MINUTES

UTAH
PHARMACY BOARD
MEETING

July 26, 2011

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

CONVENED: 8:03 a.m.	**ADJOURNED:** 12:20 p.m.
Bureau Manager:	Dave Taylor
Board Secretary:	Shirlene Kimball
Conducting:	Dominic DeRose, R.Ph Chairman
Board Members Present:	Dominic DeRose, R.Ph Kelly Lundberg, PhD public member Jan Bird, CPhT, pharmacy Technician Greg Jones, R.Ph Derek Garn, R.Ph
Board Members Excused:	David Young, Pharm D Andrea Kemper, Pharm D
DOPL Staff Present:	Connie Call, Compliance Specialist Dennis Meservy, Division Investigator Brittany Butsch, Division Investigator
Guests:	David Nay, Medco Linda Sandberg, Omnicare Betty Yamashita, IHC Greg Jensen, Target David Cheney Associated Foods Alice Jackson, Lifetree Clinical Research John Walker Dean Kotrady, Lifetree Clinical Research Jonathon Marks, Lifetree Clinical Research Bryan Nichols, Lifetree Clinical Research Gradon Jackson, Lifetree Clinical Research Roman Grobock, Lifetree Clinical Research Matthew Iverson, Lifetree Clinical Research Cheryl Blair, Jean Brown Research Georgia Simmons, Jean Brown Research Janna Thomas Espinosa, Radiant Research

	Michael Adams Radiant Research
TOPICS FOR DISCUSSION	**DECISIONS AND RECOMMENDATIONS**
May 24 , 2011 Minutes:	Dr. Lundberg made a Motion to approve the May 24, 2011 minutes with corrections. Mr. Jones seconded the Motion. All Board members in favor.
Connie Call, Compliance report:	Ms. Call reported that all monthly and quarterly probationers are in compliance. Heather Palmer requested she be allowed to fill prescriptions at two pharmacies. Dr. Lundberg made a Motion to approve her request for two pharmacies. Ms. Bird seconded the Motion. All Board members in favor. Ms. Call reported the Division has signed a contract with a new drug screening company, AffinityeHealth. The change will take place August 1, 2011.
David Taylor report on Laura Poe:	Mr. Taylor reported Ms. Poe has retired. He indicated the Division is in the process of conducting interviews for this position.
Brent McFadden, Probation interview:	Mr. McFadden reported things are going well. He indicated he is in the pharmacy 42 to 43 hours per week and will begin teaching Diabetic classes in August. Dr. Lundberg indicated the evaluation report received from the pharmacy technician rated his practice below average. Dr. Lundberg expressed concern that the pharmacy technician may not understand how to fill out the report and suggested the supervisor speak with the pharmacy technician. Mr. McFadden stated he thought the reports were to be submitted independently. Dr. Lundberg stated they do need to be submitted independently, but the supervisor needs to make sure the pharmacy technician is interpreting the evaluation in the same manner as the supervisor. **Mr. McFadden is in compliance with the terms and conditions of his Order.** His next interview is scheduled for September 27, 2011.
Mark Akagi, Probation interview:	Mr. Akagi stated he is retired and doesn't have any immediate plans to work. He stated he is not actively seeking employment but he does not want to surrender

