# Kansas State Board of Pharmacy Minutes of the May 31 & June 1, 2012 Board Meeting

#### 800 SW Jackson, Lower Level KSBHA Conference Room Topeka, KS 66612

### <u>Thursday, May 31, 2012</u>

**Meeting Called to Order:** President Jim Garrelts, PharmD called the meeting to order at 9:00am.

**Members Present:** Jim Garrelts, PharmD., President; Nancy Kirk, Public Member, Vice President; Bob Haneke, PharmD.; Michael Lonergan, RPh.; David Schoech, RPh.; Chad Ullom, RPh.; and John Worden, PharmD.

**Staff Present:** Debra Billingsley, JD, Executive Secretary; Jim Kinderknecht, RPh., Pharmacy Inspector; Carly Haynes, RPh., Pharmacy Inspector; Melissa Martin, Compliance Officer; Reyne Kenton, Compliance Officer; Doug Taylor, JD,Disciplinary Counsel; Christina Morris, JD, PDMP Director, and Randall Forbes, JD, General Counsel (1pm).

Others Present: See attached listing.

### Approval of the Agenda:

A motion was made and seconded to approve the agenda as printed. (Schoech/Haneke) Motion passed.

### Approval of the March 8, 2012 Minutes:

A motion was made and seconded to approve the minutes as presented. (Schoech/Ullom) Motion passed.

### **Board Discussion**

<u>Pilot Projects Guidelines/Policies</u> – Dr. Garrelts informed the Board that with the passage of SB 134 the Board could review and approve pilot projects. Dr. Garrelts suggested the Board consider creating guidelines so that there will be consistency in the information provided to the Board. The Board requested that the Executive Secretary create an application for individuals who request to conduct a pilot project. A template will be drafted so that an applicant can provide a scope statement, applicability matrix, goals, current impediments, process management, assessment, decision matrix, deployment, etc. Dr. Garrelts and Ms. Billingsley will work on the template within the next two weeks.

<u>Golden Living / AlixaRx Remote</u> – Albert Barber, PharmD, CGP, FASCP; Director of Pharmacy Services from Golden Living made a presentation on the Alixa medication distribution system. Golden Living would like to apply for a pilot project that would allow them to use the Alixa system in the LTCF setting. The company has pilot projects in two other states. A brief video was shown. Dr. Barber stated Kansas City metro would be the location of their second hub pharmacy. The AlixaRx medication distribution does not stock more than a 14-day supply. The machine uses all of one canister before it accesses the second. Dr. Barber will share the company policy and procedure manual with the Board. Ms. Billingsley will send the policy manual to the Board for their review.

<u>Wesley Medical Center Automation Update</u> – Robert Ragan, RPh, MHS, Pharmacy Manager and Joan Kramer, PharmD, BCPS, Research Pharmacy Specialist, provided a brief update on their progress related to the use of pyxis medstations in a LTCF setting. Wesley Medical Center will complete the pilot application as soon as it becomes available. Ms. Kirk suggested an advisory committee review pilot project applications for approval to expedite the process. Dr. Haneke and Ms. Haynes will serve as initial review and make a recommendation to the Board. Jim Dunham, R.Ph., Pharmacist in Charge with Americare, asked the Board about lower technology options and how those technologies will be addressed in the regulations. He was also concerned with how the regulations would address emergency kits. Ms. Billingsley will add Mr. Dunham's contact information for notification of the next LTCF automation Task Force Meetings. Dr. Garrelts said the Board's primary concern is patient safety.

<u>Automation in LTCF Regulations</u> – Ms Billingsley presented a partial draft of regulations to the Board. The e-kit regulations will need to be addressed as the process moves forward. Dr. Haneke said the task force should meet again to address the lower technologies and address some of the new information that was provided earlier. The task force will try to meet in June. The proposed regulations on automation in long term care facilities must be reviewed by the Department of Administration, the Attorney General's office and then published for hearing 60 days prior to the hearing. The Board will hold a phone conference to approve the final draft regulations as early as July.

