

MINUTES

**UTAH
PHARMACY
BOARD MEETING**

June 22, 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

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

Guests: Linda Sandberg, Omnicare
Betty Yamashita, IHC
Mark Schultz, University of Utah
Monique Hall, University of Utah
Russell Brown, Walgreens
Jacob Blackham, USN
Greg Jensen, Target
Jordan Sheffer, University of Utah
Rebekah Hutchins, Career Step
Melanie Jones, Career Step
Robert Hansen, Wal-Mart
Tanisha Peck, Smiths
Reid Barker, UPhA
David Cheney, Fresh Market

TOPICS FOR DISCUSSION

DECISIONS AND RECOMMENDATIONS

ADMINISTRATIVE BUSINESS:

May 25, 2010 Minutes:

The May 25, 2010 Board minutes were approved with

corrections. All Board members in favor.

Mr. Garn questioned whether or not co-dispensing as discussed in May was acceptable. Ms. Poe stated she had the same question, and Ms. Sandberg stated she has never seen the placement of labels from two different pharmacies on a prescription bottle. Board members indicated this may be something we need to define in Rule. There does need to be a way to track where the prescription came from.

Connie Call,
Compliance Report:

Ms. Call reported all quarterly probationers were in compliance with the terms and conditions of their Order.

Ms. Call stated David Barrow is requesting he be allowed to work alone in the pharmacy. Mr. Fitzpatrick stated it is too early in Mr. Barrow's recovery period to allow him to work without supervision. Mr. Barrow is in a very critical phase of his recovery and he needs to be monitored for a longer period of time before being allowed to work alone.

Ms. Call reported Kenneth Nielson has been unable to decide whether or not to surrender his license. He requested the surrender document be drafted for his signature, then decided he would rather sign an indefinite suspension order. He then called on June 7, 2010 and indicated he did not want to sign an indefinite suspension and wanted to remain on probation. He stated he would come into compliance with the terms and conditions of his Order. Ms. Call reported Mr. Nielson called yesterday, June 21, 2010 and stated he had decided to go with an indefinite suspension. Board members indicated he needs to submit his request in writing and be held to his decision. Ms. Poe indicated she will send out the indefinite suspension document and give him 20 days to sign the Order and return it to the Division. If he does not submit the signed indefinite suspension or does not come into complete compliance, the Division will move forward with an OSC Hearing.

Michael Jarman has been referred for an Order to Show Cause Hearing.

Ms. Poe stated the Division has initiated an Order to Show Cause Hearing for Jeremy Boyle. He has received his notice of agency action and he has 30 days to respond. Ms. Poe stated an indefinite suspension will not be offered, but his license could be suspended.

David Barrow,
Probation interview:

Mr. Barrow stated he has been sober 10 months. He indicated he is only working a couple of hours per week and that his recovery is progressing well. He reported his major stress at this time is financial and he is unable to find employment because of the restrictions on his license. Mr. Barrow indicated his goal is to be completely off all medications by September or October 2010. Mr. Fitzpatrick suggested Mr. Barrow go slowly and not push the recovery. Mr. Barrow has made significant progress and is currently doing very well. Both the therapist and the physician recommend against stopping the Suboxone. Dr. Lundberg stated she agrees and treatment is about how he is doing at any given time and he needs to listen to his body. Mr. Barrow requested his Order be amended to allow him to work without supervision. He would like to open and close the pharmacy and obtain more work hours. He stated he feels urine screens are a good insurance policy and will keep him clean. He stated he would not divert medications from his employer. Dr. Lundberg stated he has been on probation less than a year, he is still on Suboxone and she feels like it would be best for him to continue under supervision. Mr. Fitzpatrick stated since Mr. Barrow diverted from his employer in the past, the Board is cautious about having him work alone. Mr. Fitzpatrick made a Motion to deny the request to work unsupervised. Ms. Bird seconded the Motion. All Board members in favor. **Mr. Barrow is in compliance with the terms and conditions of his Order. He will be seen again in September.**

Trent Decker,
Telephone Interview:

