

**MINUTES
UTAH
BOARD OF PHARMACY
MEETING**

**July 28, 2015
Heber M. Wells Bldg.
Room 474, 4th Floor – 8:30 A.M.
Salt Lake City, UT 84114**

CONVENED: 8:30 A.M.

ADJOURNED: 11:28 A.M.

Bureau Manager
Board Secretary:

Dane Ishihara
Lee Avery

Board Members Present:

Greg Jones, R.Ph., Chairperson
Carl "Trip" Hoffman, PharmD
Jan Bird, CPhT
Roger Fitzpatrick, RPh

Board Members Excused:

Andrea Kemper, PharmD
Kelly Lundberg, Ph.D.
Paige Patterick, RPh

DOPL Staff Present:

Sharon Bennett, Compliance Specialist
Ray Walker, Div. Enforcement Counsel
Travis Drebing, Pharmacy Inspector
Shairlee McIntyre, DOPL Investigator
Carolyn Dennis, Management Analyst
Sterling Corbett, Assistant Attorney General
Marv Sims, CS Database Admin.

Swear in new Board Member, Roger
Fitzpatrick

Mr. Fitzpatrick was sworn in as a Board member.

Guests:

Greg Jensen, Target
Lisa Tome, Walgreens
Derek Garn, Walmart
Nicole Houghton, IHC
David Malmrose, U of U Pharm D
Krystal Moorman, U of U
Donelle Perez
Dave Davis, UFIA/URMA
Alissa Raines, IHC
Summer Naisbitt, Walmart
Janet Zarrdt, HCA
David Cheney, Associated Food Stores
Mark Brinton, Ut. Med Assn

Jeanne Brinna
Bill Stilling
David Nay, Express Scripts
Branden Cressall, Harmons
James Herroz, U of U
Shawna Webster, U of U
David Young, U of U
Kyle Anderson, Medquest Pharmacy

ADMINISTRATIVE BUSINESS:

Minutes

The Board reviewed the minutes dated June 23, 2015. Ms. Bird made a motion to accept the minutes with changes. The motion was seconded by Dr. Hoffman and carried unanimously.

PIC Testing for mail order pharmacies,
Sterling Corbett, Attorney General Office

Mr. Ishihara stated he contacted the Attorney General Office for an opinion regarding the question of requiring all PICs to pass the Utah MPJE.

Mr. Corbett met with the Board and reviewed the memo regarding PIC testing for pharmacy's that are out of state. Mr. Corbett noted that the statutes do not allow the Board or Division to require out of state PICs to pass the Utah MPJE exam. The Board may add language to the statute to require an individual at a "mail order service pharmacy" to pass the Utah MPJE exam, however, this would require a legislative change to the statute. Mr. Corbett advised the Board that if PICs fail to follow Utah statutes and rules, the PIC may be fined. It would not matter if they hold a Utah license or not. There is an implied grant of authority that requires holding people accountable.

Investigation Report

- a. CSD reporting requirements, Marv Sims

Mr. Sims met with the Board and reviewed the software updates regarding daily reporting. Mr. Sims stated that currently, most pharmacies are submitting information to the Controlled Substance Database via daily batch. The Division is in the process of writing rules regarding the statute changes. Mr. Sims stated he is willing to attend the association meetings with updated information. The Division will send information to the associations and each pharmacy. Mr. Sims stated the statute becomes effective July 1, 2015 and everyone needs to be in compliance by January 1, 2016. About 20% of pharmacies have

already transitioned over to daily reporting. Mr. Sims advised the Board that the framework, software and hardware are outdated and he is working with the State DTS personnel for an estimated cost to upgrade. The current system has not been updated since the program began.

COMPLIANCE REPORT:

Sharon Bennett, Compliance Specialist

Probationers being seen by the Board:

#1. Mr. Kyle Rootsart is meeting with the Board. He is requesting early termination of his probation. The Board is following up from the July Board meeting. The California Board indicated their probation is based on Utah's probation. There are no new charges. The California Board indicated that they are not willing to release Mr. Rootsart from probation at this time.

#2. Mr. Jilbear Hatch is not in compliance with his stipulation. He tested positive for Morphine on a court UA.

Probationers not being meeting with the Board:

#1. Mark Harward is in compliance with this stipulation. He submitted all reports on time.

#2. Reams is in compliance with the pharmacy stipulation. Their CEs are not due at this time.

#3. Scott Williams is in compliance with his stipulation. He submitted all paperwork on time.

