

**MINUTES**

**UTAH  
PHARMACY BOARD  
MEETING**

**September 25, 2012**

**North Conference Room 1st Floor – 8:30 a.m.  
Heber Wells Building  
Salt Lake City, UT 84111**

**CONVENED:** 8:34 a.m.

**ADJOURNED:** 4:33 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  
Jared Memmott, Investigator  
Jake Corsi, Investigator  
David Furlong, Chief Investigations

**Guests:**

Ginger Sykes, FDA  
Kiersten Johnston  
D'Anne Moon  
Kort Delost, RPh, Medicine Shoppe  
Dean Jolley, Jolley's Compounding Pharmacy  
Larry Durrant, Larry's Smithfield Pharmacy  
Evan Vickers, Utah House of Representatives  
Trip Hoffman, University Pharmacy  
Christine Jacobson, Wasatch Pharmacy Care  
Greg Jensen, Target  
Chris Cox, Smiths drug  
Chris Mecklenburg, Smiths Drug

Erik Sorensen, U of U pharmacy student  
Macheala Jacquez, U of U pharmacy student  
Chris Crawford  
Carolyn Kowalchik, University of Utah Hospital  
Ben Brown, IHC Outpatient Pharmacy  
Jaime Petersen, Walgreens  
Kavish Choudhary, USHP  
Betty Yamashita, IHC  
Linda Sandberg, Omnicare  
Dean Moncur, OMC  
David Nay, Express scripts  
Erin Johanson, Roseman University  
Jason Barrows, U of U  
Scott Nelson, U of U  
Michael Jacobson, MD  
Kelly Hansen  
Missy Duke, USHP  
Bill Stilling  
Mike Johnson, Maple Mountain Pharmacy  
Travis Hunt, PCMC  
Layne Kilpatrick, independent compounding pharmacy  
Mike Wright  
Kevin Jones, PCMC

### **TOPICS FOR DISCUSSION**

MPJE Item Review:

Proposed Rules:

### **DECISIONS AND RECOMMENDATIONS**

Dr. Young reported the MPJE item review has been submitted to NABP. Dr. Young thanked Derek Garn, Andrea Kemper and Betty Yamashita for reviewing the items.

Mr. Walker reviewed with Board members the proposed rule changes to the Controlled Substance Database Act Rule. Mr. Garn indicated he is concerned with 156-37f-203(1)(b)(vi) that “required data” include a diagnosis code. Mr. Garn indicated that the diagnostic code is not included on the prescription and the pharmacist would need to contact the prescribing practitioner. Mr. Garn stated this requirement would create additional work for the pharmacist. Mr. Steinagel stated it is not the Division’s intention to create a burden the pharmacist can’t meet.

The rule separates mandatory data and required data. Board members questioned what is the difference between mandatory and required? Mr. Walker stated

mandatory means that if the information is missing, the pharmacist is contacted. Required data means the data is nice to have, but the pharmacist is not contacted. Mr. Garn made a motion to change the wording in (b) from required data to preferred data that is strongly suggested. Mr. Jones seconded the motion. All Board members voted in favor of the motion. Ms. Bird made a motion to move forward with the document with the suggested changes and file the Rule. Dr. Kemper seconded the motion. All Board members voted in favor of the motion.

Dr. Hobbins reported that the proposed changes to the Pharmacy Practice Act Rule will be published in the October 15, 2012 State Bulletin. There will be a thirty day public comment period, the proposed rules will be posted to the web and a rule hearing will be held at the next Board meeting. Mr. Garn questioned how pharmacists will receive information regarding required e-mail addresses. Mr. Steinagel stated the Division will send out a fax alert like the alerts that come from the Division regarding pharmacy issues.