Mr. Decker was interviewed by telephone. Mr. Decker reported everything was going well. Mr. Garn made a Motion to have Mr. Decker meet with the Board every six months instead of quarterly. Mr. Fitzpatrick seconded the Motion. All Board members in favor. Mr. Fitzpatrick made a second Motion to eliminate the sentence from his Order that reads he

must notify the Division if he is working more than 48 hours per week. He can work up to 60 hours per week. Mr. Garn seconded the Motion. All Board members in favor. **Mr. Decker is in compliance with the terms and conditions of his Order. He will be scheduled to meet with the Board in December.**

S. Rich Wright,
Probation interview:

Mr. Wright reported he is doing very well. He indicated he works three days a week and likes the hospice setting. Dr. Kemper made a Motion to meet with Mr. Wright every six months instead of quarterly. Dr. Lundberg seconded the Motion. All Board members in favor. His paperwork will continue to be due quarterly. **Mr. Wright is in compliance with the terms and conditions of his Order. He will be seen again in December.**

Richard Lowe,
Probation interview:

Mr. Lowe reported he is doing very well. He stated his attitude has changed because of the Thinking Errors course. He indicated work is going well. Mr. Fitzpatrick stated Mr. Lowe appears to be doing very well in his probation and he would recommend Mr. Lowe consider requesting early termination of probation in October or November. He was requested to include in his request a summary of what he has learned and what changes have been made. **Mr. Lowe is in compliance with the terms and conditions of his Order.**

Aidee Torres,
Probation interview:

Ms. Torres reported work is going very well and indicated her health is good. Dr. Lundberg indicated it is good to see Ms. Torres putting forth the effort of maintaining compliance. Ms. Torres stated she has been trying very hard to remain compliant. She still needs to submit an ethics course by September. **Ms. Torres is in compliance with the terms and conditions of her Order and she will be seen again in September.**

Jeremy Boyle,
Probation interview:

Mr. Boyle could not be reached by telephone. **Mr. Boyle is out of compliance with the terms and conditions of his Order and has been referred for an Order to Show Cause Hearing.**

Break at 9:40 a.m.
Reconvened at 9:50 a.m.

Melynda Frohlich,
Interview:

Ms. Frohlich answered “yes” on the qualifying questionnaire. She reported she received a DUI in Iowa; and later received a ticket for no driver’s license in Iowa. Ms. Frohlich indicated she moved back to Utah and received a DUI in January 2010. She indicated she has completed the Iowa court requirements; however, for Utah she needs to complete community service and complete a substance abuse evaluation. She stated she is on court supervised probation, but does not have to give random urine screens. Ms. Frohlich stated she has not ingested alcohol since the January date and has changed her circle of friends. Mr. Fitzpatrick made a Motion to issue the license on a Memorandum of Understanding for a period of four years with the standards terms and conditions. A court approved evaluation and treatment will be accepted, and whatever recommendations are made by the therapist. PIR and 12-step meeting attendance is important and will be required. Mr. Garn seconded the Motion. All Board members in favor.

Patricia Esparaza, request for Intern license extension:

Ms. Esparaza stated she is a foreign pharmacy graduate and would like to retake the NAPLEX examination. However, she can not retake the examination until August 24, 2010 and her Intern license will expired August 13, 2010. Ms. Esparaza requested the intern license be extended. Mr. Fitzpatrick made a Motion to extend the intern license for six months. Ms. Bird seconded the Motion. All Board members in favor.

Discussion regarding Controlled Substance Handler license:

Ms. Poe stated during the period when Diana Baker was the Bureau manager for the Pharmacy Board, the controlled substance handler and controlled substance facility license was created to allow paramedics to restock their inventory. There were also facilities and individuals involved in research and these individuals/facilities were issued the controlled substance handler license. Ms. Poe indicated this section must have been eliminated from the Rules because the Rule no longer addresses the controlled substance handler or controlled substance facility license. She reported the Division started issuing Class E Pharmacy licenses to individuals who conduct

research. Mr. Memmott questioned whether or not we want individual researchers licensed as a pharmacy. Ms. Poe indicated the DEA refused to issue a DEA registration to researchers that received the Class E pharmacy license because the individual did not have the controlled substance handler license. She indicated the Rules provide examples for each Class of pharmacy and the DEA has indicated that if the type of facility is not listed in Rule, they will not issue a DEA registration. The DEA also indicated these individuals would have to obtain a controlled substance handler license. Ms. Poe questioned whether or not we want to license the person, who may leave a facility and not notify the Division of the change, or do we issue the license to the facility.

