

Kansas State Board of Pharmacy
Minutes of the **June 9 & 10, 2009**
Board Meeting

Landon State Office Building
900 SW Jackson, Ste. 106
Topeka, KS 66612-1231

Tuesday, June 9, 2009

Meeting Called to Order: Vice-President Karen Braman called the meeting to order at 9:00am.

Members Present: Karen Braman, R.Ph., Vice-President; Shirley Arck, Pharm. D, Investigative Member; Michael Coast, R.Ph.; Jim Garrelts Pharm. D; Frank Whitchurch, R.Ph.; and Nancy Kirk, public member.

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

Others Present: See attached listing.

Welcome new board members

Ms. Braman and the Board welcomed Dr. Jim Garrelts as the new board member. Dr. Garrelts is the Director of Pharmacy at Via Christi Regional Medical Center, Wichita Kansas. Dr. Garrelts brings many years of hospital experience to the Board. Ms. Braman and the Board congratulated Nancy Kirk on her reappointment to the Board.

Approval of the Agenda:

Ms. Braman added a discussion item to review the letter from the Kansas Joint Legislative Committee on Rules and Regulations. Dr. Arck requested the start time on Wednesday be moved to 8am. A motion was made and seconded to approve the agenda as amended. (Coast/Kirk) Motion passed.

Approval of the March Minutes

A motion was made and seconded to approve the March 2009 minutes. (Arck/Coast) Motion passed.

Approval of the May Minutes

A motion was made and seconded to approve the May 2009 minutes. (Arck/Coast) Motion passed.

Administrative Proceedings

- Pamela Stoddart - Case 09-41 The Board accepted letters of compliance from KPhA CIPP Program Director and Missouri State Board of Pharmacy. A motion was made and seconded to go into executive session for 10 minutes to discuss privileged

information to include Ms. Stoddardt's Supervisor (Debbie – I can't remember his name), CIPP representatives, Mr. Forbes and Ms. Billingsley and to return to open session at 9:15am. (Coast/Whitchurch). Motion passed. At 9:15am motion was made and seconded to extend for 10 minutes. (Coast/Kirk). At 9:25am motion was made and seconded to extend for 10 minutes. (Coast/Kirk)

Ms. Braman reconvened the meeting at 9:35am. A motion was made and seconded to go into executive session for quasi-judicial deliberations at 9:35am to include Ms. Billingsley and Mr. Forbes. (Coast/Arck). Motion passed.

Ms. Braman reconvened the meeting at 9:47am.

A motion was made and seconded to allow Ms. Stoddart to become licensed in Kansas after successfully passing the MPJE and completion of the Missouri stipulation. (Coast/Arck) Motion passed.

- Hogan's Pharmacy - Case 08-22 The Board reviewed the findings of the Administrative Hearing Officer. Mr. Forbes and Ms. Billingsley reviewed the process and the findings. With no appeals, the order has now become a Final Order. The fines have not been paid. The license of Mr. Kloxin, pharmacist, and registrations of the remaining parties has been revoked. Dr. Arck thanked the staff for their years of hard work on this case.
- Porter Drug – Case 09-28. The Board reviewed the case. Porter Drug has submitted a signed Summary Order and paid the fine for working a non-registered technician.
- Heather Ann Lindsay – Case 09-35 Ms. Lindsay's technician registration was revoked for diversion of controlled substances.
- Walgreens – Case 09-21 The Board reviewed the case. Walgreens has submitted a signed Summary Order and paid the fine for working a non-registered technician.

Investigative Member Report – Closed Cases

Dr. Arck reviewed the closed cases. There were 156 cases in 2008 with 13 still open. We currently have 45 cases for 2009 with 21 still open.

Board Discussion

Meeting Space – Ms. Kirk questioned the meeting space and why we do not book for a complete year. Ms. Billingsley explained that most facilities that are free will not let the rooms be booked a year in advance. The space in Landon Office Building is not ideal due to the lack of parking or free parking. The Board agreed to have the December meeting in Wichita. Dr. Garrelts stated he would check into a meeting room at Via Christi.

