

Kansas State Board of Pharmacy
Minutes of the January 16 & 17, 2014
Board Meeting

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

Thursday, January 16, 2014

Meeting Called to Order: President David Schoech called the meeting to order at 9:04am.

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

Staff Present: Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph., Licensed Pharmacy Inspector; Carly Haynes, R.Ph., Licensed Pharmacy Inspector; Melissa Martin, Compliance Officer; Reyne Kenton, Compliance Officer; Marty Singleton, Assistant Director; Jackie Yingling, Budget 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 presented. (Haneke/Worden) Motion passed.

Approval of the November 21 & 22, 2013 Minutes:

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

Presentation

Use of Suboxone® in Drug Treatment – Dr. Hiten Soni presented the information. Dr. Soni stated he has no financial interest in Reckitt Benckiser. Dr. Soni discussed the pharmacology of the drug Suboxone®. The Board asked questions as to when a pharmacist is safe to be back in the pharmacy if they have an addiction. Dr. Soni explained that it is all dependent on the addicted pharmacist and when they return to a rational good choice baseline if they had a good baseline. There is no way to predict who will or won't make good choices because everyone has different "go → no go" response. An addicted person has made the choice that the benefit of using the "drug" was greater than the risk. Use increases as the addiction progresses because the person chases the feeling of the original high which they will never achieve. This explains why overdoses occur and why the risk of death increases. To return to practice, a pharmacist must make good choices and be determined to make good choices and recognize the risk that continued drug use would be harmful to their professional career.

Recess: Mr. Schoech declared a break to reconvene in 10 minutes.

Reconvene: Mr. Schoech reconvened the meeting at 11:00am

Board Discussion

Budget – Ms. Yingling presented the budget for review. The projection of the budget to reduce the pharmacy fee fund to approximately \$400,000 will take about 5 years.

- Financial Report – electronically attached to the agenda
- KBOP Budget – State Finance Council Resolution 13-634. The resolution allows for the addition of another inspector.

KTRACS – Marty Singleton presented the report to the Board. Mr. Singleton provided the status update, the draft report to the legislature, information that will be shared with the Advisory Committee, the Kansas PMP initiatives (LACIE and KHIN), and the AWARxE report. Threshold letters will resume now that the system is operational. KTRACS is reaching out to licensees to get registered and use the system to obtain information to aid in patient treatment or return to using the information KTRACS can provide. Mr. Schoech discussed delinquent pharmacy submissions and what the Board needs to do to enforce the mandatory submission of controlled substance dispensing records to KTRACS.

Pharmacy Technician National Certification – Ms. Billingsley presented the proposed language of K.S.A. 65-1663. The Board discussed if any other changes needed to be considered. Representative Tom Sloan requested Ms. Billingsley give an update at the Vision 20/20 Committee on January 22, 2014. Dr. Haneke suggested the Board be proactive in the formation of proposed regulations and what standardized tests would be used. The Board discussed mandatory continuing education for technicians and that the certification needs to be maintained for renewal. The Board needs the authorization to create levels of technicians where some may not require certification to function as a technician.

The Board consensus was to allow Ms. Billingsley to draft new language and to use either a new bill or a substitute bill at her discretion.

Recess: Mr. Schoech recessed the meeting for lunch at noon to reconvene at 1:15pm.

Reconvene: Mr. Schoech reconvened the meeting at 1:20pm.

Requests

1. **U.S. Consumer Product Safety Commission** – Ms. Billingsley advised the Board that the U.S. Consumer Product Safety Commission inquired whether the Board of Pharmacy would enter into a Memorandum of Understanding with them to conduct inspections for child safety packaging compliance in pharmacies. The inspectors would be commissioned from the U.S. Consumer Product Safety Commission. Unannounced inspections would be used to look at the will call sections of pharmacies which have large populations of senior citizens. A motion was made and seconded to approve an MOU with the U.S. Consumer Product Safety Commission. (Worden/Haneke) Motion passed
2. **FDA Outsourcing** – A letter was presented from Ms. Hamburg, FDA. The letter is attached electronically to the agenda. The FDA has requested that states encourage out of state compounders who ship into their state to voluntary

register with the FDA. The letter was also sent to the Kansas Department of Health and Environment. No action was taken by the Board.

