

Kansas State Board of Pharmacy
Minutes of the November 8 & 9, 2017
Board Meeting

Meeting Location: Kansas Board of Regents Board Room
Curtis State Office Building
1000 SW Jackson, Suite 520
Topeka, KS 66612

Wednesday, November 8, 2017

Meeting Called to Order: President John Worden called the meeting to order at 8:33

Members Present: John Worden, PharmD., President; Michael Lonergan, R.Ph., Vice President ; Chad Ullom, R.Ph., Investigative Member; Robert Haneke, PharmD; Cheri Pugh, Public Member; Bill Walden, RPh; and Jonathan Brunswig, PharmD.

Staff Present: Executive Secretary 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 Program Manager; Jackie Yingling, Assistant Director; Heidi Nelson, Administrative Specialist; Andrew Serrone, Law Clerk; Fan Xiong, Epidemiologist; Randy Forbes, JD, General Counsel.

Others Present: See attached listing.

Public Hearing on Administrative Rules and Regulations

The Executive Secretary welcomed the public and gave instructions for the public hearing and provided the Board with a letter from The Joint Committee on Administrative Rules and Regulations (via Kansas Legislative Research Department) from their meeting on October 24, 2017, which included no comments or questions on the proposed regulations.

K.A.R. 68-1-3a

The Executive Secretary provided a brief statement regarding the amendments and principle reasons for adopting the regulations. There were no public comments.

K.A.R. 68-2-20

The Executive Secretary provided a brief statement regarding the amendments and principle reasons for adopting the regulations. There were no public comments.

K.A.R. 68-7-12a

The Executive Secretary provided a brief statement regarding the amendments and principle reasons for adopting the regulations. Written comments were received from

Envision Pharmacies, ExpressScripts, Walgreens Prime, CVS, and National Association of Chain Drug Stores.

The following people spoke on the regulation change:

- John Sisto, representing ExpressScripts – He indicated the board has current ability to discipline and take action against non-resident pharmacies and that the PIC being licensed doesn't give the Board any additional authority. If the Board chooses to adopt the regulation, ExpressScripts requests a PIC change grace period and request an extension of the length of time between inspections.
- John Rocchio, representing CVS Health-Regulatory Affairs – He understands that the Board wants to hold the leader of a pharmacy responsible for what happens in the pharmacy to protect the patients in Kansas, but all other states have a board of pharmacy that is enforcing the laws. Many states have had a grace period, but that doesn't solve the problem. Requiring the MPJE can be changed. You can say if you're becoming a non-resident PIC you don't have to take the Kansas MPJE, but you can issue them a reciprocity license to only practice out of Kansas. States don't have the resources to inspect pharmacies on an annual basis. NABP's VPP is good for 18 months.

K.A.R. 68-7-15

The Executive Secretary provided a brief statement regarding the amendments and principle reasons for adopting the regulations. There were no public comments.

K.A.R. 68-7-20

The Executive Secretary provided a brief statement regarding the amendments and principle reasons for adopting the regulations. There were no public comments.

K.A.R. 68-11-2

The Executive Secretary provided a brief statement regarding the amendments and principle reasons for adopting the regulations. There were no public comments.

Dr. Worden closed the public hearing.

Board discussion on proposed regulations.

The Executive Secretary indicated extending the inspection period to 18 months would be reasonable, consistent with the VPP, and considered an immaterial change that wouldn't have to be rerouted through the administrative rules process.

The Board discussed the pros and cons of licensing non-resident PICs and asked Board staff to explain the PIC change process and timeline.

A motion was made and seconded to amend the proposed K.A.R. 68-7-12a from 12 to 18 months. (Haneke/Lonergan)

Motion passed.

The Board discussed the implications of amendments to K.A.R. 68-2-20 on pharmacist's prescriptive authority. The Executive secretary provided context regarding

2017 Senate Substitute for House Bill 2055, anticipated legislative changes related to telemedicine, and the probability of needing to revise K.A.R. 68-2-20 again in the near future. After discussion, Board consensus was to table the regulation.

A motion was made and seconded to adopt K.A.R. 68-1-3a, 68-2-20, 68-7-15, 68-7-20, and 68-11-2. (Haneke/Lonergan)

An amendment was offered and seconded on the motion to remove K.A.R. 68-2-20 from the regulations to be adopted. (Walden/Ullom) Motion passed.

Roll Call: Dr. Worden – Yes, Mr. Lonergan – Yes, Mr. Ullom – Yes, Mr. Walden – Yes, Ms. Pugh – Yes, Dr. Haneke – Yes, Dr. Brunswig – Yes.

The motion passed. The regulations will become effective 15 days after publication in the Kansas Register.

