

Kansas State Board of Pharmacy
Minutes of the March 9 & 10, 2011
Board Meeting

KU School of Pharmacy
2010 Becker Drive
Lawrence, KS 66047

Wednesday, March 09, 2011

Meeting Called to Order: President Shirley Arck called the meeting to order at 9:00am.

Members Present: Shirley Arck, Pharm. D., President; Jim Garrelts, Pharm. D., Vice-President; Michael Coast, R.Ph.; Nancy Kirk (9:05am -3:25pm), Public Member; David Schoech, R.Ph.; and Frank Whitchurch, R.Ph.

Staff Present: Debra Billingsley, Executive Secretary; Tom Frazier, R.Ph., Pharmacy Inspector; Carly Haynes, R.Ph., Pharmacy Inspector; Melissa Martin, Compliance Officer; Reyne Kenton, Compliance Officer; and Randall Forbes, General Counsel.

Others Present: See attached listing.

Welcome to Dean Ken Audus and the KU School of Pharmacy

Dean Audus welcomed the Board to the KU Campus and the first Board meeting held in the new school of pharmacy. Joe Heidrick, Pharm.D, and Barb Woods, R.Ph. were present representing the faculty.

Approval of the Agenda:

A motion was made and seconded to approve the agenda as amended. Remove Case 10-09; add a discussion at 1:30pm regarding Unused Medications; and tour of the KU School of Pharmacy at the end on the day. (Schoech/Garrelts). Motion passed.

Approval of the December 2 & 3, 2010 Minutes:

A motion was made and seconded to approve the minutes as printed. (Schoech/Coast) Motion passed.

Approval of the December 22, 2010 Minutes:

A motion was made and seconded to approve the minutes as printed. (Coast/Schoech) Motion passed.

Approval of the January 17, 2011 Minutes:

A motion was made and seconded to approve the minutes as printed. (Garrelts/Coast) Motion passed.

Approval of the February 10, 2011 Minutes:

A motion was made and seconded to approve the minutes as printed. (Schoech/Garrelts) Motion passed.

Administrative Proceedings

- Dillons #49 (2-09637) **Case 10- 20**. Scott Hesse, Disciplinary Counsel for the Board, presented the case on behalf of the Board. Terry Bradstreet, R.Ph, was present representing Dillons. Dillons was assessed a fine in the amount of \$5000 for failing to cure a lapse in security of controlled substances in a timely manner. A motion was made and seconded to approve the Summary Order. (Coast/Whitchurch) Motion passed.
- Jean Ricard (14-00764) **Case 11-04**. Scott Hesse, Disciplinary Counsel for the Board, presented the case on behalf of the Board. Ms. Ricard's pharmacy technician registration was revoked due to diversion of controlled substances from her employer. A motion was made and seconded to revoke the technician registration. (Schoech/Whitchurch) Motion passed.
- Quinn Nelson (14-08397) **Case 10-94**. Scott Hesse, Disciplinary Counsel for the Board, presented the case on behalf of the Board. Mr. Nelson's pharmacy technician registration was revoked due to diversion of controlled substances. A motion was made and seconded to revoke the technician registration. (Coast/Garrelts). Motion passed.
- Justin Hutmacher (14-09084) **Case 10-104**. Scott Hesse, Disciplinary Counsel for the Board, presented the case on behalf of the Board. Mr. Hutmacher's pharmacy technician registration was revoked due to diversion of controlled substances. A motion was made and seconded to revoke the technician registration. (Coast/Whitchurch)

Investigative Member Report – Closed Cases

Ms. Billingsley provided an updated list of drugs that have been diverted in Kansas. The closed cases were presented. Currently the Board has 20 cases for 2011. The Board discussed having security to sit in during the meeting.

Board Discussion

Unused Medications –Ms Billingsley provided the Board with a current copy of the statutes and regulations related to the Unused Medication Program. When the program was originally implemented the understanding was that all the entities dispensing the unused medications would be registered with the Board of Pharmacy. Donating entities were to be mail order services, medical care facilities, and long term care facilities. There was no regulatory provision for a repository but it was developed to provide a single location where the drugs could be donated and verified by a pharmacist. The repository was to be registered at no charge as a distributor. Recent information has been received that the repository is repackaging. The repository has received many bulk medications that could be used by more patients if they were in 30 day dosage supplies. The Board discussed options. The Board does not want to impede the ability to get the meds to the people that can use the medications but does not want patient safety to be compromised. Discussion tabled.

