

Kansas State Board of Pharmacy
Minutes of the March 3 & 4, 2009
Board Meeting

KU School of Pharmacy
Malott Hall, Room 6056
Lawrence, KS

Tuesday, March 3, 2009

The Board spoke with Barb Woods' law class from 9am until the meeting was called to order.

Meeting Called to Order: President JoAnne Gilstrap called the meeting to order at 9:51am.

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

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

Others Present: See attached listing.

Approval of the Agenda:

Add "in the Hospital Setting" to the Tech check Tech discussion.

A motion was made and seconded to approve the agenda as amended. (Arck/Coast)
Motion passed.

Approval of the February Minutes

The following corrections were made:

- Page 2 – under Board Discussion change: "Task Force" to "Advisory Committee".
Add "dose packs" after Emergency Room.
- Page 3 – change Ms. Braman "suggested" to Ms. Braman "brought up for suggestion that" the Board provide a ...

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

Administrative Proceedings

- Matt Gray – Case 08-129. Mr. Gray's technician registration was revoked.
- Michael Stephens – Case 08-154. Mr. Stephens' technician registration was revoked.
- Zachary McMahon – Case 09-07 – License Transfer Application. Mr. McMahon was in attendance. A motion was made and seconded to go into executive session for 15

minutes to discuss privileged information to include Mr. Forbes and Ms. Billingsley, and Ms. Morris to return to open session at 10:15am. (Coast/Arck). Motion passed. Ms. Gilstrap reconvened the meeting at 10:15am. A motion was made and seconded to allow Mr. McMahon to take the MPJE to reciprocate. (Braman/Kirk) Motion passed.

- Farm and Ranch Hand, LLC – Case 08-108. Mr. Forbes presented the case. Mr. Frazier conducted the investigation. A motion was made and seconded to accept the stipulation as presented and to have Mr. Frazier to reinspect the facility for compliance. (Braman/Whitchurch) Motion passed 3-2(Coast and Kirk) Mr. Coast was concerned that the treated animals were entering the food supply and that could cause negative outcomes for consumers.
- Jim’s Pharmacy – Case 08-57. Mr. Forbes presented the case to the Board. Ms. Haynes conducted the investigation. A motion was made and seconded to accept the stipulation as presented. (Coast/Braman). Motion passed.
- James Brown – Case 07-82. Mr. Forbes presented the case to the Board. Mr. Brown was not in attendance. Mr. Brown holds licenses in Colorado and Kansas. Mr. Brown entered a disciplinary agreement with Colorado and the stipulation would reciprocate the agreement with Kansas. A motion was made and seconded to accept the stipulation as presented. (Kirk/Coast). Motion passed.
- Lansing Pharmacy – Case 08-146. Mr. Forbes presented the case to the Board. Lansing Pharmacy had no representation present. A motion was made and seconded to accept the stipulation as presented. (Coast/Kirk). Motion passed.
- Jonathan Miller – Case 08-153. A Voluntary Consent Order has been signed. A settlement has not been reached.
- CVS Pharmacy – Case 08-69. Mr. Forbes presented the case to the Board. The case involved an unsigned incident report. CVS has submitted a signed Summary Order and paid the fine. A motion was made and seconded to accept the signed order as presented. (Braman/Whitchurch). Motion passed.

Investigative Member Report – Closed Cases

The Board reviewed the closed cases. The Board posed questions as to facts and findings of the cases. Dr. Arck and the investigators answered their questions.

Board Discussion

Hospital Telepharmacy Update – Mike Coast gave the Board an update from the meeting on Monday, March 2, 2009. The issues require fitting the regulations to the needs of multiple size hospitals. Middle-sized hospitals cannot justify 24-hour service and need to outsource overnight review of orders and Critical Care Access hospitals want more pharmacists input and review. The Board discussed the differences between the retail telepharmacy regulations and the hospital telepharmacy regulations. Mr. Whitchurch stated that the Board should be careful and not put barriers up that would impede patient care. Ms. Gilstrap reiterated the Board of its mission and that the Board needs to concentrate on patient safety. The Board discussed the number of technicians that a pharmacist could adequately supervise at multiple sites. Mr. Coast will schedule another meeting.

