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

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

Wednesday, June 9, 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; David Schoech, R.Ph.; and Frank Whitchurch, R.Ph.

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:

The start time for Thursday, June 10, was changed to 8am. A motion was made and seconded to approve the agenda as amended (Schoech/Arck). Motion passed.

Approval of the March Minutes:

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

Administrative Proceedings

William Pollard (1-12224) Case 09-58. Mr. Pollard was in attendance. Mr. Pollard was to enter the CIPP program after the March 2010 Board meeting and return to the Board meeting in June 2010. Justin McFarland, attorney on behalf of the Board, reviewed the case and the stipulations from the April board meeting. Mr. McFarland requested to present information from the CIPP committee. A motion was made and seconded to enter into executive session for 15 minutes to receive protected information and to include Mr. Pollard, Mr. McFarland, Ms. Billingsley, Mr. Forbes, and Ms. Iverson, CIPP. (Kirk/ Schoech) Motion passed. A motion was made and seconded to extend the executive session for the reasons listed previously for 20 minutes. Motion passed. Ms. Braman reconvened the meeting at 9:38am. A motion was made and seconded to enter into executive session for quasi-judicial deliberations at 9:38am to include Mr. Forbes. (Coast/Kirk) Motion passed. Ms. Braman reconvened the meeting at 9:59am. Mr. Forbes spoke on behalf of the Board to the stipulation Mr. Pollard would be willing to sign. The Board stipulation would require Mr. Pollard to enter into a 5-year contract with CIPP retroactive to

- March 2010. The signed stipulation would remove the suspension to practice. Mr. Pollard was agreeable. A motion was made and seconded to enter into the stipulation with Mr. Pollard. (Coast/ Kirk) Motion passed.
- Kelly Gauthier (1-14381) Case 09-59. Ms. Gauthier was not in attendance. Mr.
 Forbes presented the Stipulation and Final Agency Order. A motion was made and
 seconded to approve the Stipulation and Final Agency Order. (Garrelts/Coast).
 Motion passed.
- Randy Hilgers (1-09211) Case 08-79. Mr. Hilgers was not in attendance. Justin McFarland, attorney on behalf of the Board, reviewed the case and the stipulations. A motion was made and seconded to approve the Stipulation and Final Agency Order. (Schoech/Coast) Motion passed.
- Karen Moeder (1-12799) Case 09-95. Ms. Moeder was not in attendance. Mr. Forbes presented the Stipulation and Final Agency Order. Mr. Forbes requested a closed session to receive protected information. A motion was made and seconded to enter executive session for 15 minutes to receive protected information and to include Ms. Billingsley and Mr. Forbes. (Schoech/ Coast) Motion passed. Ms. Braman reconvened the meeting at 10:35am. A motion was made and seconded to approve the Stipulation and Final Agency Order. (Coast/Garrelts). Motion passed.
- Kimberly Turner (1-11436) Case 09-93. Ms. Turner was in attendance. Bill Rein, attorney on behalf of the Board, presented the case. Mr. Rein presented the Stipulation and Final Agency Order. A motion was made to enter into executive session for 15 minutes to receive protected information and to include Mr. Rein, Ms. Turner, Ms. Iverson, and Mr. Forbes (Garrelts/Arck) Motion passed. Ms. Braman reconvened the meeting at 10:52am. A motion was made and seconded to go into executive session for quasi-judicial deliberations at 10:52am to include Mr. Forbes. (Arck/Whitchurch) Motion passed. Ms. Braman reconvened the meeting at 10:59am A motion was made and seconded to approve the Stipulation and Final Agency Order. (Arck/Garrelts). Motion passed.
- Rick Kloxin. Mr. Kloxin was in attendance. Ms. Billingsley presented the application for reinstatement of Mr. Kloxin's pharmacist license. A motion was made and seconded to go into executive session for quasi-judicial deliberations at 11:15am to include Mr. Forbes. (Schoech/Coast) Motion passed. Ms. Braman reconvened the meeting at 11:25am. A motion was made and seconded to deny reinstatement of Mr. Kloxin's pharmacist license for lack of demonstrated consciousness of the wrongful conduct and disrepute which the conduct has brought upon the pharmacy profession, proof of the extent of Mr. Kloxin's rehabilitation, the lack of Mr. Kloxin's acknowledgement as to the nature and seriousness of the original misconduct, and proof of Mr. Kloxin's present moral fitness. (Arck/Schoech). Motion passed. Mr. Kloxin asked for guidance from the Board in what the Board wants. The Board sited the case Vakas v. Kansas State Board of Healing Arts, 23 Kan.App.2d 889. The Board responded that Mr. Kloxin should take the Vakas case requirements to his attorney for clarification and guidance in how he should proceed to garner and submit proof.

