

**MINUTES**

**UTAH  
BOARD OF PHARMACY  
MEETING**

**August 26, 2014**

**Heber M. Wells Bldg  
474, 4th floor – 8:30 A.M.  
Salt Lake City, UT 84114**

**CONVENED:** 8:33 A.M.

**ADJOURNED:** 12:53 P.M.

**Bureau Manager:  
Board Secretary:**

Richard Oborn  
Lee Avery  
Jana Johansen

**Board Members Present:**

Derek Garn, R.Ph., Chairperson  
David Young, PharmD  
Andrea Kemper, PharmD  
Jan Bird, CPhT  
Kelly Lundberg, Ph.D.  
Carl "Trip" Hoffman, PharmD

**Board Members Absent:**

Greg Jones, R.Ph., Excused

**DOPL Staff Present:**

Connie Call, Compliance Specialist  
David Furlong, DOPL Chief Investigator  
Travis Drebing, DOPL Inspector  
Jennifer Healey, DOPL Investigator  
Lynn Hooper, DOPL Lead Investigator  
Sherilee McIntyre, DOPL Investigator  
Camille Farley, DOPL Investigator

**Guests:**

Greg Jensen, Target  
Karen Kellogg, Utah Cancer Specialists  
Judith Turner, IMC Outpatient  
Donelle Perez, Peterson's Pharmacy  
Glade Baldwin, Hyland Pharmacy  
Adam Jones, UPhA  
Jamie Peterson, Walgreens  
David Nay, ESI  
Dean Jolley, Jolley's Pharmacy  
Mark Brinton, UMA  
Paige Patterick, Smith's Pharmacy  
Erin Johanson, Roseman University  
Pam Ahlmer, 4 Care Pharmacy

Dean Nielson, PCH  
Mark Morgan, Discovery House

**ADMINISTRATIVE BUSINESS:**

Minutes

The Board reviewed the minutes dated July 22, 2014. Dr. Lundburg made a motion to accept the minutes with changes. The motion was seconded by Mr. Young and carried unanimously.

**DISCUSSION ITEMS:**

1. Investigation report

Mr. Furlong reviewed the pharmacy investigation actions taken by the Division against licensees for July 2014. Mr. Furlong introduced Ms. Jennifer Healey as the new pharmacy inspector and Sherilee McIntyre as the new pharmacy investigator.

2. Compounding Task Force report

Mr. Hoffman advised the Board that the Compounding Task Force is currently working on for office use and USP 800, pain cream, billing and marketing concerns. They started a master list of cleaning supplies.

USP 800 was having an open comment session up until July 31. Earliest we will see this is Spring 2015. After implementation pharmacies will have six months to come into compliance. The biggest concerns are the negative pressure room. There is concern that these changes will have a major impact on pharmacies.

There is a concern that the way some pain cream is being marketed is illegal. In some cases, marketing is being done by 1099 employees not employed by the facility. There is concern that the marketers give large numbers of free samples in large quantities without prescriptions.

The Task Force would like to share a master cleaning list with the Board by the November Board meeting

DOPL investigators indicated that they will look into the allegations.

3. Proposed rule amendments  
a. Office-use compounding

Mr. Oborn reviewed the proposed standards for office-use compounding. After consulting with a representative of FDA on the phone, Mr. Oborn

realized that it would be possible for a pharmacy to be in compliance with state standards and out of compliance with federal standards. There is a question of whether the Board of Pharmacy recommends that the Division adopt rules that put a Utah pharmacy in this position.

One of the reasons to adopt the proposal is that Utah pharmacies are already selling compounded medication to doctors without patient specific prescriptions under Senate Bill 77.

The FDA requested to know some examples of medications that have been in short supply. They feel the doctors could do a better job of informing them of which medication are in short supply. The FDA has still not appointed an advisory committee to provide input regarding the regulations used to implement the new law.

Reasons to not adopt the proposal include the fact that under informal guidance from the FDA, office use compounding with a patient specific prescriptions is prohibited unless strict exemption requirements are met. One exemption is for a pharmacy to register as an outsourcing facility, but this only applies to sterile compounding.

There is a possibility that the FDA will issue a citation or fine to a pharmacy that engages in selling of compounded drugs for office use without a prescription and without qualifying for a federal exemption. The federal law is not as clear as it should be. FDA issued a warning to a pharmacy in North Carolina for failure to register as an out-sourcing facility.

Idaho is getting ready to adopt their own rule to allow office use compounding with patient prescriptions under certain conditions. Michigan and Colorado have adopted standards as well.

Florida law states that you need to register as an outsourcing facility for sterile compounding for office use but leaves non-sterile as it is.

Dr. Lundberg questioned what the consequences were for adopting or not adopting. Pharmacies could still be fined by FDA despite whether this language is adopted or not. Not adopting could lead to denying patients access.

One option is to send a formal letter to the FDA, requesting clarification. In the meantime, we still have some pharmacies doing it. The concern is that they may not be under the standards the Board and Division believe protect the public.

