

Kansas State Board of Pharmacy  
Minutes of the September 2010  
Board Meeting

Via Christi – St. Joseph Campus  
3600 E. Harry  
3rd Floor, Conference Room A  
Wichita, KS 67218

**Wednesday, September 8, 2010**

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

**Members Present:** Karen Braman, R.Ph., President; Shirley Arck, Pharm. D., Vice-President; Michael Coast, R.Ph., Investigative Member; Jim Garrelts, Pharm. D.; Nancy Kirk, Public Member; and Frank Whitchurch, R.Ph. David Schoech, R.Ph. was not in attendance.

**Staff Present:** Debra Billingsley, Executive Secretary; Jim Kinderknecht, 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.

**Approval of the Agenda:**

A motion was made and seconded to approve the agenda as amended with the following changes – start tomorrow at 8am and move the agenda items after the public hearings to before the hearings. Move the election of officers to today if Mr. Schoech can be contacted by phone (Coast/Arck). Motion passed.

**Approval of the June 2010 minutes:**

A motion was made and seconded to approve the June 2010 minutes as printed. (Garrelts/Coast) Motion passed.

**Approval of the July 21 minutes:**

A motion was made and seconded to approve the June 2010 minutes as printed. (Arck/Whitchurch) Motion passed.

**Approval of the August 24 minutes:**

A motion was made and seconded to approve the June 2010 minutes as printed. (Arck/Kirk) Motion passed.

**Administrative Proceedings**

- Kansas Spine Hospital (2-09907) **Case 8-139** Mr. Forbes said the general terms have been approved but the KSH attorneys are still in process and hope to have the signed agreement to the Board tomorrow.

- Stephen DeFever (1-09137) **Case 7-48.** Mr. Forbes presented the order. A motion was made and seconded to approve the Stipulation and Final Agency Order (Kirk/Coast). Motion passed.
- **Stephanie Ketcher (14-05899) Case 10-21** Ms. Ketcher's technician registration was revoked for diversion of controlled substances from her employer.
- **Angela Fuller (14-09794) Case 10-17** Ms. Fuller's technician registration was revoked for diversion of controlled substances from her employer.
- **Travis Fyler (14-05982) Case 10-19** Mr. Fyler's technician registration was revoked for diversion of controlled substances for his employer.

### **Controlled Substance Diversion Report**

Ms. Billingsley presented the controlled substance and prescription drug list that have been diverted by pharmacy staff.

### **Investigative Member Report – Closed Cases**

Mr. Coast reported the cases that have been investigated with no finding of violations.

### **Board Discussion**

Long Term Care Automated Drug Dispensing Update – Ms. Billingsley reported that she and Jim Kinderknecht, R.Ph. had met with Senior Care Pharmacy and reviewed a proposed policy and procedure manual. The automation that Senior Care proposes to use is not available in Kansas at this time. Ms. Billingsley presented information as to how other states have addressed the issue of automation in nursing homes. Ms. Billingsley suggested the Board consider writing regulations to control the placement of non-patient specific drugs using automation in nursing home facilities. Joe DeLallo, Senior Care Pharmacy, had requested pilot approval from the Board in June. Dr. Arck said the Board needs some basic principals such as a licensed health care practitioner between the machine and the patient and local control by a Kansas licensed pharmacists. Mr. Coast, Dr. Garrelts, Mr. Whitchurch, and Ms. Kirk will make up the automated drug dispensing committee and will make a recommendation to the Board.

### **Board Discussion**

Hard Copy Data Storage – Mr. Whitchurch presented the information from the taskforce he served on with NABP. Electronic records are being recommended and encouraged and NABP wanted to encourage Boards of Pharmacy to consider electronic storage and decrease large volumes of paper storage. The Board, in considering regulations, will need to specify storage security and access. Ms. Billingsley will look for model language or language from other states. Mr. Whitchurch volunteered to help Ms. Billingsley with the language and present it at the December Board meeting.

Drug Utilization Review and Pharmaceutical Care – Ms. Billingsley compared the definition of the practice of pharmacy to other states. Most states allow collaborative practice and have language in their statutes. Drug management should be made part of the definition. Dr. Garrelts gave two handouts to the Board – one was how Georgia

addressed the question and the other was from the AMA and their definition of pharmacy practice. The Board considered whether a statute change would be required. Many states have specific language that could be used to pursue the statute change. Consensus was to pursue the change. Ms. Billingsley and Mr. Forbes will work on the language and approach Kansas Medical Society. Ms Braman volunteered to attend any meetings with KMS on this topic. Mr. Garrelts will ask for doctors already working with pharmacists to write letters of support.