PMP Update – Karen Braman told the Board that the Harold Rogers grant has been submitted. HIE and HIT (Health Information Exchange and Health Information Technology) projects are eligible for federal stimulus monies. The Health Policy Authority

is compiling a list of projects that would qualify for the stimulus dollars. Ms. Braman requested the PMP and PSE electronic databases be added to the list. The federal government will use a competitive bid application process to award grants. Ms. Braman suggested that key legislators be invited to the March 25th meeting.

Safety Clinic Registrations and Policy and Procedures Manual for Safety Clinics – Ms. Billingsley updated the Board and shared the Shawnee County Health Agency policies that they are using in their health department. The safety net clinics are in the process of filling out applications and securing a pharmacist in charge for their facilities. The Pittsburg facility will warehouse the drugs and eventually KDHE hopes to maintain a web site for other clinics to use in search of drugs. The PIC responsibilities in a safety net clinic will be similar to those of a health department.

Automation – Ms. Billingsley stated the Board of Healing Arts had conducted a joint inspection with the Board of Pharmacy of a facility using automation. This topic was on the BHA agenda. The BHA did not discuss automation and in turn requested Ms. Billingsley send them a request for information on automation. Mr. Witchurch asked who was ultimately responsible for any errors that occur from automation. The Pharmacy Board can make the determination that this automation is a pharmacy without a pharmacist in charge and therefore not legal.

Recess: Ms. Gilstrap recessed the meeting for lunch at noon to reconvene at 1pm.

Reconvene: Ms. Gilstrap reconvened the meeting at 1:06pm.

Board Discussion

Automation – The Board continued the discussion. Mr. Forbes encouraged the Board to discuss becoming more aggressive on the topic. Mr. Forbes reviewed applicable laws. Pete Stearns encouraged the Board to act quickly to answer the questions and assume control of the issue. Ms. Gilstrap requested Mr. Forbes to draft a position paper that would address automation. Mr. Forbes will have the draft available by March 24, 2009.

Legislative and Regulatory Update – Debra Billingsley sent the Board an email concerning HB 2008 regarding epinephrine kits in public schools. The Board discussed the problems with the current language which are: ownership of the drug, liability for the schools, nurses diagnosing and who is responsible for errors and injuries resulting from inappropriate administration. The Board recommended that Ms. Billingsley meet with Rep. Horst and advise her of the Board's concern with the current bill language. They recommended that the bill require a protocol between a physician and a school nurse.

Electronic Tracking of PSE – Ms. Billingsley shared the proposed changes related to SB 248. Ms. Kirk made comments about letter (d). Real time was the preferred method of information receipt. The chain drug stores prefer the batch method and not having a stop sale format that would require real time. Law enforcement has signed off on the proposed changes that would permit the batch format. Ms. Braman suggested striking in (d) “that is capable” and “in real time” plus the last new added portion. Remove from (e) “showing imposition of additional cost by the pharmacy”. Remove the additional new portion beginning with “for various other...”

Ms. Braman expressed concern over the excessive wordiness of the New Sec. 3. Rewrite (a) to read: "The cost of establishing and maintaining the statewide electronic logging system shall be borne by the state. Pharmacies and pharmacists shall not be required to bear the costs associated with establishing and maintaining the electronic logging system." In (b) delete all language after "applicable to a statewide program." In (c) delete most of (c) leaving "If the state is unable to bear the costs of establishing and maintaining the electronic logging system pharmacies shall still be subject to maintain a log as provided by K.S.A. 65-1643(k)(1)(B)." Ms. Braman suggested language be added to allow an individual to obtain their own individual data as in the PMP language. While the Board agrees with the intent of the language, there is too much unnecessary verbiage.

