

MINUTES

**UTAH
PHARMACY
BOARD MEETING**

April 27, 2010

**Room 474 – 4th Floor – 8:00 A.M.
Heber Wells Building
Salt Lake City, UT 84111**

Convened: 8:03 a.m.

Conducting: Dominic DeRose, Chair

Division Director: Mark Steinagel
Bureau Manager: Laura Poe
Board Secretary: Shirlene Kimball
Compliance Specialist: Connie Call
Compliance Officer: Ray Walker

Board Members Present: Roger B. Fitzpatrick
Derek D. Garn
David C. Young
Dominic DeRose
Kelly Lundberg
Jan Bird

Board Member Excused: Andrea Kemper

Guests: James Petersen, Walgreens
David Cheney, Fresh Market
Linda Sandberg, Omnicare
Betty Yamashita, IHC
Greg Jensen, Target
Reid Barker, UPhA
Mark Munger, University of Utah

TOPICS FOR DISCUSSION

ADMINISTRATIVE BUSINESS:

March 23, 2010 Minutes:

Connie Call,
Compliance Report:

DECISIONS AND RECOMMENDATIONS

The March 23, 2010 Board minutes were approved with corrections. All Board members in favor.

Ms. Call reported the following individuals are out of compliance with the terms and conditions of their Order: Sheryl Ledet, Kenny Nielson, Michael Jarman

and Jeremy Boyle.

Mr. Fitzpatrick made a Motion to refer Mr. Jarman for an Order to Show Cause Hearing due to non-compliance to the terms and conditions of his Order. Mr. Young seconded the Motion. Mr. Garn abstained. All other Board members in favor.

Dr. Lundberg made a Motion to refer Mr. Boyle for an Order to Show Cause Hearing for non-compliance to the terms and conditions of his Order. Mr. Garn seconded the Motion. All Board members in favor.

Ms. Call indicated the following individuals or pharmacies are in compliance with their Orders: Andrea Lowry, Mary Jo Cates, Mike Hodges, Zion's Pharmacy, Phuong Sheffer, David Barrow, Mark Akagi and Susan Macon.

Mark Munger,
Discussion regarding live CE:

Dr. Munger indicated it is becoming more difficult to find funding to provide live continuing education courses for pharmacists. He questioned whether or not a webinar sponsored by the University of Utah would qualify as live CE under the Pharmacy Practice Act Rules, subsection R156-17b-309(5)(a)(i) - attendance at live or technology enabled participation. Dr. Munger indicated the webinar would be 1 ½ hours of interactive ACPE approved CE and each participant would be required to complete an evaluation. Dr. Munger stated the webinar would be offered four to eight times a year. Dr. Munger requested the Board's decision regarding whether or not the webinar would be accepted as live CE and be noted in the minutes.

Mr. Barker stated that the UPhA will continue to offer CE through the UPhA Spring and Fall seminars, but would eliminate the Winter seminar. Mr. Barker stated he feels the webinar would be a great way to reach those who can not attend the UPhA seminars.

Board members indicated they are supportive of the webinar as meeting the requirements for approved continuing education and for live continuing education. Ms. Poe stated the rule regarding technology enabled participation was kept broad so that as technology changes, the Board would be able to

accept the technology. Mr. Fitzpatrick stated the webinar meets the standards in the Rule as well as ACPE standards. The Board and the Division agree that the webinar is accepted as live continuing education. Dr. Munger also stated that the webinar is stored for a period of time and then can be reviewed. Once it is stored, it would no longer be considered interactive, but would be accepted as non-live continuing education.

Zion's Pharmacy,
Telephone Probation Interview:

Mr. DeRose conducted the interview by telephone. Mr. Stirland reported the pharmacy is USP 795 compliant. He also stated it is his understanding that compounding HCG subcutaneous administration does not fall under sterile compounding. Board members stated if he provides HCG to the patient to mix themselves, it does not need to be compounded under USP 797. However, if he is mixing the HCG, he needs to meet sterile compounding requirements. **Zion's Pharmacy is out of compliance with the terms and conditions of the probation until the Board receives policies and procedures documenting compliance with USP 795 and USP 797 standards.**

Kenneth Nielson,
Telephone Probation Interview:

Mr. Fitzpatrick conducted the telephone interview. Mr. Nielson stated he relapsed by ingesting alcohol on April 25, 2010. He indicated he also got into a fight with a friend and was arrested for trespassing, assault and a DUI. Mr. Nielson stated he understands he may have to serve significant jail time due to three DUI's in a ten year period. Mr. Nielson stated he will contact Ms. Call and let her know the outcome of the court proceedings. Board members informed Mr. Nielson that if he has to complete a significant time in jail, he may want to consider signing an indefinite suspension.