Meth Precursor Electronic Logging Update – Ms. Billingsley updated the Board on the timeline that has been pushed back due to the incorrect MOU being given to Kansas. Mr. Forbes presented the new MOU, Memorandum of Understanding, but he has received no feedback on the changes made to make the MOU consistent with Kansas’ law. The MOU is between Appriss and the Board of Pharmacy. Mr. Forbes requested the Board discuss how to give approval for use of the system to pharmacists and KBI and to the appointment of state system administrators. Mr. Forbes will draft the agreement documents with the administrators. KPhA has offered to be the state pharmacy administrator in order to provide support to pharmacists.

**Recess:** Ms. Braman declared a break to reconvene in 15 minutes.

**Reconvene:** Ms. Braman reconvened the meeting at 11:10am

**Board Meeting Dates 2011**

February	10 <sup>th</sup>	Thursday	Topeka
March	9 <sup>th</sup> and 10 <sup>th</sup>	Wednesday and Thursday	Lawrence
June	8 <sup>th</sup> and 9 <sup>th</sup>	Wednesday and Thursday	Topeka
September	8 <sup>th</sup> and 9 <sup>th</sup>	Thursday and Friday	Wichita
November	30 <sup>th</sup>	Wednesday	Topeka
December	1 <sup>st</sup>	Thursday	

**Approval of New Pharmacists and New Registrants**

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

**Staff Reports**

Debra Billingsley – reported that she and David Schoech, R.Ph. will be attending the NABP District 6 Meeting in September.

Jim Kinderknecht – told the Board about diversion of controlled substances by dentist and physicians from the wholesale distributor via inappropriate orders.

Melissa Martin – reported to the Board that the MPJE had been reviewed and new questions accepted.

Reyne Kenton – reported that the agency vehicle had been involved in an accident and that she had received estimates. The Board discussed the need to purchase a replacement vehicle.

Carly Haynes – asked the Board about the first fills in long term care facilities. The Board did confirm that the prescriptions MUST be transferred to the pharmacy providing the first fill and then the prescription could be transferred back to the long-term care facility.

## **Executive Session Attorney/Client Discussion**

A motion was made and seconded to go into executive session for 30 minutes to discuss client/attorney-privileged information and to reconvene the regular meeting at noon in the same room. The executive session is to include Mr. Forbes, Ms. Billingsley and the Board staff. (Arck/Coast) Motion passed.

Ms. Braman reconvened the meeting at noon.

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

**Reconvene:** Ms. Braman reconvened the meeting at 1pm.

## **Board Discussion**

### Regulatory Update –

- DME Regulations – The Board discussed the proposed regulations and made recommendations for changes and clarifications. Ms. Billingsley will make the changes and send the regulations to Kansas Department of Administration.
- Distributor Regulations – The regulations were proposed approximately three years ago and due to changes at the federal level were not pursued. The Board reviewed and made a few corrections. Ms. Billingsley will make the changes and send the proposed regulations to Kansas Department of Administration.
- Compounding Regulations – Mr. Forbes asked the Board for approval on suggested language offered by the Attorney General's office concerning out of state products sent into Kansas for a Kansas patient. The Board consensus was to accept the language. Mr. Forbes questioned the Board as to authority to prohibit a compounder from compounding a commercially available product. The Attorney General's office questioned the provision of "compounding in advance". The Board gave Mr. Forbes examples and explanations he may use in conferring with the Attorney General's office. Jean Macias, R.Ph, director of Via Christi Home Medical Services, addressed the Board. She requested the ability to share services in sterile compounding and to compound in advance of need. Ms. Braman asked how billing would be completed. Ms. Macias said the compounding facility would bill the hospital for the products and in turn the hospital would bill the patient as if the product was produced totally in-house. The Board discussed how to change the regulations to allow facilities (under the same ownership) to share compounding services for administration to patients. Ms. Braman requested the same subcommittee to formulate a recommendation for the Board and report back in December. Dr. Arck, Mr. Coast, Dr. Garrelts, and Jean Macias will serve as the subcommittee.
- Telepharmacy Retail Setting – Mr. Forbes presented the revised proposed regulations for the Board's review. Mr. Forbes asked about the term "bar code verified" and what would be a definition and what would verification "look" like. Ms. Braman suggested the regulation focus on verification not the specific process. Mr. Forbes will make the necessary changes and send the regulations on to the Department of Administration.

- Electronic Prescriptions – Mr. Forbes looked at the existing regulations as to electronic prescription transmission. He proposed changing K.A.R. 68-20-10a’s title to clarify the actual intent of the regulation and adding a proviso at the end. Electronic prescriptions, per federal definition, are different from faxed prescriptions.

