

Kansas State Board of Pharmacy  
Minutes of the November 3, 2016  
Board Meeting

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

**Thursday, November 3, 2016**

**Meeting Called to Order:** President Chad Ullom called the meeting to order at 9:03am.

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

**Staff Present:** Alexandra Blasi, JD, MBA, Executive Secretary; Jim Kinderknecht, R.Ph., Licensed Pharmacy Inspector; Carly Haynes, R.Ph., Licensed Pharmacy Inspector; Shelley Rosebrook, R.Ph., Licensed Pharmacy Inspector; Melissa Martin, Compliance Inspector; Kayla Jones, Compliance Inspector; Reyne Kenton, KTRACS; Randall Forbes, General Counsel.; and Michele Tunnell, JD, General Counsel.

**Others Present:** See attached listing.

**Administrative Hearings**

**Case 15-247** Jamie Martin (14-17860) – Request for Reconsideration

- The Board was represented by Mr. Forbes.
- Ms. Martin failed to appear.
- The original case was a Summary Order and Ms. Martin did not file a timely request for hearing.
- A default order will be prepared by Ms. Tunnell.

**Case 15-051** Christopher Wuenstel (1- 13939)

- The Board was represented by Mr. Forbes
- Mr. Wuenstel was pro se
- Ms. Blasi was sworn in as a witness as custodian of records
- A motion was made and seconded to close the hearing to receive and discuss records regarding peer review pursuant to K.S.A. 65-4915 to include Respondent, Mr. Forbes, Judge Tunnell, the Executive Secretary for the Board, and the KsPRN representatives – Kelly Rockers, Ralph Holbrook, and Mike Larkin. (Haneke/Schoech) Motion passed.
- Mr. Ullom reconvened the open hearing at 9:55am.
- Ms. Kenton was sworn in as a witness. Ms. Kenton was the inspector/investigator of the case

- Mr. Wuenstal presented his statement
- A motion was made and seconded to close the hearing to receive and discuss records regarding peer review pursuant to K.S.A. 65-4915 to include Respondent, Mr. Forbes, Judge Tunnell, the Executive Secretary for the Board, and the KsPRN representatives – Kelly Rockers, Ralph Holbrook, and Mike Larkin. (Haneke/Schoech) Motion passed.
- Mr. Ullom reconvened the open hearing at 10:16am
- Quasi-judicial deliberations began at 10:22am
- Mr. Ullom reconvened the hearing at 10:36am.
- A motion was made and seconded to continue the suspension of Mr. Wuenstal's license to practice pharmacy, to re-enter the KsPRN program for 5 years, maintain compliance for one full year before making any request of the Board to lift the suspension. (Ullom/Worden) Motion passed.

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

**Reconvene:** Mr. Ullom reconvened the meeting at 10:46am

**Case 16-008** Jeffrey James Scott (Applicant for Technician Registration)

- The Board was represented by Mr. Forbes
- Mr. Scott failed to appear
- Ms. Tunnell will prepare a default order

**Case 11-049** Mohammed Elberry (1-14805) Request to Modify Consent Agreement

- The Board was represented by Mr. Forbes
- Mr. Elberry appeared with counsel, Randy Debenham
- A motion was made and seconded to close the hearing to receive and discuss records regarding peer review pursuant to K.S.A. 65-4915 to include Respondent, Mr. Forbes, Judge Tunnell, the Executive Secretary for the Board, and the KsPRN representatives – Kelly Rockers, Ralph Holbrook, and Mike Larkin. (Haneke/Schoech) Motion passed
- Quasi-judicial deliberations began at 10: 54am
- Mr. Ullom reconvened the open hearing at 10:56am
- A motion was made and seconded to reinstate Mr. Elberry's pharmacist's license with no restrictions. (Garrelts/Haneke) Motion passed.

**Recess:** Mr. Ullom declared a break to reconvene in 5 minutes.

**Reconvene:** Mr. Ullom reconvened the meeting at 11:02am

**Board Member Reports**

Chad Ullom – Mr. Ullom presented information regarding Idaho's pharmacy technician. The technician ratio has been eliminated and the duties have been expanded. A pharmacist may delegate anything including immunizations, taking new phoned-in prescriptions. He suggested the Board look at options before finalizing any changes in technician regulations.

David Schoech – attached a letter from the DEA with information regarding security. Older versions of software may not provide a pharmacy the ability to maintain security.

The DEA is using higher versions and to use CSOS the pharmacy must be on the higher version.

Michael Lonergan – made comments on the analytics and software available to comply with HIPAA. Mr. Lonergan was requested to write an article for the newsletter concerning the security and confidentiality a pharmacy needs to maintain.

Jim Garrelts – responded to an email regarding the appropriate time for order review in hospitals even small hospitals. Dr. Garrelts stated it was appropriate for a pharmacist to review all orders before the patient receives the medication. This is the direction The Joint Commission is going and CMS seems to be proceeding the same way.

John Worden – echoed Dr. Garrelts but said the challenge is how to handle the different needs of the facilities as to capabilities versus cost.