Administrative Proceedings

- Ignacio Ruiz (14-06763) **Case 10-106.** (10:05am) Scott Hesse, Disciplinary Counsel for the Board, presented the case on behalf of the Board. Mr. Ruiz was present to represent himself. Mr. Ruiz allegedly diverted a Schedule V drug from the pharmacy for the use of another individual. A motion was made and seconded to go into executive session for quasi-judicial deliberations at 10:20am to include Ms. Billingsley and Mr. Forbes, Board General Counsel. (Coast/Garrelts) Motion passed. Ms. Arck reconvened the meeting at 10:38am. A motion was made and seconded to fine Mr. Ruiz \$300, stay the fine unless there is another violation of law, place the respondent on probation for 2 years while working as a technician and to limit administrative tasks. The pharmacy that employs Mr. Ruiz must agree to submit controlled substance inventories to the Board for 6 months. Mr. Ruiz will need to inform any employer of these stipulations prior to beginning employment. Mr. Ruiz agreed to the stipulations. (Schoech/Kirk) Motion passed.
- Bruce Ballard (1-13362) **Case 10-36.** Scott Hesse, Disciplinary Counsel for the Board, presented the case on behalf of the Board. Mr. Ballard was not in attendance. Mr. Ballard is on probation in Missouri and the Kansas Order will require the same restrictions. A motion was made and seconded to approve the Settlement Agreement and Final Agency Order. (Coast/Kirk) Motion passed.

Pharmacy Class

The Board recessed to attend a classroom as guest of Barb Woods, R.Ph, in the KU School of Pharmacy Law Class

Recess: Dr. Arck recessed the meeting for lunch at noon to reconvene at 1pm.

Reconvene: Dr. Arck reconvened the meeting at 1pm.

Board Discussion

CIPP Contract with KPhA – Ms. Billingsley introduced Sharon Iverson. The Board's 3 year contract with KPhA expires on June 30, 2011. Pharmacists that self refer to CIPP are reported to the Board as a number only. Ms. Iverson asked if the reporting was beneficial. Ms. Billingsley said the reporting of self-referrals was not beneficial and is reflected in the reports sent to the Board by KPhA. KPhA CIPP Committee provides an annual report to the Board on services provided and expenses. Ms. Iverson asked the Board if they would consider funding a consulting physician for the determination of treatment options available for the pharmacists. The cost of \$2500 would be added to the current contract. A motion was made and seconded to approve the addition of the physician be added to the contract. (Coast/Schoech) Motion passed.

Disciplinary Counsel Contract – Ms. Billingsley informed the Board that Bill Rein has taken a job as Chief Counsel with the Department on Aging. Scott Hesse had previously represented the Board as an Assistant Attorney General and various cases were transferred to Mr. Hesse. The Board directed Ms. Billingsley to seek additional counsel either on a contractual basis or as an employee of the Board.

Prescription Transfers – First fills for long term care facilities. The Board discussed a letter received from Melissa LeBar, R.Ph., Heartland Homecare Services. Ms. LeBar

described her pharmacy practice for long term care patients and asked that the Board provide an exception related to first dosing. Ms. Billingsley will search other states for applicable laws and regulations and provide it to the Board at their next meeting.