<u>KTRACS Report</u> – Christina Morris, KTRACS Program Director presented a report on changes to the PMP law and she provided a quarterly program report. The report documents are attached electronically to the agenda. The program appears to be effective because the threshold patient number has declined. SB134 has created a peer review process to review those prescribers prescribing over the norm. It also provides a mechanism to report illegal activity to the appropriate law enforcement or regulatory agency.

Kansas Health Information Network – Laura McCrary, Ed.D., Executive Director, KHIN, made a presentation to the Board. The report documents are attached electronically to the agenda. Dr. McCrary advised that KHIN was endorsed by the Kansas Medical Society and the Kansas Hospital Association. The goal of KHIN is to improve health care quality, coordination, and efficiency through the exchange of health information through a secure electronic network by a collaboration of health care organizations. Dr. McCrary said one of the first things would be to discontinue using fax machines. Dr. McCrary showed the website and how easy the information is to access. The advantage of allowing pharmacies to participate in the network is that it would decrease the time spent on phone calls and would increase patient care when drug questions arise. Another advantage to pharmacies participating in KHIN - the information would show not only what was prescribed but also whether the patient was compliant with refills. Dr.

McCrary suggested becoming a technology partner with KTRACS. KTRACS would be able to send threshold letters via KHIN rather than by mail. Christina Morris requested permission to discuss interfacing with KHIN as well as discussing potential funding mechanisms for KTRACS. Ms. Billingsley recommended that the contract be sent to Mr. Forbes for his review before signing. Ms. Billingsley also asked for clarification as to the two Health Information Exchanges in the state and whether an agreement with one would preclude the other from obtaining information. It was explained that whatever access KHIN received would be available to the other network. Ms. Billingsley reminded the Board that KTRACS has no funding after this year. Ms. Billingsley asked if pharmacies would have to pay to access KHIN for information or to upload data. Dr. McCrary has been seeking input as to how pharmacy can work in the system. A motion was made and seconded to authorize continued discussion with KHIN regarding funding and for KTRACS to partner with KHIN. The Board further authorized any contract draft go to Mr. Forbes for review. (Schoech/Haneke) Motion passed

<u>Cardinal Health</u> – Martha Russell, JD, Director of Corporate Regulatory Affairs Julie Turner, RPh, and Whitney Newman, Pharm Tech, were present on behalf of Cardinal Health. KDHE has issued a restricted license to Cardinal in Wichita and did not require a pharmacist to operate the manufacturing portion of the business. Cardinal has been working on the sterility, QC and QA testing. They are looking at around mid to late August before they will begin production. KDHE plans to observe the production of FDG from start to finish before issuing a full license for commercial distribution. Ms. Billingsley explained how other states handled nuclear pharmacies and told the Board they could allow a waiver or require a pharmacist. Cardinal Health has an ANDA on file with the FDA and they must follow all the good manufacturing requirements. There can be no deviation from procedure and testing of the product. KDHE and FDA also inspect the facility. A motion was made and seconded to approve a waiver for the Cardinal Health facility, to require them to supply to the Board the reports from KDHE and the FDA, and to review the waiver in a year from the time the receive the full license from KDHE. (Kirk/Ullom) Motion passed

Legislative Update - The report documents are attached electronically to the agenda.

- Electronic Prescriptions Ms. Billingsley provided information from SureScripts.
- Utilization of Unused Medications Ms. Billingsley shared the inquiry with the Board and the progress of the program.
- SB134 made the changes necessary to allow **electronic prescriptions** for controlled substances. The bill was passed and signed. Kansas prescribers and dispensers may proceed to fulfilling the DEA requirements to begin sending and receiving electronic controlled substance prescriptions.
- SB 134 contained the **pilot study** authorization.
- SB 134 mandated a study on **electronic prior authorizations**. Ms. Billingsley suggested an August meeting with the stakeholders. A report must be completed by January 15, 2013. Mr. Lonergan said many states and CMS already have designated turn around times. Nancy Zogleman, from Polsinelli Shughart,PC, told the Board the stakeholders wanted it pharmacy related and not insurance related. The report needs to suggest regulatory language. Mr. Lonergan asked if this was more than just pharmacy and could it not be prior

authorizations for other medical procedures. Mr. Lonergan will work with Ms. Billingsley on the study.