Substitution Statute – Ms. Billingsley shared with the Board comments from some pharmacists with the proposed changes to K.S.A. 65-1637 in SB 249. Under (a)(2)(B) strike iii and iv. Modify ii to include "a bioequivalent product". Mr. Whitchurch will discuss the changes with Dan Moran.

Other Legislative Updates – Ms. Billingsley gave updates on the following bills:

- SB 16 – Pharmacy Act Exemption for donation and distributions of drugs under Cancer Drug Repository/Unused Medication Act has passed the Senate committee but not been scheduled for a hearing in the House Health and Human Services committee.
- SB 33 – Board of Pharmacy expanded board/fingerprinting/pharmacy technicians has passed the senate. The Senate committee amended the bill to increase the statutory cap for technician registration from \$50 to \$100. The House Health and Human Services has not held a hearing nor is one scheduled.
- SB 87 – Administrative Proceedings. The bill has passed the Senate and has been referred to Judiciary.
- SB 248 – The hearing for Electronic-logging system for sale of methamphetamine precursors will be heard Thursday March 5, 2009.
- SB 249 – Dispensing substitution of drug product has passed senate and waiting to be heard in the House Health and Human Services committee.
- HB 2298 – Long distance learning was scheduled for a hearing but there has been no vote.
- HB 2201 – Conditions placed on licensees for child support has been referred to Judiciary Committee
- HB 2236 – Recodification of certain drug crimes. Moving from our statutes into the criminal code for ease of retrieval. Passed Corrections and Juvenile Justice and been referred to Judiciary.
- SB 28 – Suspension of license for transportation of controlled substances passed the Senate Judiciary committee and referred to Corrections and Juvenile Justice.
- HB2291 – Healthcare Price Transparency for health insurance carriers, health maintenance organizations and preferred provider organizations was referred to Health and Human Services.
- HB2288 – Healthcare Price Transparency Act has not made it out of Health and Human Services.

- SB 166 – Mental Health drugs. No vote was taken in the Senate Public Health and Welfare Committee.

The bill for a valid prescription and the bill for life of a prescription were not introduced.

Board Discussion

Tech Check Tech in the Hospital Setting – Place on June agenda. Information will be gathered from other states and current practices within the state.

Technician Functions – The Board discussed technician functions. All people behind the counter do not have to be technicians and pharmacists. Technicians are restricted to nonjudgmental portions of prescription processing. Clerks could be used to free up technicians to perform their duties while a clerk would perform functions that do not require a technician registration.

Classifications of Pharmacy – Frank Whitchurch requested the Board pursue classifications of pharmacies. Mr. Whitchurch will meet with the Inspectors and Compliance Officers to propose language for classification. A preliminary report will be presented at the June meeting.

Pharmacist Survey – JoAnne Gilstrap asked if the Board wanted to pursue the survey. Ms. Billingsley said NABP could run the survey for the Board. The office will check into the options.

Update Matrix – Christina Morris quickly reviewed the agenda items that require action by a specified individual and the date the action is due.

Adjourn: Ms. Gilstrap adjourned the meeting at 4:03pm.

Wednesday, March 4, 2009

Meeting Called to Order: President JoAnne Gilstrap called the meeting to order at 9:00am.

Members Present: JoAnne Gilstrap, R.Ph., President; Karen Braman, R.Ph. (9:04am), Vice-President; Shirley Arck, Pharm. D, Investigative Member; Michael Coast, R.Ph.; Frank Whitchurch, R.Ph.; and Nancy Kirk, public member.

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

Others Present: See attached listing.

Public Hearings for Proposed Regulations

K.A.R. 68-16-3 – Donation of cancer drugs.

Ms. Gilstrap adjourned the meeting and opened the public hearing at 9:01am

Ms. Gilstrap asked for public comment. There were no comments

Ms. Gilstrap closed the public hearing.

Ms. Gilstrap called the meeting to order at 9:01am.