Discussion regarding compounding and rule development:

Dr. Hobbins reported she invited the following individuals to give a five-minute presentation regarding compounding: Ginger Sykes, FDA, Evan Vickers, Reid Barker and Missy Duke. Dr. Hobbins reported Mr. Barker could not be present and she read a letter from Mr. Barker. Dr. Hobbins indicated several other individuals were also invited to provide a presentation but were unable to attend. Dr. Hobbins read to Board members an e-mail she received from Marcia Scoville, APRN. Ms. Scoville provided background information regarding her practice using iso-molecular hormones. She indicated these hormones are prescribed and compounded according to individual test results and provide coverage for a wide range of symptoms. Ms. Scoville indicated she is concerned with the pressure to eliminate the estriol component. She indicated she considers the estriol component key to safety and efficacy of low dose therapy.

Ginger Sykes, FDA:

Ms. Sykes reported that estriol is not a component of any FDA approved drug and it has not been shown to be safe.

Ms. Sykes reported the FDA has an investigational new drug application (IND) that a compounding pharmacy can apply for if they are compounding a hormone therapy drug containing estriol. Ms. Sykes stated it is a violation of FDA law if a compounding pharmacy does not receive approval for an investigational new drug. She indicated the FDA has issued several warning letters and took action in January 2008 against a pharmacist compounding a hormone therapy drug containing estriol without FDA approval. She reported the FDA reviews the internet to monitor compounding pharmacies. Mr. Jones questioned how long the application process takes to receive approval for an investigational new drug once an application is submitted? Ms. Sykes stated she is not sure of the length of time. Mr. Corsi stated he thinks the process is shorter than receiving approval from an insurance company. Mr. Garn questioned how many IND applications are submitted nationwide on a monthly basis? Mr. Garn also questioned what happens if the pharmacy changes owners, or adds another pharmacy? Ms. Sykes stated she does not know; however, it is the prescriber that applies for the IND number. Ms. Sykes reported one application covers multiple patients. Mr. Garn questioned whether or not there was a way to get estriol on the list of approved drugs? Ms. Sykes reported there is a process to go through.

Dr. Young questioned if the FDA monitors USP monograph recommendations? Ms. Sykes stated the FDA does not monitor USP monograph recommendations. Ms. Sykes stated compounding guidelines are different from the USP monograph recommendations. The compounding pharmacy needs to make sure it is using only USP grade products. A guest stated that the FDA is treating compounding like manufacturing. Ms. Sykes stated the FDA does not consider compounding pharmacies to be manufacturing. Mr. Steinagel questioned if any warning letters have been issued to prescribing practitioners. Ms. Sykes stated no, the warning goes to the compounding pharmacy. Ms. Duke stated that the pharmacy is receiving the prescription from the practitioner, the pharmacist can not change the prescription, yet the pharmacy is receiving the warning. Mr. Stilling stated his understanding of the warning letter is that it is the

opinion of FDA that this is what you are doing wrong. Ms. Sykes stated the warning letter is an official action and further action may be taken if corrections are not made. Mr. Stilling questioned if any further action was taken regarding the warning letters that were issued. Ms. Sykes stated no. Mr. Stilling questioned whether or not USP can grade drugs if not approved. Ms. Sykes stated there are guidelines that the USP follows. The FDA issues a warning letter for using non-approved drugs.

Rep. Vickers indicated he recognizes that it is extremely important that compounding pharmacies compound medication in a safe and effective manner and follow USP Chapters 795 and 797. Rep. Vickers indicated that the Midland Court Cases established a number of clarifications. The Food, Drug and Cosmetic Act of 1938 gives State Boards of Pharmacy the authority to regulate pharmacy compounding and that Congress never intended to transfer states' regulatory authority over compounded preparations to the FDA. Federal law differentiates between manufacturing and compounding and acknowledges that compounding is a state-regulated practice. The Court ruling stated it was in the best interest of public health to recognize an exemption for compounded drugs that are based on a prescription written for an individual patient by a licensed practitioner. Therefore, compounded prescriptions do not need to be classified as a new drug or require an IND. States alone have full inspection authority and the FDA may not inspect pharmacies that are compliant with state and local laws. Compounding pharmacies work closely with practitioners and patients on all compounded prescriptions. Practitioners ask pharmacies to compound medications that meet their individual patient's needs. Pharmacies prepare a compounded medication using USP entities that have been manufactured in an FDA registered facility and recognize the need for practitioners and pharmacies to avoid using products that fall on the FDA "do not dispense list." Estriol is not on the FDA "do not dispense list" and is manufactured in an FDA registered facility. Estriol is available in at least five OTC products. He questioned why Estriol is being challenged. If Utah takes action against Estriol, we would be the first state in the nation to do so. Rep.

