Kansas State Board of Pharmacy Minutes of the March 28 & 29, 2013 Board Meeting

KU School of Pharmacy 2010 Becker Drive Lawrence, KS 66047

Thursday, March 28, 2013

Meeting Called to Order: President David Schoech, R.Ph. called the meeting to order at 9:11am.

Members Present: David Schoech, R.Ph., President; Bob Haneke, Pharm D., Vice President; Jim Garrelts, Pharm. D.; Nancy Kirk, Public Member; Michael Lonergan, R.Ph.; Chad Ullom, R.Ph., Investigative Member; and John Worden, Pharm D.

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; Christina Morris, PDMP Director, 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 printed. (Worden/Ullom) Motion passed.

Approval of the November 2012 Minutes:

A motion was made and seconded to approve the November 2012 minutes as printed. (Haneke/Ullom) Motion passed.

Approval of the December 2012 Minutes:

A motion was made and seconded to approve the December 2012 minutes as printed. (Garrelts/Haneke) Motion passed.

Board Discussion

<u>KTRACS</u> – Christina Morris presented the report to the Board. The report included statistics, top threshold recipients by prescribers and dispensers, and the summary of the SAMSHA Grant project. The reports are attached electronically to the agenda. The SAMSHA grant project includes the discussion with Via Christi, KHIE collaboration (KHIN and LACIE), and retail chain, Walgreens, collaboration.

<u>Mitre/Cerner/KTRACS Pilot Project Presentation</u> – Alex Benson, Cerner, made a presentation on the pilot project between Mitre, Cerner, KTRACS, and participating prescribers/hospitals. The system sends the prescriber the information from KTRACS

when the prescriber has a patient that is over threshold. The system utilizes secure direct email and saves the prescriber time in accessing the KTRACS information. The Board discussed the pilot and the possibility of extending the pilot.

<u>LACIE/KTRACS Integration Project</u> – Mike Dittemore, RN, BS, eMBA, Lewis and Clark Information Exchange Executive Director, presented the project. LACIE is a multistate health information exchange which includes the whole state of Kansas. The Board discussed the proposed MOU with LACIE that would provide access to KTRACS through the HIE. A motion was made and seconded to approve the MOU with LACIE. (Worden/Lonergan) Motion passed.

A motion was made and seconded to extend the pilot project with Cerner until March 2014. (Haneke/Lonergan) Motion passed.

<u>Budget</u> – Ms. Billingsley gave a budget update. The Governor recommended that fees be reduced 50% for several years and draw down the balance of the pharmacy fee fund. The Board currently has more revenues than expenditures. The Appropriations and Ways and Means agreed with the recommendation although the percentage level was at 20%. The Appropriations bill is currently in conference committee and additional language in Sub HB 2133 placed a cap on Board salary expenditures that was a little over \$700 short for FY14, FY15, and FY16. This would prevent the Board from paying full salaries for all current employees. It would also prevent the Board from hiring an additional inspector in the future. The Board asked what they could do to help get the funds necessary to continue working as regulators. The Board recommended hiring another inspector due to increase demands in inspection of pharmacies that compound. This recommendation was made after an intergovernmental meeting with the FDA related to the deadly outbreak of fungal meningitis that has now killed over 50 patients. A motion was made and seconded to table the decision until Friday. (Haneke/Ullom) Motion passed.

<u>Compounding Pharmacies</u> – The Board received information concerning compounding regulations and the AG's problems in approving the language. The definition of compounding in the regulation conflicted with the statutory definition of manufacturing since manufacturing also includes compounding.

The Board reviewed information related to pharmacies that compound medications that are essentially a copy of a commercially available product. The Board determined that the Board would need to have regulations in place since they cannot enforce federal law. Ms. Billingsley shared communication from the FDA; the director of pharmacy for Allergychoices Pharmacy in Wisconsin; and an FDA comment on veterinary compounding.

Executive Session:

A motion was made and seconded to go into executive session for 15 minutes to discuss personnel matters and to reconvene the regular meeting at 11:45 am in the same room. The executive session is to include Mr. Forbes, Ms. Billingsley and the Board staff. (Haneke/Worden) Motion passed.