### **Legislative Discussion for 2011**

Review Disciplinary Requirements - Ms. Billingsley suggested the Board consider reviewing the following items. If the Board wanted any item addressed the information needs to be gathered and prepared for presentation in the 2011 legislative session. Ms. Billingsley will work on the language needed to move the statute needs forward. Resolution to Review and Standardize Disciplinary Statutes – NABP encouraged Boards of Pharmacy to amend state language on disciplinary provisions to the model language.

Controlled Substance List Update – Ms. Billingsley has prepared the legislative report that will be sent to the President of the Senate and to the Speaker of the House. The letter specifies changes that need to be made to bring Kansas statutes up to date with federal regulations on controlled substances.

Attorney’s Fees and Hearing Costs – Ms. Billingsley provided the Board a copy of the Board of Healing Arts statute for proposed adoption by the Pharmacy Board to allow collection of fees in relation to investigations and proceedings.

Registration of All Persons Behind the Counter – This topic will be tabled until the December meeting.

Review KAR 68-20-15a (c) (3) – Sample Law for Schedule V – Ms. Billingsley presented the proposed regulation change. The Department of Administration has signed off on the proposed regulation. The suggestion was to identify the drug, Lyrica, as it is identified in federal regulations. Ms. Billingsley will make the correction and send the proposed regulation back to the Department of Administration.

**Recess:** Ms. Braman declared a break to reconvene in 15 minutes.

**Reconvene:** Ms. Braman reconvened the meeting at 3:15pm

### **Board Discussion**

Budget for FY2011; FY2012; and FY2013 – Ms. Billingsley said the state’s switch to the “SMART” has slowed down the entire financial budget process. Bills were not being processed by the “SMART” system but the budget department believes the system will be back on schedule very soon. Ms. Billingsley will give the Board the financials when they become available. Mr. Coast said the accounting system change has affected the entire state, even way out in Dodge City. Ms. Braman said the Board should request statutory authority to receive and spend grants and gifts that the Board receives. The request should be added to the legislative agenda.

Discussion regarding use of APAP on prescription labels – Ms. Braman reviewed the NABP information. The FDA is concerned with the overdosing of acetaminophen. Dr. Arck suggested NABP provide statistics to show how large of a problem there appears

to be in the state of Kansas. The Board can place this item in the newsletter as a recommendation to counsel patients about drugs containing acetaminophen and specific precautions.

### **Update Matrix – Review of Action Items for the Board**

Ms. Billingsley reviewed the agenda items requiring action by the specified individual and the date the action is due.

### **Board Member Reports**

Frank Whitchurch – reported Prescription Solutions had received numerous unsolicited C-2 prescriptions with driver's licenses and credit cards for filling. The DEA was notified to the potential misuse of prescriptions to obtain controlled substances. Prescription Solutions calls on all C-2 prescriptions for diagnosis and length of treatment. The obligation to fill appropriately should be a primary concern and not based on "if it goes through the insurance". Mr. Whitchurch said the DEA has an online slide presentation with information about internet diversion and methamphetamine.

Shirley Arck – will be attending the NABP issues conference in Chicago. Board members are requested to share with Dr. Arck their concerns with pharmacy practice.

Karen Braman – apologized to the Board that she will not be in attendance in person on Thursday. Governor Parkinson appointed Ms. Braman to the Kansas Health Information Exchange Board. The Board has two pharmacist Board members, Jonalan Smith and Ms. Braman.

Jim Garrelts – asked the retail pharmacy members if they had experienced as many drug shortages as the hospitals. The shortages have occurred for many reasons from lack of raw materials to an explosion in a manufacturing facility. He said the shortages have made patient care more complicated. Dr. Garrelts said the federal ARRA, American Recovery and Reinvestment Act, is driving health systems to increase the use of electronic records. Via Christi has opened the new hospital in west Wichita.

Michael Coast – told the Board that the DEA has designated a "Take Back Day" for any drugs, including controlled substances. The police departments are providing the service. Mr. Coast verified prescribing information about Suboxone. Only physicians with the DEA "X" number designations may prescribe. Mr. Coast asked about the "agent of the physician" and what the compliance officers and inspectors were seeing and expecting during inspections.

Mr. Schoech joined by phone 4pm.

### **Election of Board Officers**

Ms. Braman thanked the Board for the opportunity to serve as president. The Board thanked Ms. Braman for a job well done.

#### President:

Ms. Braman nominated Shirley Arck. Nancy Kirk seconded the motion. No other nominations were offered. Dr. Arck was elected unanimously.