Vickers stated the rule needs to be changed in R156a-17b-614a(3)(c) to read “bulk active ingredients must be procured from a facility registered with the Federal Food and Drug Administration and must not be listed on the Federal Food and Drug Administration list of drug products withdrawn or removed from the market for reasons of safety or effectiveness.” Rep. Vickers also stated R156-17b-614a(3)(d) needs to be stricken. He stated this action would bring Utah into compliance with good compounding practices.

Mr. Stilling questioned if there were any law or rules in the Utah Pharmacy Practice Act that would prevent women from going to an out-of-state pharmacy to have the medications compounded. Board members stated there is nothing in rule to prevent a patient from going out-of-state to fill a prescription.

Mr. Kilpatrick stated that the point is that most people do not realize how many drugs used every day aren't approved. He questioned whether or not the Board really wants to go after all of those drugs and questioned what brought up this issue? Mr. Steinagel stated the investigators had several concerns and met with him to discuss the issue. The FDA was contacted and after discussing the issues, Mr. Steinagel stated he felt it would be a good idea to send out an educational letter. However, a lot of individuals mistook the educational letter as an enforcement letter. Mr. Steinagel stated if he had it to do over, he would not have sent out the letter. However, he stated the Division will not lead out on this unless the Board determines it is necessary. From the safety standpoint, we have bigger issues. He stated he is not saying we don't enforce the law, but from the estriol standpoint, he doesn't see a public safety issue. He indicated his concern is that this puts the investigators in a hard spot and what rules do they ignore? Mr. Kilpatrick stated he doesn't see a real compelling reason to make a change.

Missy Duke, USHP: Ms. Duke reported Mr. Barker, UPhA, couldn't be present today. Ms. Duke read a joint statement regarding their shared concerns relating to the language in the Pharmacy Practice Act Rule. Ms. Duke stated their emphasis and primary objective is to ensure the safety and welfare of the public.

Ms. Duke stated that the primary concern is the current rule, R156-17b-614a(3)(c) and (d), which indicates “bulk active ingredients must be a component of FDA approved drugs listed in the approved drug products prepared by the Center for Drug Evaluation and Research of the FDA” and that compounding using drugs that are not part of an FDA-approved drug listed in the approved drug products prepared by the Center of Drug Evaluation and Research of the FDA requires an investigational new drug application (IND).

Ms. Duke stated they are proposing two minor modifications to the Pharmacy Practice Act Rule which would follow good compounding practices as well as allow pharmacist to exercise professional judgment in the selection of compounding components. They would like to strike whole sections R156-17b-614a (3)(c) and R156-17b-614a (3)(d) from the rule and then strike the word “extensive” from section R156-17b-614a (3).

Ms. Duke indicated that R156-17b-614a (3)(a) indicates that compounding pharmacists must follow USP-NF Chapter 795 and Chapter 797. These chapters guide the practice of compounding and provide adequate safeguards for public safety and the Pharmacy Practice Act should continue to require compounding pharmacists adhere to these standards and that no further rules on pharmaceutical compounding are necessary. Also, by striking the word “extensive” from R156-17b-614a (3) would indicate that all compounding pharmacies would be subject to this rule.

Mr. Stilling stated that the standard in Federal Court is that FDA authority is limited, but the pharmacy must be in compliance with state law. Mr. Steinagel stated that the FDA could still issue warnings if a pharmacy is not compliant.