Board members questioned whether or not he was still working for his brother. He stated he has not discussed his employment status with his brother since his arrest, but will be speaking with him soon. He reported he last worked as a pharmacist on April 19, 2010.

Board members reminded Mr. Nielson to call CVI everyday and keep in contact with Ms. Call. Board

members also requested the therapist include a revised therapy plan to address the relapse. **Mr. Nielson is out of compliance with the terms and conditions of his Order.**

J. Michael Hodges,
Probation Interview:

Mr. Young conducted the interview. Mr. Hodges stated he continues to work for Meds for Vets two days a week. Mr. Hodges stated he attends 12-Step meetings, but feels that since these meetings are not related to his problem, they are of no value. He indicated the extensive counseling he completed helps him abstain from unacceptable behavior. Mr. Hodges appears to be doing well and Board members indicated his meetings with the Board could be moved to every six months. He will be seen in October 2010 and then for a last time in March 2011 if he remains in compliance. He questioned whether or not he could request early termination of probation. Board members indicated he could request termination of probation in October and the Board could make a decision at that time. Board members reminded him that his paperwork will still be due quarterly. **Mr. Hodges is in compliance with the terms and conditions of his Order.**

Mary Jo Cates,
Probation Interview:

Mr. DeRose conducted the interview. Ms. Cates reported things are going well and she is moving in a positive direction. Ms. Cates submitted her controlled substance log and is current on all reports. She reported she feels she is ready to work alone without supervision. Board members indicated her supervisor will need to submit a letter of support and she could request termination of supervision at the next meeting. **Ms. Cates is in compliance with the terms and conditions of her Order.**

Mark Akagi,
Telephone Probation Interview:

Mr. Garn conducted the telephone interview. Mr. Akagi reported things have been going fine. He stated he has not looked for employment and does not intend on going back to work in a pharmacy. He stated he is thinking of volunteering at Salt Lake County Health and Aging where he would counsel the elderly regarding their medications. Mr. Fitzpatrick requested Mr. Akagi contact Salt Lake County Health and Aging and have them provide an outline of the type of work he would be doing and how many hours

would be involved. Board members stated this would be a valuable service, but he would need to meet the terms and conditions of the Order. He would need to have the coordinator fill out the employer report and would need to submit a practice plan. **Mr. Akagi is in compliance with the terms and conditions of his Order.**

Phuong Sheffer,
Probation Interview:

Mr. DeRose conducted the interview. Mr. Sheffer stated he has been volunteering at the 4th Street Clinic Pharmacy for about two months. He indicated he works two days a week and he stated he feels comfortable with the people who come into the pharmacy. Board members requested a practice plan regarding his responsibilities. Mr. Sheffer questioned whether or not he could request early termination of probation. Board members indicated he could make a request anytime, but his probation just started in February due to the length of time he was unemployed. **Mr. Sheffer is in compliance with the terms and conditions of his Order.**

Sheryl Ledet,
Probation Interview:

Dr. Lundberg conducted the interview and expressed concern because Ms. Ledet has only been in compliance with her Order once in the last seven months. Ms. Ledet reported she is doing well and feels she is doing well in her recovery. Mr. Fitzpatrick indicated Ms. Ledet has come a long way since her first meeting with the Board and commended her for her commitment to her recovery. However, Mr. Fitzpatrick stated Ms. Ledet needs to be in complete compliance including calling CVI everyday as required. Ms. Ledet stated she understands she needs to set up a system to help her remember to call everyday. Dr. Lundberg stated if she remains out of compliance for the next quarter, she may be issued a citation. Ms. Ledet indicated she is happy with her recovery and understands the only way she can demonstrate her commitment to her recovery is by submitting the paperwork on time. She will be seen July 27, 2010. **Ms. Ledet is out of compliance with the terms and conditions of her Order for failing to call CVI.**

Susan Macon,
Probation Interview:

Mr. Young conducted the interview. Ms. Macon submitted her revised practice plan and all reports.

She stated she has been doing very well. Ms. Macon requested her Order be amended to allow her the personal use of alcohol and to remove the random urine screens for alcohol. Ms. Macon pointed out that the evaluation indicated a low possibility of relapse. She stated she does not see how ingesting alcohol during her personal time affects her practice of pharmacy and she feels there should be a distinction between private time and time working as a pharmacist. Dr. Lundberg stated the restriction was placed in the Order because her evaluation indicated she had a history of substance abuse. Mr. Young stated there is concern that individuals with substance abuse issues turn to alcohol and since she has been on probation for less than a year, the Board would need to monitor her for a longer period of time. The Board would like to see her establish a pattern of compliance for a period of time before making any amendments to her Order. She will be scheduled to meet with the Board on July 27, 2010. Mr. Fitzpatrick made a Motion to deny the request to remove urine screen testing and personal use of alcohol. Mr. Young seconded the Motion. All Board members in favor. **Ms. Mason is in compliance with the terms and conditions of her Order.**