#4. Skyline Pharmacy/David Blackburn. Nothing due at this time.

#5. Stone Drug/Michael Stone is in compliance with the pharmacy stipulation.

APPOINTMENTS:

Erek Montoya, Pharmacy Tech Trainee,
review CH

Mr. Montoya met with the Board. The Board reviewed Mr. Montoya's criminal history information. Mr. Montoya stated that two of the cases are being closed. He will need to pay a fine. Other charges are still pending. The pretrial date is September 28, 2015 and final trial date October 3, 2015. He is nine weeks into the pharmacy program at Eagle College. He is

scheduled to finish this program January, 2016. The Board discussed the possibility of issuing Mr. Montoya a probationary pharmacy tech trainee license. Mr. Ishihara will work on the language in an MOU with the Board setting the above standards.

Kyle Rootsart, probation interview

Mr. Rootsart is requesting early termination of probation. Ms. Bird conducted the interview via telephone. The Board noted that Mr. Rootsart's probation term is April 11, 2012 to April 11, 2017. He has completed at least half of his probation term. Mr. Rootsart stated that things are going well in California. The Board reviewed Mr. Rootsart's request for early termination of his probation. Ms. Bennett stated she contacted the California Board. They stated that they have Mr. Rootsart on probation because of sanctions taken in Utah and indicated that even though Utah may terminate Mr. Rootsart's Utah probation they will not terminate his California probation. Ms. Bird made a motion to terminate Mr. Rootsart's probation. The motion was seconded by Mr. Fitzpatrick and carried unanimously.

Beatriz Valdez, review pharmacy technician trainee application, CH

Mr. Hoffman made a motion to close the Board meeting at 9:49 A.M. to discuss the character, professional competence, or physical or mental health of an individual. The motion was seconded by Mr. Fitzpatrick. There were no written notes. A recording was not made. The Board meeting opened at 10:02 A.M.

Mr. Ishihara will review Ms. Valdez's application to ensure all documents are there. Ms. Bird made a motion to reinstate Ms. Valdez's license, or issue a trainee license if Mr. Ishihara finds her deficient in areas. Mr. Hoffman seconded the motion. The motion carried unanimously.

Jilbear Hatch, probation interview

Mr. Hatch met with the Board. Mr. Jones conducted the interview. Mr. Hatch stated that he is back in school. On June 22, his UA was positive for Morphine. The only medication he has taken has been over the counter Ibuprofen and he is not sure why he tested positive for Morphine. He is currently in rotation in school. He goes to therapy two times a month, and 12 step meetings two times a month. The Board asked Mr. Hatch to submit his therapy reports and the drug screen

reports from drug court. The Board advised Mr. Hatch that these are due monthly for the first six months. His last report was received May 27, 2015. Mr. Hatch stated he has been sober for a year now and counseling has been very helpful in developing skills to deal with his addiction. The Board wants to see Mr. Hatch August 25, 2015. **Mr. Hatch is not in compliance with his stipulation because his reports have not been received and he tested positive with Morphine on a court UA.**

DISCUSSION ITEMS:

1. Draft various administrative rules

The Board reviewed proposed language for R156-17b-610.5 Dispensing in emergency department – Patients’ immediate need and made the following suggestions:

1. (3) add (f) beyond use date. This date is what is on the packaging according to the USP.
2. (4) delete the word “class” in #4 and change the wording to “ must be provided to the appropriate pharmacy so that the applicable prescription data can be reported to the CSD.”

Mr. Hoffman made a motion to approve the language with suggested changes. The motion was seconded by Ms. Bird and carried unanimously.

(1)(b) Central processing rules

The Board reviewed the following Pharmacy Practice Act and Rules:
58-17b-102(9) Central Prescription processing;
R156-17b-102, (7) Centralized Prescription Filling and (8) Centralized Prescription Processing;
R156-17b-614f, Operating Standards – Class A, B, D, and E.

Mr. Ishihara will have draft language for the Board to review at the August Board meeting.

(1)(c) Labeling of dispensed compounds, proposed language change

The Board reviewed R156-17b-614a(f) noting that this section of the rule refers to batch labeling only. There is nothing in the rules that addresses labeling of dispensed compounds.

