

Kansas State Board of Pharmacy  
Minutes of the April 24 & 25, 2014  
Board Meeting

800 SW Jackson, Lower Level  
KBHA Conference Room  
Topeka, KS 66612

**Thursday, April 24, 2014**

**Meeting Called to Order:** President David Schoech called the meeting to order at 9:10am.

**Members Present:** David Schoech, R.Ph, President; Jim Garrelts, Pharm. D; Michael Lonergan, R.Ph; Chad Ullom, R.Ph, Investigative Member; and John Worden, Pharm. D.

Members absent: Robert Haneke, Pharm. D; and Cheri Pugh, public member.

**Staff Present:** Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph., Licensed Pharmacy Inspector; Carly Haynes, R.Ph., Licensed Pharmacy Inspector; Melissa Martin, Compliance Inspector; Reyne Kenton, Compliance Inspector; Marty Singleton, Assistant Director; Jackie Yingling, Accounting & Human Resources; and Kevin Fowler, General Counsel.

Mr. Schoech welcomed the representatives from Oklahoma, John Foust, Pharm D, Executive Director; and Betty Beil, R.Ph., Compliance Officer.

**Others Present:** See attached listing.

**Approval of the Agenda:**

A motion was made and seconded to approve the agenda as amended. (Worden/Lonergan) Motion passed. An executive session for the purpose of attorney client privilege was added to the agenda prior to lunch.

**Approval of the February 28, 2014 Minutes:**

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

**Public Hearings for Proposed Regulations**

**K.A.R. 68-11-1 Fees for examination and licensures as a pharmacist**

Mr. Schoech adjourned the regular meeting and opened the public hearing at 9:11am. Mr. Schoech asked for public comment. There were no comments from the attending public.

Ms. Billingsley provided a letters from ---

The Joint Committee on Administrative Rules and Regulations - The letter is electronically attached to the Board agenda for their review.

Kansas Legislative Research Department requested the economic impact statement be amended to reflect the impact on the pharmacy fee fund. Ms. Billingsley provided a

copy of the cash balance projections and will be attached as an amendment to the economic impact statement per the request.

Mr. Schoech closed the public hearing.

Mr. Schoech called the regular meeting to order at 9:16am.

A motion was made and seconded to adopt the proposed regulation. (Ullom/Worden)

Roll call: Dr. Garrelts – Yes, Mr. Lonergan – Yes, Mr. Schoech – Yes, Mr. Ullom – Yes, and Dr. Worden – Yes.

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

### **K.A.R. 68-11-2 Fees for premises registrations and permits**

Mr. Schoech adjourned the regular meeting and opened the public hearing at 9:18am

Mr. Schoech asked for public comment. There were no comments from the attending public.

Ms. Billingsley provided a letters from ---

The Joint Committee on Administrative Rules and Regulations - The letter is electronically attached to the Board agenda for review.

Kansas Legislative Research Department requested the economic impact statement be amended to reflect the impact on the pharmacy fee fund. Ms. Billingsley provided a copy of the cash balance projections and it will be attached as an amendment to the economic impact statement per the request.

Mr. Schoech closed the public hearing.

Mr. Schoech called the regular meeting to order at 9:20am.

A motion was made and seconded to adopt the proposed regulation. (Worden/Ullom)

Roll call: Dr. Garrelts – Yes, Mr. Lonergan – Yes, Mr. Schoech – Yes, Mr. Ullom – Yes, and Dr. Worden – Yes.

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

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

Mr. Schoech adjourned the regular meeting and opened the public hearing at 9:21am

Mr. Schoech asked for public comment. There were no comments from the attending public.

Ms. Billingsley provided comments from ---

Robert Tomasu, Dillons Pharmacy Sales Planner emailed asking for clarification of the patient ID number.

John Sisto, Express Scripts phoned the Board office and asked for a guidance document from the Board and clarification on whether mail order would have to make all efforts to obtain a driver's license for their patient before they could go to the second or third option of a form of ID. Nursing Home patients generally do not have a driver's license and they often do not have direct contact with the pharmacy. The interpretation of the Board was that if pharmacy did not have access to a driver's license then one of the other forms could be used without going to extreme lengths to make sure a driver's license did or did not exist. Likewise, if there is no middle initial for a patient the option could still be used. The Board agreed that it would be appropriate to draft a guidance document that addresses and clarifies the patient ID section of the regulation and directed the Executive Secretary to a guidance document.