# **Regulation Update**

 Retail telepharmacy regulation – Mike Coast, RPh, Cimarron and Carol Dunn, Stafford Economic Development were present to discuss the regulations. There was a hearing in March of 2011; however the Board did not pass the regulations at that time. The Joint Committee on Rules and Regulations did not like the "direct supervision" verbiage. The regulations were rewritten to address the security of direct supervision but could not obtain approval from all the necessary entities to proceed to the Board for hearing and approval. Dr. Haneke recommended changing the definition of remote supervision to get approval to allow the branch pharmacies. Safety would need to be addressed with possibly a security system required that provides 24/7/365 monitoring. Dr. Garrelts said the issue is political in nature and that to continue the Board needs to be aware of the political implications. A pilot project would allow data to be collected and shared to support the proposed branch pharmacies.

### Investigative Member Report – Closed Cases

Mr. Schoech presented the closed cases and asked for any questions. A motion was made and seconded to accept the closed cases. (Haneke/Ullom) Motion passed.

**Recess:** Dr. Garrelts recessed the meeting for lunch at 12:18pm to reconvene at 1pm. **Reconvene:** Dr. Garrelts reconvened the meeting at 1pm.

# Administrative Hearings

- Mary Richardson, R.Ph. (1-09936) Case 11-22. Ms. Richardson was present with counsel, Jason Hoffman. Mr. Taylor presented the case and recommended the Board accept the Consent Agreement. The Agreement stipulates Ms. Richardson be place on probation for 5 years, participate and be in compliance with the CIPP program for 5 years which includes 30 days inpatient treatment for chemical addiction, must comply with all state and federal laws, notify the Board of any changes to her name or address, refrain from acting as a PIC, and have another licensee/registrant in the pharmacy with her at all times. A motion was made and seconded to go into executive session for 15 minutes to discuss protected information to include Mary Richardson, Jason Hoffman, Mike Larkin for CIPP, Mr. Taylor, Mr. Forbes, and Ms. Billingsley and to return to open session at 1:15pm. (Kirk/Haneke) Motion passed. Dr. Garrelts reconvened the open meeting at 1:11pm. A motion was made and seconded to accept the Consent Agreement. (Haneke/Ullom) Motion passed.
- Melisandre Pope (14-10007) Case 12-31. Ms. Pope was not present. Mr. Taylor presented the case and recommended the Board accept the Petition to Revoke Melisandre Pope's pharmacy technician registration. A motion was made and seconded to revoke Ms. Pope's pharmacy technician registration. (Ullom/Haneke) Motion passed. The registration was revoked due to diversion of controlled substances from her employer

Celeste Ontjes (1-12633) Case 12-46. Ms. Ontjes was not present. Mr. Taylor presented the case and recommended the Board accept the Consent Agreement. The Agreement stipulates Ms. Ontjes pay a civil fine of \$500 and submit the names of the two drugs involved in the incident to ISMP. A motion was made and seconded to accept the Consent Agreement with Ms. Ontjes. (Kirk/Haneke)

# **Executive Director Report**

- Hydrocodone scheduling Ms. Billingsley asked the Board for input about how scheduling will affect patient care. Mr. Coast said the cost will be much higher for patients. Ms. Billingsley will respond to the Congressional delegation from Kansas.
- Memo regarding RxTEC Act and Letter to Rep. Waxman (Pharmaceutical Traceability Enhancement Code – Ms. Billingsley explained the Act as stronger pedigree requirements. The Board consensus was that the Act will not affect Kansas.
- Expanded Access to Rx Drugs initially appeared in the "Pharmacy Letter". The Board consensus was this could expand the pharmacists practice capabilities.
- KDHE will send another press release on the medication disposal program. Pharmacies that would like to provide the service should make application to KDHE.