Legislative Update

- HB 2023 – Updating Controlled Substance Act – The Senate debated March 9, 2011
- HB 2048 – Establishing a Prescription Drug Disposal Program – Representative Sloan of Lawrence requested the bill. This bill did not get a hearing.
- HB 2049 – Tetrahydrocannabinols Amendment to Controlled Substance Act - The Senate debated March 9, 2011.
- HB 2069 – Adverse Medical Outcome Transparency Act – The “I’m Sorry” Bill was in the Judiciary Committee Monday March 7, 2011.
- HB 2098 – Making Meth Precursors Schedule III – Did not get a hearing
- HB 2120 – Government Effectiveness and Efficiency – Hearing scheduled in Federal and State Affairs. Bill concerns the agencies becoming more efficient. May be more of an issue next year.
- HB 2123 – KS Adverse Medical Outcome Transparency – No action.
- HB 2129 – Health Care Freedom Act – Blessed but no hearing scheduled. The Bill concerns National Health Care.
- HB 2136 – Prohibiting Health Insurance Plans from Creating Specialty Tiers – No action.
- HB 2158 – State Agency Performance Measures – Senate Ways and Means – No action.
- HB 2178 – Granting Professional License to Nonresident Individual – Most medical profession Boards testified against the Bill. The Bill would require only a signed affidavit to issue a license to a spouse of a military person stationed in the state.
- HB 2182 – Concerning mail service pharmacies – Testimony taken. Ms. Billingsley requested the Bill not be attached to 2048.
- HB 2232 – Culpability for the Unlawful Possession of Prescription Drugs – No action.
- HB 2249 – Bath Salts – The hearing was March 3, 2011.
- HB 2318 – Recodifies Controlled Substances – Blessed. Hearing was March 7, 2011. The Bill updates the State controlled substance lists with regards to the Federal lists.
- HB 2330 – Cannabis Compassion Act – No hearing.
- SB 51 – School District Administration of OTCs – Ms. Billingsley requested the term “dispense” be replaced with the term “administer”. Action possible on March 8, 2011.
- SB 88 – Naturopathic Medicine – No action. The naturopathic physicians are pursuing prescriptive authority of drugs.
- SB 91 – Sexual Assault Survivors Right to Emergency Contraception – No action.
- SB 99 – Electronic Transmission of Prescription Orders – Hearing with no action. Pfizer was only group speaking for the Bill.
- SB 117 – DUR Program – Hearing was in February with no further action.
- SB 131 – Making Meth Precursors Schedule III - A hearing was conducted March 7 and 8th with the vote scheduled for March 14, 2011. Ms. Billingsley and Dr. Larry Anderson spoke in favor of the Bill. BCBS, CHIPAS, and NACDS spoke against the

Bill. Mr. Schoech was interviewed after the hearing and appeared on many television stations.

- SB 132 – Dental Care Access – The Bill has advanced with many drugs removed and many left for prescriptive authority for dental hygienist.
- SB 134 – ARNP Licensure – Advanced Registered Nurse Practitioners were seeking licensure rather than registration. The Bill has passed.
- SB 138 – Pharmacy Integrity Act – Final action was continued until March 10, 2011. Compromise or the Legislature will decide.
- SB 162 – Residential Real Estate and Meth Labs – Blessed in committee. The seller must disclose if there has ever been a “meth lab” in the house.
- SB 167 – Health Care Freedom Act – No action.
- SB 211 – Pharmacists Dispensing – Currently no hearing scheduled. The Bill concerns the 90-day fill without physician consultation if refills would be adequate to cover the amount dispensed.

Board Discussion

Unused Medications – Discussion continued. A question was raised about the ability of a long term care pharmacy to participate. As the statute and regulations are currently written, a pharmacy dispensing only to long term care facilities may not be a donating entity.

Emergency Scheduling

Emergency Scheduling of JWH-081, [1-Pentyl-3-(4-methoxy-1-naphthoyl)indole]

Emergency Scheduling of JWH-122, [1-Pentyl-3-(4-methyl-1-naphthoyl)indole]

Emergency Scheduling of JWH-210 [1-Pentyl-3-(4-ethyl-1-naphthoyl)indole]

Emergency Scheduling of AM-2201 (1-(5-fluoropentyl)-3-(1-naphthoyl)indole)

Request of Salina Police Department and Saline County District Attorney

A motion was made and seconded to emergency schedule JWH-081, JWH-122, JWH-210 and AM-2201. (Kirk/Coast) Motion passed.

Recess: Dr. Arck declared a break to reconvene in 15 minutes.

Reconvene: Dr. Arck reconvened the meeting at 3:10pm

Regulatory Update

- Nuclear Pharmacy Regulations – A meeting will be scheduled for June 9 in the afternoon.
- Hospital Telepharmacy Regulations – The changes were made and have been sent back to the Department of Administration and will be sent to the Attorney General’s office. A public hearing will be scheduled as soon as they are received back from the AG’s.
- Compounding Regulations – The regulations need the changes made and sent back to Department of Administration and the Attorney General’s.
- Wholesale Distributors – The regulations are at the Department of Administration.

