

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

Via Christi – St. Joseph Campus  
3600 E. Harry  
3rd Floor, Conference Room A  
Wichita, KS 67218

**Thursday, October 16, 2014**

**Meeting Called to Order:** President Robert Haneke called the meeting to order at 9:05am.

**Members Present:** Robert Haneke, Pharm D., President; Chad Ullom, R.Ph., Vice President; Jim Garrelts, Pharm. D.; Michael Lonergan, RPh., Investigative Member; Cheri Pugh, Public Member; David Schoech, R.Ph.; and John Worden, Pharm. D., Alternate Investigative 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, PDMP Director; and Randall Forbes, General Counsel.

**Others Present:** Maggie Blowey, KU 6P Intern. For others: See attached listing.

**Approval of the Agenda:**

A motion was made and seconded to add a discussion of the Compounding Regulations status. The item will be added to the afternoon discussion.

(Garrelts/Worden) Motion passed.

A motion was made and seconded to approve the agenda as amended (Ullom/Garrelts) Motion passed.

**Approval of the July 24 & 25 Minutes:**

A motion was made and seconded to approve the minutes as printed.

(Schoech/Worden) Motion passed.

A motion was made to adjourn the regular meeting for the Public Hearing

(Worden/Lonergan) Motion passed.

Dr. Haneke adjourned the regular meeting at 9:06am.

A motion was made and seconded to enter the Public Hearing (Schoech/Ullom) Motion passed.

Dr. Haneke convened the Public Hearing at 9:07am.

**Public Hearings on Proposed Administrative Regulations**

**K.A.R. – 68-21-7. Drugs of Concern**

Dr. Haneke asked for public comment.

Ms. Billingsley provided the following letters ---

- The Attorney General's Office stating the proposed regulation "does not present any legal concerns".
- The Joint Committee on Administrative Rules and Regulations had no comments that would result in changes to the proposed regulation.
- Hein Law Firm, Derek R. Hein, on behalf of Kansas Association of Chain Drug Stores suggested adding all C-V drugs to the PDMP to eliminate the need for continual additions to the drugs of concern list. Their other suggestion was to allow ample time for the changes to be made.

The following people spoke on the regulation change:

Derek Hein representing KACDS

Pat Hubbell representing CHPA

Susan Zalenski representing Johnson & Johnson

Dr. Haneke closed the public hearing at 9:22am.

A motion was made and seconded to reconvene the regular meeting. (Ullom/Worden)

Motion passed.

Dr. Haneke called the regular meeting back into session at 9:23am.

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

(Schoech/Lonergan)

Roll call: Dr. Garrelts – Yes, Dr. Haneke – Yes, Dr. Lonergan – Yes, Ms. Pugh – Yes,

Mr. Schoech – Yes, Mr. Ullom – Yes, and Dr. Worden – Yes.

The motion passed. The regulation will become effective 90 days after publication in the Kansas Register.

## **Reports and Discussion**

NPLEx Report / Legislative Report Draft – Ms. Billingsley presented the information to the Board. The Legislative Report Draft is attached electronically to the agenda. A motion was made and seconded to approve the report to the legislators.

(Schoech/Ullom) Motion passed.

CHPA-PSE Information – Pat Hubbell provided the information and there was discussion on a potential law enforcement request that felony methamphetamine convictions create a stop sale in the NPLEx system.

## **Pilot Project Requests**

1. ***Omnicare of Wichita*** – Kara Tindal and William Maguire represented Omnicare. The proposal requests approval to use an Omnicell Automated Dispensing Machine for first doses and emergency medications. The machines can narrow who accesses the machines and who does not scan the drug. The pilot requests approval for allowing an RN to place the drugs in the Omnicell. Omnicare is requesting approval to pilot in two facilities located in Wichita. Omnicare must be able to obtain DEA registrations for the machines before any controlled substances may be placed in them. The Board requested other information be provided. Omnicare will be placed on the January board meeting.
2. ***Wesley Medical Center*** – Joan Kramer, Jack Bond, and Bob Elsbernd represented Wesley. Ms. Kramer made the presentation as to number of medications dispensed and the near nonexistent error rate. Patients are taking