The Joint Committee on Rules and Regulations provided a letter that recommended deleting the references to specific sections of the statute to alleviate the need to change the regulation in the future if the statute was ever changed. The change would not be substantive. The Board's General Counsel advised that adding the specific subsection gives clarity to the reader and that it would be better to provide a clear and distinct regulation even if we might eventually have to amend the regulation in the future.

Mr. Schoech closed the public hearing.

Mr. Schoech called the regular meeting to order at 9:34am.

A motion was made and seconded to adopt the proposed regulation. (Garrelts/Ullom)

Roll call: Dr. Garrelts – Yes, Mr. Lonergan – Yes, Mr. Schoech – Yes, Mr. Ullom – Yes, and Dr. Worden – Yes.

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

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

Mr. Schoech adjourned the regular meeting and opened the public hearing at 9:35am

Mr. Schoech asked for public comment. There were no comments from the attending public.

Ms. Billingsley provided a letter from ---

The Joint Committee on Administrative Rules and Regulations: The Committee provided a letter that requested the ASAP version be adopted by reference because the Board was delegating their authority unlawfully. Ms. Billingsley had spoken with the Attorney General's Office and they advised that the regulation met the legality requirements of a regulation and that the Board was not delegating their authority. They advised that the ASAP standard was informational only and would not need to be adopted by reference. The Board's General Counsel agreed with the Attorney General's Office that the Board was not delegating their authority and that it would be preferable to leave the language as written.

Mr. Schoech closed the public hearing.

Mr. Schoech called the regular meeting to order at 9:42am.

A motion was made and seconded to adopt the proposed regulation.

(Worden/Lonergan)

Roll call: Dr. Garrelts – Yes, Dr. Lonergan – Yes, Mr. Schoech – Yes, Mr. Ullom – Yes, and Dr. Worden – Yes.

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

**Budget** –Ms. Yingling presented the budget to the Board for their review. Any money not spent remains in the pharmacy fee fund balance. The FY14 and FY15 budget do not have final approval the Legislature wraps up the session. The Legislature meets again on April 30, 2014 and will finalize the state budget. There have been no decisions yet on whether the state employees will receive a raise as recommended by Governor Brownback.

### **Approval of New Pharmacists and New Registrants**

A motion was made and seconded to approve the new licenses and registrations.

(Garrelts/Worden) Motion passed.

### **Fifty Year Pharmacists Recognition**

The following pharmacists have achieved 50 years of service to the Kansas public by serving as pharmacists:

Loy F. Rowland	---	Blue Springs, MO
Glen A. Hadaway	---	Emporia
Jay S. Gruver	---	Platte City, MO
Allen J. Gordon	---	Hermosa Beach, CA
Mary A. Donaldson	---	Mulvane
Andrew Bodner, Jr.	---	Prairie Village
David Black	---	Derby
Charles E. Bishop	---	Belle Plaine

A motion was made and seconded to recognize and congratulate the 50-year pharmacists. (Ullom/Worden) Motion passed.

### **Pilot Project Update**

**Wesley Medical Center** - Jack Bond, RPh; Joan Kramer, RPh; Brandon Schminke, RPh; and Bob Elsbernd, RPh, were present. Ms. Kramer and Mr. Schminke made the presentation. The report is electronically attached to the agenda. Dr. Garrelts asked specifically about interaction with physicians. Ms. Kramer and Mr. Schminke stated the physicians have received the program very well and are asking to have their residents work with the facility. The Board asked if overall the program was working to make drugs more economical for the patient and reducing overall waste. Mr. Elsbernd spoke to waste especially to warfarin. The waste in warfarin and over the counter medications has decreased significantly. Cost to the patients has also decreased due to the patient paying only for the medications they use. Significant pharmacy drug interventions have also decreased the overall quantity of medications patients are being prescribed as the pharmacists are working to optimize drug regimens.