- Durable Medical Equipment Regulations – The regulations are at the Department of Administration.
- Electronic Prescriptions – Ms. Billingsley will bring the updated regulations Thursday.
- Schedule V Samples – The regulations are at the Attorney General's. A public hearing will be scheduled once the regulations are approved by the AG's office.

Board Discussion

PSE Electronic Logging Update – Ms. Billingsley updated the Board on progress. Ms. Billingsley talks with APPRISS weekly. Next letter will give training sessions via Webinars and Internet. APPRISS is not quite ready to set pharmacies up to use the system. Many pharmacies are ready to roll since they participated in the pilot program. Ms. Billingsley gave the Board a letter to review.

Budget – Ms. Billingsley updated the Board on the status of the funds being set aside for legal fees. The state is doing an analysis of how much the agencies are using the Department of Administration. The state may charge for those activities and the Board portion may be around \$10,000. The state is looking to consolidate activities occurring at individual agencies like bill paying to increase overall efficiencies. The vehicles are a possibility but no definitive answer. The Board needs to reduce the fees they are collecting. The Board discussed whether their excess money in the fee fund could be used for tuition loan forgiveness for pharmacists willing to go to an under served area. The Board staff will explore this option with the Director of Budget.

Approval of 50 – Year Certificates. A motion was made and seconded to approve the 50 – Year Certificates. (Coast/Garrelts) Motion passed. The pharmacists receiving the 50-year certificates are:

- William Richmond, Leawood, Kansas
- Charles Evans-Lombe, Cherryvale, Kansas
- Thomas Dyer, Hutchinson, Kansas
- Hal Schwarz, Wichita, Kansas
- Thomas Todd, Versailles, Missouri
- Theresa Morgan, Garden City, Kansas
- Janice Parsons, Manhattan, Kansas
- James Kinderknecht, Topeka, Kansas
- Eugene Peterson, Wichita, Kansas
- Kim Ong, Sunnyvale, California
- Hugh Charles, Parsons, Kansas

Instymeds – Mr. Forbes stated that the case against College Family Practice is settled.

Approval of New Pharmacists and New Registrants

A motion was made and seconded to approve the new licenses and registrations. (Coast/Schoech) Motion passed. Mr. Schoech is still in process of redesigning the pharmacist's license.

Adjourn: Dr. Arck adjourned the meeting at 3:27pm.

Thursday, March 10 , 2011

Meeting Called to Order: President Shirley Arck called the meeting to order at 9:00am.

Members Present: Shirley Arck, Pharm. D., President; Jim Garrelts, Pharm. D., Vice-President; Karen Braman, R.Ph.; Michael Coast, R.Ph.; Nancy Kirk (9:08am), Public Member; David Schoech, R.Ph.; and Frank Whitchurch, R.Ph.

Staff Present: Debra Billingsley, Executive Secretary; Tom Frazier, R.Ph., Pharmacy Inspector; Carly Haynes, R.Ph., Pharmacy Inspector; Reyne Kenton, Compliance Officer; Randall Forbes, General Counsel; Christina Morris, PDMP Director /Assistant Executive Director; and Amiee Grubb, PMP Administrative Specialist.

Others Present: See attached listing.

Public Hearings for Proposed Regulations

Dr. Arck adjourned the regular meeting and opened the public hearing at 9am.

Electronic Transmission of Prescriptions

K.A.R. 68-2-22. Electronic Transmission of Prescription

K.A.R. 68-20-10a. Electronic Transmission of a Controlled Substance Prescription.

Dr. Arck asked for public comment.

Ms. Billingsley provided a letter from:

NACDS – requesting further revisions to the regulation. Letter attached.

The Joint Committee on Administrative Rules and Regulations stating they had no comment on the proposed regulation.

Kansas Legislative Research Department – comments attached.

There were no comments made by the attending public.

Branch Retail Telepharmacy

K.A.R. 68-17-1. Definitions

K.A.R. 68-17-2. Status of Telepharmacy Branch Pharmacy

K.A.R. 68-17-3. Requirements for Approval of Location.

K.A.R. 68-17-4. Application for Approval of a Telepharmacy Branch Pharmacy.