According to Mr. Hoffman, 26 states have already adopted standards to allow office use compounding. Four states have recently adopted it and Idaho is working on adopting it.

The board may want to get legal advice from the AG's office on this issue. Mr. Young will ask for input from those attending an upcoming NABP meeting. Mr. Hoffman will consult with the Idaho Executive Director, request informal legal advice from the Office of the Attorney General, and draft a letter to the FDA requesting clarification. We want this on their radar with the clock ticking and hopefully get a response back with guidance.

Wyoming created their own rules on compounding and it may be a good idea to look into their rules.

b. Physician dispensing

Mr. Oborn reviewed the handout with the Board and shared general information about the recommendations made by the SB 55 Task Force. Dispensing medical practitioner (DMP) clinic pharmacies are closed door pharmacies. In most cases, DMP clinic pharmacies should be required to comply with Class B pharmacy operating standards. The Task Force is identifying some current standards that are overly burdensome that should possibly be eliminated. For example, a **separate sink** should only be required if doing repackaging. Regarding security systems, the Task Force also recommended removal of language requiring that a pharmacy "have an individual respond quickly, assess the entry, and resolve the matter." The Task Force concluded that this language was overly burdensome. The Board also discussed whether the

rule should require that all pharmacies maintain a temperature log. The Board agreed to discuss this and other issues related to dispensing medical practitioner clinic pharmacies further at a future Board meeting.

c. Clarification of R156-17b-614a (2) requirement to store drugs at appropriate temperature

Covered above.

d. Definition of "positive identification"

Mr. Oborn reported to the Board that as of October 31, 2010, 13 states required that government ID for an individual picking up a prescription for a controlled substance be provided in order to positively identify the individual. Some states require only a photo ID. Some states do not require ID at all because the pharmacist confirms ID in another way. The Board reviewed language from the Alabama law. It makes sense to maybe have a list of types of identification that are acceptable and unacceptable. The Board requested that Mr. Oborn draft language for them to review at a future Board meeting.

e. Limit on number of pharmaceutical administration facilities for which a pharmacist can act as consulting pharmacist

Mr. Oborn reported to the Board that there is not a limit on number of pharmaceutical administration facilities for which a pharmacist can act as a consulting pharmacist. In addition, a pharmaceutical administration facility is not required to notify changes in who they identify as their consulting pharmacist. The Board discussed the issue and determined to not recommend that a limit be established.

f. Clarification of qualification to be an approved preceptor as defined in R156-17b-606

Mr. Oborn noted that the current rule requires that an approved preceptor be licensed for at least two years before they begin supervising a pharmacy intern. the statute states that they only need to have one year of licensure. The rule needs to reflect the one year standard. Dr. Lundberg motioned to accept the change, seconded by Mr. Young, motion was carried unanimously.

g. Other

Ms. Bird received the Pharmacy Technician of the Year award from a professional association.

**APPOINTMENTS:**

Connie Call, compliance report

At 10:48 A.M. Ms. Bird made a motion to close the Board meeting to discuss the character, professional competence or physical or mental health of an

individual. The motion was seconded by Dr. Lundberg and carried unanimously. There were no written notes taken. A recording was not made. The Board meeting re-opened at 11:09 A.M.

William Cordova, probation interview

Mr. Cordova met with the Board for his probation interview. Ms. Bird conducted the interview. Mr. Cordova stated he is not working in the field. He is meeting with the Board because he failed to submit his paperwork on time. The Board noted that this is not the first time his paperwork was received late. Mr. Cordova stated he is applying for employment in the field. Mr. Cordova stated that issues with his personal life contributed to getting his paperwork into the Division on time. However, he feels he has resolved these issues.

4 Care Pharmacy/Pam Ahlmer, PIC

Ms. Ahlmer, PIC, met with the Board regarding 4 Care Pharmacy license on probation. Mr. Garn conducted the interview.

Ms. Ahlmer was only employed about a month when the second inspection occurred. During the second inspection, all violations from the first inspection were found to be corrected.

Ms. Ahlmer reported that they are including a packing slip with an offer to counsel with drugs that are shipped to long term care facilities. The statute may need to be amended to exempt a long term care facility from having to offer counseling. Some states exempt long term care facilities from having to offer counseling. The Board will discuss the possibility of recommending that the legislature make an amendment to statute at a future meeting.

Ms. Ahlmer reported that the inspector that visited the pharmacy expressed concern about the ratio of pharmacist to pharmacy personnel at the pharmacy. The ratio was 12 to 1 and he suggested that they may be too high. As a result, the pharmacy made changes to follow the inspector's suggestion. The pharmacy needs to have another inspection before they are removed from probation. 4 Care Pharmacy is in compliance with the terms of their probation.