fewer medications and therefore have less potential for drug interactions that would require hospitalization. The Board asked if the facility had documentation to show a decrease in hospitalizations and emergency room visits – Mr. Bond said the statistics were not formalized yet, but the trends show that hospitalizations and ER visits for these patients have decreased. The request was made to expand the pilot to test for reproducibility of the results. The expansion is to two off-site facilities that would be serviced by the same pharmacy. The Board expressed appreciation as to the transparency of the pilot. A motion was made and seconded to approve the expansion of the pilot to two off-site facilities. (Schoech/Garrelts) Motion passed.

Recess: Dr. Haneke declared a break to reconvene in 15 minutes.

Reconvene Dr. Haneke reconvened the meeting at 10:49am

### **Reports and Discussion**

**KTRACS** – Marty Singleton presented the report to the Board. The report included:

- KTRACS Records – 261 individuals exceeded the threshold. The top individual visited 23 prescribers and 27 dispensers. The system is receiving 1,224 queries per day and the consolidation rate has decreased.
- Harold Rogers Grant for enhancements has been amended because the enhancement request made when the grant was requested became obsolete with the change to AWARxE PDMP software. KTRACS is looking into options to have all people licensing as prescribers or dispensers be automatically registered in KTRACS through licensure and renewals of their license. Automatic registration would encourage utilization of the system by eliminating an extra step. Although the Board does not use Systems Automation it is one licensing contract vendor with the state that the Board can use for licensing. The Board currently uses Access for their licensing software and it is not robust enough to accommodate an integration. Mr. Singleton is checking to see if Systems Automation could accommodate this type of integration since the Board is reviewing whether to transition to Systems Automation licensing software. Other licensing boards would have to integrate into their own licensing system to accomplish this initiative if it were to move forward.
- Via Christi
- LACIE
- Kroger – The MOU is almost complete and hopefully will be reviewed by January Board meeting.
- KHIN – An MOU has been signed and they are working with Via Christi. Mr. Singleton gave the Board information regarding Appriss moving to a new platform called Gateway. This change will affect KHIN in particular because they currently are using the Via Christi system, The Board discussed whether the grant project should continue in its current format since it will be obsolete in 2015. Kroger and any other entity the Board allows to access KTRACS information will also use Gateway but they all have the capability to do so. Mr. Singleton will initiate a phone call with KHIN, Via Christi and Gateway to determine how the project should move forward with this new information.

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

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

## **Reports and Discussion**

National Transportation Safety Board Letter – Ms. Billingsley presented the letter from NTSB and their concerns of persons using modes of transportation under the influence of pain medications. The NTSB requested an article be placed in the newsletter as information to pharmacists. The article says pharmacists should talk to their patients about concerns with impairment while using drugs that can cause impairment. The consensus was to place the article on website with information in the newsletter referencing the website.

**Recess:** Dr. Haneke recessed the meeting for lunch at 11:54am to reconvene at 1pm.

**Reconvene:** Dr. Haneke reconvened the meeting at 1:05pm.

Pharmacy Technician Education Task Force Update – Mr. Schoech reported on the meeting. He said the discussions went well and the task force is beginning to come to some consensus. Grandfathering may be up to 5 years. CE will be required. Trainee status may last for up to 24 months. Ratio was discussed but will be left to the Board. Biggest point of discussion was the training component and if it will be required. Several groups are trying to develop training. Next meeting will be November 7, 2014 in the Board of Healing Arts board room from 2:00-4:00. Mr. Schoech believes regulations may be drafted in the first part of 2015 with the hope to have them approved and in place by July 2015.

## **Reports and Discussion - continued**

Hydrocodone – Ms. Billingsley clarified that the DEA has no problem using the C-II drugs to refill the C-III hydrocodone. Some drugs have a new label stuck over the old label. Labels should not be peeled as that would be construed as misbranding. The DEA says the pharmacy must transfer if there are refills and another pharmacy will fill the prescription. The pharmacy still has a choice to fill only as C-IIs. The Board will update their information sheet and put it on the Board website.