Mr. Schoech reconvened the meeting at 11:45am.

Recess: Mr. Schoech recessed the meeting for lunch at 11:45am to reconvene at 1pm. **Reconvene:** Mr. Schoech reconvened the meeting at 1pm.

Board Discussion

<u>AlixaRx Pilot Project Application</u> – Al Barber, PharmD, Melissa Hutchinson, RPh, and Blake Griese, JD, PharmD, presented the request of AlixaRx to conduct a pilot project in Kansas. A motion was made and seconded to accept the pilot project contingent upon the receipt of the policies and procedures for review; if there is no Board Member objections submitted within 14 days, the pilot project will be approved for an initial 5 facilities; and to have AlixaRx make a report to the Board in June 2013. (Lonergan/Ullom) Motion passed.

Recess: Mr. Schoech declared a break to reconvene in 10 minutes. **Reconvene:** Mr. Schoech reconvened the meeting at 2:54pm

<u>NABP Control and Accountability Task Force Recommendations</u> – Ms. Billingsley presented the model act language regarding some responsibilities recommended for the pharmacist in charge. The Board discussed the implications as to practice in Kansas. The consensus was to not incorporate this language into the practice act.

Kansas Medication Disposal Program – Ms. Billingsley provided an update. Ms. Billingsley is working with the state environmentalist in developing a newsletter article and a video for the website. The Board will be assisting KDHE in surveying some pharmacies currently participating in drug disposal as to benefits and suggestions to improve the system. Compliance with federal law may be a little more difficult for pharmacies because of the container requirements.

<u>Unused Medication Program</u> – Ms. Billingsley informed the Board a new statute will require regulations to be written for the program. While the Board has the responsibility, the Board must consult with KDADS in the writing of the regulations.

<u>2013 Legislation Update</u> – Ms. Billingsley provided the information for the Board's reading.

- Technician Certification Update
- E-mail form Greenhaw Pharmacy
- PTCB Certification Program Changes

<u>Regulatory Update</u> – Ms Billingsley provided the update. The Board has regulations drafted related to automation in LTCF's, fee structure, permitting schedule II electronic prescriptions, and compounding.

Board Member Reports

Dr. Garrelts asked if the inspectors were in the process of receiving the Clinical IQ training with options to attend hands on training. He also encouraged the Board to watch the proposed statutes in other states regarding physician clinic compounding.

Nancy Kirk – No report. Mr. Schoech thanked her for her services and hoped she will be at the June meeting.

Michael Lonergan – inquired as to technician registration. Ms. Billingsley related the bill is being carried over to next legislative year.

David Schoech – reported on the pharmacy technician certification meeting held at KPhA on Wednesday, March 27, 2012. The taskforce plans to meet on the 4th Wednesday of April, May and June to determine the best track for Kansas to take. The goal is to get all stakeholders input before the Bill is addressed next year in the legislature.

Investigative Member Report – Closed Cases

Mr. Ullom presented the closed cases and asked for any questions. There were no questions.

Executive Director Report

- How Does Your Board Resolve Minor Complaints?
- 2012 District Meeting Resolutions The 2013 district meeting will be in Boulder, Colorado. The NABP annual meeting is in May in St. Louis – Ms. Billingsley, Mr. Lonergan, Mr. Ullom, and Dr. Haneke will be attending.
- KMOM Letter
- Website Update Ms. Billingsley has hired a professional designer with the goal of having a more user friendly website.
- Web-based Reporting Update The site should be useful. NABP operates and most states are using the site.
- State of Kansas Social Media Policy. There are several policies attached to the agenda electronically.
- NPLEX
 - 2012 Stats
 - January 2013
 - February 2013

Staff Reports

Melissa Martin – reported on the collaboration of Iowa and NABP. They are inspecting pharmacies in Kansas that ship to Iowa. She and Mr. Kinderknecht went to PetNet with the surveyor. Ms. Martin told the Board that she, Ms. Haynes and Ms. Kenton wrote and submitted 20 questions to NABP for the MPJE.

Reyne Kenton – informed the Board on her recent visit from Ms. Billingsley and the meeting they had with Western Plains in Dodge City. Ms. Kenton said it was wonderful that Ms. Billingsley came to Dodge City and that the community appreciates the opportunity to relate concerns and differences they face in western Kansas.