- Jeff Rivers (1-12334) Case 10-23. Mr. Rivers was not in attendance. Bill Rein, attorney on behalf of the Board, presented the case. Mr. Rein requested a closed session. A motion was made to enter into executive session for 10 minutes to receive protected information to include Mr. Rein, Ms. Turner, Ms. Iverson, and Mr. Forbes (Garrelts/Arck) Motion passed. Ms. Braman reconvened the meeting at 11:42am. A motion was made and seconded to approve the Stipulation and Final Agency Order. (Arck/Garrelts). Motion passed.
- Diane Wasinger (1-11386) **Case 09-44.** Ms. Wasinger was not in attendance. Bill Rein, attorney on behalf of the Board, presented the case. Ms. Wasinger did not request a hearing due to revocation of her Missouri license. Mr. Rein presented the Final Agency Order to revoke the pharmacist license.
- Donald Pohl (1-10652) Case 08-51. Mr. Pohl was not in attendance. Bill Rein, attorney on behalf of the Board, presented the case. Mr. Pohl was licensed in the state of Washington. The state of Washington Board of Pharmacy suspended his pharmacist license. Mr. Pohl did not request a hearing and his Kansas pharmacist license was suspended.
- Cristina D. Gray (1-14434) Case 09-85. Ms. Gray was not in attendance. Bill Rein, attorney on behalf of the Board, presented the case. Ms. Gray's Missouri pharmacist license was placed on probation with limitations on practice capabilities. A Missouri court stayed the order. Mr. Rein presented the initial agency order indicating awareness of the Missouri action and that the Kansas Board of Pharmacy will take action after the Missouri case has been concluded.

Drug Diversion Report – The report was not prepared for this meeting.

Recess: Ms. Braman recessed the meeting for lunch at noon to reconvene at 12:45pm. **Reconvene:** Ms. Braman reconvened the meeting at 12:45pm.

Investigative Member Report – Closed Cases

Dr. Arck asked about the Cease and Desist orders sent to Discount Pet Drugs. Ms. Billingsley said they have not applied for registration. The next step will be District Court if the Board has evidence that they have shipped drugs into Kansas. Mr. Coast thanked the compliance officers, inspectors and office staff for their work on the cases. The Board discussed sharing the investigative casesload to decrease the work placed on one investigative member. The caseload will be shared and cases will be distributed based on expertise in the area of the complaint. A motion was made and seconded to approve Mr. Schoech, Dr. Arck, Mr. Coast, Dr. Garrelts, and Mr. Whitchurch as the investigative member on the cases they are individually assigned. (Arck/Coast). Motion passed.

Board Discussion

<u>Automated Drug Dispensing</u> – Senior Care pharmacy, Topeka, representatives Robert Beady, Joe DeLallo, and Jason Spears appeared before the Board to request placement of automated dispensing machines in long-term care facilities via a pilot

project. The machine described has 240 drug bays, and would cover about 80% of routine drugs seen in long term care facilities. The drug bays hold bulk drugs that are packaged and labeled by the machine when dispensed from the machine. The Board had additional questions about the dispensing device and related policies and procedures. Ms. Billingsley will work with Senior Care to obtain additional information.

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

Reconvene: Ms. Braman reconvened the meeting at 1:58pm.

<u>Electronic Prescriptions</u> – Ms. Billingsley presented the Q and A from the DEA regarding e-prescribing of controlled substances. Authentication, credentials, identity proofing, and audits of e-prescribing systems must be done prior to the sending of by prescribers or receipt of by pharmacies. The Board looked at Kansas regulations and statutes to determine if amendments would be necessary to bring Kansas' law into as alignment with the new federal regulations. Mr. Forbes and Ms. Billingsley will review and propose the necessary changes by the September meeting.