Mr. Memmott also had a question regarding animal control. Mr. Memmott stated we are now issuing animal control a Controlled Substance Handler Facility license and questioned whether or not the Division should be issuing a Class E pharmacy license? He stated animal control is not the practice of pharmacy, but they need access to limited controlled substances in order to do their job. Mr. Memmott stated that in the past, animal control has been issued a controlled substance handler license. Ms. Poe questioned whether or not the Board would be comfortable having these individuals obtain a Class E pharmacy license so that they can store and administer drugs. Mr. Fitzpatrick stated that requiring a Class E pharmacy makes them accountable. The language could be taken from the Pharmacy Practice Act and added to the Controlled Substance Act. Board members questioned whether or not the investigators have any authority under the Controlled Substance Act to conduct an inspection. Mr. Memmott stated only the Pharmacy Practice Act addresses inspections; however, he could obtain a special search warrant to inspect a facility licensed under the Controlled Substance Act. Mr. Walker stated the question should be "is this the practice of pharmacy"? If they are not required to obtain a primary license, they should be placed under the Controlled Substance Act rather than the Pharmacy Practice Act. Mr. Fitzpatrick stated we could extract operating standards from the Pharmacy Practice Act and add to the Controlled Substance Rule

and license the facility.

Animal research would fall under similar language as for animal euthanasia. If using controlled substances, give the facility a controlled substance handler license.

Ambulance: Board members indicated there was an agreement that the driver would be responsible for the drugs and a controlled substance license would not be necessary. There is a medical director who dispenses drugs to the driver based on a standing order. However, there was concern expressed that ambulance staff are going to the ER to obtain medications. Mr. Walker indicated that only a pharmacy can dispense, the medical director would not be dispensing. Mr. Walker also had a question whether or not stockpiling medications is dispensing and the practice of pharmacy. Ms. Poe stated the ambulance driver has been an extension of the medical director and the medications have been administered by standing order. Mr. Walker stated that whatever the model is, it needs to be in rule so there is no confusion.

Mr. Memmott indicated that a group of practitioners applied for a pharmacy license for their office. They applied for a Class A, B, D and E pharmacy license. They indicated they would only fill prescriptions for their own patients (Class B), but would like to also be a central order pharmacy (Class E). Board members indicated that if they have a third party contract, it could not be a closed door pharmacy. Board members also indicated that the pharmacy can not offer financial incentives to the practitioner.

Board members also discussed whether or not a PIC can be the PIC for both a Class A and a Class B pharmacy in the same facility at the same time. Mr. Fitzpatrick indicated the rules do not allow a PIC to be a PIC over two Class A pharmacies at the same time; however, it doesn't address a PIC over a Class A and a Class B at the same time. Ms. Poe indicated that if a PIC could not be over two Class A pharmacies at the same time, it is logical that they can not be over a Class A and Class B at the same time. However, they would not be in violation because the rule doesn't specifically say Class A and Class B. Board members

did express concern that if there are two separate physical locations, the PIC would not be available to both facilities at the same time.

Review Proposed Rule Language to implement SB 88:

Ms. Poe discussed with Board members the proposed Rule language for cosmetic and weight loss drugs that a physician would be allowed to dispense. Ms. Poe indicated the language was presented to the Physicians Licensing Board. That Board suggested two changes: on page two, insert a new D and include a lot number. Add to section H: document patient counseling was provided. Ms. Poe stated if the Board is comfortable with these additions, a motion could be made to go to the Rule making process. The Rules would then be filed and opened for public comment. Mr. Fitzpatrick indicated 8(a)(i)(ii) has been left out of this draft. Ms. Poe stated this was unintentionally dropped and will be added back. Ms. Poe indicated the Physician's Licensing Board did review the correct draft. Ms. Poe indicated the corrections will be made. Mr. Fitzpatrick made a Motion to approve the June 21, 2010 draft with the corrections. Dr. Kemper seconded the Motion. All Board members in favor.

Adjourned to lunch at 11:33 a.m.
Reconvened at 1:30 p.m.