## **Introductions**

Dr. Garrelts introduced his residents: Anthony Neises, Rishonna Martin, and Brett Unruh. Dr. Garrelts also introduced Mallory Schroeder the current pharmacy student at Via Christi. Ms. Billingsley introduced the Board intern Maggie Blowey, 6P.

## **Request to schedule 2,5-dimethoxy-4-methyl-n-(2-methoxybenzyl)phenethylamine (25D-NBOME), as an analog of 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOME) –**

An Assistant District Attorney from the Johnson County District Attorney's Office advised the Board that it was charging a juvenile with possession of 25D-NBOME and requested that the Board review 25D-NBOME to determine whether it is an analog of 25C-NBOME and should be scheduled. The Assistant District Attorney also provided the Board a

copy of the arrest report and criminal lab report. The Board reviewed the information received from the Assistant District Attorney and other medical and research information concerning the drugs listed above. The Board determined to consider if the 25D is an analog of 25C and if the drug is a hazard to the public.

The Board discussed the information provided and determined the following:

1. It had received notice pursuant to K.S.A. 21-5715.
2. 25D-NBOME is an analog, as defined at K.S.A. 65-4101(bb), of the controlled substance 25C-NBOME.
3. Considering the factors specified in K.S.A. 65-4102(e), 25D-NBOME is an imminent hazard to the public safety.
4. Preservation of the public health, safety and welfare necessitates and makes desirable putting into effect a temporary regulation scheduling 25D-NBOME prior to the time a regulation could be put into effect if the Board were to comply with the notice, hearing and publication requirements of the Rules and Regulations Filing Act, K.S.A. 77-415 et seq., or prior to the effective date prescribed by K.S.A. 77-426, and amendments thereto.

A motion was made and seconded to adopt K.A.R. 68-20-31 as a temporary regulation scheduling of 2,5-dimethoxy-4-methyl-n-(2-methoxybenzyl)phenethylamine (25D-NBOME), as an analog of 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOME) as a Schedule I controlled substance and to initiate the procedure to adopt a regulation pursuant to K.S.A. 65-4102(a) and pursue permanent scheduling with the legislature. (Lonergan/Ullom). The Board discussed that they have met the intent of the Legislature and there is an individual currently charged.

Roll Call: Dr. Garrelts – Yes, Dr. Haneke – Yes, Dr. Lonergan – Yes, Ms. Pugh – Yes, Mr. Schoech – Yes, Mr. Ullom – Yes, and Dr. Worden – Yes. Motion passed.

Mr. Lonergan suggested the office develop a form to answer all the pertinent questions required to streamline the process in the future.

**Budget** – Ms. Yingling (by phone) gave the budget report. The budget analyst wanted the Board to know the state may sweep the pharmacy fee funds as they continue to look for money because of the state's budget problems.

**Attorney General Opinion No. 2014-07 Re: Open Meeting Act** – Ms. Billingsley sent the opinion to Mr. Forbes for his review and to provide information to the Board. Mr. Forbes said the Investigation committee does not fall under the requirements of KOMA because there is only one Board member present. KOMA requires a majority of the total members to be in attendance to have a meeting and be subject to KOMA. Staff reports on investigations fall under the Administrative Procedures Act. The opinion is to continue as we have in the past.

**Good Storage and Shipping Regulations** – Ms. Billingsley provided the information from USP 36 on” USP<1079> *Good Storage and Distribution Practices for Drug Products*”. The Board does not currently have any regulations or statutes specifically concerning storage and shipping. The Board will need to open the Wholesale Distributors statutes and regulations to address the federal changes. While these are open would present the ideal time to address storage and shipping. Mr. Lonergan volunteered to help draft some language.