#### Vice President

Mike Coast nominated Jim Garrelts seconded by Frank Whitchurch. No other nominations were offered. Dr. Garrelts was elected unanimously.

Investigative Officer:

All members except the president will be investigative officers. Ms. Billingsley will assign cases to Board members based on the member's area of expertise.

The meeting tomorrow will begin at 8:30am.  
Mr. Schoech left the meeting at 4:08pm.

Ms. Billingsley gave the Board a letter for the Public Hearings for tomorrow.

**Adjourn:** Ms. Braman adjourned the meeting at 4:09pm.

**Thursday, September 9, 2010**

**Meeting Called to Order:** President Shirley Arck called the meeting to order at 8:33am.

**Members Present:** Shirley Arck, Pharm. D., President; Jim Garrelts, Pharm. D., Vice President; Karen Braman, R.Ph. (by phone); Michael Coast, R.Ph; Nancy Kirk, Public Member; and Frank Whitchurch, R.Ph. David Schoech, R.Ph, joined by phone. Karen Braman, R.Ph, joined the meeting by phone at 9:30am.

**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; Christina Morris, PDMP Director /Assistant Executive Director (joined by phone), and Randall Forbes, General Counsel.

**Others Present:** See attached listing.

**Board Discussion**

PMP Update – Christina Morris gave the Board an update. The PMP tracking name will be "K-TRACS". K-TRACS is an acronym for Kansas Tracking & Reporting Controlled Substances. Ms. Morris has applied for two grants in hopes to secure additional funding for the program. The contract has been signed with the vendor Health Information Design. The go live date will be in February with a specific day to be identified later. Retroactive data will be collected for the prior 6 months. The vendor would like a meeting with the Board possibly at the December meeting. The vendor is working on the training manual for the dispensers. The vendor has requested the DEA number be used as the primary identifier since many prescribers may not have an NPI number. The NPI number would serve as a secondary number. Ms. Billingsley and Ms. Morris will be attending the NASCA meeting in October. The next meeting for the committee has not be scheduled

**Recess:** Dr. Arck declared a break to reconvene in 10 minutes.

**Reconvene:** Dr. Arck reconvened the meeting at 9am

**Public Hearings for Proposed Regulations**

**Article 22** – Electronic Supervision of Medical Care Facility's Pharmacy Personnel.

K.A.R. 68-22-1. Definitions

K.A.R. 68-22-2. Application for approval to utilize electronic supervision.

K.A.R. 68-22-3. Prior approval and training required.

K.A.R. 68-22-4. Electronic Supervision.

K.A.R. 68-22-5. Minimum operation requirements.

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

Dr. Arck asked for public comment.

Ms. Billingsley provided letters from ---

The Joint Committee on Administrative Rules and Regulations stating that “indirect” is in conflict with “direct supervision”. Mr. Forbes did not believe the Board’s language is inconsistent with other parts the regulation.

Mark Gagnon, Via Christi, provided a letter to the Board.

The following people spoke on the regulation change:

Mark Gagnon, Via Christi, asked a question about the ratio (pharmacist to technician).

He also asked about medication leaving the pharmacy area. Cart fills done off the MAR and checked electronically.

Charles Eisenberg, Manhattan, spoke on the issue and how it impacts the process of tech check tech. Mr. Eisenberg stated that Mr. Gagnon’s question about cart fills can be answered by tech check tech.

Dr. Arck closed the public hearing.

Dr. Arck called the regular meeting to order at 9:10am.

There was no motion.

The Board will make changes to address the comments. Ms. Billingsley, Mr. Garrelts, Mr. Gagnon will work on the changes. Ms. Billingsley will resubmit the changes to the Department of Administration.

## **Public Hearings for Proposed Regulations**

### **Article 10 – Nuclear Pharmacies**

K.A.R. 68-10-4. Definitions.

K.A.R. 68-10-5. General Requirements.

K.A.R. 68-10-6. Minimum equipment.

Dr. Arck adjourned the regular meeting and opened the public hearing at 9:15am

Dr. Arck asked for public comment.

Ms. Billingsley provided letters from ---

- The Joint Committee on Administrative Rules and Regulations had issues with the incorporation by reference. They would like the regulation to be more specific.
- Integrated Nuclear Enterprises
- Dr. James Owen
- Model Rules for Nuclear Pharmacies were presented.

The following people spoke on the regulation change:

Brett Wilkins, Leavenworth, requested the Board adopt a more practical stance. Mr. Wilkins facility has been providing service for the last 25 years and been through numerous surveys by KDHE and has had no problems in passing those surveys.