A motion as made and seconded to adopt the proposed regulation. (Coast/Braman)

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

Motion passed. The regulation will become effective 15 days after published in the Kansas Register.

K.A.R. 68-19-1– Continuous Quality Improvement.

Ms. Gilstrap adjourned the meeting and opened the public hearing at 9:03am

Ms. Gilstrap asked for public comment – Ms. Morris provided a letter from NACDS. The letter addressed the concern of discussing minor incidents. The other concern was the requirement to provide a list of people attending the meeting.

Ms. Gilstrap closed the public hearing.

Ms. Gilstrap called the meeting to order at 9:05am.

A motion was made and seconded to adopt the proposed regulation. (Arck/Whitchurch)

The Board discussed the NACDS letter and their concerns.

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

Motion passed. The regulation will become effective 15 days after published in the Kansas Register. However this regulation will take effect July 1, 2009 as per statute.

The first quarterly meeting will be due September 30, 2009, Ms. Billingsley will place an article in the June newsletter notifying pharmacists and pharmacies.

Board Discussion

Tramadol and its use – presented by Johnson and Johnson. Susan Zalenski from the Johnson and Johnson introduced Dr. Gary Vorsanger. Dr. Vorsanger presented the tramadol information to the Board. Johnson and Johnson had a three-year agreement with the FDA to have an independent steering committee monitor tramadol for potential abuse and diversion after the drug was approved in 1995. The company continued to use RADARS, an independent steering committee after the three-year period to monitor tramadol use. Dr. Arck requested the information from the RADARS data showing the drugs and where the eight drugs rank. Ms. Gilstrap thanked Dr. Vorsanger for the information.

Recess: Ms. Gilstrap declared a break to reconvene in 5 minutes

Reconvene: Ms. Gilstrap reconvened the meeting at 10:16am

KPhA Update regarding contract with HAPN – Mike Larkin represented KPhA in the discussion. KPhA will provide the service in-house. The pharmacists currently in the program have responded positively to the change. The contract between KPhA and the Board will be the same.

Policy and Procedure Manual for Board Staff – Ms. Billingsley presented the Board the manual for discussion. Other portions of the policy and procedure manual are in the process. Ms. Billingsley will bring the other portions to the June meeting.

Retention of Hard Copy Prescription Records

K.S.A. 65-1642(b)

K.A.R. 68-2-22(g)

K.A.R. 68-20-10a

Mr. Whitchurch led the discussion on changes that may be needed when e-scribing for controlled substances becomes federally allowable. Retention of the hard copy as a paper copy will become an issue when prescriptions are received electronically and the image can be electronically stored. Mr. Whitchurch requested the Board consider changing K.A.R. 68-2-22(g) to allow electronic storage of electronic prescriptions rather than printing the prescriptions and storing a paper hard copy. Mr. Forbes will prepare the change and forward the change to Department of Administration

Budget – Ms. Billingsley described the budget and showed the Board the funds where money is deposited. Some of the money is available to spend and within the budget for the agency. Other money resides in funds that are not available and that money can be swept by the legislature. Ms. Billingsley described the cuts the agency could, if needed, cut from the budget and presented the report to the Budget Advisory Committee. Ms. Braman asked if there were any cuts to existing staff. Ms. Billingsley stated that there were no cuts to the current staff. The staff positions she presented for cuts were the unfilled administrative assistant position and a reduction in hours of the temp position. The Board pays approximately \$26,000 per year in rent. They also pay a monument fee that must be in the budget. The software RFP is in the process of review and technical assistance is being provided by DISC. The Board requested copies of the budget information and to the day to day operating budget.

Board Member Reports

Michael Coast – Mr. Coast related a scenario for the Board’s input. The issue posed the question “drop station or not”. The Board consensus was the delivery person should go to the patient’s house otherwise the scenario would be considered a drop station. Mr. Coast thanked the staff for all their work.

Shirley Arck – Dr. Arck reported on Mission of Mercy, the dental day for under served patients in Manhattan.