PMP Update – Karen Braman presented an update from the March 2009 meeting. Dana Droz's presentation slides will be sent to the Board. The committee tabled the discussion on Emergency Room reporting exemption because the Kansas Hospitalization had expressed wanting to change the language but were unable to have a representative present at the meeting. The PMP Advisory committee is recommending that carisoprodol, tramadol, and butalbital be reported as drugs of concern. Action items dependent on PMP funding include preparing data recovery system protocols and RFPs. No future meetings have been scheduled due to funding issues. The Board discussed the

possibility of using the pharmacy fee reserve account to partially fund the PMP and/or the Meth Precursor program.

Meth Precursor Regulations – Mike Coast reported that both pilot programs are still running. Ms. Braman requested representatives from both pilot programs attend the September meeting to provide the Board an update on how the pilots are going so the Board can consider this information when discussing next steps on pursuing funding for both the meth precursor and PMP programs. The PSE committee will be reconvened to review the RFP, begin writing regulations, and review all grant options.

Administrative Proceedings

- Bill Poulos – Case 09-27 The Board reviewed the request for licensure. Ms. Billingsley provided the Board an overview of the case. Mr. Poulos is currently on probation with the Iowa Board of Pharmacy. A motion was made and seconded to go into executive session for 30 minutes to discuss privileged information to include Mr. Forbes and Ms. Billingsley and to return to open session at 11:05am. (Coast/Kirk) Motion passed. Ms. Braman reconvened the meeting at 11:05am. A motion was made and seconded to go into executive session for quasi-judicial deliberations for 10 minutes to include Ms. Billingsley and Mr. Forbes and return to open session at 11:15am. (Coast/Garrelts) Motion passed. A motion was made and seconded to extend for 15 minutes and return to open session at 11:30am. Ms. Braman reconvened the meeting at 11:30am. Ms. Braman outlined the stipulations for licensure in the State of Kansas. A motion was made and seconded to allow Mr. Poulos to license in Kansas after successful completion of the MPJE and the signed agreement of the following: 5 years in the CIPP program, work a maximum of 40 hours per week, not be a preceptor or pharmacist in charge, and not work alone. (Whitchurch/Kirk) Motion passed.

Recess: Ms. Braman recessed the meeting for lunch at 11:45am to reconvene in 1 hour.

Reconvene: Ms. Braman reconvened the meeting at 12:45pm.

Board Discussion

Kansas Legislative Letter – The Board reviewed the letter from the Legislative Joint Committee on Rules and Regulations dated May 22, 2009. The Legislative Joint Committee requested a response from the Board within 60 days. The Board discussed what type of response should be offered and what information was actually being requested. Mr. Forbes suggested the Committee wanted a response per each regulation the Committee reviewed and provided a comment. Ms. Billingsley told the Board that sufficient information was provided from the letter to formulate a response. Ms. Braman will review the response. In the future the Board will make a diligent effort to respond in writing to each suggestion from the Legislative Joint Committee.

Compounding Update – Shirley Arck presented the update. The regulation is almost ready to forward on to the Legislative Committee and Attorney General's office.

Tech Check Tech in the Hospital Setting – Ms. Billingsley presented the update. The Board considered regulations from Iowa and California. No language has been written or

suggested by the stakeholders currently utilizing tech check tech. Minnesota has a quite extensive manual but no regulations. Mr. Coast and Dr. Garrelts will work on drafting regulations for tech check tech with input from other hospital pharmacies such as Stormont Vail and Lawrence Memorial. The proposed regulation will be presented at the September meeting.

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Automation / Physician Dispensing – Ms. Billingsley presented the update. The Board reviewed letters from Instymeds, past Board discussion and action. The Board will send a letter to the Board of Healing Arts stating the position of the Pharmacy Board and send a position letter to the facilities utilizing Instymeds before sending cease and desist letters. The Board also discussed drop stations and where medications can be delivered.

Safety Net Clinics and Unused Medication Act – Robert Stiles, KDHE, addressed the Board on KDHE’s role in the unused medication act and their oversight of safety net clinics. According to Mr. Stiles, the last several months have been spent on planning and implementing the program. Mr. Stiles reported that the safety net clinic in Emporia has a pharmacy that has set up a clearinghouse to properly store, inventory, and track the donated medications. Five clinics have registered to participate in the program to date. The list of available drugs is quite extensive. Prescription Solutions has donated an estimated \$220,000 to the program so far. KDHE is working to increase the number of clinics participating and the number of eligible donating entities. They are also working to inform the public on proper disposal of drugs that cannot be donated. KDHE must statutorily keep track of drugs collected and dispensed. Ms. Braman thanked Mr. Stiles for his work and enthusiasm for the program. Ms. Braman requested the Board receive a copy of the report Mr. Stiles must provide to the legislature.