Reports

Financial Report by Ms. Yingling

Cash balance through the end of October was \$1,425,582.18.

Revenues through October was \$311,130.

Expenses through October were \$422,087.

With a third of the year completed, we've used approximately 29% of our budget.

Director

The Executive Secretary provided the following updates.

- The Executive Secretary provided an overview of the FY 2018 and 2019 budget submission (previously approved by the 2017 Kansas Legislature) and indicated the report from the Division of Budget was anticipated tomorrow.
- Carly Haynes has accepted the position of Director of Compliance.
- A request has been made to the Governor's office to fill a vacant licensing position with a focus on facility registration.
- Kansas will host two national meetings in 2018 at the Westin Crown Center in Kansas City, Missouri on the following dates:
 - MALTA-GON October 11-14
 - NABP/AACP District VI-VII-VIII October 14-17
- Positive feedback has been received after the August 2017 PDMP Administrator's Roundtable and we are in discussions with TTAC/BJA to repeat the event in 2018.

Recess: Dr. Worden recessed the meeting at 9:38 am

Reconvene: Dr. Worden reconvened the meeting at 9:57 am

Director Report Continued

- Administrative regulations
 - Compounding regulations are awaiting final approval from the AG's office and will go out to public comment once received.

- Other regulations going out for public comment include adding gabapentin to drugs of concern in Kansas, pharmacy technician certification exam, and allowing nurses access to automated dispensing systems.
- New and amended regulations in 2018 will include epinephrine kits, registrants under the DSCSA, and mandatory reporting of theft/loss/diversion in the pharmacy.

K-TRACS Report by Ms. Kenton

- K-TRACS received the Harold Rogers grant for prescriber's report card.
- Peer review committee reviewed 5 cases from the third quarter. A letter will be sent to prescribers who are continually in the top ten list of prescribers in the state.
- As of October 27, 2017, there are 8 hospitals, 32 pharmacies, and 1 prescriber practice w/ 6 prescribers that have integrated with K-TRACS.
- K-TRACS will be adding Excessive PMP Alerts and are currently working to set the right numbers. Other enhancements will include seeing what states are looking up patients.
- A pilot project with the Board of Healing Arts is reviewing prescribers. There were 3 cases that needed investigation.

Board Discussion:

2018 Legislative Session

1. PDMP Funding
Funding for K-TRACS is the primary concern. A stakeholder group was formed consisting of prescribers, insurance, dispensers, etc. to approach the Lt. Governor for State General Fund funding.
2. Controlled substance act updates
3. Telepharmacy/telemedicine: The Board of Pharmacy submitted written comment during the 2017 Legislative session and to the Interim Committee on Telehealth on October 19 & 20, 2017. Sen. Schmidt would like to see a telepharmacy bill during the 2018 session. KPhA task force is putting together language for the Board's review.
4. PDMP Act expansion- Legislators have approached the board expressing interest in expanding law enforcement access and mandating PDMP use.
5. KPhA Executive Director Aaron Dunkel provided a report on plans to expand pharmacist's scope of practice during the 2018 legislative session using statewide protocols.

2018 Meeting Dates

December 20, 2017 (video conference), March 7, 2018 at the University of Kansas, June 7 2018, September 6 2018, and November 29, 2018.

2018 Election Officers

Robert Haneke nominated Jonathan Brunswig for vice-president and later withdrew the nomination.

A motion was made and seconded to re-elect the current officers for 2018. (President Dr. Worden, Vice-President Mr. Lonergan, Investigative Member Mr. Ullom) (Ullom/Walden) Motion carries.

Appointments

Collaborative Drug Therapy Management Committee: Katie Burenheide Foster submitted an application for reappointment.

A motion was made and seconded to reappoint Ms. Foster. (Ullom/Walden) Motion carries.

Notification of Theft/Break-in/Burglary-more vague

KPhA annual meeting- licensees expressed interest in receiving notification of thefts/break-in/burglary.

Board consensus was to provide annual newsletter on security, awareness, and perhaps statistics on break-ins or attempted break-ins from the previous year.

Request to re-take NAPLEX (> 5 times)

The Board's attorney indicated the procedural administration of the exam is governed by the exam vendor and therefore the Board can rely on the 5 time limit to deny further exam attempts.

A motion was made to deny the re-take. (Ullom/Brunswick)

Recess: Dr. Worden recessed the meeting at 11:29 am

Reconvene: Dr. Worden reconvened the meeting at 11:43 am

Presentation from MedAvail Technologies, Inc. by Seema Siddiqui, PharmD, MBA

Licensing Report

The Executive Secretary provided a status report.

Recess: Dr. Worden recessed the meeting for lunch at 12:38 pm

Reconvene: Dr. Worden reconvened the meeting at 1:07 pm

Public Comment:

Public Comment from Angela Lenz.