K.A.R. 68-17-5. Equipment Requirements.

K.A.R. 68-17-6. Minimum Operating Requirements.

K.A.R. 68-17-7. Minimum Security Requirements

K.A.R. 68-17-8. Renewal Registration.

K.A.R. 68-17-9. Fees.

Ms. Billingsley provided a letter from ---

The Joint Committee on Administrative Rules and Regulations stating they had concerns on the proposed regulation. The Kansas Legislative Research Department sent a letter dated March 4, 2011.

The following people spoke on the regulation change:

- Aaron McReynolds, Lincoln County – Controlled drugs would be counted twice. Many rural states have similar regulations and have shown a decrease in errors. He

told the Board they did a good job to try to provide access in rural areas and preserve the integrity of the profession of pharmacy.

- Gene Hotchkiss provided that KU School of Pharmacy was interested in telepharmacy. Mr. Hotchkiss said he embraced technology but please give the pharmacy school time to serve the under-served areas in Kansas. The school has increased the class size to 150 students on the Lawrence campus in the fall of 2010 and will add an additional 20 students on the Wichita campus in the fall of 2011.
- The Board related comments they have heard from pharmacists concerning these regulations.
- Cathy Thrasher spoke to the regulations concerning technician requirements.

Prescription Drug Monitoring Regulations: K-TRACS

K.A.R. 68-21-2. Electronic Reports

Dr. Arck asked for public comment.

Ms. Billingsley provided a letter from:

Kansas Legislative Research Department – letter dated January 10, 2011. Letter attached.

The following people spoke on the regulation change:

- Christina Morris has reviewed the Kansas Legislative Research Department and made comments addressing the concerns the Joint Committee on Administrative Rules and Regulations raised.

Dr. Arck closed the public hearing.

Dr. Arck called the regular meeting to order at 9:38am.

The Board discussed the Electronic Transmission of Prescriptions.

A motion was made and seconded to adopt the proposed regulation on **Electronic Transmission of Prescriptions**. K.A.R. 68-2-22 and K.A.R. 68-20-10a (Braman/Coast)

Roll call: Dr. Arck – Yes, Ms. Braman – Yes, Mr. Coast – Yes, Dr. Garrelts – Yes, Ms. Kirk – Yes, Mr. Schoech – Yes, and Mr. Whitchurch – Yes.

The motion passed. The regulation will become effective 15 days after publication in the Kansas Register.

A motion was made and seconded to adopt the proposed regulation on **Branch Retail Telepharmacy** K.A.R. 68-17-1 through 68-17-9. (Coast/Garrelts)

The Board discussed the Branch Retail Telepharmacy. Ms. Braman suggested the Board address the concerns of the Joint Committee on Administrative Rules and Regulations before proceeding. Mr. Whitchurch suggested the Board not upset the very people the Board must work with on many legislative issues. Mr. Garrelts suggested the Board use this as a pilot program. Mr. Forbes was concerned that the AG's office would not sign off on regulations for a pilot program and they might not approve if any changes were made and resubmitted. Ms. Kirk agreed with Mr. Whitchurch.

Each Branch Retail Telepharmacy must have Board approval before opening and the Board could use that to establish a pilot program with the approved regulations. A

motion was made and seconded to table the motion to approve the regulations. (Kirk/Schoech). Motion to table passed 6-1(Coast).

A motion was made and seconded to adopt the proposed regulation on **Prescription Drug Monitoring Regulations: KTRACS** K.A.R. 68-21-2. (Braman/Coast)

Roll call: Dr. Arck – Yes, Ms. Braman – Yes, Mr. Coast – Yes, Dr. Garrelts – Yes, Ms. Kirk – Yes, Mr. Schoech – Yes, and Mr. Whitchurch – Yes.

The motion passed. The regulation will become effective 15 days after publication in the Kansas Register. Ms. Morris will respond to the Kansas Legislative Research Department on the concerns listed in their letter.

Board Discussion

K-TRACS Report – Christina Morris, K-TRACS Director, introduced Aimee Grubb, Administrative Specialist. Ms. Morris reported 74% of the pharmacies have registered to report but only 47% have been reporting. She will begin sending letters and emails to increase compliance. Access request forms are being developed.