The Board reviewed the proposed language changes to add to the Pharmacy Act Rule to include the following:

#1. R156-17b-614a(f)(i-v)(g)(h)

(g) all prescription labels for compounded sterile and non-sterile medications when dispensed to the ultimate user or agent shall bear at a minimum in addition to

what is required in UCA 58-17b-602L;

(h) generic name and quantity or concentration of each active ingredient;

(i) In the instance of a sterile preparation for parenteral use, labeling shall include the name and base solution for infusion preparation;

(ii) assigned compounding record;

(iii) "This is a compounded preparation" or similar language shall be indicated;

(h) the beyond use date assigned shall be based on currently available drug stability information and sterility considerations or appropriate in-house or contract service stability testing.

#2.R156-17b-614a(3)(d)(iv)

(iv) sample labeling information, which shall contain, in addition to legally required information:

1. generic name and quantity or concentration of each active ingredient;

2. assigned BUD;

3. storage conditions; and

4. prescription or control number, whichever is applicable.

#3. R156-17b-614a(f)(i-v)

(i) all active solution, and ingredient names, amounts, strengths, and concentrations, when applicable;

#4. R156-17b-614a(3)(d)

(i) official or assigned name;

(ii) strength; and

(iii) dosage form of the preparation;

(iv) calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients;

(v) description of all ingredients and their quantities;

(vi) compatibility and stability information, including references when available;

(vii) equipment needed to prepare the preparation;

(viii) mixing instructions that should include:

a. order of mixing;

b. mixing temperatures or other environmental controls;

c. duration of mixing;

d. other factors pertinent to the replication of the

preparation as compounded.

(viii) sample labeling information, which shall contain, in addition to legally required information:

a. generic name and quantity or concentration of each active ingredient;

b. assigned BUD;

c. storage conditions;

d. prescription or control number, whichever is applicable.

(ix) container used in dispensing;

(x) packaging and storage requirements;

(xi) description of final preparation;

(xii) quality control procedures and expected results.

#5. R156-17b-614a(3)(e)

(i) official or assignment name,

(ii) strength, and

(iii) dosage of the preparation;

(iv) Master Formulation Record reference for the preparation;

(v) names and quantities of all components;

(vi) sources, lot numbers, and expiration dates of components;

(vii) total quantity compounded;

(viii) name of the person who prepared the preparation;

(ix) and name of the compounder who approved the preparation;

(x) name of the person who performed the quality control procedures;

(xi) date of preparation;

(xii) assigned control, if for anticipation of use or prescription number, if patient specific, whichever is applicable;

(xiii) assigned BUD;

(xiv) duplicate label as described in the Master Formulation Record;

(xv) description of final preparation;

(xvi) results of quality control procedures (e.g., weight range of filled capsules, PH of aqueous liquids);

(xvii) documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient caregiver.

The Board had several suggested changes. Mr. Ishihara will have a draft with these changes for further review

and input at the August Board meeting.

Not on the agenda:

Mr. Hoffman noted that the next Pharmacy Compound Task Force meeting is August 18, 2015. It will be in the North Conference room at the Heber M. Wells Bldg. starting at 7:30 A.M

#2. Information required on hard copy of RX

Out of order on the agenda:

The Board reviewed a concern regarding the information required on a hard copy of a prescription. The Board felt that putting a tag or sticker on the back of a prescription has not been a problem in past. The Board may consider clarifying existing rule if a problem arises in the future. Mr. Hoffman made a motion for the DOPL inspectors to accept the back tag on a prescription. Mr. Fitzpatrick seconded the motion. The motion carried unanimously.

#3. Out of State Reverse Distributors

Tabled for another Board meeting.

#4 Temporary license rules

The Board reviewed definitions in the Pharmacy Practice Act Rule, R156-17b. The Board noted that under definition there is no language regarding residency or fellowship programs under the temporary pharmacist license, subsection 304. The Board feels this would allow individuals to apply for the temporary license. Mr. Ishihara will have language for the Board to review at the August Board meeting.

NEXT SCHEDULED MEETING:

2015 Board Meetings:

2015 Board Meetings Tentatively Scheduled

August 25, September 22, October 27, November 17, December 15

2016 Board Meetings Tentatively Scheduled:

January 26, February 23, March 22, April 26, May 24, June 28, July 26, August 23, September 27, October 25, November 15, December 20

ADJOURN:

Motion to adjourn at 11:28 A.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.

8-25-15

Date Approved

8.25.15

Date Approved

(ss) 

Chairperson, Utah Board of Pharmacy

(ss) 

Bureau Manager, Division of Occupational &
Professional Licensing