E-Prescribing:

Ms. Poe presented the Federal Interim Final Rule regarding e-prescribing for review. Ms. Poe indicated the Division needs to move forward with Rules and suggested a volunteer subcommittee be formed to develop Rule for the Boards review. The subcommittee would include Board members, former Board members, and individuals in informatics or an IT person who understands internet security. Board members suggested were: David Young, Jan Bird, and Dominic DeRose. Former Board members suggested: Linda Sandberg, Betty Yamashita and Mark Munger. IT individual recommended was Trent Colvin. Ms. Yamashita stated she would also find an IT person to help. Ms. Poe stated she would send an e-mail to the individuals to set up a time to meet.

Discussion regarding possible Rule change including remote entry and central fill standards:

Ms. Poe presented a June 21, 2010 draft regarding central fill prescription processing. Ms. Poe indicated she reviewed other state definitions and tried to

incorporate their definitions on what would work for us. Remote fill is basically doing everything but dispensing. Mr. Fitzpatrick indicated he was okay with this. Mr. Garn stated that Class D is out-of-state pharmacies and this language may imply that it also includes in-state pharmacies. He stated by giving examples, it makes it sound inclusive instead of exclusive. Ms. Poe stated there are no in-state Class D pharmacies. Mr. Garn indicated the confusion is with the word “include” which makes it appear to be more than non-resident pharmacies. Ms. Poe indicated all class definitions use the same wording. Mr. Walker stated the original intent of the wording “includes but not limited to” is to give examples. Mr. Walker stated this is standard for legislative wording. Ms. Poe indicated the DEA is refusing to issue a DEA registration if the type of pharmacy is not listed in Rule. Ms. Poe indicated if it said “such as” it would be no different than “include”. Mr. Fitzpatrick suggested leaving in the word “include” and provide examples (a. mail order; and b. remote entry).

Discussion regarding duration of prescription for oxygen:

Ms. Poe indicated the federal regulations regarding oxygen prescription is that the first prescription is good for one year, then, after the practitioner sees the patient, the prescription would be good for 99 years. Our law states that the prescription has to be issued on a yearly basis. Board members recommend our rules be left at one year.

Discussion regarding R156-17b proposed changes:

R156-17b-616: Changes Class D Pharmacy – out of state mail order, to non-resident pharmacies.

Add section R156-17b-622 Operating standards for remote order processing.

Discussion regarding counseling. R156-17b-610 number (5)(a) that requires the pharmacist provide counseling on all new prescriptions and once yearly on maintenance medications applies if the patient is picking up the medication. If the prescriptions are mailed, number (8) applies and the information required in number (1) has to be delivered with every prescription. Board members stated the rule allows once a year counseling on maintenance medications if the patient who goes to the pharmacy to picks up the

prescriptions. However, if the patient receives the medications by mail, counseling must be provided with every delivery. Ms. Poe questioned whether or not it is necessary to make the differential between those picking up and those by mail. Mr. Fitzpatrick stated the pharmacist can ask the patient if they have any more questions if they are picking up the medications. It is more difficult for the patient to have his/her questions answered if receiving the medications by mail. Ms. Poe indicated a large mail order pharmacy has questioned whether or not mailing documentation with each prescription can be eliminated. Mr. Fitzpatrick stated this company is trying to save money and this is not in the best interest of the patient. Mr. Garn stated he disagrees and more and more companies are going paperless. Mr. Garn suggested that number (8) be reworded so that the information can be provided in writing, by e-mail, or by calling so that the patient has a choice. The default should be to paper, but the patient can call and request how they want the information provided.

Adjourned to Rule Hearing at 2:05 p.m.
Board meeting reconvened at 3:45 p.m.

Rule Hearing was held.

Rules discussion:
Present: Mark Steinagel, Division Director
Jared Memmott, Division Investigator

Rules discussion: It appeared from the hearing that the public wanted to keep an overall number in for the ratio of pharmacists to pharmacy technicians. Dr. Lundberg stated she trusts the profession is safe to regulate themselves and to be able to determine the ratio and their own comfort level. Mr. Walker stated he also heard concern regarding the enforcement of the rule if there is no ratio. There is fear that more pharmacists will be charged with unprofessional conduct. Board members stated the investigators would need to focus on the professional standards in the pharmacy rather than on the number of individuals in the pharmacy. Mr. Fitzpatrick indicated risk management will determine how to minimize the risk to the company. The Board's direction is to look at the risk to the public. Ms. Poe stated if the data comes back and indicates changes in error rates and harm to the patient, the rule could be changed back to a number. Ms. Poe stated she understands the investigators would prefer to stay with a number, but they will need to look at error rates and significant

changes. Ms. Bird stated from the technician's point of view, there are already times when the technician is asked to do things outside the scope of practice as a technician, and he/she may be pushed to do more than he/she should. Ms. Bird stated there are not enough technicians secure enough to say no, or who may not understand they should be saying no. Ms. Bird stated there should be standardize education for technicians. Dr. Young reported NABP is discussing this issue.