**Drug Supply Chain Security Act - FDA Guidance** – Ms. Billingsley provided the information she received from the NABP Executive Meeting. Many of the cases are registering every entity in the process of drugs manufacturer to end user. Ms. Billingsley stated that Oklahoma invited all stakeholders to the table to review their statutes and regulations and that they did a complete overhaul. As third party logistic providers are removed from the wholesale distributor statutes, the Board must request the legislature to give authority to register third party logistic providers. There is a gap in regulatory oversight with the changes in the federal law and that state should make sure that the gap is filled.

**Investigative Member Report – Closed Cases.** Mr. Lonergan presented the closed cases and asked for any questions. There were no questions.

**Recess:** Dr. Haneke **declared a break to reconvene in 15 minutes.**

**Reconvene** Dr. Haneke **reconvened the meeting at 3pm**

## **Reports**

**District 6 Meeting** – Ms. Billingsley, Mr. Lonergan, Mr. Ullom, and Mr. Schoech attended the meeting. District 6 has been meeting with Districts 7 and 8. 2015 was the year the meeting was to come to Kansas; however the multi-districts decided to meet in Las Vegas for 2015. If the rotation continues Kansas will host in 3 years.

## **Executive Director Report**

- NABP Executive Director Forum – Ms. Billingsley attended the Executive Forum on Tuesday and Wednesday in Illinois.
- PARE: A multidimensional tool designed as a 210 question test. The test is 50% drugs, 25% ethics, and 25% clinical. The test grades each portion separately. The test is given 4 times per year with each testing session open for 2 weeks.
- MPJE will be convening a standards setting committee and will meet November 13 & 14, 2014. NABP is looking for interested members to serve on the committee.
- The Executive Directors discussed that the State Boards look at requiring a pharmacist to practice 2 years before accepting a pharmacist in charge position.
- The Executive Directors discussed that a Board place a stipulation of “No PIC” as a possible penalty if the pharmacist faces disciplinary action.
- The annual meeting of NABP will be May 16-19, 2015 in New Orleans.
- The Joint Policy on Pain is still in review by a committee that Ms. Billingsley is on and they hope to have the final version for the January meeting.
- Physician Assistant regulations are being written by the Board of Healing Arts. The PA can now dispense a 72 hour supply of medications when the patient

needs them and the pharmacies are closed. The statute is not effective until 2015. This does not mean they can enter a hospital pharmacy and remove drugs to send home with a patient. The only drugs a hospital can supply are the drugs prepackaged and labeled for Emergency Room dispensing and only enough until a pharmacy can fill the prescription. Ms. Billingsley will discuss the pharmacy act rule with the Board of Healing Arts as they complete their regulations.

### **Staff Reports**

Jim Kinderknecht and Melissa Martin

DEA Meeting – Mr. Kinderknecht, Ms. Martin, Mr. Singleton, and Ms. Billingsley attended the national meeting hosted by the DEA. The DEA discussed the disposal regulations. A pharmacy must have their DEA registration updated to indicate they are a disposer. The pharmacy must have numbered liners and a receptacle that is permanently affixed to the ground. The DEA will be completing random audits of those pharmacies.

### **Board Member Reports**

Jim Garrelts – suggested the Board consider developing a position paper as to what technician may do outside the normal pharmacy activities.

Michael Lonergan – reported he attended the NABP Task Force meeting on Medication Synchronization. At this time NABP did not want the meeting particulars to be shared.

David Schoech – attended the NABP Task Force on the Standards for Use of PMP Data with Debra Billingsley but also cannot report on the particulars due to confidentiality agreements.

John Worden – told the Board about the Rural Hospital Summit in Salina. Ms. Billingsley and Ms. Haynes had attended to present information on items of concern for the small hospitals.

### **Reports and Discussion**

Collaborative Practice Regulations – Dr. Garrelts gave an update. Representatives have not been appointed by the Board of Healing Arts. Healing Arts was to appoint their members at their October meeting but due to a death of a board member the meeting was canceled. BOHA will most likely meet in December. The pharmacy committee will meet on November 7, 2014 at the DCF Office in Emporia to begin considerations of regulations that they can use when they meet with the physician group. The meeting will be open to the public.