Discussion:

Ms. Poe questioned the difference between compounding and reconstituting? Mr. Young stated reconstituting is a form of compounding. The drug manufacturer will indicate whether or not a product should be compounded in a sterile or non-sterile environment. If the drug is injected into the body, ophthalmic, or subcutaneous, it must be a sterile compound. If HCG is being compounded, the sterile standards of USP 797 apply. Ms. Poe questioned if using a multiple use vial is considered administration. Board members indicated that if the drug is split for two different patients, then it is compounding and the USP 797 standards apply. It does not need to be sterile compounding if only reconstituting a single dose vial or if showing the patient how to use it at home.

Tom Harper,
Discussion regarding Controlled Substance
Database web site:

Mr. Harper reviewed with Board members the updated Controlled Substance Database web site. Mr. Harper indicated a focus group is working out the bugs. Mr.

Harper indicated if anyone is having a problem with the system, they can contact him for help.

Lunch 11:50 a.m. - Reconvened: 1:00 p.m.

David Barrow,
Probation interview:

Dr. Lundberg conducted the interview. Mr. Barrow stated things are going well and he is now 233 days sober. He discussed the number of urine screens he has to take and indicated this is a financial hardship. Board members indicated the urine screens are on a random basis and are necessary to help monitor compliance. Mr. Barrow reported he had received a ticket for leaving his kids in the car unattended and entered a plea in abeyance. He submitted his practice plan addressing his access to controlled substances. Mr. Garn made a Motion to approve the practice plan. Mr. Fitzpatrick seconded the Motion. All Board members in favor.

Mr. Barrow will be seen again in June and then moved to quarterly meetings with the Board. **Mr. Barrow is in compliance with the terms and conditions of his Order.**

Discussion regarding Rules for S.B. 88 and S.B. 274:

Mr. Steinagel and Mr. Walker met with the Board to discuss S.B. 88 and the exemptions allowing physicians to dispense cosmetic and weight loss drugs. The drugs specifically mentioned during the Legislative session were Latisse and HCG. Mr. Steinagel stated other drugs can be added at a later date as determined by Board of Pharmacy, Physicians Licensing Board and the Osteopathic Licensing Board. Mr. Steinagel reported the Division has been contacted by individuals who would like to have multiple drugs included on the list; and other individuals have contacted the Division who do not want any additional drugs added to the list. Mr. Steinagel stated the Division has discussed multiple ways to handle this issue.

Ms. Poe questioned whether Latisse should be listed as a Brand name or if there was a generic name or classification that would include other drugs. Board members recommended listing Brand name Latisse in the rule.

Ms. Poe stated additional drug types have been suggested including retinoids and benzoylperoxides. Mr. Young stated those drugs would be off the list immediately because they are used to treat a disease. Mr. Fitzpatrick suggested only those drugs that have FDA approval as a cosmetic drug should be included. If the drug is used for any other reason, it can not be on the list. Mr. Walker indicated the Physician's Licensing Board recommended that Latisse and HCG be placed in Rule now and move slowly and methodically adding additional drugs. Board members indicated an individual can request a drug be added, but we need to have standards to determine whether or not to include the drug. Mr. Walker stated requiring FDA approval as a cosmetic drug would be a good starting point for the standards.

Board members indicated there should be a way to ensure that the stability of the drug is appropriate for the supply dispensed. According to Mr. Young, research has found the average stability of compounded HCG is nine hours. If the prescribing physician dispenses a 30-day supply of HCG, the effectiveness of the drug will continually decrease after nine hours. The physician may not be aware of the drug stability. The pharmacist is an additional check that the drug is safe. The pharmacist is aware of other issues and can inform the physician if there is a problem. Concern was expressed on who would complete the quality check if the physician is mixing or sending the drug out of the office?

Mr. Walker stated when setting standards, the Board needs to go beyond FDA approval or all drugs approved for cosmetic use would be on the list. The Board could also choose not to add those drugs with multiple uses. He stated three different Boards have to approve the list and he suggested a peer advisory committee be established so that the request did not have to go before all three Boards, but the Committee would review and make the recommendations to the Division.

Board members recommended the following criteria for adding a cosmetic drug: 1. The drug has to be used for the conditions for which FDA approval was

granted. 2. The drug has to be FDA approved for self-administration (This would eliminate sending Botox home). 3. Have to meet the USP 797 and 795 standards. 4. The stability of the drug has to be adequate for the supply dispensed.