End of public comment

The Board discussed the implications of and discipline associated with the 2017 CE audit including historical Board actions. The Board president recommended the investigative review members consider the Board's discussion and take necessary actions for the 2017 and future audits.

Pilot Project Application – Final Review

The Committee's recommendation was to approve with the following conditions:

- An official start date be provided to the Board.

- Any compliance issued may result in immediate termination of the pilot project or a request for changes.
- Any changes in the facility ownership, PIC, policies or procedures shall be submitted to and approved by the Board prior to implementation.

The Board also asked for quarterly updates.

Doug Bagget-plan to start immediately getting ready and will notify of the start date. A motion was made and seconded to accept the committee's recommendation and approve the pilot project. (Ullom/Lonergan) Motion carries. (Mr. Brunswig voted no.)

Reports

Compliance

Carly Haynes, the Director of Compliance, reported 226 cases have been assigned so far this year. 53 have been sent to inspectors for investigation. The inspectors have completed 1250 inspections during 2017. 600 have been pharmacies.

The inspectors will be working to incorporate detailing including teaching pharmacists about K-TRACS and counseling.

Ms. Haynes requested the Board's opinion on education and/or discipline regarding Continuous Quality Improvement. The Board consensus was to continue education and bring violations for review by the Investigative Member.

Inspector Reports

Kayla Jones attended MALTA-GON and said it was very beneficial

Melissa Martin attended MALTA-GON as well and had some takeaways including educating pharmacies & pharmacists. She also attended the FDA 50 state intergovernmental meeting and said the FDA wants to keep sharing information with states. She will attend the NABP Legal and Compliance Forum later this month which is very valuable. She thanks the board for the opportunity.

Shelley Rosebrook completed CLEAR Basic investigator training. She is hoping to complete sterile compounding training next year. She also went to MALTA-GON.

Board Member Reports

Dr. Brunswig is excited to be a part of the Board. He likes where the Board is headed with rural health and backing them up.

Dr. Haneke says that Amazon looks like they're going to be deciding if they get into mail-order pharmacy.

Dr. Worden encouraged everyone to use the Naloxone protocol because it brings value to your community. He talked to Fan about where Kansas is with opioid crisis. We have a lot of opioids floating around, but our number of deaths is low for now. His community started an opioid roundtable with first responders, EMS, fire, police, and schools. K-TRACS staff provided data for McPherson & surrounding area to tease out info about his area.

He also commended the office and inspectors on how much has been accomplished-thanks for work you've been doing.

Mr. Lonergan expressed appreciation for the work and quality of work of the Board staff. He highlighted changes related to opioid prescribing in other states and requested

additional reporting from Board staff. Kansas has no quantity or day supply limit on any prescription.

Mr. Ullom attended the KPhA meeting, NABP, MALTA-GON, and chain meeting. He watched 'Warning: This Drug will Kill You' and 'Chasing the Dragon' and said they literally changed the way he practices every day including counseling on disposal of leftover meds. He thinks the Board should consider alternative forms of discipline such as a letter of guidance or citation. Says it is nice to see what other states are doing. Idaho cut 19,000 words and 60% of regulations from practice act. He would like to see Kansas tackle tech ratio and says pharmacy is the only profession where someone's telling us how much help we can have.

Approvals

1. Summary Disciplinary Actions
2. Minutes from Quarterly Board Meeting – August 17, 2017
3. New Licensees and Registrants

A motion was made and seconded to approve the Summary Orders, Minutes of the August 17, 2017 Quarterly Board Meeting, and New Licensees and Registrants. (Haneke/Pugh) Motion carries.

Strategic Planning

The Executive Secretary provided a summary of the 5-year action plan associated with the Boards stated goals and objectives, including completed items from 2017 and planned action items for 2018. The eLicensing project has taken more time to complete than originally anticipated, but additional enhancements have provided needed improvements and delayed completion of other modules in the original scope of work. Staff responsibilities have been streamlined to optimize efficiency and resources, and vacancies are being promptly filled. Collaboration with other state agencies has been improved and expanded.

The Board specifically requested work on the technician ratio, adoption of the pending compounding regulations, and facilities management with a focus on security.

The Board wants to consider necessary budget enhancements related to K-TRACS and PDMP funding that is sufficient to do more than just the bare minimum.

Executive Session

A motion was made and seconded at 2:39 pm to enter into executive session per KSA 75-4319(b) to discuss personnel matters of nonelected personnel to reconvene at 3:10 pm, and to include the Executive Secretary and Board's attorney. (Ullom/Haneke) Motion Passed.