	the license. Mr. Akagi was reminded that if he is not employed as a pharmacist he needs to continue to submit reports and meet with the Board. However, the probation period is not reduced if he is not employed as a pharmacist. Mr. Garn made a Motion to amend Mr. Akagi's Order to have him meet with the Board and submit documentation on a yearly basis unless he finds employment or volunteers as a pharmacist. Mr. Jones seconded the Motion. All Board members in favor. **Mr. Akagi is in compliance with the terms and conditions of his Order.** He will be scheduled to meet with the Board July 2012.
Sheryl Ledet, Probation interview:	Ms. Ledet was excused and will be seen next month.
Susan Macon, Probation interview:	Ms. Macon reported she is doing well, but has concerns regarding the controlled substance database. Ms. Macon stated she is being reported as non-compliant each quarter based on incorrect database information. Ms. Macon indicated she obtained a copy of her controlled substance database report and had her pharmacist compare it with her pharmacy records. Ms. Macon handed out the copy for Board member review and indicted that the pharmacist placed a notation by those prescriptions that she did not pick-up. There is a discrepancy between the number the controlled substance database indicated she picked-up (12 prescriptions) and the number she actually picked-up (7 prescriptions). Ms. Macon stated this is concerning because a lot of weight goes on the controlled substance database when looking at compliance. Ms. Macon stated she will submit her controlled substance database report to Ms. Call once a month to show that she is in compliance. **Ms. Macon is in compliance with the terms and conditions of her Order**. She will be seen again October 25, 2011.
Danny (Will) Carter, Probation Interview:	Mr. Carter reported he has been sober 162 days. He indicated he is working in a detox unit as an aide. He stated he answers medication questions and explains medications to patients, nurses and physicians. Mr. DeRose stated that if he is providing counseling regarding medications, he may be able to count that toward the practice of pharmacy. However, he would need to find supervision and submit a practice plan.

Mr. Carter stated he would speak with his employer to see if they could provide documentation of what type of practice they would allow and if supervision could be provided. Mr. Carter also indicated he may be reviewing the agency's medication logs, but would not be around the actual medications. The Board would have to determine if a physician would be accepted as the supervisor in a non-pharmacy setting. Board members indicated if this is accepted, he would still need to work in a pharmacy before ending probation. **Mr. Carter is in compliance with the terms and conditions of the Order** and will be seen October 25, 2011.

Layne Kilpatrick,
New Order:

Mr. Kilpatrick explained the circumstances that brought him before the Board. Mr. Kilpatrick stated his Order indicated he operated an unlicensed pharmacy within two separate pharmacies and that he sold and dispensed HCG to prescribing practitioners and left the prescriptions at the prescribing practitioner's office rather than dispensing directly to the patient. His Stipulation and Order also indicated he sold and dispensed prescriptions to residents outside of Utah where he did not have a license. Mr. Kilpatrick stated his Order does not allow him to discuss the issues any further with the Board. He indicated he takes responsibility even though he was told what he was doing was okay by the Division investigator and Bureau Manager. Mr. Jones informed Mr. Kilpatrick that once the Stipulation is signed, the Board is here to help him get through the probation process.

Mr. Kilpatrick stated Mt. Olympus Compounding now has a license, however, it took over a year to become licensed and he lost a lot of money waiting for the Division to issue the license. He indicated the Division wanted him to sign an affidavit that the pharmacy would stock prescription medication for walk-ins. Mr. Kilpatrick stated he would not sign the affidavit because the pharmacy is a compounding facility. DOPL also wanted an affidavit that the pharmacy would not manufacture drugs. This delayed the application again. He stated he faced losing the business so he had to sell the pharmacy. He indicated that his wife is now the owner of Mt. Olympus

Pharmacy, Michelle Tate is the PIC and he works as an employee of the pharmacy. The pharmacy does mostly compounding, but does have a few walk-in clients.

Dr. Lundberg stated this is Mr. Kilpatrick's second time on probation and questioned why he was placed on probation the first time. Mr. Kilpatrick stated he would not talk about it because it is not related to this probation.

Mr. Kilpatrick questioned what ethics courses are approved by the Board. Board members indicated the UPhA will have a live law and ethics course. There are also courses at the University of Utah and also a law course offered in Cedar City on August 6, 2011. Board members indicated if he finds a course other than those mentioned, he will need to submit the course description to Ms. Call to forward to Board members for review and approval. Board members indicated since he is currently working he needs to submit the practice plan as quickly as possible. Mr. Kilpatrick stated he understands the terms of the probation. His next meeting with the Board will be October 25, 2011. **Mr. Kilpatrick is in compliance with the terms and conditions of his Order.**

David Abrams,
New Order:

Mr. Abrams is out of town and will be rescheduled for next month.