Michael Jacobson, MD stated that as a physician, it is within his right to give supplements. There are three basic hormones in the body and estriol is produced by the body according to studies coming from other countries. In the past, women were given estrogen, but this caused unopposed endometrial stimulation, so progesterone was prescribed. Unopposed estrogen

increased the chance of cancer and with estriol, the cancer risks were decreased. He indicated other countries are producing these drugs. The US has patent laws and a number of drugs can not be compounded. He reported that there are five grades of estriol from medical grade down to the agriculture grade. The over-the-counter products with estriol can be used; however, those with the pharmaceutical grade can not be used. Dr. Jacobson stated we need to look at the ultimate goal, and that is to serve the patient in the best way possible. There are a lot of impurities in over-the-counter products.

Larry Durrant strongly suggested that the Board adopt rules in the interest of compounding pharmacies. Dean Jolley stated he feels the Board is on the right course regarding compounding pharmacies.

Mr. Stilling suggested including that a compounded drug is acceptable as long as it is USP grade as listed in the Food, Drug and Cosmetic act.

Dr. Young made a motion to strike the word “extensive” from section R156-17b-614a (3). Also strike sections R156-17b-614a (3)(c) and R156-17b-614a (3)(d) because USP chapters 795 and 797 is already listed in rule. Mr. Garn seconded the motion. All Board members voted in favor of the motion.

NABP Forum:

Dr. Young reported he attended the NABP interactive forum. Dr. Young stated he questioned what other states are doing in regard to medication dispensing for administration or use outside an institutional facility. Linda Sandberg provided information from Idaho and indicated they have written rule that states that a drug or device prepared for self-administration or use by a patient while outside the institutional facility must comply with the standard drug labeling requirements.

Break at 10:20 a.m.  
Reconvened at 10:40 a.m.

Centralized prescription filling:

Dr. Hobbins stated rules for Centralized prescription filling are basically non-existent and the Board needs to draft rule. She indicated we need a definition for intra-company transfer as opposed to a distributor. Mr. Jones

stated that the transfer of inventory is different than transferring an individual prescription. Dr. Hobbins questioned whether or not Centralized prescription fill should be placed under Class E pharmacy, or create a new category. Mr. Garn stated he feels Central Fill should be a closed door, Class B pharmacy. Dr. Young stated the Model Practice Act has excellent language for remote entry, central fill and order fill.

It was questioned whether or not the pharmacist processing the orders should be licensed in Utah? Mr. Stilling stated the Board needs to be careful and not make it too burdensome or complicated. Ms. Brennen stated she feels those pharmacists should be licensed in Utah. A guest indicated that he is aware of a pharmacy in Colorado that fills orders for patients in Utah, Idaho and Alaska and those pharmacists do not need to be licensed in those states but are licensed in Colorado. Some states may require the PIC to be licensed in those states, but not all pharmacists. A guest questioned how mail order pharmacists are held accountable? Board members indicated it is different in every state. Ms. Duke questioned whether or not we can hold a pharmacy licensed in another state accountable. The Board may need to create a separate licensing category. Mr. Walker stated it needs to fit into one of the current categories because they are outlined in Statute; however, the operating standards could be developed for guidance. The Board would need to find a class where it would fit, and then develop operating standards.

Ms. Sandberg stated there are Class A and Class B pharmacies doing this. Mr. Walker stated it depends on the task the remote pharmacy fills. Mr. Garn questioned whether or not both Class A and Class B pharmacies can do central fill? Both Class A and Class B would be allowed, and maybe central order would fall under Class E because there is no requirement for a pharmacist. For central prescription processing, the pharmacist would follow the rules in the state where they are located. It needs to be determined which type of pharmacy will be doing this. Dr. Young suggested for the next meeting, review the NABP Model Practice Act for central processing. Then determine where it will fit and add operating standards. If it is determined they fall under Class D, non resident pharmacy, then the pharmacy and

the PIC would be accountable. Mr. Stilling stated that if it is a non resident pharmacy, then the responsibility defers to that state. Board members discussed making a change that the pharmacist needs to be licensed in Utah. This issue will need to be revisited at other Board meetings.