# Presentations

A special presentation was made to Dr. Shirley Arck and Mike Coast, RPh for appreciation of unselfish service to the profession of pharmacy. Mr. Coast, RPh thanked the inspectors for their dedication. He told the Board he would be happy to serve on committees in the future. Dr. Arck said she gave her good byes during March but that she too would be available for committees.

**Recess:** Dr. Garrelts declared a break to reconvene in 15 minutes. **Reconvene:** Dr. Garrelts reconvened the meeting at 2:03pm Dr. Arck introduced two students from Kansas University School of Pharmacy.

# Administrative Hearings

- Marilyn Mix, RPh. (1-12340) Case 12-35. Ms. Mix was not present. Mr. Taylor presented the case and recommended the Board accept the Consent Agreement. The Agreement stipulates Ms. Mix voluntarily surrenders her license to practice pharmacy in the State of Kansas which will be treated as a revocation for reporting purposes. The order requires the surrender to be effective within 60 days of the Consent Agreement date. Further, the respondent agrees to close her pharmacy, Dighton Drug (2-08520) within the same 60 day period; and pay a \$1000 fine. If Ms. Mix wishes to practice pharmacy in the future she must apply for reinstatement of the license and appear before the Board. The Notice to Appear stipulated that if Ms. Mix did not appear, she is considered in default. A motion was made and seconded to accept the signed Consent Agreement. (Haneke/Worden) Motion passed.
- Don Kaufman, RPh. (1-10029) **Case 07-69**. Review of Probation. Mr. Kaufman was present with counsel, Darin Conklin, Alderson, Alderson, Weiler, Conklin, Burghart

& Crow,LLC. A motion was made and seconded to go into executive session to discuss protected information from the CIPP committee to include Mr. Kaufman, Mr. Conklin, Mike Larkin for CIPP, Mr. Taylor, Mr. Forbes and Ms. Billingsley . (Haneke/Ullom) Motion passed. Dr. Garrelts reconvened the meeting at 2:43pm. A motion was made and seconded not to extend Mr. Kaufman's probation with the Board for an additional year as done by CIPP. (Kirk/Lonergan) Motion passed. Dr. Haneke recused himself from all discussion as he knows Mr. Kaufman.

Armantine Lee – Case 12-12. Pharmacist License Application. Ms. Lee was present with counsel, Jim Willard. Mr. Taylor presented the case and requested guidance from the Board. A motion was made and seconded to to into executive session to discuss protected information to include Ms. Lee, Mr. Willard, Mr. Taylor, Mr. Kinderknecht and Mr. Forbes. (Haneke/Ullom) Motion passed Dr. Garrelts reconvened the meeting at 4:13pm. A motion was made and seconded to consider the application incomplete because Ms. Lee did not have someone from the reciprocity state fill out the voucher on the application. The reciprocity state is Illinois. (Ullom/Schoech) Motion passed.

Mr. Lonergan left the meeting at 4:15pm.

**Recess:** Dr. Garrelts declared a break to reconvene in 10 minutes. **Reconvene:** Dr. Garrelts reconvened the meeting at 4:25pm.

- Western Plains Regional Hospital (2-10304) Case 11-166. Western Plains had no representation present. Mr. Taylor presented the case and recommended the Board approve the Summary Order. The Summary Order stipulates a fine of \$3740 for operating without a pharmacist-in-charge for 137 days. A motion was made and seconded to direct the Board to file a proposed default order to be imposed on WPRH with a fine of \$5000. (Haneke/Schoech) Motion passed. During the time the hospital did not have a PIC, they allowed a pharmacist with a stipulated agreement with the Board to work alone thereby violating his probation and agreement with the Board. Dr Garrelts asked the Board's opinion in regards to the pharmacist. The Board consensus was two issues were involved and would be addressed separately. Ms. Kenton will file a follow up case.
- John Preble, R.Ph. (1-09834) Case 12-16b. Mr. Preble was present in the audience but did not speak. Mr. Ullom recused himself from the discussion because Mr. Preble is employed with Walgreens. Mr. Taylor presented the case and recommended the Board accept the Consent Agreement. The Agreement stipulates Mr. Preble be place on probation for one year, provide documentation of any incident report which identifies him as the pharmacist and pay a civil fine of \$1000. A motion was made and seconded to approve the Consent Agreement with John Preble. (Worden/Kirk) Motion passed.
- James Reilly, R.Ph. (1-11531) **Case 11-193A** Mr. Reilly was present with counsel, Christopher S. Cole, Woodard, Hernandez, Roth & Day, LLC. Mr. Ullom recused himself from the discussion because the case involved a Walgreens.