Collaborative Practice Pharmacy Patient Care – Lindsey Hogg, Pharm. D. presented the information. The biggest challenge she envisions in gaining the support of prescribers. The numbers she provided from her practice setting show patients having better outcomes than just through doctor appointments. This translates into fewer hospital admissions, better lab values, lower costs, and better patient outcomes.

Compounding Regulations – Ms. Billingsley reported the AG’s office must re-stamp the regulations. Then there must be a 60-day notice of hearing before a hearing can take place.

**Adjourn:** Dr. Haneke adjourned the meeting at 4:06pm.

### **Friday, October 17, 2014**

**Meeting Called to Order:** President Robert Haneke called the meeting to order at 9:04am.

**Members Present:** Robert Haneke, Pharm D., President; Chad Ullom, R.Ph., Vice President; Jim Garrelts, Pharm. D.; Michael Lonergan, RPh., Investigative Member; Cheri Pugh, Public Member; David Schoech, R.Ph.; and John Worden, Pharm. D., Alternate Investigative 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; and Randall Forbes, General Counsel.

**Others Present:** See attached listing.

### **Administrative Hearings**

- James Williams, R.Ph. **Case 14-70.** Mr. Williams was present without counsel. Mr. Forbes requested an executive session to receive confidential information from the impaired pharmacist program. A motion was made and seconded to enter into executive session to receive and discuss records regarding peer review pursuant to K.S.A. 65-4915 to include Randy Forbes, Debra Billingsley, Melissa Martin and the KsPRN representatives - Vicki Whitaker and Ralph Holbrook. (Worden/Garrelts) Motion passed. Dr. Haneke reconvened the regular meeting at 9:19am. A motion was made and seconded to modify the stipulation to include a conditional order of acceptance of the CIPP contract and that Mr. Williams may return to work when he is approved through KsPRN and that he cannot act as a pharmacist in charge. (Worden/Ullom) Motion passed.
- Ankeyta White, Pharmacy technician (14-11873) **Case 14-21.** Ms. White was not present. Mr. Forbes stated he had been working with Ms. White’s attorney. Mr. Forbes proposed that the Board accept a stipulation requiring Ms. White to submit to random UA for no less than 365 days with KsPRN monitoring (Drug testing only), that Ms. White may not test positive for anything. By voluntary accepting and signing the stipulation, Ms. White may keep her technician registration as long as she is in compliance with the stipulation. A motion was made and seconded to accept the proposed stipulation with Ms. White. (Schoech/Lonergan) Motion passed.



- Jessica Allen, Pharmacy technician applicant **Case 14-60**. Ms. Allen was present without counsel. Mr. Forbes presented seven exhibits for the Board's review. Ms. Allen was sworn in and she accepted the exhibits. Dr. Haneke accepted the exhibits. Ms. Allen was given an opportunity to address the Board.

Mr. Lonergan recused himself from the discussion due to employment with Optum Rx.

Ms. Allen explained her job functions for OptumRx and that she primarily works from home. She processes prior authorizations when patients' insurance require. Ms. Allen was never charged nor convicted of any crime.

A motion was made and seconded to enter into executive session for quasi-judicial deliberations at 9:52am to include Mr. Forbes, Board Counsel. (Garrelts/Schoech) Motion passed.

Dr. Haneke reconvened the meeting at 9:58am.

A motion was made and seconded to approve the pharmacy technician registration for Jessica Allen with no drug access. If Ms. Allen was to desire and obtain a job function with drug access she must return to the Board for permission. (Garrelts/Schoech) Motion passed.
- Kingsley Ubah, R.Ph. (1-15999) **Case 14-24**. Mr. Ubah was present with counsel, Becky Mann. Mr. Forbes presented the case to the Board with the proposed resolution of \$1000 fine, 18 hours of specified Continuing Education to be completed within 30 days from November 15, 2014, and 365 days of probation from the date of the signed order. Mr. Ubah addressed the Board and answered questions. The Board discussed options.