Develop Rules for S.B. 161:

Mr. Walker stated that rule for S.B. 161 needs to be developed regarding the purchasing and distribution, operating, treatment and quality of care requirements for prescribing dispensers. These rules need to be submitted by November 4, 2012.

Rep. Vickers stated the Board could use the same pharmacy standards in the Pharmacy Practice Act Rule. Mr. Walker suggested adding the same language in R156-17b-310 Exemption from Licensure; R156-17b-602, Operating Standards – Pharmacist-in-charge; R156-17b-604 Operating Standards – Closing a Pharmacy; R156-17b-605 Operating Standards – Inventory Requirements; R156-17b-60 Operating Standards – Medication Profile System; R156-17b-610 Operating Standards – Patient Counseling. Mr. Memmott stated that the more that is referenced in rule, the clearer it is for investigators.

Rep. Vickers stated we recognize that Dr. Munger's study will not be complete until mid-session of the Legislature; however, we need to begin the process. Dr. Young reported that Oregon passed a physician dispenser rule but had to make a whole new pharmacy class. Rep. Vickers reported the UMA indicated this is not a burning issue and he feels we have time to look at the results of the study before more physicians come forward wanting a Statute change. Mr. Jones stated he is concerned that a physician may not disclose to the patient that the cancer drug treatment regimen may be obtained from a pharmacy unaffiliated with the prescribing practitioner. He stated he is also concerned that the practitioner will not offer the patient the opportunity to consult with a pharmacist if the patient desires patient counseling.

Ms. Duke stated she likes having the Rule require physicians to adhere to the pharmacy standards and must have a pharmacist on staff. She stated the Board

may also want to consider requiring a record of how the offer to counsel interaction was disclosed and if counseling was provided.

Mr. Walker also indicated that a Rule that references the Controlled Substance Database needs to be added.

Dr. Kemper made a motion to add: In accordance with the Pharmacy Practice Act, section 58-17b-309 4(c) and 58-17b-309.5(2)(b)viii the standards for reporting to the Utah Controlled Substance Database follows labeling, recordkeeping, patient counseling, purchasing and distribution, operating, treatment, quality of care, and storage requirements shall be the same standards as set forth in the Pharmacy Practice Act Rule R156-17b; The Utah Controlled Substance Act R156-37; and the Utah Controlled Substance Database Act 58-37f. Ms. Bird seconded the motion. Discussion: Ms. Duke questioned how the investigator will know that the physician is addressing counseling with the patient. Mr. Walker suggested adding the above language to the rule filing before November 4, 2012 and then address other issues that pertain to this section.

Adjourn to lunch at 12:13 p.m.  
Reconvened at 12:45 p.m.

Connie Call,  
Compliance report:

Ms. Call reported the following individuals are out of compliance with the terms and conditions of their Order:

- David Barrow has not paid fees associated with the Stipulation and the therapist will not release his aftercare report until payment has been received.
- Paul Martz has not paid fees associated with the Stipulation and the therapist will not release his report until payment has been received.
- Colton Dale, late on submitting paperwork.

Ms. Call reported that Kyle Rootsart had contacted the Division requesting he be placed on the agenda to discuss several matters. Ms. Call reported Mr. Rootsart was informed he could not meet with the Board because it was less than 24 hours required for the agenda notice. If he did meet with the Board, no action could be taken. Ms. Call reported she informed Mr. Rootsart that the board would review his letter and he would be placed on the agenda for October. Board

members reviewed the letter. Mr. Jones stated it is not clear what Mr. Rootsart is requesting and would like Mr. Rootsart to provide clarification before meeting with the Board next month. Mr. Garn stated it appears Mr. Rootsart would like to have an unencumbered license. Dr. Hobbins stated she would like the Board to realize that when there is an investigation, the Stipulation is the result of much negotiation and compromise. There is a lot of background information that never makes it to the Board. Dr. Lundberg stated that whatever is negotiated, the Board should hold the individual to that Order. The individual has agreed to the Order by signing the Order. Dr. Lundberg stated it was not clear in his letter what he is requesting. He will be invited to meet with the Board next month

