15, 2012
Date Approved

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

November 15, 2012
Date Approved

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