Discussion regarding investigational drug research facilities:

Mr. Ray Walker, Division compliance officer and Jared Memmott, Division investigator were present for the discussion. Mr. Taylor reported the Division received several e-mails and telephone calls inquiring about recent statute changes for research facilities. Mr. Taylor indicated there have been no recent changes to the Pharmacy Practice Act or Rules. Mr. Taylor reported representatives from Lifetree Clinical Research contacted him and requested a meeting with the Board to discuss concerns regarding regulation. Mr. Memmott stated by law, medication is dispensed by pharmacists and the law does not allow physicians to dispense with the exception of cosmetic drugs under certain guidelines.

Gradon Jackson, attorney for Lifetree Clinical

Research, questioned what class of licensure would be required for research facilities. Mr. Walker stated the current rule is silent regarding research facilities and he explained that in the past, the Division determined that pharmaceutical research best fit with the Class C pharmacy license, however, some research facilities were issued a Class B license. Mr. Walker indicated if it is determined that the best fit for pharmaceutical research is with Class B or with Class C, the operating standards would need to be amended or a section added for research facilities.

Mr. Jackson reported the industry is heavily regulated and governed by the Federal Food, Drug and Cosmetic Act. Mr. Jackson stated that when a drug study is introduced, strict protocols have to be followed. He reported Section 312.1 of the Code of Federal Regulations sets forth the procedures for new investigational drugs. Investigational drug facilities have to follow these guidelines in order to stay in business. Activities such as how labeling must occur, control and the handling of the investigational drugs and controlled substances, and dispensing are regulated by the Federal Government. Mr. Jackson stated that DOPL has raised the argument that the Federal Regulations are preempted by Utah law and that Lifetree Clinical Research is subject to the licensure provision in the Utah Controlled Substances Act. Mr. Jackson stated that the Legislature has recognized the significant federal oversight and provided an exception to the general licensure requirements under the Controlled Substance Act for entities that have previously been granted a license from the FDA to engage in the manufacture, production, distribution, dispensing, and administration to conduct research related to controlled substances. He indicated the facility completes regular audits by the Federal Government and they would be willing to notify the Board of the audit results. Mr. Walker stated any activity that is regulated must be licensed or exempt. Because the Federal Government regulates an activity, does not preclude the state from additional regulation (such as the state controlled substance license and the Federal DEA license). According to Utah law, in order to dispense a medication, the facility needs to be licensed

as a pharmacy or be exempt. Mr. Jackson stated these research facilities have been in existence for over a decade, they are Federally regulated and the state does not have a pharmacy licensure category that fits. Mr. Walker indicated the Assistant Attorney General could look at the statue and rules, determine which pharmacy category research facilities would fall under, and then expand the operating standards to include research facilities. Mr. Walker stated he feels there is jurisdictional authority and the rules could address specific type of pharmacy, or if determined, exempt from licensure. Mr. Jackson questioned what these facilities need to do to come into compliance so they can proceed without interruption. Mr. Memmott stated there are a few research facilities that are currently licensed as Class B, pharmaceutical facilities with administration purposes only and the understanding they would not be dispensing. Ms. Jackson, owner of Lifetree Clinical Research stated she looked at applying for a Class B pharmacy license but did not feel comfortable with that category because the facility does not meet the requirements of a Class B pharmacy. She stated she would like to have the correct license and know what the requirements are.

Mr. Jackson also stated that certain requirements in the Utah Pharmacy Practice Act Rules for packaging, labeling and dispensing are different from what the federal government requires. He stated he feels like the research facilities may move to another state because it will be impossible to follow both standards. Mr. Jackson stated their request of the Board is to recognize that the Federal Government has control, it is a highly regulated area and these companies have existed for decades. Or, if no exemption can be given, help them find a category that fits and does not contradict Federal requirements.