Carly Haynes – shared with the Board the passing of three pharmacists: Bob Duncan, former inspector; Randy Sanders; and Roberta Hirst. Mr. Duncan has a memorial on the Board website. Ms. Haynes gave the Board a source for medication reminder capabilities on smart phone. One free app is "Dosecast". Ms. Haynes brought up the dangers of HIPAA violations from copier equipment storing information that is not erased before the equipment is disposed of or sold. She related another newspaper

article about the millions doctors and hospitals had received through the Medicaid Electronic Health Record Incentive Program.

Approval of New Pharmacists and New Registrants

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

Fifty Year Certificates

- David Burnstein, Overland Park
- Rodney Riggs, Pittsburg
- David Dyke, Topeka
- Bob Cushman, Lee's Summit
- Robert Couch, Elkhart
- Ralph Bauman, Salem
- Robert Atkins, Fairbury
- Dean Johnson, Minneapolis
- Donald Milligan, Ashland

A motion was made and seconded to accept the Fifty-Year Certificates as presented. (Worden/Ullom) Motion passed.

Executive Session:

4:18pm - A motion was made and seconded to go into executive session for 25 minutes to discuss client/attorney privileged information. The executive session is to include Mr. Forbes, Ms. Billingsley and Jim Kinderknecht. (Haneke/Lonergan) Motion passed. Mr. Schoech reconvened the meeting at 4:18pm.

Adjourn: Mr. Schoech adjourned the meeting at 4:20pm.

Friday, March 29, 2013

Meeting Called to Order: President David Schoech, R.Ph. called the meeting to order at 9:03am.

Members Present: David Schoech, R.Ph., President; Bob Haneke, Pharm D., Vice President; Jim Garrelts, Pharm. D.; Nancy Kirk, Public Member; Michael Lonergan, R.Ph; Chad Ullom, R.Ph., Investigative Member; and John Worden, Pharm. D.

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; Christina Morris, PDMP Director, and Randall Forbes, General Counsel. **Others Present:** See attached listing.

Administrative Hearing and Other Matters

- Gregory Stites (1-12790) Case 11-89. Motion for Modification of Board Order. Mr. Stites was present with counsel, Mark Stafford. Ms. Billingsley presented the case to the Board. Mr. Stafford explained the request for modification. Mr. Stites is moving to Texas and Texas will not process a license application if there are any sanctions on the license. Mr. Ullom recused himself from the discussion due to having worked with Mr. Stites. A motion was made and seconded to go into executive session for quasi-judicial deliberations at 9:13am to include Mr. Forbes, Board Counsel. (Haneke/Worden) Motion passed. Mr. Schoech reconvened the meeting at 9:26am A motion was made and seconded to deny the request. (Kirk/Haneke) Motion passed.
- Steven Stoecker (1-14152) Case 12-196. Consent Agreement. Mr. Stoecker was present with Mike Burns, employer. Mr. Worden informed the Board of his acquaintance with Mr. Stoecker. He asked Mr. Stoecker if he, Mr. Worden, should recuse himself from the case. Mr. Stoecker said Mr. Worden could remain. Ms. Billingsley presented the case to the Board. A motion was made and seconded to enter executive session for 15 minutes to discuss privileged information to include Mike Larkin, KPhA; Vicki Whitaker, KPRN; Ralph Holbrook, Chairperson of CIPP; Mr. Forbes, and Ms. Billingsley and to return to open session at 9:45am. (Worden/Haneke) Motion passed. Mr. Schoech reconvened the meeting at 9:58am. A motion was made and seconded to accept the signed Consent Agreement as presented. (Haneke/Garrelts) Motion passed.
- Adrianne Johnson (14-01608) Case 12-204. Hearing. Ms. Johnson requested the hearing but did not appear. Ms. Billingsley presented the case to the Board. Exhibits were presented: The Summary Order as Exhibit A, Ms. Martin's investigation report and the Police report are Exhibit B, and the Statement from Adrian Johnson Belcher as Exhibit C. A motion was made and seconded to revoke Adrianne Johnson's pharmacy technician registration. (Lonergan/Worden) Motion passed. Adrianne Johnson's technician registration was revoked due to diversion of controlled substances from her employer.