**Recess:** Mr. Schoech declared a break to reconvene in 15 minutes.

**Reconvene:** Mr. Schoech reconvened the meeting at 10:36am

**AlixRx** - Amanda Stewart, RPh presented the pilot project update. The Kansas City pharmacy has dispensed over 2 million dosage units into facilities in Kansas, Missouri and now Nebraska. Dispensing errors are less than 0.01%. Ms. Stewart asked if the Board would consider allowing them to expand to the additional Golden Living facilities. Mr. Schoech advised that he would not bring the question to a vote because he believed the pilot was meant to serve as a tentative model for future development. He said that he would not allow for expansion or a vote on the issue because we were pursuing finalization of proposed regulations.

### **Discussion**

**Proposed Automation Regulations K.A.R. 68-7-10, 68-9-2, and 68-9-3.** – Ms. Billingsley presented the regulations. Changes have been completed per request of the Department of Administration. Ms. Billingsley has received comments from an outside group that would like the language to be expanded to allow kiosk type machines to be located outside of the pharmacy such as in an emergency room setting. The current language would not allow for automation outside of the pharmacy unless it was for

administration only. The Board discussed the options. Mr. Worden suggested the regulation be moved forward as presented and address the other issues at a later time. The consensus was to move forward.

## **Reports**

**Continuing Education Committee Report** – Ms. Billingsley and Joan Kramer, RPh served on the committee to review the CE requirements. The committee felt 30 days would allow sufficient time to evaluate each request and that ACPE only required 30 days for their review. The committee would review the submitted CE and then use conference call to finalize. Kansas has used Oklahoma’s system as a model. Kansas will accept any CE approved by the Kansas Board of Pharmacy, a MALTAGON participating state and/or ACPE approved continuing education. A motion was made and seconded to change the review period to 30-days in advance. (Ullom/Worden) Motion passed.

**Collaborative Practice Pharmacy Patient Care** – Ms. Billingsley gave the report. The bill that permitted collaborative practice agreements codifies the role of the pharmacist in drug therapy management. The protocol is between pharmacists and a person licensed to practice medicine and surgery in Kansas. The statute defined prescriber and “means a person licensed to practice medicine and surgery in this state.” The other change will be to add the language of the “Collaborative drug therapy management” and “Collaborative practice agreement”. The Legislature has passed the new language. The bill has been signed; however there will be a ceremonial signing with the Governor on April 30, 2014 at 2:00 PM. The law will go into effect July 1, 2014. The law requires an advisory committee. The Board of Healing Arts will select three physicians and the Board of Pharmacy will select three pharmacists. The committee should have pharmacists and physicians that are familiar with collaborative practice agreements. C Joan Kramer, RPh commented that Wesley Medical has collaborative agreements with pharmacists and physicians currently and they would like to volunteer a pharmacist for consideration. Dr. Garrelts thanked Ms. Billingsley for her hard work in getting the legislation passed. The Board will need to appoint a nonvoting chairperson for the committee.

**Pharmacy Technician Certification** – Ms. Billingsley gave the report. The statute change will allow the Board to set in regulation what tests are approved for pharmacy technicians and a timeline for a technician to pass the test(s). The change also allows the Board to determine when technicians will renew their registrations every two years, either maintaining the current schedule of October or some other schedule. This will be accomplished through regulations. Lindsey Massey spoke to the recommendations from the pharmacy technician certification task force. The task force did recommend a technician-trainee category as technician. This would allow for a 24-month period for the technician to obtain all necessary training and complete testing. The other recommendations included grandfathering existing technicians and language allowing the Board authority to authorize an exemption to address technicians having problems with the 24-month time period. The trainee status would not prevent the technician from performing any technician function.

The next step for the Board is to write regulations. The Board will need to identify people interested in helping to write rules and regulations. The Board consensus was to work with the same task force.

### **Executive Session**

#### **Attorney Client---**

A motion was made and seconded to enter into executive session for 10 minutes with the Board's attorney pursuant to K.S.A. 75-4319(b)(2) to discuss privileged information deemed to be in the attorney client relationship to include Kevin Fowler, Board Counsel; and Executive Secretary, Debra Billingsley and to return to open session at 12pm. (Worden/Ullom) Motion passed.