## **Board Discussion**

### 1. Legislative Session –

- ✓ Pharmacy Practice Act Amendments - The Executive Secretary presented the information. The changes in the practice act will be the same as requested last year with a few additions. Some additional definitions will be added and request for expanded authority on discipline issues and disposition of fine money.
- ✓ PMP Act
  - PMP Act Revisions –
    - ❖ The term “delegate” would be added to clarify intention
    - ❖ All physicians, mid-levels, and pharmacists would be mandated to register for the PMP either at initial licensure or renewal time until all are registered. Concerns were raised about prescribers and dispensers who do not possess or work for pharmacies that have DEA registration numbers.
    - ❖ Fees could be collected from prescribers and dispensers to maintain the program
    - ❖ Gives discretion to block inappropriate use of the program
    - ❖ Restructures advisory committee and sets term limits
    - ❖ Plus other changes – electronically attached to the agenda
  - Proposed New Regulations – regarding delegates access
- ✓ Biosimilars Update – Berend Koops presented the information and the requested statute changes. The Board reviewed and discussed what changes might need to be made to keep the requested legislation consistent with the statutes already in place for drugs not classified as biosimilars. The request adds definitions for “Biological Product”, “Interchangeable”; requirements for electronically accessible information; and requirements for the Board to maintain a link showing all FDA approved biosimilars that are interchangeable.

**Recess:** Mr. Ullom recessed the meeting for lunch at 12:15pm to reconvene at 1pm.

**Reconvene:** Mr. Ullom reconvened the meeting at 1pm.

**Public Comments** – There were no public comments.

## **Board Discussion** - continued

### Legislative Session - continued

- ✓ Controlled Substances Act Updates and Emergency Scheduling Authority – This is a yearly bill keeping the controlled substance list current. This year the bill will request a change in the emergency scheduling process.
  - ✓ Naloxone Draft and 2016 naloxone National Report – The Board reviewed the information presented and will watch the statute in regards to obligation to provide or oversee.
2. Strategic Planning: Goals and 5 year plan – The Executive Secretary presented the plan for Board comment and review. Board consensus was acceptance. Dr. Garrelts stated, “If you never have a plan, you never get there.”
  3. 2017 Board Meeting Dates –  
January 6, 2017 Topeka  
April 6, 2017 Topeka  
August 2-4, 2017 Topeka  
November 2, 2017 Topeka  
January 4, 2018 Video Conference  
A motion was made and seconded to accept the dates as proposed.  
(Schoech/Haneke) Motion passed
  4. Joint Policy Statement on the Use of Controlled Substances to Treat Chronic Pain – The Board reviewed the information provided. A motion was made and seconded to accept the “Joint Policy Statement on the Use of Controlled Substances to Treat Chronic Pain” as presented. (Worden/Schoech) Motion passed.
  5. Delayed Implementation of USP 800 – The consensus of the Board was to keep working on the implementation of compounding regulations and needed statutory changes.
  6. Handling Lapse in Facility Licensure – Pharmacists would always keep their same numbers. Facilities would be determined based on the length of lapse. One month should not create a problem if working towards renewal. Lapses of longer periods like four months would be required to make application and the registrations would not be back dated.
  7. Nurses Labeling of Multi-Use Products in Long Term Care Facilities (LTCF)– Automation allowed in LTCF may have multiuse products. The products must be labeled with the patient’s name and directions. Currently a similar situation occurs in hospital emergency rooms – the pharmacist labels the product leaving the patient’s name blank and the directions are the typical with fill in the blanks where dosing may be different. The Board consensus was to have the pharmacy place a similar type label on the product before it is placed into the machine and have the nurse add the patient’s name and fill in any appropriate blank.
  8. Automation Verification Process when K.A.R. 68-9-3(h) Fails – Ms. Rosebrook shared the information with the Board based on several questions received.

After Board discussion, the consensus was IF the facility is using automation to obtain patient dosing then the medication must be verified by a pharmacist before administering to a patient unless it is in a emergent case where the practitioner is present.

9. ESS Recording – Electronic supervision of technicians in medical care facilities. The question was asked as to when a technician must be video and that video retained for 5 years when being electronically supervised. The Board consensus was when the technician was in the hospital pharmacy retrieving medication based on medication orders. Before those medications may leave the pharmacy, a pharmacist shall review the order and the medication pulled by the technician – A picture or video of this must be retained for 5 years. However, if a technician is loading automation machines outside of the pharmacy and a pharmacist has verified the medications to be placed in the automated machine, no video retention is required, only electronic supervision.
10. Commissioning Inspectors and Peace Officers – Ms. Jones presented the information regarding commissioning. All inspectors would not be required to obtain commissioning. The commissioning would allow an inspector to essentially arrest an impaired pharmacist or technician as well as other law enforcement duties. Dr. Worden said this was not the mission of the Board and the Board agreed.