Reports

NPLEx Report – Ms. Billingsley presented the final draft of the annual report to the Senate standing committee on Public Health and Welfare and the House standing committee on Health and Human Resources reviewing the effectiveness of the NPLEx program in Kansas. The data from 29 states is aggregated in order to track purchases of PSE products through NPLEx. Pharmacies have adjusted to using the NPLEx system as well as the patients. The Board's collaboration with law enforcement continues to indicate that NPLEx is a valuable tool in detecting criminal activity. Therefore, the Board does not have any plans to recommend legislative change during 2014. The report is attached electronically to the agenda.

Collaborative Practice Pharmacy Patient Care Services – Ms. Billingsley provided the Board with a resource for pharmacist called "Collaborative Practice Pharmacy Patient Care Services provided by the National Center for Disease Control. CMS and Kancare both require managed care plans and this involves medication therapy management and collaboration between pharmacists and physicians regarding patient outcomes. The CDC information has a map of the United States which shows that Kansas is one of four states that has such limited authority that it would be difficult to provide the type of service required in a managed care plan. All prescription drug plans under Medicare Part D are also required to offer MTM services to patients with high annual drug spending and multiple chronic conditions. Some plans offer MTM services to all beneficiaries. The definition of the practice of pharmacy is outdated and the University of Kansas School of Pharmacy indicated that they would support some type of change to the definition. Dr. Haneke requested any and all support to move this forward, legislatively. A motion was made and seconded to review the task force documents and use the information to draft a bill updating the practice of pharmacy. The proposed bill will be forwarded to the Board members for review. (Garrelts/Worden) Motion passed.

Investigative Member Report – Closed Cases. Mr. Ullom asked the Board to consider developing a policy as guidance for discipline on drug/alcohol impairment. Dr. Soni was invited to give background information as to why people abuse drugs and how or when the pharmacist may truly be safe to work in a pharmacy with unlimited access with drugs. Dr. Soni specifically focused on how and where Suboxone® fits into a treatment plan or a bridge from illicit use. The Board asked if there is any documentation as to recidivism. KPhA and the KsPRN program will gather their recidivism data and present it to the Board at the next meeting. Mr. Ullom presented the closed cases and asked for any questions. There were no questions.

Approval of New Pharmacists and New Registrants

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

Board Member Reports

Jim Garrelts – Accountable Care will need more collaboration between the hospital and ambulatory care services. The need is to decrease readmission to the hospital within a 30-day period. Some chain pharmacies are reaching out to hospitals to provide a continuity of care to help patients remain compliant and out of the hospital.

Bob Haneke – inquired as to the KU pilot project. They will be placed on the next meeting agenda for an update.

Michael Lonergan – Quality incentives are impacting all facets of pharmacy and pharmacy will need to be responsive and attentive to the changes being required. Mr. Lonergan inquired as to Bio-similar drugs and where the Board was on the issue. NABP has no statement and he suggested the Board follow the FDA's lead. Dr. Haneke said that not all of the bio-similar drugs are the same but that they differ in how they come through the process.

Cheri Pugh – thanked the profession of pharmacy for the timely services in care during the outbreak of the H1N1 flu which affected her granddaughters.

David Schoech – inquired as to where the state is in terms of e-prescribing. Ms. Billingsley stated the regulations are in the process.

Chad Ullom – asked if the application form on PIC changes could be modified so the corporate officer no longer had to sign the form. He also requested the website verification process for pharmacies give the name of the PIC.

Executive Secretary Report

NABP – The National meeting is in Phoenix, Arizona in May 2014. The voting delegate needs to be identified. There are travel scholarships available.

District 6, 7, & 8 Meeting will be September 21-24, 2014 at Grouse Mountain Lodge in Whitefish, Montana.

The Federal Trade Commission continues to pursue state board actions that appear to infringe on free trade. Board members are to represent the public and promote public safety and not protect personal business interests.

Staff Reports

Reyne Kenton – reported on the interactive NABP meeting she and Ms. Billingsley attended in December. Time was spent on how to build a case, corporate versus pharmacy responsibilities, and PIC self-inspection reports. As an example – Oregon uses self-inspection reports to stop the complaint not knowing something was required. The report helps increase compliance, decrease the time looking for inspection documents and allows more communication addressing problems.

Carly Haynes – A pharmacy motto from Wyatt Earp would be very appropriate: “Fast is fine but accuracy is everything!”