David Barrow,  
Probation interview:

Mr. Barrow stated he was not aware that he was out of compliance with his order. He stated nothing has changed. He requested he be allowed to attend 12-Step meetings in lieu of aftercare meetings. Dr. Lundberg stated the meetings have different purposes, and the Board would like him to attend the meetings that have the most benefit for him. Dr. Lundberg stated that she feels it would be acceptable as long as he attends at least four meetings per month. She suggested Mr. Barrow also consider attending PIR meetings. Mr. Barrow requested the deadline date for paying his fine be extended an additional year. Dr. Lundberg made a motion to extend the deadline date to June 30, 2013. Mr. Jones seconded the motion. All Board members voted in favor of the motion. **Mr. Barrow is out of compliance with the terms and conditions of his order.** He will be seen again in December or January.

Paul Martz,  
Probation interview:

Mr. Martz met with Board members. He reported things are going well and he is attending his meetings. Mr. Martz is out of compliance with the terms and conditions of his Order. He has not paid the therapist and the therapist will not submit therapy reports until he receives payment. Mr. Martz stated he received a bill from the therapist with all charges and it has been difficult to pay the bill. Mr. Martz stated he thought non-compliance would be for relapse, not submitting paperwork, but did not realize he would be non-compliant by not paying the therapist. Mr. Martz requested he be allowed to discontinue therapy. Dr.

Lundberg stated the therapist will need to submit a report indicating therapy is no longer necessary. Dr. Lundberg questioned why he was surprised by the therapist bill? He knew the therapist would need to be paid. He indicated he just didn't think that he would receive the bill in one lump sum. Mr. Martz stated other than that, he feels good, is working full time under general supervision. **Mr. Martz is out of compliance with the terms and conditions of the Order.** He will be seen again in December.

Colton Dale,  
Probation interview:

Mr. Dale reported things are going well. Mr. Dale is out of compliance for failing to submit paperwork. He indicated he just forgot to submit the paperwork, but has submitted all the reports he failed to submit. Mr. Dale indicated he is BMX racing and feels better about himself. He reported he has completed treatment and feels he is doing well. He reported he is considering returning to school. **Mr. Dale is out of compliance due to submitted paperwork last.** He will be seen again December 2012.

Michael Wright,  
New Order:

Mr. Wright explained the circumstances that brought him before the Board. He reported he suffers from chronic pain and has had numerous surgeries. He reported he received a DUI in the middle of afternoon after he had taken methadone and clonazepam. Mr. Wright indicated he was on medical leave from the University of Utah Pharmacy program from 2007 to 2009 and let his intern license expire. He indicated he last worked as a pharmacy intern in 2007. In 2011 he went back to pharmacy school for a period of time, and then decided to go on medical leave. Mr. Wright reported he has completed the psychiatric and substance abuse evaluations. He indicated he has completed the physical examination. He reported he restarted the pharmacy program yesterday and feels he will graduate next September. Dr. Lundberg questioned whether or not he feels he has a substance abuse problem. Mr. Wright stated his family does not think he does. Dr. Lundberg indicated she would like to see the evaluation before making any recommendations regarding the terms of probation. Dr. Young questioned whether or not the preceptors in the rotations are aware of his probation and problems? Mr. Wright stated that they are aware of the probation and the issues surrounding

the probation. **Mr. Wright is in compliance with the terms and conditions of his Order.** He will be seen again in December 2012.

*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 13, 2012  
Date Approved

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

November 13, 2012  
Date Approved

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