Mr. Schoech reconvened the meeting at 12:17pm.

**Recess:** Mr. Schoech recessed the meeting for lunch at 12:18pm to reconvene at 1pm.

**Reconvene:** Mr. Schoech reconvened the meeting at 1:03pm.

### **Reports - continued**

**NPLEx Report** - Ms. Billingsley presented the report. The Board office is in the process of verifying that all the pharmacies are reporting. Each inspector has received a list of pharmacies not reporting and will be following up to determine if the pharmacy is selling OTC pseudoephedrine and/or ephedrine.

**KTRACS** – Marty Singleton presented the status update. The report included:

- SAMHSA has approved a date extension to carryover and use the funds.
- 2961 threshold letters have been sent to prescribers and dispensers
- Minnesota has requested Mr. Singleton to come and present information on integration of the PMP and HIE systems
- Discrepancy of KTRACS Records – approximately 175 stores are not reporting. Some of those may have an exemption but may need to re-file the exemption.
- Viewing of reports – multiple similar patient entries must match 3 out of 4 areas to be able to view (Name, DOB, address, phone number). Viewing information not belonging to the person queried is deemed a HIPAA violation.
- Harold Rogers Grant Ideas/Projects – Stacy Chamberlin with DCF and Frank Papish with KBI are being consulted and MOUs are being developed.
- LACIE –Cerner has finished software development and will begin the first hospital pilot by mid-May. This program is similar to the Via Christi project.
- KHIN – will run through Via Christi with their ID number then the information will be sent back to them through Via Christi. KHIN will be able to provide medical information state wide.
- Kroger – SAMHSA has approved the grant in three states for the PMP to be integrated in the Kroger software. The MOU is still in the formulation process. The idea is to develop the software to be able to plug into any pharmacy software and make the information more accessible to the pharmacist filling a prescription.
- Zohydro – Information on Zohydro was provided in an article by Dr. Bob Twillman. Zohydro ER was approved by the FDA despite not having an abuse-deterrent formulation. There is no concern as to efficacy of the drug only that it presents a very large and imminent abuse potential. Zohydro ER is made by Zogenix Inc.

Since the approval, Massachusetts Governor has directed his administration to ban the drug by placing it in Schedule 1. Zogenix has filed suit in Massachusetts to obtain a ruling as to whether a state can ban a drug approved by the FDA. Other states have place restrictions on the drug while the US House and Senate have legislation pending in regards to Zohydro ER. The American Academy of Pain Management, while concerned, believes Zohydro ER is a valuable tool for people with uncontrolled chronic pain. Zohydro ER does not contain other drugs like acetaminophen or ibuprofen making it safer to use than the combination products.

Forbes magazine discussed the FDA dilemma of Zohydro ER. The FDA Commissioner defended the approval of Zohydro ER.

Purdue Pharmaceuticals is working on a tamper resistant form of hydrocodone. Bob Moser, M.D. is seeking input from all the healthcare providers before Kansas decides how to respond to Zohydro. Dr. Moser would like to know if healthcare providers think Zohydro could present a healthcare problem in Kansas.

The Board suggested retrieving any data on court cases and overdoses of commonly available hydrocodone products to provide to Dr. Moser.

- Joint Policy Statement of the Boards of Healing Arts, Nursing and Pharmacy on the Use of Controlled Substances for the Treatment of Pain. Dr. Twillman is revising the old statement per committee input. The revised statement will be presented at a later Board meeting.