Sheila Connolly, R.Ph. (1-11650) **Case 11-193B**. Ms. Connolly was present with counsel, Christopher S. Cole, Woodard, Hernandez, Roth & Day, LLC. Mr. Ullom recused himself from the discussion because the case involved a Walgreens.

Richard Barrows, R.Ph. (1-09270) **Case 12-24**. Mr. Barrows was present with counsel, Christopher S. Cole of Woodard, Hernandez, Roth & Day, LLC. Mr. Ullom recused himself from the discussion because the case involved a Walgreens.

Mr. Taylor presented the cases against Mr. Reilly, Ms. Connolly, and Mr. Barrows and recommended the Board accept the Consent Agreement. Mr. Cole, counsel for the respondents, presented the information on behalf of the Walgreens pharmacists. Dr. Haneke asked if the pharmacists are prepared to tell the Board what they will do to make sure the errors like this do not reoccur. Ms. Kirk asked if the failure was pharmacists or systems.

A motion was made and seconded to go into executive session for quasi-judicial deliberations at 5:50pm to include Mr. Forbes. (Haneke/Worden) Motion passed. Dr. Garrelts reconvened the meeting at 6:04pm The Board took the matter under advisement in the cases 11-193A, 11-193B and 12-24 and will continue deliberations in September.

 KMart #3358, (2-09716) Case 11-67. KMart was represented by E. Dudley Smith of Fisher Patterson Sayler & Smith. Mr. Taylor presented the case and recommended the Board accept the Consent Agreement. The Agreement stipulates KMart pay a civil fine of \$2500; within 30 days of execution of Consent Agreement, hold a CQI meeting to review the violations in the Agreement, implement safeguards to ensure violations do not occur in the future, and provide a written report to the Board on the completion of the CQI meeting. A motion was made and seconded to accept the Consent Agreement with KMart. (Ullom/Haneke) Motion passed.

Adjourn: Dr. Garrelts adjourned the meeting at 6:09pm.

### Friday, June 1, 2012

**Meeting Called to Order:** President Jim Garrelts, PharmD called the meeting to order at 9:00am.

**Members Present:** Jim Garrelts, PharmD., President; Nancy Kirk, Public Member, Vice President (9:03am); Bob Haneke, PharmD.; David Schoech, RPh.; and Chad Ullom, RPh.

**Staff Present:** Debra Billingsley, JD, Executive Secretary; Jim Kinderknecht, RPh., Pharmacy Inspector; Carly Haynes, RPh., Pharmacy Inspector; Melissa Martin, Compliance Officer; Reyne Kenton, Compliance Officer; Doug Taylor, JD, Disciplinary Counsel; and Randall Forbes, JD, General Counsel.

Others Present: See attached listing.

# **Board Discussion**

<u>Annual CIPP Update</u> – Mike Larkin, KPhA; Ralph Holbrook, RPh., Chairman of CIPP; and Vicki Whitaker, Program Administrator, presented the update. Ms. Whitaker's first day was June 1, 2012. The update documents are attached electronically to the agenda. Mr. Larkin reviewed the year's data with the Board. Ms. Kirk asked about referrals from the Board on issues other than drugs and specifically on dementia. Mr. Larkin said CIPP differentiates the cases and applies the appropriate evaluations and follow-up. A dementia referral would not undergo random drug screens. Ms. Billingsley said she was at first in doubt that KPhA taking CIPP in-house would be acceptable, but has been pleased at the service and believes there is more communication leading to better consequences. CIPP has changed to First Lab. First Lab provides more information and documentation helping CIPP monitor participants better and more efficiently. Ms. Billingsley attends all CIPP meetings. Self referred individuals are protected by the discussion only referring to case number not by name. Dr. Haneke requested CIPP provide more information during the closed session of disciplinary cases.