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

Reconvene: Mr. Schoech reconvened the meeting at 2:55pm

Administrative Hearing

- Nick Bluel (1-13763) Case 13-140. Nick Bluel was present with counsel, Darin Conklin. A motion was made and seconded to enter into executive session for 20 minutes to receive and discuss records regarding peer review pursuant to K.S.A. 65-4915 to return at 3:20pm and to include Randy Forbes, Debra Billingsley, the KsPRN representatives - Vicki Whitaker, Mike Larkin, and Ralph Holbrook. (Haneke/Pugh) Motion passed.
Mr. Schoech reconvened the meeting at 3:35pm.
A motion was made and seconded to enter into executive session for quasi-judicial deliberations at 3:35pm to include Mr. Forbes, Board Counsel. (Haneke/Lonergan) Motion passed.
Mr. Schoech reconvened the meeting at 4:02pm
A motion was made and seconded to modify the Consent Agreement restrictions to allow Mr. Bluel to return to work and leave the case open for further investigation and review. (Lonergan/Haneke) Motion passed.

Summary Orders

- Danielle Eagles (pharmacy technician application) **Case 13-79**. Ms. Eagles was not present. The Summary Order was to deny the registration of Ms. Eagles as a pharmacy technician.
- Walgreens #12815 (2-10269) **Case 13- 58**. Mr. Ullom recused himself from the discussion due to employment with Walgreens. Mr. Schoech recused himself from the discussion due to employment with Walgreens.
Walgreens did not have a representative present specifically for this case. Clay Pingel was present for the Walgreens 13-133 case. The Summary Order was a fine for no pharmacist-in-charge within the allowed time period. Walgreens has paid the fine.
- Ryan Revoir (pharmacy technician application) **Case 13-152**. Mr. Revoir was not present. The Summary Order was to deny the registration of Mr. Revoir as a pharmacy technician.
- Walgreens #5768 (2-09497) **Case 13-133**. Mr. Ullom recused himself from the discussion due to employment with Walgreens. Mr. Schoech recused himself from the discussion due to employment with Walgreens.
Clay Pingel was present representing Walgreens. The Board discussed the reasons pertaining to the inability to obtain a pharmacist-in-charge in a timely manner. Several suggestions were made and Mr. Pingel will pursue a resolution. Walgreens has paid the fine.
- Johnell Davis (pharmacy technician application) **Case 13-66**. Johnell Davis was not present. The Summary Order was to deny the registration of Johnell Davis as a pharmacy technician.

A motion was made and seconded to accept the summary orders for Danielle Eagles, Ryan Revoir, Johnell Davis, Walgreens #12815, and Walgreens #5768. (Worden/Garrelts) Motion passed.

Administrative Proceedings

- Udechukwunyere Chukwukelu (1-15109) **Case 13- 109** Ms. Chukwukelu was present via phone. Ms. Chukwukelu told the Board that she had moved and in the process she could not retrieve her continuing education. A motion was made and seconded to modify the Summary Order to fine Ms. Chukwukelu \$500 and provide proof of enrollment in the NABP CPE Monitor, and accept the continuing education she had submitted as replacement. The Board will allow Ms. Chukwukelu to pay the fine in payments. (Loneragan/Pugh). Motion passed.

Administrative Hearings

- Kimberly Turner (1-11436) **Case 13-130**. Mr. Schoech recused himself because he knows the licensee. Ms. Turner was not present. Ms. Turner has voluntarily chosen to surrender her license to practice pharmacy in the State of Kansas. A motion was made and seconded to accept the Final Order and the voluntary surrender of Ms. Turner's pharmacist license. (Worden/Garrelts) Motion passed.

Adjourn: Mr. Schoech adjourned the meeting at 4:50pm.

Friday, January 17, 2104

Meeting Called to Order: President David Schoech called the meeting to order at 9:00am.

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

Staff Present: Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph., Licensed Pharmacy Inspector; Carly Haynes, R.Ph., Licensed Pharmacy Inspector; Melissa Martin, Compliance Officer; Reyne Kenton, Compliance Officer; Marty Singleton, Assistant Director; and Randall Forbes, General Counsel.

Others Present: See attached listing.

Mr. Schoech called the regular meeting to order at 9:04am.

Administrative Hearings

- David Neil (1-09830) **Case 13-144**. Mr. Ullom recused himself from the discussion due to employment with Walgreens. Mr. Schoech recused himself from the discussion due to employment with Walgreens.