**Federal-State Meeting to Discuss Pharmacy Compounding** – Ms. Billingsley attended the meeting with the FDA and all fifty states and Washington DC. 503A requirements were discussed. Ms. Billingsley provided the definition of an Outsourcing Facility. The FDA has issued some guidance for compounders and outsourcing facilities. A Memorandum of Understanding under Section 503A was discussed. If a state does not enter into an MOU with the FDA then a pharmacy may not exceed 5% distribution to out of state vendors/providers. NABP is working with the FDA to draft an MOU that will be offered to each state. The Kansas Board will want to review the MOU before they can make a decision on what direction they would like to go. The states need to keep moving forward to protect the health of their citizens. Oklahoma is looking to make an Outsourcing Facility obtain a Manufacturer's registration. Currently, the statutory definition of a manufacturer requires that they hold an FDA permit but this will be revised in Oklahoma. The Kansas Board will need to determine whether they need to make statutory changes since the FDA is advising outsourcers that they cannot be a pharmacy even though they can provide patient specific drugs. The FDA requirements seemingly conflict with state law. More information will be provided as it becomes available.

**2014 Legislative Changes** – Ms. Billingsley updated the Board on the pharmacy items that have been approved by the Legislature. The PAs did get an expanded role to dispense until a prescription may be filled.

Health Stabilization Fund – the Board discussed who was included

**Investigative Member Report – Closed Cases** – Mr. Ullom presented the closed cases and asked for any questions. The Board discussed ways to increase awareness of the Board's duty to protect the public. Oklahoma Board requires every

senior pharmacy student to attend a Board meeting and receive a certificate to file with their application for a pharmacy license. If they do not have the certificate they cannot receive a pharmacist license until they attend and receive a certificate.

### **Board Member Reports**

Jim Garrelts – provided an article “AAFP, CMS Clarify ‘Incident to’ Rules Relating to Pharmacists’ Services”. The article discusses billing procedures performed by persons other than the physician. Dr. Garrelts asked the Board about pharmacy technicians administering medications. Medication aides attend a certification class provided by KDADS and should be certified to pass meds. Pharmacy technicians desiring to administer medications may need to become certified as CMAs. The Board did not have a consensus that this was an appropriate direction or use of pharmacy technicians.

### **Executive Director Report - Ms. Billingsley**

Resolutions as Received from 2013 NABP District Meetings – Ms. Billingsley asked the Board members to begin looking at their calendars to determine availability at the upcoming regional meetings.

Maltagon – Will be in St. Petersburg Florida, October 26-29, 2014.

### **Staff Reports**

Carly Haynes – requested the Board add a regulation requiring pharmacies to inform the Board when they experienced a loss or theft of a drug. Currently the pharmacies only report to the DEA and the reports from DEA are not always complete. The Board has not been receiving all employee theft reports in a timely manner that would protect the public safety.

Melissa Martin – informed the Board new questions have been submitted to NABP for the MPJE. This is a yearly activity and one that takes time to format the questions appropriately.

Marty Singleton – reported the two new office staff have been in training. There are 15 types of registrations/permits/licenses and a manual has been developed to aid in training of the current staff and for the future. The office staff have developed a manual for training and reference on KTRACS. The physical files in the office have been reorganized and culled files sent to Archives. The office is now gearing up for renewals. Current licensing numbers are posted on the website. Legislative post audit is completing their audit on the Board’s IT security. Processes have been added to comply with the need for increased security.

**Adjourn:** Mr. Schoech adjourned the meeting at 3:20pm.

### **Friday, April 25, 2014**

**Meeting Called to Order:** President David Schoech called the meeting to order at 9:14am.



**Members Present:** David Schoech, R.Ph., President; Jim Garrelts, Pharm. D; Michael Lonergan, RPh; Chad Ullom, R.Ph., Investigative Member; and John Worden, Pharm. D.

Members absent: Robert Haneke, Pharm. D; and Cheri Pugh, public member.

**Staff Present:** Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph., Licensed Pharmacy Inspector; Carly Haynes, R.Ph., Licensed Pharmacy Inspector; Melissa Martin, Compliance Inspector; Reyne Kenton, Compliance Inspector; Marty Singleton, Assistant Director; Jackie Yingling, Accounting & Human Resources; and Kevin Fowler, General Counsel.