The Utah School is June 17-22. Board members are encouraged to attend.

<u>Budget</u> – Ms. Billingsley provided an update of the budget. The Legislature approved using \$250,000 for KTRACS if the program does not find sufficient funding. Ms. Billingsley said the money would be from the distributor renewal fees. The Board is currently taking in \$100,000 per year more than the budget requires. She asked the Board to consider cutting fees 10% or lowering some of the fees for distributors, DME providers. She will put a proposal on the September agenda with the appropriate regulation change. Appropriations will cut any unfilled, authorized position. The Board encouraged Ms. Billingsley to make sure all authorized positions are filled.

<u>NABP Annual Meeting Report</u> – Mr. Ullom told the Board about the resolutions voted on by the NABP membership. The only one denied was presented by Arkansas. Their proposal was to deny all cards by manufacturers for rebates on drugs. The concern was the proposal could impact discount cards as well.

Mr. Ullom shared information about the real time pharmacist profile and CPE monitoring.

Mr. Kinderknecht handed out the flier on the PARE test. The PARE test allows Boards to give a test of pharmacy knowledge to pharmacists seeking to regain their license or retain a license that is being proposed to be sanctioned. The test, which lasts up to 4  $\frac{1}{2}$  hours, may be given in the Board office.

Mr. Kinderknecht told the Board Nevada requires documentation of all counseling and that during a case investigation the inspectors ask for a copy of the documentation. Oklahoma won the Fred Mahaffey award.

Ms. Haynes gave the Board a handout highlighting different parts of the NABP meeting. New Mexico takes any picture or video of a pharmacy thief and sends it to all surrounding pharmacies who will give the police a lead on the thief's identity.

The Canadian representative said that any drugs returned to Canada get the attention of Canadian Customs. They pursue and prosecute those illicit drug outlets.

NABP 109<sup>th</sup> Annual Meeting will be in St. Louis, Missouri, May 18-21, 2013.

# **Executive Director Report**

Debra Billingsley – report documents are electronically attached to the agenda.

- University of Kansas School of Pharmacy Annual Advisory Council Meeting
- Kansas PCMH Initiative Engagement Coalition (Patient Centered Medical Home Initiative)
- Article on White Bagging Issue
- Drug Shortages Information
- NPLEX Update with March and April Dashboard Report
- PSDA Bill

# Staff Reports

Carly Haynes – reported on the recent DEA action concerning controlled substance prescriptions. The DEA cited a national pharmacy for allowing the doctor or agent to simply sign off on the page containing the most recent dispensing information. Most pharmacies in Kansas process the refill and continuing prescriptions the same way as the cited pharmacy. The DEA should provide interpretation guidelines to the State Boards.

# Approval of New Pharmacists and New Registrants

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

# **Board Member Reports**

Jim Garrelts – asked the Board what other information they would like for the next Board meeting in regards to cases. The Board asked for a rubric or disciplinary fine list as a reference.

Bob Haneke – will talk with Dean Audus about the possibility of taking the Collaborative Practice to another level with Pharmacist Clinicians (dual practice). The program would allow a pharmacist to also receive a physician's assistant degree. The pharmacy program could diversify, and give students the option to choose either Pharm Ds or Pharmacist Clinician. Most states already have collaborative practice, prescriptive authority and two states (NM & NC) allow the dual practice. Ms. Billingsley said Larry Buening wrote a letter stating doctors can enter collaborative practice with anyone they believe competent. Malpractice insurance may be the biggest hindrance for the doctors. Representative Don Hill should be contacted for legislative research. Model legislation would be helpful if NABP could supply.

David Schoech – said the current supply of certificates are almost gone and the new design will be available starting in September.

Chad Ullom – aske Mr. Ullom told the Board he would take them to Walgreens at 10<sup>th</sup> and Topeka for a tour and viewing of the verification process.

Adjourn: Dr. Garrelts adjourned the meeting at 10:56am.