Classification of Pharmacy – Mr. Whitchurch presented the update. The Board staff reported on the areas researched with the idea to rewrite the regulations for clarity and consistency across the state. Mr. Whitchurch suggested the first thing we need to propose is a non-dispensing pharmacy registration. The Board will place this item on the September agenda.

Technician Functions – The Board reviewed a prior list of non-technician and technician functions. The inspectors will meet and update the list for presentation at the September meeting.

Continuing Education – The Board reviewed the joint letter from ACPE and NABP on guidance regarding continuing education. The Board discussed who would review non-ACPE continuing education if the Board continued to offer that service. Mr. Forbes reviewed the proposed regulation. Barb Woods addressed the Board as to ACPE standards. ACPE does not approve CE, they approve providers who in turn must approve the CE while remaining accredited with ACPE. The Board consensus was to leave the regulation as it currently appears and to revisit the issue in September.

Special Presentation

Ms. Braman, on behalf of the Board, presented Ms. JoAnne Gilstrap, R.Ph., a plaque in appreciation of her years of unselfish service to the profession of pharmacy as a member of the Board of Pharmacy.

Recess: Ms. Braman declared a break to reconvene in 10 minutes

Reconvene: Ms. Braman reconvened the meeting at 3:50pm

Internet Pharmacy – Haight Law – The Board reviewed the position paper from NABP. This federal law was enacted to prevent doctors from writing controlled substance prescriptions over the Internet without seeing the patient. The Board was considering options to define “legitimate medical purpose” for writing and filling a prescription. The Haight Law exempts telemedicine. Mr. Forbes and Ms. Billingsley searched for the proposed language and will respond back to the Board.

Pharmacist Survey – Ms. Braman presented the provided information, including a survey conducted by the Board from 2000 and a copy of a survey recently conducted by the KS Board of Healing Arts. Ms. Braman questioned the purpose of the survey, which survey should be used, and how to best solicit responses. The consensus was to complete a web-based survey. The questions were reviewed. Ms. Kirk recommended that the word “feel” should be changed to “think”. The questions on the Kansas Board of Pharmacy Survey of 2000 should be used but with the Board of Healing Arts format. The Board also added one question from the Board of Healing Arts survey. The Board considered other questions to be asked. The survey will be posted for 30 days on the Board of Pharmacy website and will also be e-mail to KS-licensed pharmacists using the distribution list that is used for the newsletter.

Legislative and Regulatory Update – Ms. Billingsley presented the update.

Nuclear pharmacies questioned if they would be accountable to the proposed compounding regulations. Dr. Garrelts stated that USP 797 for sterile compounding should cover all sterile compounding including nuclear medications. An exclusion sentence may be added for a nuclear pharmacy for some portions of the regulations.

Retail Telepharmacy - A pharmacist has requested that controlled substances be allowed and cited the South Dakota regulations. There is also a request to reduce the mileage requirement.

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Institutional Drug Rooms, Records and Inventory, Foreign Pharmacy Graduate Equivalency Examination, and Qualifying Pharmaceutical Experience will be on the September agenda for public hearing.

Faxing of CII for Assisted Living regulations need to be drafted.

Adjourn: Ms. Braman adjourned the meeting at 4:50p.m.

Wednesday, June 10, 2009

Meeting Called to Order: Vice-President Karen Braman called the meeting to order at 8:00am.

Members Present: Karen Braman, R.Ph., Vice-President; Shirley Arck, Pharm. D, Investigative Member; Michael Coast, R.Ph.; Jim Garrelts Pharm. D; Frank Whitchurch, R.Ph.; and Nancy Kirk, public member.

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

Others Present: See attached listing.

Budget

Ms. Billingsley presented the budget and the shortfall created by the legislative process. Authorization must be obtained from the Finance Council to restore part of the transferred amount. The Finance Council will not meet until July. The licensing software RFP came in over the \$110,000 allocated. The software RFP is for licensing and includes inspection format improvements. The software would allow licensing to be connected with disciplinary actions. Currently, disciplinary actions are tracked manually. The Board discussed the shortfall and the two unfunded mandates from the legislature. Those mandates were the Prescription Monitoring Program and the Electronic Tracking of Meth Precursors. Those mandates will require additional staffing. Ms. Billingsley will schedule a meeting with the Finance Council and will notify Board members of the meeting date and time so they may attend as schedules permit.