**Others Present:** See attached listing.

### **Administrative Hearings**

- Leticia Bailon (Pharmacy Technician Application 14-15447) **Case 14-05.** Leticia Bailon was present without counsel. Mark Brinkworth presented the information to the Board regarding Ms. Bailon's criminal history. A motion was made and seconded to enter executive session for quasi-judicial deliberations. (Ullom/Lonergan) Motion passed. Mr. Schoech reconvened the meeting at 9:30am. A motion was made and seconded to allow Ms. Bailon time to provide evidence to prove no charges were filed against her or will be filed and to provide that evidence by the July 2014 meeting at which time a decision will be given as to the application for registration as a pharmacy technician (Garrelts/Lonergan). Motion passed.
- Steven E. Doane, R.Ph. (1-15069) **Case 14-06.** Steven Doane, R.Ph. was present without counsel. Mark Brinkworth presented the information to the Board. A motion was made and seconded to enter into executive session for 10 minutes to receive and discuss records regarding peer review pursuant to K.S.A. 65-4915 to include Kevin Fowler, Debra Billingsley, the KsPRN representatives - Vicki Whitaker, Mike Larkin, and Ralph Holbrook. (Lonergan/Worden) Motion passed. Mr. Schoech reconvened the meeting at 9:57am. A motion was made and seconded to continue the emergency suspension until further information has been received by KsPRN and the Board can review at the next meeting. (Worden/Lonergan) Motion passed.
- Steven Stoecker, R.Ph. (1-14152) **Case 13-142.** Steven Stoecker, RPh was present without counsel. Mr. Stoecker requested a modification in his stipulation entered into on January 29, 2014 with the Board, specifically the 1 year license limitation that prohibits Mr. Stoecker from dispensing prescription drugs and practicing or working in a setting in which he would have access to prescription drugs. A motion was made and seconded to deny the request for modifications to the stipulation with Mr. Stoecker in Case 13-142. (Garrelts/Lonergan) Motion passed.
- Robert Sims, R.Ph. (1-10882) **Case 13-157.** Robert Sims was present without counsel. Mark Brinkworth presented the information to the Board. A motion was made and seconded to enter into executive session for 15 minutes to receive and discuss records regarding peer review pursuant to K.S.A. 65-4915 to include Kevin

Fowler, Debra Billingsley, the KsPRN representatives - Vicki Whitaker, Mike Larkin, and Ralph Holbrook. (Garrelts/Ullom) Motion passed. The meeting reconvened at 11:04 and a motion was made to go into executive session for ten minutes to include Kevin Fowler for the purpose of deliberation.

Mr. Schoech reconvened the meeting at 11:15am.

A motion was made and seconded to revoke Robert Sims' pharmacist license and have an order so drafted to reflect the revocation. (Lonergan/Worden) Motion passed. Mr. Fowler said the order should reflect the decision of the hearing today and that the hearing had substantiated the allegations.

**Recess:** Mr. Schoech declared a break to reconvene in 15 minutes.

**Reconvene:** Mr. Schoech reconvened the meeting at 11:32am

### **Summary Orders**

- CVS Pharmacy 5257 (2-09932) **Case 13-78.** The Summary Order was a fine for working a technician with an expired registration. CVS paid the fine. The Board requested a letter be sent to the pharmacist-in-charge stating it is a PICs responsibility to make sure everyone working as a pharmacist or technician be currently licensed or registered by the Board. The Board consensus was in the future to fine the PIC for any non-current employees. Ms. Billingsley will place the information in the newsletter.
- Kimberly Jones, Pharmacy Technician (14-02795) **Case 14-14** The Summary Order was to revoke the pharmacy technician registration of Kimberly Jones due to diversion of controlled substances.
- Rachael E. Woody (Pharmacy Technician application 14-16586) **Case 13-158.** The Summary Order was to deny the registration of Rachael Woody as a pharmacy technician based on her background.
- Kimberly Mackey, Pharmacy Technician (14-04666) **Case 14-33.** The Summary Order was to revoke the pharmacy technician registration of Kimberly Mackey due to diversion of controlled substances.

### **Other discussion:**

Mr. Lonergan asked that a discussion be placed on the next meeting agenda concerning diversion and accountability methods to decrease opportunity specifically whether inventory requirements are sufficient.

The next Meeting is scheduled for July 24 and 25, 2014 in Topeka.

**Adjourn:** Mr. Schoech adjourned the meeting at 11:55am.