Review K.A.R.68-20-15a(c)(3) — Request for amendment of the regulation sample law for Schedule V drugs. Pfizer representatives, Jim Baumann and Phil King, came to request a change in the regulations to allow sampling of schedule V non-narcotic drugs to prescribers. Mr. Baumann presented information to the Board to support the change. Mr. Baumann gave an example of the proposed language change they are requesting. Pfizer wants to be able to sample Lyrica rather than provide prescriber's offices with vouchers for their patients. The Board consensus was to change the regulation to allow sampling of pregabalin and other non-narcotic Schedule V Depressants.

<u>Centralized Sterile Compounding</u> – The Board discussed centralized sterile compounding between co-owned entities. Dr. Garrelts will follow up with more information at the September meeting. Ms. Kirk said the most important consideration is that the product is sterile and prepared in the appropriate environment.

Non-Dispensing Drug Provider – Ms. Billingsley requested that this item be removed from discussion.

Recess: Ms. Braman declared a break to reconvene in 12 minutes.

Reconvene: Ms. Braman reconvened the meeting at 3:27pm

<u>Pharmacist Medication Therapy Management</u> – The Board discussed specifics of pharmacist medication therapy managment. The Board reviewed whether a pharmacist calling in the prescriptions for a physician after assessing the patient for changes in medication care was under the definition of medication therapy managment. The pharmacist would be adjusting medications based on lab results per protocol with the physician. The Board has requested more information regarding medication therapy management by a pharmacist. The Board will review again in September.

<u>Annual CIPP Report</u> – Mike Larkin and Sharon Iverson presented the annual CIPP report. All CIPP patients are identified and referred to by number. Ms. Iverson went

over the program description, the procedures taken when an individual is referred, and CIPP's tracking of compliance.

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 Discussion

<u>PMP Discussion</u> – The Board discussed appropriation statutes requiring legislative authority before non-federal grant money can be spent by an agency. Ms. Billingsley contacted the Budget Department to determine how to get the legislative authority prior to 2011. Budget Provided the Board office with a process that could be used to spend the funds. The request for statutory authority to receive and spend non-governmental funds must be pursued during Legislative session.

Executive Session:

A motion was made and seconded to go into executive session for 25 minutes to discuss personnel matters to begin at 4:35pm and to reconvene the regular meeting at 5pm in the same room. The session is to include Mr. Forbes and Ms. Billingsley (Arck/Coast) Motion passed.

Ms. Braman reconvened the meeting at 5pm.

Adjourn: Ms. Braman adjourned the meeting at 5pm.

SRS Strategic Development/SRS Learning Center 2600 SW East Circle Drive S. Room C Topeka, KS, 66606

Thursday, June 10, 2010

Meeting Called to Order: President Karen Braman called the meeting to order at 8:05am.

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; David Schoech, R.Ph.; and Frank Whitchurch, R.Ph. (8:17am)

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 Justin McFarland, General Counsel.

Others Present: See attached listing.

Board Discussion

<u>Budget</u> – Ms. Billingsley presented the update on the agency budget. She is in the process of closing the books for the 2010 fiscal year. The budget for 2012 is due in September. Ms. Billingsley will send the ending budget to the Board at the end of June.

Rent for the entire year at the new facility will be \$25,000. This includes space, parking, utilities and trash. The current rent in the Landon State office building was \$16.90 per square foot and will increase to \$17.10, no parking included. The new facility is \$12.50 per square foot. The state is finding creative new ways to charge for services provided to the agencies. Ms. Billingsley told the Board about the "Smart" training as the new financial managment system for the state. Ms. Braman told the Board about the Board of Regents' contractor permitted to consult with the PMP RFP process. The consultation has been at no cost to the Board or PMP.

Regulatory Update –The Board discussed regulations that are in the process. Tech Check Tech in the Medical Facility has a public hearing scheduled today. Nuclear Regulations are scheduled for public hearing September 9, 2010. Compounding Regulations are still in the process. Telepharmacy – retail regulations are with Mr. Forbes. Prescription drug monitoring has a public hearing scheduled today. Utilizing electronic supervision of technician in a medical care facility has a public hearing scheduled September 9, 2010. The Electronic Logging system for meth precursors has a public hearing scheduled for August 17, 2010.