Issues are being addressed as they arise like patient identification numbers – can be any number but the number is not being used for anything purposeful.

Another grant has been secured. Ms. Morris will be looking into state to state data sharing as hosted by NABP. PurduePharma has donated a million dollars to fund the Interconnect. Ms. Braman asked if the Board could review the MOU between NABP and Appriss, Inc. as to security for the data.

Board Member Reports

Karen Braman – thanked the Board for their support on SB133 – Health Information Exchanges. Ms. Braman thanked Ms. Billingsley for the legislative update.

David Schoech – reported on several observations. First, the diligent job performed by the inspectors is responsible for more technician diversions being caught and registration revoked. Mr. Schoech questioned the technician ratio and the ability of pharmacists to watch everything being done in a pharmacy. The inability to watch everyone increases potential risks of diversion. Second, K-TRACS was already decreasing the inappropriate use of controlled substances prescribed. There are some doctors decreasing the quantity they are prescribing. The Board expressed concern about the chilling effect this might have in dealing with patients with true, documented pain.

Michael Coast – thanked Mr. Whitchurch and Ms. Braman for the years of service they have contributed to the Board. He hoped Ms. Braman would be reappointed for another 4 years. Mr. Coast thanked the Inspectors, Ms. Billingsley, and the office staff.

Frank Whitchurch – thanked the Board for the experience. He stated that pain management was a very large issue. Florida has dispensed 500 million Oxycontin/oxycodone tablets in the past year. However, there are some patients that genuinely suffer pain. The entire medical community must find a way to address the issue. As to technician diversion, stores must develop ways to prevent the ability to divert. One way would be to have one technician order the drugs but a different technician check in the drugs.

Nancy Kirk – thanked Mr. Whitchurch and Ms. Braman for their service to the Board. The Board needs to look at diversion and find solutions to prevent. Ms. Kirk thanked the Board and staff on the movement of regulations.

Jim Garrelts – thanked Mr. Whitchurch and Ms Braman for their service to the Board. He said that hospitals struggle in preventing diversion as well and are always vigilant in increasing those efforts. Mr. Garrelts said the hospital issues would include “Meaningful Use” requirements and the move to electronic medical records and the sharing of those records. Pharmacists need to become politically active in the Federal legislation concerning medical reimbursement so they will not be left out of the overall plan.

Shirley Arck – thanked Mr. Whitchurch and Ms. Braman for their service to the Board of Pharmacy. She thanked the staff and Ms. Billingsley for the hard work. Ms. Arck thanked Barb Woods for the enjoyable law class time on Wednesday.

Staff Reports

Tom Frazier – brought up several concerns. First, pharmacies receive prescriptions from the large hospitals with only a doctor or midlevel signature, many unreadable. There are no DEA or NPI numbers and the phone numbers are rarely useful. Most hospitals cannot or will not provide the discharge practitioner thus leaving the patient with a prescription that cannot be billed to insurance or processed, if it is a controlled substance. Mr. Frazier asked the Board for help in resolving the problem. Mr. Garrelts suggested the Board write a letter to the hospitals to educate them on the problems of patients filling discharge prescriptions. Mr. Frazier told the Board that Larned State Hospital, 600 beds, was losing their PIC. The loss of Betty Seba, R.Ph, will create a problem for continued care at the facility.

Randall Forbes – said it had been a pleasure working with Mr. Whitchurch and Ms. Braman.

Debra Billingsley – said she was not taking Mr. Whitchurch and Ms. Braman off the Board member list until they were replaced which could be any day or next year. The law states that they will continue to serve until replaced, whenever that may occur. Ms. Billingsley thanked Gene Hotchkiss for the hospitality of KU School of Pharmacy in hosting the March Board meeting. Ms. Billingsley told the Board about the “Jazz It Up” award Dean Audus was receiving for service to the Douglas County Senior Services. If any of the Board members wish to attend the award program they should inform the Board office so reservations can be made.

The NABP meeting is approaching in May and Ms. Braman, Ms. Arck, Mr. Schoech are planning to attend. Other members may inform the Board if they wish to attend. Substantial Interest Forms will be sent and should be submitted back by the deadline as required by law of employees and Board members.

Adjourn: Dr. Arck adjourned the meeting at 11:02am.