H1N1 Virus

Ms. Billingsley helped draft the emergency order the governor would have signed (or will sign) if H1N1 had become a larger problem. Mr. Kinderknecht was the state pharmacist consultant for this project. He helped troubleshoot the distribution and patient communication issues. Mr. Kinderknecht assisted KDHE in the Tamiflu distribution and developed a destruction form to be used when or if the drugs outdate.

Board Member Reports

Dr. Shirley Arck – thanked the staff for the work the staff has done on the investigations.

Karen Braman – told the Board that Christina Morris is attending a meeting concerning PMP. Ms. Braman will give an update to the Health Policy Oversight Committee on health information exchange at their upcoming meeting this Friday.

Michael Coast – welcomed Dr. Garrelts to the Board.

Dr. Jim Garrelts – presented the letter from NABP asking Boards of Pharmacy to formalize technician training.

Nancy Kirk – had nothing else to report.

Frank Whitchurch – reported on the NABP convention. NABP is encouraging more training for technicians even to the extent of several years of college. Counseling was presented as an issue. If counseling was not offered and an error occurs prosecution becomes a larger issue. The DEA demonstrated small quantity meth production. Mr.

Whitchurch said it was a good meeting with a lot of usable information. He suggested the Board to review the counseling regulations. Ms. Kirk asked the Board to have Mr. Whitchurch and Mr. Coast present their recommendations to make counseling more meaningful. Mr. Whitchurch asked if the Board would consider another retreat.

Staff Member Reports

Debra Billingsley – Ms. Billingsley told the Board that many independents were having trouble with CQI's first meeting and CMS certification being due at the same time. The Board did not extend the date for the CQI meeting but suggested that additional information be placed on the Board's webpage to assist pharmacies in understanding what their responsibilities would entail.

Carly Haynes – reported on several interesting questions since the beginning of the year. The first involved who was responsible in the State of Kansas for Hyperbaric Chambers. They are high-pressure vessels and the Department of Labor Boiler inspectors do the inspections on the hyperbaric chambers. The issue was asked due to an unregulated chamber in use in Butler County. The second issue dealt with Medical Gases. NFPA, National Fire Prevention Association, has a Standard 99 that requires plumbers to purge medical gas lines with Nitrogen, NF. Ms. Haynes explained the work around being used to allow oxygen distributors to distribute nitrogen, as a medical gas, to plumbers. The last issue asked the opinion of the Board on the use of volunteers in a hospital to perform clerical and delivery duties. The Board consensus was that it was okay as long as the volunteers were HIPAA trained and compliant and were not performing technician or judgemental duties.

Jim Kinderknecht – reported on the drug destruction project in Saline County. The citizens took outdated and unused medications to the sheriff's department and fire departments for destruction. KDHE's only concern was - if the county had a permit and how much plastic was going into the incinerator. DEA said the collection was okay since it was law enforcement performing the service. Ms. Braman asked if the Board could work with the DEA to set up guidelines pharmacies could use to help their communities perform the service and post those on the Board of Pharmacy website. The Board suggested a letter to be written to the sheriff association to delineate the concerns of the Board.

Melissa Martin – reported on the MPJE writing experience.

Randy Forbes – commented on the counseling. In past disciplinary cases, the Board has commented on the lack of counseling and that counseling could have prevented the error.

Executive Session

A motion was made and seconded to go into executive session for 25 minutes to discuss client/attorney privileged information to reconvene at 9:45am in the same room. The executive session is to include Mr. Forbes, Ms. Billingsley and the inspectors. (Coast/Whitchurch) Motion passed.

Reconvene – Ms. Braman reconvened the meeting at 9:45am.

Approval of New Pharmacists and New Registrants

A motion was made and seconded to approve the new licenses and registrations.
(Coast/Kirk) Motion passed.

Update Matrix - Review of Action Items for the Board

Ms. Billingsley quickly reviewed the agenda items that require action by a specified individual and the date the action is due. The Board reviewed items needing to be placed on the September board meeting.

Adjourn: Ms. Braman adjourned the meeting at 10:07am.