<u>DME Regulations</u> – Ms. Billingsley said the regulations have been written and she will send a copy to the Board members for their review.

Legislative Discussion for 2011 – Mr. Whitchurch believes the Board should pursue the authority to allow pilot programs to advance the profession of pharmacy. Ms. Billingsley told the Board that there are several areas that could be amended in the statutes. An example would be pharmacy interns should be held to the same standards of professional behavior as pharmacists. She will bring the list to the September board meeting. Ms. Braman stated the Board needed to ask for funding for the PMP. Funding must be secured or the program can only be sustained for 2 years with the current grant monies.

Board Member Reports

Shirley Arck - asked about adopting rules and regulations for the veterinary medical teaching hospital pharmacy regulations. She will work on putting a draft together. Dr. Arck attended the NABP national meeting and it was very enjoyable. North Carolina presented a good program about controlled substances.

Karen Braman – Ms. Braman encouraged Board members to review the resolutions passed by the NABP during the annual meeting.. They are in the board member packets for their review. In April, Ms. Braman stated she attended the Attorney General's office Orientation for public Boards and Committees. The AG's office provided attendees a copy of the Kansas Open Records Act summary and suggested Board members contact the Board Office if they would like a copy.

Michael Coast – Mr. Coast stated that his issues are under staff reports and he will provide input at that time.

David Schoech – Mr. Schoechasked if the Board collected immunization certification information when pharmacists renewed their licenses He stated that he thinks this information would be helpful to the public. Mr. Schoech talked to the Kentucky

executive director at the NABP annual meeting and discussed how they get their PMP funding. He suggested that the Board may need to press the PMP funding issue with the legislature by showing what other states are doing. Mr. Schoech stated that the NABP meeting was a great experience and he learned much from other state representatives.

Frank Whitchurch — Mr. Whitchurch mentioned the NABP discussion related to multistate licenses. He stated that he believes it is a good idea especially for pharmacists that maintain multiple licenses. Mr. Whitchurch told the Board that there is a push to standardize punishment for" like" infractions across the nation. Mr. Whitchurch said that to date Prescription Solutions has donated \$770,000 in unused drugs to the Unused Medication Program. He encouraged the board to look at regulations that will allow better use of technology and not to impede use of technology in helping the practice of pharmacy to be more efficient and accurate.

Nancy Kirk and Jim Garrelts stated that they had nothing to report.

Public Hearings for Proposed Regulations

K.A.R. 68-7-11 Medical Care Facility Pharmacy. The change is in regard to Tech Check Tech in a hospital setting.

Ms. Braman adjourned the regular meeting and opened the public hearing at 9am Ms. Braman asked for public comment.

Ms. Billingsley provided a letter from Kansas Legislative Research Department.

There were no comments from the public.

Ms. Braman closed the public hearing.

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

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

Public Hearings for Proposed Regulations

K.A.R. 68-21-1 Prescription Monitoring Program 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

Ms. Braman adjourned the regular meeting and opened the public hearing at 9:07am Ms. Braman asked for public comment.

Ms. Billingsley provided the letters from:

- The Joint Committee on Administrative Rules and Regulations
- Kansas Legislative Research Department
- Max Hedrick
- Bill Lockwood, Executive Director, American Society for Automation in Pharmacy (ASAP) – Ms. Braman read part of his letter for Board consideration. Mr. Lockwood

stated that the requirement of prescriber address is not consistend with ASAP 2007 standards.

Medco

The following people provided oral comments regarding the regulation change:

- Max Hedrick Mr. Hedrick stated the committee had wrestled with the regulations and tried to be fair with all entities.
- David Root, Medco Medco requested an amendment to the regulation that would exempt mail order pharmacies from the 24 hour reporting requirement. Mail order pharmacies would still submit data, but on a weekly basis. Mr. Root stated that he had contacted CVS Caremark and Express Scripts and that with their permission, he was also speaking on their behalf. Medco and other mail order pharmacies that ship to all states have the added administrative burden of following different data submission standards for each individual state and they would like for the process to be standardized. Mr. Whitchurch stated that he understands Medco's position and suggested that the exemption be granted for a time-limited period in order to study the impact of allowing mail order pharmacies to submit data weekly. Mr. Schoech questioned the ability to have current information that local pharmacists could review before dispensing prescriptions. Medco is the second largest mail order pharmacy provider.
- Dr. Joe Davison Dr. Davison said the exemption could cause problems with being able to monitor patients.