Recess: Mr. Schoech declared a break to reconvene in 15 minutes. **Reconvene:** Mr. Schoech reconvened the meeting at 10:28am

- Michael Fillmore (1-13456) Case13-01. Consent Order and Final Agency Order. Mr. Fillmore was present with friend Terry Miller. Ms. Billingsley presented the case to the Board and recommended approval of the Order. A motion was made and seconded to enter executive session for 15 minutes to discuss privileged information to include Mike Larkin, KPhA; Vicki Whitaker, KPRN; Ralph Holbrook, Chairperson of CIPP; Mr. Forbes, and Ms. Billingsley and to return to open session at 10:45am. (Haneke/Worden) Motion passed. Mr. Schoech reconvened the meeting at 10:40am. A motion was made and seconded to go into executive session for quasi-judicial deliberations at 10:41am to include Mr. Forbes, Board Counsel. (Ullom/Worden) Motion passed. Mr. Schoech reconvened the meeting at 10:45am. A motion was made and seconded to accept the signed Order. (Kirk/Garrelts) Motion passed.
- Wendy Villers (1-11827) **Case12-75**. Motion to Amend Board Order. Ms. Villers was present without counsel. Ms. Billingsley presented the case to the Board. A motion was made and seconded to enter executive session for 15 minutes to discuss privileged information to include Mike Larkin, KPhA; Vicki Whitaker, KPRN; Ralph

Holbrook, Chairperson of CIPP; Mr. Forbes, and Ms. Billingsley and to return to open session at 11:05am. (Haneke/Worden) Motion passed. Mr. Schoech reconvened the meeting at 11:02am. A motion was made and seconded to go into executive session for quasi-judicial deliberations at 11:04am to include Mr. Forbes, Board Counsel. (Garrelts/Haneke) Motion passed. Mr. Schoech reconvened the meeting at 11:12am. A motion was made and seconded to deny the motion to amend the Board Order for Ms. Villers at this time. (Kirk/Lonergan) Motion passed.

Executive Session:

A motion was made and seconded to go into executive session for 4319(b)(5) for 15 minutes to protect the privacy rights. The executive session is to include Mr. Forbes, Ms. Billingsley, and Mr. Kinderknecht. (Haneke/Garrelts) Motion passed. Mr. Schoech reconvened the meeting at 11:30am.

Surrender of License

• Mary Richardson (1-09936) **Case 11-22**. The Board reviewed whether to accept the surrender of license of Mary Richardson in lieu of continuing her case. A motion was made and seconded to accept the surrender of Ms. Richardson's license to practice as a pharmacist in Kansas. (Garrelts/Ullom) Motion passed.

Board Review

Notification of Summary Orders

- Advanced Compounding Pharmacy (applicant) **Case 13-04.** No hearing was requested.
- Abbey Beezley (14-07073) Case 13-25. No hearing was requested.
- Yolanda Woods (14-01165) Case 12-186. No hearing was requested.
- Jeffrey Vaughn, (Technician Applicant). Case 12-208. No hearing was requested.

Notification of Emergency Orders

• RX3 Compounding Pharmacy (22-02818) Case 13-30.

Notification of Cease and Desist

 Village Fertility Clinic (not registered) Case 13-3. Village Fertility Clinic was ordered by the Massachusetts Board of Registration in Pharmacy to cease and desist compounding sterile products due to a black particulate in the product. The pharmacy had shipped product into the State of Kansas without being registered. Village Fertility Clinic received a cease and desist letter from the Kansas Board of Pharmacy.

Board Discussion of Tabled Item

<u>Budget</u> – The Board discussed the fees charged for licenses, registrations and permits. The proposal is to contact the Legislative committee and the Governor explaining the need of a new inspector and funds to increase our ability to regulate pharmacy compounding and all the other entities that the Board registers. Public safety should not be compromised due to the inability to use the funds the Board currently has. The Board consensus was to wait until the Appropriations bill was finalized before the Board authorizes a fee reduction. Adjourn: Mr. Schoech adjourned the meeting at 12:08pm.