Mr. Neil was present without counsel. Mr. Forbes presented the information in the signed Final Agency Order and recommended an executive session to receive protected information. 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 return to open session at 9:30am and to include Randy Forbes, Debra Billingsley, the KsPRN representatives - Vicki Whitaker, Mike Larkin, and Ralph Holbrook. (Haneke/Worden) Motion passed.

Mr. Schoech reconvened the meeting at 9:20am.

A motion was made and seconded to approve the Final Agency Order with two amendments. First – To prohibit Mr. Neil from practicing pharmacy in a dispensing role for 12 months. Second – To allow Mr. Neil to have the Order modified at the end of the intensive outpatient treatment based on information stating he is able to work safely. Mr. Neil was agreeable to the amendments. (Haneke/Pugh). Motion passed.

Recess: Mr. Schoech declared a break to reconvene when the next case arrives.

Reconvene: Mr. Schoech reconvened the meeting at 9:37am

- Leigh Angell (1-12362) **Case 13-141.** Ms. Angell was present without counsel. Mr. Forbes presented the information in the signed Final Agency Order and recommended an executive session to receive protected information. 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 return to open session at 10am and to include Randy Forbes, Debra Billingsley, the KsPRN representatives - Vicki Whitaker, Mike Larkin, and Ralph Holbrook. (Haneke/Pugh) Motion passed.

Mr. Schoech reconvened the meeting at 9:44am.

A motion was made and seconded to approve the Final Agency Order with Ms. Angell (Haneke/Lonergan). Motion passed.

Recess: Mr. Schoech declared a break at 9:46am to reconvene when the next case arrives.

Reconvene: Mr. Schoech reconvened the meeting at 10:15am

- Angela Little (1-14114) **Case 13-132.** Ms. Little was present without counsel. Mr. Forbes presented the information in the signed Final Agency Order and recommended an executive session to receive protected information. 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 return to open session at 10:25am and to include Randy Forbes, Debra Billingsley, the KsPRN representatives - Vicki Whitaker, Mike Larkin, and Ralph Holbrook. (Garrelts/Haneke) Motion passed.

Mr. Schoech reconvened the meeting at 10:23am.

A motion was made and seconded to approve the Final Agency Order for Ms. Little with the added stipulation that she may return to work in a non-dispensing role for 6 months with Board review at the end of 6 months. (Haneke/Lonergan). Ms. Little was agreeable with the added stipulation. Motion passed. The added stipulation was written on the Order and initialed by the president, Mr. Schoech, and Ms. Little.

Recess: Mr. Schoech declared a break at 10:25am to reconvene when the last case arrives.

Reconvene: Mr. Schoech reconvened the meeting at 10:30am.

- Steven Stoecker (1-14152) **Case 13-142.** Mr. Stoecker was present without counsel. Dr. Worden asked Mr. Stoecker if he needed to recuse himself since they are acquaintances. Mr. Stoecker said Dr. Worden could stay and hear the case. Mr. Forbes presented the information as stipulated in the signed Final Agency Order and recommended an executive session to receive protected information. 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 return to open session at 10:50am and to include Randy Forbes, Debra Billingsley, the KsPRN representatives - Vicki Whitaker, Mike Larkin, and Ralph Holbrook. (name/name) Motion passed.

Mr. Schoech reconvened the meeting at 11:50am.

A motion was made and seconded to amend the Final Agency Order with Mr. Stoecker.

The amendments:

1. Re-enroll in CIPP today (January 17, 2014)
2. Limit professional practice to a non-dispensing role (zero access to drugs) for one year. May request reconsideration in one year.
3. Submit quarterly reports to the Board from the doctor treating the addiction and CIPP
4. Cannot serve as PIC, pharmacist-in-charge
5. Limit work to not more than 80 hours in a two week period of time.

(Loneragan/Haneke). Motion passed. Mr. Forbes will place the amended order dated January 17, 2014 in the mail for signatures on Tuesday, January 21, 2014. Mr.

Stoecker gave verbal agreement to the Board on the amendments. The documents may be mailed to Mr. Stoecker's home per Mr. Stoecker.

Cheri Pugh left the meeting at 11:58am.

Board Discussion

CIPP – The Board discussed with the KsPRN representatives when a pharmacist could or should return to work. The discussion included the possibility of a pharmacist taking Suboxone® and whether they should or should not work. The consensus was the decision should be based on a recommendation from a physician with a specialty the treatment of addiction.

Adjourn: Mr. Schoech adjourned the meeting at 12:40pm.