Mr. Poe questioned whether or not Latisse could be added to the list of drugs prescribed online. Mr. Fitzpatrick stated the bill needs to be implemented the way it is written and then after more experience, it can be evaluated for on-line prescribing.

Sherry Pandya, discussion regarding pharmaceutical services at Kane County Hospital:

Ms. Pandya indicated Kane County Hospital is looking at making changes to their pharmacy system. She reported the pharmacy currently uses a contractual pharmacist and does not employ an in-house pharmacist. Ms. Pandya stated this system is cumbersome and not in the best interest of the patient. Ms. Pandya stated the pharmacy would like to put in a Pyxis machine and use a remote web cam. She stated they have contracted with 4 Care Pharmacy in Salt Lake and the pharmacist would visit the pharmacy on a monthly basis. She questioned if they could implement this system and remain in compliance with the Pharmacy Practice Act and Rules. Mr. Fitzpatrick stated the Pharmacy Practice Act Rules, subsection R156-17b-620 Operating Standards - Automated Pharmacy System outlines the criteria they will need to meet. It does not require an on-site pharmacist-in-charge. Mr. Fitzpatrick suggested Ms. Pandya read through the Rules and then write policies and procedures for the Pyxis machine. Mr. Fitzpatrick indicated those selling the Pyxis machine most likely have model policies and procedures available.

Joanita Lake,
Application review:

Ms. Lake completed a pharmacy program in South Africa and completed 2136 pharmacy internship hours in 2001. She moved to England to obtain a degree in evidenced based health care and has not practiced as a pharmacist since 2001. Her education is the equivalent of a pharmacy program in the United States according to the FPGEC.

Board members approved her for licensure as an intern and she must complete 1500 intern hours. Once the hours are completed, she can submit the pharmacist

application and be approved to sit for the NAPLEX and MPJE examinations.

Determine a Board member to serve on the newly created Controlled Substance Advisory Committee:

David Young agreed to serve on this Committee. Ms. Poe also indicated the Board could recommend Dr. Lundberg as the individual working for a substance abuse agency. Board members recommended David Young and Kelly Lundberg be appointed to this Committee.

Discussion whether or not a pharmacist can issue a prescription or order pursuant to a collaborative practice agreement:

Ms. Poe questioned whether or not a pharmacist can issue a prescription pursuant to a collaborative practice agreement. She questioned whether or not in a community setting a pharmacist with a collaborative agreement can write a prescription. Board members indicated the pharmacist can write a prescription, but would not be able to sign the prescription. Board members indicated this is done over the telephone all the time. Ms. Poe questioned whether or not it can be done under a standing Order. Board members indicated it can be done based on protocol and what has been agreed to. Board members indicated it would be the same as the immunizations. The pharmacist is authorized to administer based on the physician collaborative agreement. There must be a protocol and a collaborative agreement. For example, the pharmacist then writes a prescription and it is transferred over the phone. The pharmacist can not sign the prescription for the patient to send in to mail order pharmacy (however, it can be called in).

Annual Open and Public Meeting Act Training:

Reviewed.

Executive Order establishing ethics policy for Executive Branch Agencies:

Reviewed.

Environmental Scan:

Ms. Poe indicated there was misinformation sent out regarding Scheduled II controlled substance prescriptions and the information regarding what changes or additions a pharmacist can make to a Scheduled II controlled substance prescription. Ms. Poe indicated the Division will issue a statement that will be posted on the web page for clarification. Board members confirmed that a pharmacist can not add or change a written prescription for a Schedule II

for the following: date the prescription was written; patient name; name of the controlled substance being prescribed except for generic substitutions as noted on the prescription; or the signature of the prescribing practitioner. If a prescription is missing any of these areas, the prescription is invalid and must be re-issued by the prescribing practitioner. After consulting with the prescribing practitioner, a pharmacist may add to or change the following: the dosage form, drug strength, drug quantity and directions for use. The change or addition must be noted on the prescription and that the prescribing practitioner verified the change. The practitioner's agent can not verify the change. The pharmacist is permitted to make patient information changes/additions such as the patient's address and date of birth if verified.

If the practitioner does not put his own DEA number on the prescription, the pharmacist can add it if known. Board members suggested a follow up with the Utah Medical Association to make sure they also understand the requirements.

Discussion:

Ms. Poe reported the Division will no longer issue a license or temporary license to an individual who does not have a social security number.

Pharmacy Technician Program Review:
Oquirrh Mountain Pharmacy:

The Oquirrh Mountain Pharmacy Technician Program was approved.

Birch Family Pharmacy Technician Program:

The program information will be sent to Ms. Kemper for review.

Adjourned:

2:58 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.

May 25, 2010
Date Approved

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

May 25, 2010
Date Approved

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