#3. Hyland Pharmacy/Lisa Burrup, PIC first probation

Ms. Lisa Burrup, PIC, first probation interview. Ms. Bird conducted the interview. Ms. Burrup is the new PIC for Hyland Pharmacy. She has reviewed the stipulation and order. The pharmacy owner, Glade Baldwin submitted a practice plan and this was approved. A new supervisor, Judith Anderson, has been found. Judith Anderson's pharmacist license was issued before 1988 and is active and in good standing.

Ms. Bird motioned to approve Ms. Anderson as the supervisor for the pharmacy, seconded by Dr. Lundberg. Carried unanimously. The first supervisor report is due October 1, 2014.

The pharmacy has not done any compounding since they signed the order. They are working on getting the formulas and the required documents in order. They have removed all of the expired medication. They completed an annual inventory at the end of July. They have simplified the filing system so that all employees can find the information. The pharmacy can find templates for standard operating procedures on the IJPC website.

The pharmacy should submit a letter to the Board when they are ready to resume compounding. Hyland pharmacy is in compliance with the terms of their probation.

#4. Bryan Nichols, first probation interview

Mr. Nichols met with the Board for his first probation meeting. Mr. Young conducted the interview. Mr. Nichols stated there was financial mismanagement which caused the pharmacy to run into problems. During the follow up investigation in April, Mr. Nichols was at a conference out of town. He had a fill in pharmacist who didn't know where everything was. Temperature logs were on location and were fine at the previous two inspections, but the temporary pharmacist could not locate them. Firestone Pharmacy did not do the necessary paperwork for the merger that was supposed to take place. Prescriptions were accepted from facilities that were signed by a nurse instead of the practitioner and some prescriptions were not signed at all.

The Board wants to know what mechanisms are in

place to help Mr. Nichols avoid the problems that arise from having financial issues. If the same problems come up in the future, Mr. Nichols states that he would resign.

Mr. Nichols can work under general supervision. He can be a staff pharmacist with no managerial responsibilities. Reports need to be submitted monthly for the first six months, quarterly thereafter.

First supervisor report will be due September 1, 2014. All reports are due on the first of the month. Mr. Nichols is working now and his supervisor has signed the forms.

The Board recommends that Mr. Nichlos complete the Cognitive Restructuring Thinking Errors course through Clinical Consultants. This is approved.

Continuing education needs to be completed within a year of the signed stipulation. The essay must be submitted within 30 days of finishing the course. the Board needs to pre-approve the continuing education course on compounding that he chooses.

Payment of the fine is due October 25. He has worked out a payment plan.

His probation is for five years, as long as he stays in compliance with his stipulation, the Board may be willing to let him off probation sooner. This all hinges on being compliant.

Mr. Nichols is working at a closed door pharmacy, Red Rock, where the pharmacist in charge is Mark Longo.

He is also working one day a week for a methadone clinic, Discovery House with Mark Morgan. The lead pharmacist is Dean Nelson. Mr. Nelson has read the order. The Board will approve Dean Nelson as his supervisor. The Board asked to see Mr. Nichols at the meeting on November 18, 2014.

#5. Brent Call, public reprimand

Mr. Call met with the Board for his public reprimand. Mr. Hoffman conducted the interview. Mr. Call stated

he is now working at Target Pharmacy.

At the Omnicare Pharmacy inspection in 2012, they were out of compliance with temperature logs and had controlled substance issues also renewing of prescriptions on a yearly basis for long term care. The issues mostly pertained to being out of compliance with USP 797 and USP 795.

Mr. Call says he jumped into the PIC position, before he did he asked why the previous two pharmacists had resigned and was not told about the issues in the pharmacy.

Right after the inspection, he tried to make sure things were compliant. He took over about one year prior to the inspection.

He is currently working at Target part-time. He will continue until he can get on with them full-time. He is not currently a PIC but would like to be again.

He needs to do eight hours of CE in compounding. He did compounding at Omni Care but he is not doing it at Target. Mr. Hoffman motioned to amend the continuing education requirement to require that he complete only two hours of CE compounding, pre approved by the board, and 6 hours in other areas. The motion was seconded by Dr. Lundberg and carried unanimously.

Mr. Call must have his continuing education done within one year of the effective date of the order.

Note: The agenda indicates Mr. Call was meeting with the Board for a probation interview. His meeting with the Board is due to a public reprimand.

**NEXT SCHEDULED MEETING:**

September 23, 2014

2014 Board Meetings:

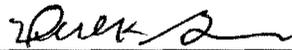
**2014 Board meetings tentatively scheduled:**  
September 23, October 28, November 18 (changed from 25), December 16 (changed from 23).

**ADJOURN:**

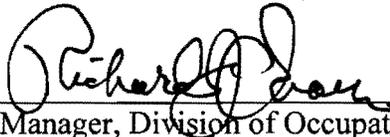
Motion to adjourn at 12:53 P.M.

*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.*

9-23-14  
Date Approved

(ss)   
Chairperson, Utah Board of Pharmacy

9-23-14  
Date Approved

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