Steve Austin, Infusion Pharmacy, made comments concerning the regulations and the problem with hiring authorized nuclear pharmacists, ANP. The requirement will limit patient care in western Kansas. Electronic supervision might be appropriate for nuclear pharmacies. The nuclear technicians are very well trained, 2-4 years, and use pharmacists to answer medication and other medical questions. Mr. Austin said pharmacists might have 12 weeks of training to become an ANP.



Julie Turner, Cardinal Board certified nuclear pharmacist, spoke about the proposed regulations and recommended their approval.

Dr. Arck closed the public hearing.

Dr. Arck called the regular meeting to order at 9:32am.

There was no motion.

The Board will make changes to address the comments with input from Mr. Austin, Mr. Wilkins, Ms. Turner, Dr. Arck, Mr. Coast and Ms. Billingsley. Ms. Billingsley will send the reworked proposed regulations back to the Department of Administration.

## **Public Hearings for Proposed Regulations**

### **Article 21 – Prescription Monitoring Program**

K.A.R. 68-21-1. Definitions.

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

K.A.R. 68-21-3. Waivers for electronic reports.

K.A.R. 68-21-4. Notice of requests for information.

K.A.R. 68-21-5. Access to information.

K.A.R. 68-21-6. Reciprocal agreements with other states to share information.

K.A.R. 68-21-7. Drugs of concern.

Dr. Arck adjourned the regular meeting and opened the public hearing at 9:34am.

Dr. Arck asked for public comment.

Ms. Billingsley provided letters from ---

- The Joint Committee on Administrative Rules and Regulations
- National Association of Chain Drug Stores
- William Lockwood, American Society for Automation in Pharmacy
- Medco Health Services, Inc.
- Max Heidrick, R.Ph.
- Ron Hein

The following people spoke on the regulation change:

John Sisco, Medco Health, stated that Medco supports the prescription monitoring program. He supports the choice of vendors in that HID is very easy to work with. Medco does not agree with 24-hour reporting. In the reporting process there is always going to be submission problems and whether that is done daily or weekly can become a time management problem especially if daily reporting is required. Daily reporting does not have any added benefits to prevent doctor and pharmacy shopping. Mr. Sisco asked about the submission process as to whether it was manual or automatic. HID does provide the option of automatic login.

Dr. Arck closed the public hearing.

Dr. Arck called the regular meeting to order at 9:50am.

The Board discussed the reporting issue and the identifier number of the prescriber.

The regulations must specify the required information. The regulations could specify use of the DEA or NPI number. Both DEA and NPI numbers have been defined in the regulations.

Mr. Coast asked about the zero reporting. Ms. Morris said other states did not address in the regulations. Ms. Braman prefers to address zero reporting in the policy.

The Board discussed the proposed regulations be changed to reflect the use of the DEA number as primary identifier and NPI as the secondary number and the frequency in reporting changed to weekly during the implementation process with 24 hour reporting to be implemented on January 1, 2013.

To address the public comments a motion was made and seconded to make the following changes:

- K.A.R. 68-21-1(g) “Prescriber identification number” means the DEA, and if the prescriber does not have a DEA number use the NPI number.
- K.A.R. 68-21-2(a) add “On and after January 1, 2013” to the beginning of the second sentence.
- K.A.R. 68-21-2(d) “During the implementation period following publication of this regulations until January 1, 2013, each dispenser in this state shall submit such report writing a time frame no later than 7 days from the dispensing of such substance.”

(Coast/Garrelts) Motion passed.

By Board consensus, the above changes were viewed as not substantive.

A motion was made and seconded to adopt the proposed regulations K.A.R. 68-21-1 and 68-21-2 as amended and to adopt K.A.R. 68-21-3, 68-21-4, 68-21-5, 68-21-6, and 68-21-7 as presented as a permanent regulations. (Coast/Braman)

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.

Discussion continued on the zero reporting requirements, waivers, and drugs of concern. NACDS had requested 90 days to comply when adding drugs of concern, however they do not feel the time is necessary since adding drugs must be done through the rules and regulations process. No changes will be needed in 68-21-7.

Ms. Morris will make the recommended changes to:

- 68-21-2 in regards to zero reporting.
- 68-21-3 Waivers – If the dispenser does not dispense any controlled drugs or drugs of concern the dispenser is to file for a waiver so they will not need to file a zero report.

Ms. Morris will take the substantive changes, due to public comments, to the Department of Administration and set the public hearing for the December meeting, provided the timeline can be accomplished.

**Adjourn:** Dr. Arck adjourned the meeting at 11:05am.