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

**Reconvene** Mr. Ullom reconvened the meeting at 2:50pm

11. MALTA-GON and NABP District VI, VII, VIII Meeting in 2018 – Options were presented. The Board will consider the options and begin gathering information.
12. Separate email for Board Members – Mr. Forbes, General Counsel for the Board, explained the hazards of using personal emails to receive Board of Pharmacy information. He encouraged the Board to be aware especially the Investigative Board Member.
13. Delegate Authority to Executive Secretary for Signing Summary Orders – The executive secretary and the Board discussed the possibilities and the time constraints the office must meet in timely response of Summary Orders. A motion was made and seconded to delegate and authorize the Executive Secretary of the Kansas Board of Pharmacy to sign the summary orders. (Haneke/Schoech) Motion passed.
14. Designate Board Member to handle Petitions for Review or Reconsideration – The Board discussed with general counsel and the executive secretary. The ability to schedule one Board member is much easier than trying to schedule a quorum of the Board. A motion was made and seconded to appoint the Alternate Investigative Member as the Hearer of the petition for Review or Reconsideration.

15. Genoa Letter – Genoa/QOL requested the Board reissue a letter stating they can maintain samples and dispense to the patient when requested to do so by the prescriber. The Board consensus was to reissue the letter.
16. EpiPen labeling and expiration dates – This was an issue brought by NABP regarding the dating on EpiPens. There was no action on this as the Board discussed the expiration date on the pen is the expiration date. Most are short dated.

## Reports and Updates

1. Board of Pharmacy Financial Report
  - Estimated Ending Cash Balance
  - Budget – the state budget office has not responded as of yet to the proposed budget.
  - KDHE CDC Grant – the grant is for enhancements to the PMP program
2. Staffing – The office has added another part-time law clerk. This allows for 5-day coverage. The Board of Pharmacy is currently full-staffed.
3. Technician Renewals – The online window has been left open to enable any last minute stragglers to register. The window will be closed soon any nonrenewed technician will need to complete an application with a fingerprint card.
4. Inspector/Staff reports –
  - Reyne Kenton – KTRACS has been working on delinquent pharmacy reporting. There are 3 in state pharmacies and 115 nonresident pharmacies currently delinquent. There are some Missouri physicians requesting to be allowed to participate in KTRACS.
  - Carly Haynes – reported on the MPJE review of the question pool. She attended the FDA 50 State meeting on compounding. The FDA has been inspecting 503A compounding facilities (including hospitals) on insanitary conditions. Ms. Haynes also received Certification in Sterile Compounding for Inspectors (CISCI) for the course work and testing by Critical Point. She and Ms. Martin attended CLEAR – Advanced and both passed to receive certification in specialized training (NCIT-Specialized).
  - Kayla Jones was introduced as the new Compliance Inspector taking the western 40 counties.
5. Conference/Training Update – Staff and Board have had several conferences and meetings including: NABP District VI, VII, VIII; MALTA-GON; NASCA; FDA 50-State; AAP. The executive secretary attended the American Academy of Pediatrics and attended some very good seminars on pediatric immunizations.
6. Newsletter Sign-ups and NABP updates – Pharmacists wanting to receive the newsletters must sign up for them on the NABP website. There is a link on the Board's website. Newsletters provide an opportunity to keep current with any changes in regulations. The office sends a blast out to all pharmacist letting them know a new newsletter is available.
7. NPLeX Dashboard – This is the dashboard for ephedrine and pseudoephedrine products. Law enforcement continues to access the data.
8. NAPLEX / MPJE 2016 Graduate Data – Kansas MPJE rates sixth in the nation with a pass rate of 95.73%.

## **Election of 2017 Officers**

1. President – John Worden was nominated and elected unanimously
2. Vice President – Mike Lonergan was nominated and elected unanimously
3. Investigative Member – Chad Ullom was nominated and elected unanimously
4. Alternate Investigative Member – David Schoech was nominated and elected unanimously and will serve until term is complete

## **Approvals**

1. Minutes from July 14-15, 2016
2. New Licensees and Registrants
3. Summary Orders
  - Case 16-028 Tasha Ramos
  - Case 16-050 Comprehensive Health Planned Parenthood
  - Case 16-055 Daniel Rodriguez
  - Case 16-074 Erica Jenkins
  - Case 16-089 K-Mart
  - Case 16-111a Heydon White
  - Case 16-114 Jason Kim
  - Case 16-122 Coram CVS Specialty Infusion Services
  - Case 16-135 Alex Martinez
  - Case 16-146 CVS #05271
  - Case 16-179 Malcolm Starks

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

## **Stipulation and Consent Agreement**

- Case 16-030c -- Daina Smith. A motion was made and seconded to accept the signed Stipulation and Consent Agreement with Daina Smith. (Haneke/Schoech) Motion passed
- Case 16-111b – KU Hospital. KU has paid the fine. The case was tabled until January.

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

**Reconvene** Mr. Ullom reconvened the meeting at 3:50pm

## **Executive Session - Personnel**

**Executive Session** – A motion was made and seconded to enter into executive session for 40 minutes to discuss matters pertaining to personnel in order to protect the privacy of non-elected personnel and to reconvene the meeting at 4:30pm, and to include the Executive Secretary, staff, and Mr. Forbes. (Worden/Pugh) Motion passed.

Mr. Ullom reconvened the meeting at 4:39pm.

**Adjourn:** Mr. Ullom adjourned the meeting at 4:40pm.