Mr. Walker stated there needs to be a standard set. Unreasonable risk is a standard that is difficult to enforce but at least it is a standard. He stated the audience was concerned because the standard is not black and white. They expressed concern there will be more litigation and more pharmacists may be charged with unprofessional conduct. Ms. Poe stated the Division is complaint based, and if the circumstances lead to harm, or would lead to harm if the action continued, the offenses would come before the Board. Ms. Poe stated she did not hear a strong argument that this rule would not work. The Board wants to give the professional more control and more accountability. The pharmacists don't want to give up professional accountability, but feel it will be taken away from them by employer. Mr. Fitzpatrick stated he agrees with Dr. Munger's comments that the pharmacist can be better involved in patient healthcare; spend more time interacting with physicians, third party payers and patients. It is the professional responsibility of the pharmacist to make sure the pharmacy technicians are competent. Mr. Fitzpatrick made a Motion to approve the rule as written, without any changes, either substantive or non substantive, accept public comment until July 1, 2010 and unless the Board and Division receives significant comment that alters that view, allow the rules to go into effect July 8, 2010. Dr. Lundberg seconded the Motion. All Board members in favor. Mr. Walker stated the Motion will have to be revisited after the public comment period.

Remote entry refill standards:

Ms. Poe presented the proposed rule regarding remote entry refill standards. Board members requested this be tabled and placed on the agenda next month.

Review E-Mails received by the Division:

Ms. Poe questioned the process regarding the

distribution of immunization medications. She stated the immunization would be ordered by a prescriber, stored in a pharmacy under CDC guidelines. Dr. Young stated that the CDC guidelines only recommend ten immunizations at the most. If a manufacturer has shipped the immunizations to the pharmacy, and the immunization is then administered by a nurse, and a company has a contractual agreement that orders the immunization under a standing order, can the nurse doing the administration pick up the medications from the pharmacy. Board members indicated it would be acceptable as long as the cold chain requirement and the CDC requirements are met. It can not be sent to one pharmacy and then mailed to another pharmacy for the nurse to pick it up.

Over the Counter Medications:

Ms. Poe questioned if there were any regulations regarding over the counter medications and whether or not the company would need to have a manufacture license. Board members indicated there is no state licensure required but the company would need to have FDA authorization.

Prescription record rules:

Ms. Poe questioned since there is a five year retention on prescription record, if it was acceptable to have those records off site in a controlled environment that meets HIPPA rules as long as the records are readily accessible? Board members indicated this would be acceptable as long as it readily available and accessible to the investigators. However, records for the current year must be on site. Board members indicated that Medicare requires records be kept for ten years and it is easier to store all records for ten years rather than try to separate out the Medicare records.

NABP Annual Meeting report:

Dr. Young reported on the NABP meeting. He indicated the multi-state licensure proposal passed. Attendees discussed standardized definitions, and indicated developing national pharmacy practice standards will be hard to do. Also discussed were standardized disciplinary guidelines, but this will also be difficult to develop. He stated they supported the development of the use of technology, labeling of patient assistance programs, quality of standards for compounding and looking at use for dietary

supplements.

NABP District meeting:

NABP District meeting will be held September 28-30, 2010 in Albuquerque NM. Ms. Poe reported two assistant attorney generals from Utah will attend the meeting. Mr. Fitzpatrick stated he would be attending, however, not in an official capacity.

Appreciation expressed to Mr. Fitzpatrick:

Board members thanked Mr. Fitzpatrick for his years of dedicated service on the Board. Mr. Fitzpatrick has been an excellent Board member and all Board members thanked him for his direction.

Jonathan Rapp Pharmacy Technician Program:

Board members approved the program. However, Board members recommend the program be given a name.

Target Pharmacy,
Final exam update:

Dr. Kemper reported the final exam looks good and was approved.

Adjourned:

4:55 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.

July 27, 2010
Date Approved

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

July 27, 2010
Date Approved

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