Karen Braman – Ms. Braman stated the Hospital Association gave a report about controlled substance reporting to the PMP Advisory Committee. The Committee has exempted hospital emergency rooms from reporting as long as they dispense less than six dosage units. Mr. Braman thanked JoAnne Gilstrap for her years of service.

Nancy Kirk – Ms. Kirk thanked the Board and staff for all their hard work on the legislative issues. The Board and staff have presented the legislature timely and well-prepared information and that has resulted in better results.

Frank Whitchurch – Mr. Whitchurch thanked Dr. Arck for her work as the investigative member and her consideration of all the cases. He thanked all the individual Board members for their service on the various committees and time spent with the legislature.

JoAnne Gilstrap – With this possibly being Ms. Gilstrap’s last meeting she wanted to individually thank each Board, staff member and former members for their service:

- Jim Kinderknecht for all the wisdom and years of service he brings to the agency.
- Tom Frazier for inspiring us all in service for other people.
- Carly Haynes for helping the Board abide by laws and taking minutes, and keeping time.
- Melissa Martin for the good work on inspections and investigations.
- Reyne Kenton for the long hours she spends in the car getting her to places in western Kansas for inspections and investigations.
- Shirley Arck for all the time involved in reviewing investigation cases and the thought put in on each case as to appropriate action.
- Karen Braman for all the work on the PMP Advisory Committee.
- Mike Coast for the time spent as committee chairperson for the PSE task force, for representing the independent pharmacies and hospitals, and for the time spent as chairman for the hospital telepharmacy task force.
- Nancy Kirk for asking the right questions at the right time and for her insight to the legislature.
- Frank Whitchurch for his forward thinking on issues like CQI, strategic planning and classification and for taking time to testify at the legislature.
- Merlin McFarland, Max Heidrick, Mike Hurst, Jeff Thompson, and LaTonyua Rice for the years of service they provided to the pharmacists over the years.
- Randy Forbes for representing the Board as General Counsel and providing excellent representation, advice, research, and opinions to the Board and staff.
- Christina Morris for the energy and efficient she brings to the office.
- Debra Billingsley for everything that is done in the agency and for an enjoyable association over the past years.

Staff Member Reports

Randy Forbes – no report

Debra Billingsley – Ms. Billingsley said she and Christina Morris are in training for the state's new process for employee performance reviews and with the new state Sunflower project system for bill processing. Ms. Billingsley thanked Shirley Arck and Randy Forbes for the volumes of work and time spent on processing the disciplinary cases as well as the compounding regulations.

Carly Haynes – Ms. Haynes presented the Board a prescription from the Wichita area for their perusal. The prescription type is very confusing and many times extra refills are added to prescriptions due to the format of the prescription. Ms. Haynes also encouraged the Board to pull approval of the ICPT technician certification as ICPT gives misinformation on technicians’ functions.

Melissa Martin – Ms. Martin reported that during the past year approximately 14 technicians were revoked due to drug diversion.

Reyne Kenton – Ms. Kenton thanked Ms. Gilstrap for her years of service to the Board.

Jim Kinderknecht – Mr. Kinderknecht reported on a fire that affected two pharmacies and the involvement of paper records that were stored at the pharmacies.

Tom Frazier – Mr. Frazier told the Board he would cut his hours if needed to help with the current budget problem.

50-Year Certificates – Ms. Billingsley presented the 50 year certificates. Gerald Adams, Wellington; Charles Bowlin, Emporia; Frank Kolkin, Prairie Village; Orla(Lee) Phelps, Stockton; Rex Rasmussen, Leavenworth; Max Starns, Odessa Mo.; and Benji Wyatt, Lawrence. A motion was made and seconded to accept the 50-year certificates as presented. (Arck/Coast) Motion passed.

Approval of New Pharmacists and New Registrants

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

Update Matrix – Christina Morris quickly reviewed the agenda items that require action by a specified individual and the date the action is due.

Adjourn: Ms. Gilstrap adjourned the meeting at 11:40am.