A motion was made and seconded to decrease the fine to \$750; require the 18 hours of specified CE to be completed within 30 days from November 15, 2014; successfully take the PARE test given by NABP before June 2015. Mr. Ubah was agreeable to the decision. (Schoech/Garrelts) Motion passed.
- Pharmerica (2-09794) **Case 14-45**. Pharmerica had no representation present and none was required. The pharmacy was found to be over pharmacy technician ratio. The fine was \$500 and has been paid. A motion was made and seconded to accept the signed stipulation with Pharmerica. (Worden/Pugh) Motion passed.
- World Impact, Inc. (applicant) **Case 14-93**. John Kraft, R.Ph. and Hayley Ramsey, Mobile Medical Coordinator, was present for World Impact. Mr. Kraft and Ms. Ramsey described the clinic and how the services work for the indigent population they serve. Ms. Billingsley said the model does not fit any of the Board's registration categories. The Board suggested World Impact look into Physician Dispensing otherwise the only way the Board could possibly register is through a pilot program.
- Morris County Hospital Pharmacy (2-06245) **Case 14-85**. Kristie Hayes was present and represented Morris County Hospital Pharmacy. The violation in discussion was no pharmacist in charge within the 30-day grace period. Mr. Forbes provided the information and requested four exhibits be entered as evidence. Ms. Hayes had no objections. Ms. Hayes was sworn in and addressed the Board. Mr. Hayes stated the hospital never knew Mr. Neil had notified the Board and had continued to function as what they considered the pharmacist in charge. The letter sent to the

Board by the hospital did state Mr. Neil's last day but that he would continue working to allow the new pharmacist time.

A motion was made and seconded to modify the stipulation to reduce the fine to \$2120 as the hospital was without a PIC for 56 days. (Worden/Ullom) Motion passed.

- Michelle L. Simoneau, Pharmacy Technician (14-14848) **Case 14-101 Ms.** Simoneau was not present. Mr. Forbes presented the case. Four exhibits were accepted into evidence. A motion was made and seconded to accept the findings of diversion of drugs from Wal-Mart and to revoke the pharmacy technician registration of Michelle L. Simoneau. (Garrelts/Worden) Motion passed.

The Board was concerned over the length of time the diversion has continued. The Board requested a case be open to address the accountability of Wal-Mart.

- Chris Henington, R.Ph. (1-13153) **Case 14-55 Mr.** Henington was present without counsel. Mr. Forbes requested an executive session to receive confidential information from the impaired pharmacist program. A motion was made and seconded to enter into executive session to receive and discuss records regarding peer review pursuant to K.S.A. 65-4915 to include Randy Forbes, Debra Billingsley, Jim Kinderknecht, Melissa Martin; the KsPRN representatives - Vicki Whitaker and Ralph Holbrook; and Ms. Henington, Chris' mom. (Worden/Garrelts) Motion passed. Dr. Haneke reconvened the regular meeting at 12:20pm. A motion was made and seconded to suspend the Emergency Order until January 9, 2015 and to place the Respondent on inactive status until the Board administrative proceeding on January 9, 2015. (Pugh/Garrelts) Motion passed.

#### **Notification of Summary Orders**

- Walgreens #6362 (2-09725) **Case 14-22**
- Mercy Medical Plaza Pharmacy (2-09221) **Case 14-43**
- Jarratt Asher, R.Ph. (1-13267) **Case 14-66**
- Wal-Mart Pharmacy 10-2893 (2-09449) **Case 14-80**
- Walgreens #7152 (2-09824) **Case 14-81**
- Target Pharmacy T-0092 (2-09323) **Case 14-82**
- Coram CVS/Specialty (2-10384) **Case 14-83**
- Bowen Pharmacy South (2-10275) **Case 14-86**
- Starla Ann Hall, Applicant **Case 14-98**

A motion was made and seconded to accept the Summary Orders as listed above in the Notification of Summary Orders. (Schoech/Worden) Motion passed.

**Adjourn:** Dr. Haneke adjourned the meeting at 12:22pm.