Dr. Lundberg suggested a rule change that would capture the operating standards and determine which class the research facilities would fall under. Mr. Garn stated the Code of Federal Regulations outline the standards for these facilities. He suggested only adding to the rule that they follow the Code of Federal Regulations. Mr. Walker stated the Board and the Division could develop a rule that defers to the Code

of Federal Regulations. Mr. Jackson stated he would be willing to assist in drafting rule and questioned whether or not these companies can continue as is until the rules have been adopted. Mr. Walker stated it is not the intent of the Division to change or shut down these companies. The Division wants to work out a solution and to ensure the intent of the Legislature is followed. In the meantime, a rule could be written referencing the CFR, provide operating standards and address the controlled substance database. A definition could be added for research facilities and indicate these facilities are not drug outlets. Mr. Walker also stated the Pharmacy Practice Act approves location and it would be burdensome to have a family practitioner obtain a pharmacy license. Mr. Walker suggested a group from the industry, members of the Board and physicians develop rule that would allow the activity out of the physician's office. Mr. Walker also indicated that another solution would be to wait until the Legislature meets to address the problem. If a rule change is not a good solution for all involved, just let it ride until the Legislature meets.

Board members indicated they would like to wait until the next Legislative session to make any changes and to continue as is for now. The industry will need to approach a sponsor and go through the Legislative process.

Discussion Items,
Remote Participation for MPJE Item writers:

A meeting to review the MPJE examination will be set for August 9, 2011 at 8:00 a.m. Participants will be: Dominic DeRose, David Young, Greg Jones and Betty Yamashita.

Discussion the ACPE-NABP CPE monitoring program:

Mr. Jones stated he feels participation in the ACPE-NABP CPE monitoring program would be a great help to the pharmacist and to the state. Mr. Taylor indicated the Division's attorneys will need to review the information to determine if the Division can participate. Mr. Jones made a Motion to have the Division's attorney review the information and move forward in accepting the ACPE-NABP CPE monitoring system and if possible, have it in place by the September 30, 2013 renewal period. Mr. Garn seconded the Motion. All Board members in favor.

Report on Patient and Safety Centered Prescription Labels Resolution Workgroup:

Mr. DeRose stated the meeting was beneficial and those involved were able to express their concerns. Representative Poulson put forward some good ideas. Mr. DeRose stated that if changes are made to the label, those changes be kept simple. He stated he is concerned that if some of the changes are made, such as adding a diagnosis, the pharmacist would spend all his/her time on the phone speaking with the prescribing practitioner. Mr. DeRose indicated they had a good starting point and he indicated the workgroup will meet in August and maybe again in September. Mr. DeRose stated he felt Rep. Poulson understood the concerns a little better after the meeting. Workgroup members would like to keep it in the rules making process instead of going through the Legislature. The Medical Association should be included so that physicians would be aware the prescription may have to be changed.

Discussion regarding accepting residency programs as meeting continuing education requirements for renewal:

Mr. Jones made a Motion to accept a residency program as meeting the requirement for the continuing education requirement for renewal. Mr. Garn seconded the Motion. All Board members in favor.

Evan Draper
Clarification regarding whether or not licensure is required for a business model proposal:

Mr. Draper reported he would like to open a business to provide medication consultation to patients. He would provide a service as a consultant to the patient, offer a comprehensive review in an office, then over the phone he would conduct the therapeutic drug therapy. Mr. Draper questioned whether or not he would need to apply for a pharmacy license. The process is to have the physician provide the prescription to the pharmacy to be filled, the insurance company would refer clients to him, and he would provide the consultation. He submits billing to the outcomes pharmacy online and they keep the records. Mr. Walker stated that the definition section of the Pharmacy Practice Act, 58-17b-102, the practice of pharmacy, is providing pharmaceutical care and subsection (45) states in collaboration with a prescribing practitioner. Mr. Walker stated it appears Mr. Draper is describing pharmaceutical care and he needs to determine where the care will be provided and where the drugs are dispensed. He would need to obtain both a pharmacist and a Class E pharmacy license.

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.

August 23, 2011
Date Approved

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

August 23, 2011
Date Approved

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