Ms. Braman closed the public hearing.

Ms. Braman called the regular meeting to order at 9:39am.

number can be used to obtain the prescriber's address.

The Board discussed comments from the public hearing. Mr. Whitchurch supported a way to ease the initial burden for Medco. Mr. Garrelts stated that Medco's concern was financial and not in the best interest of providing appropriate care for patients. Ms. Braman would like to see the address of the prescriber struck from the regulation 68-21-2 requiring pharmacies to report the address and the DEA number. The DEA

The Board discussed exempting mail order from the 24 hours reporting.

K.A.R. 68-21-7 Drugs of Concern - the term stakeholders was recommended by Rules and Regulations to be defined. The Board will leave as it currently reads.

A motion was made and seconded to remove the prescriber's address requirement from K.A.R. 68-21-2; to change the "by" to "be" as recommended by The Joint Committee on Administrative Rules and Regulations, and to send the appropriate regulations back to the Department of Administration and the Attorney General. (Arck/Coast). Motion passed. Once the regulations are received back from the DoA and AG's office a meeting will be scheduled to accept.

The Board will postpone approving the regulations until they may be approved as a complete section.

<u>NABP Annual Meeting Report</u> – Ms. Billingsley reminded the Board they can sign up for NABP committees.

Staff Reports – Ms. Billingsley

<u>Multiple prescriptions</u> Debra Billingsley – asked the Board how to deal with multiple prescriptions on the same paper. Mr. Coast said the filling system should allow tracking the original. The inspectors and compliance officers agreed with Mr. Coast.

<u>Pharmacists in Charge</u> A pharmacist in charge of more than one place was the other question Ms. Billingsley brought to the Board. The Board discussed the issue and will explore the possibility of changing the regulation K.A.R. 68-7-13 to allow pharmacist owners to be PICs at multiple locations. Ms. Billingsley will research what other states are doing.

Recess: Ms. Braman declared a break to reconvene in 15 minutes. **Reconvene:** Ms. Braman reconvened the meeting at 10:49am

Staff Reports

Melissa Martin – CVS is rolling out the new software that they had committed to Board more than two years ago. All new locations receive the software and the existing locations are being upgraded on a slower schedule. The rollout should be completed by fall 2010.

Jim Kinderknecht – reported on the Lipodissolve issue. Kansas banned lipodissolve several years ago and now the FDA has labeled it as a scam.

Christina Morris –Ms. Braman congratulated Christina Morris and her family on the birth of her son Brady Morris.

Debra Billingsley - The pharmacy office is moving and the new address is 800 SW Jackson, Suite 1414 at the end of the month.

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 – 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. Ms. Billingsley will send the link for the public announcements to the Board and associations for comments.

Next Meeting

The meeting in September is in Wichita.

Executive Session – Proprietary RFP – <u>Discussion Closed to the Public</u> Vendor Demonstrations

A motion was made and seconded to enter into executive session at 11:10am until 4pm to accept RFP vendor demonstrations, to protect the Board's negotiating rights, and im compliance with the Department of Administration Division of Purchases confidentiality requirements for RFPs. The session is to include: Ms. Billingsley, Board staff (Jim Kinderknecht, Carly Haynes, Reyne Kenton, and Melissa Martin); members of the PMP Advisory Committee (Christina Morris, Dr. Joe Davidson, Max Hedrick, LeAnn Bell, and

Bob Twillman); Randall White, consultant to the Board; Slone Schultz (KU pharmacy student on rotation with LeAnn Bell), Sweta Patel (KU pharmacy student on rotation with David Schoech), Jake Osmundson (KU pharmacy student on rotation with Max Hedrick); Bonnie Edwards, Department of Purchasing; Tami Sherley, Department of Purchasing, and the vendors. Lunch will be available during the executive session. (Arck/Coast) Motion passed.

A motion was made and seconded to extend the executive session for the reasons listed above and include the individuals listed above until 4:50pm. (Schoech/Arck) Motion passed.

Reconvene: Ms. Braman reconvened the meeting at 4:50pm **Adjourn:** Ms. Braman adjourned the meeting at 4:52pm.