Reconvene: Dr. Worden reconvened the meeting at 3:15 pm

A motion was made and seconded at 3:17 pm to enter into executive session per KSA 75-4319(b) to discuss personnel matters of nonelected personnel to reconvene at 3:30

pm, and to include the Executive Secretary and Board's attorney. (Haneke/Ullom)
Motion Passed.

Reconvene: Dr. Worden reconvened the meeting at 3:30 pm

A motion was made and seconded at 3:30 pm to enter into executive session per KSA 75-4319(b) to discuss personnel matters of nonelected personnel to reconvene at 3:45 pm, and to include the Executive Secretary and Board's attorney. (Worden/Ullom)
Motion Passed.

Reconvene: Dr. Worden reconvened the meeting at 3:40 pm

Adjourn: Dr. Worden adjourned the meeting at 3:40 pm

Thursday, November 9, 2017

Meeting Called to Order: President John Worden called the meeting to order at 8:41pm.

Members Present: John Worden, PharmD., President; Chad Ullom, R.Ph., Investigative Member; Robert Haneke, PharmD; Cheri Pugh, Public Member; Bill Walden, RPh; and Jonathan Brunswig, PharmD.

Staff Present: Executive Secretary 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, Inspector; Kayla Jones, Compliance Inspector; Heidi Nelson, Administrative Specialist; Andrew Serrone, Law Clerk; Randy Forbes, JD, General Counsel; Michele Tunnell, JD, Administrative Law Judge.

Others Present: See attached listing.

Administrative Proceedings

Case 17-003 Brett Wolford

- The Board was represented by Mr. Forbes.
- Brett Wolford represented himself and appeared without counsel.
- Ms. Tunnell swore in Executive Secretary Blasi who gave testimony.
- Ms. Tunnell swore in Mr. Wolford who gave testimony.
- The Board entered into closed session for KAPA deliberations and included the Executive Secretary.
- Dr. Worden reconvened the proceedings at 9:07 am

- Motion made to hold the disciplinary action through the completion of the diversion and provide the records of the completion of the diversion to the Board. (Haneke/Ullom) Motion carries.

Case 16-178 Dale Heckethorn

- The Board was represented by Mr. Forbes
- Dale Heckethorn represented himself and appeared without counsel.
- Ms. Blasi was still under oath.
- Ms. Tunnell swore in Kelly Rockers of KsPRN who gave testimony.
- Mr. Forbes requested the hearing be closed for the Board to hear sensitive information.
- Ms. Tunnell closed the hearing.
- Ms. Tunnell swore in Mr. Heckethorn who gave testimony.
- The Board entered into closed session for KAPA deliberations and included the Executive Secretary.
- Dr. Worden reconvened the proceedings at 9:25 am.
- Motion made to accept the recommendation of KSPRN and reinstate Mr. Heckethorn to active practice with the committee's stipulations. (Haneke/Ullom) Motion carried.

Case 17-146 Richard Brent Blankenship

- The Board was represented by Mr. Forbes.
- Richard Brent Blankenship represented himself and appeared without counsel.
- Ms. Tunnell swore in Mr. Blankenship who gave testimony.
- Mr. Forbes requested the hearing be closed for the Board to hear sensitive information.
- Ms. Tunnell closed the hearing.
- The Board entered into closed session for KAPA deliberations and included the Executive Secretary.
- Ms Tunnell reconvened the proceedings at 10:38 am.
- Motion was made to table the application for a year to allow Mr. Blankenship to continue his participation KsPRN for one year and return to the Board with localized references. (Walden/Haneke) Motion carried.

Case 17-120 Karastin Pacheco

- The Board was represented by Mr. Forbes.
- Ms. Pacheco represented herself and appeared without counsel.
- Ms. Tunnell swore in Ms. Pacheco who gave testimony.
- The Board entered into closed session for KAPA deliberations and included the Executive Secretary.
- Ms. Tunnell reconvened the proceedings at 11:02
- Motion was made to grant a technician registration pending a letter of recommendation from Dillons and verification of drug and alcohol counseling certification within 30 days. (Ullom/ Brunswig) Motion carries

Case 14-070 James Williams

- The Board was represented by Mr. Forbes.
- James Williams was represented by himself and appeared without counsel.
- Ms. Tunnell swore in Mr. Williams who gave testimony.
- Mr. Forbes requested the hearing be closed for the Board to hear sensitive information.
- Ms. Tunnell closed the hearing.
- The Board entered into closed session for KAPA deliberations and included the Executive Secretary.
- Ms. Tunnell reconvened the proceedings at 11:39.
- Motion was made to continue in the KSPRN program with blood or hair test with a zero-tolerance policy for missed calls or tests. A new statement of understanding will be required with the stipulation that the 5 year time period of probation be restarted. (Ullom/?) Motion carries

Adjorn: Dr. Worden adjourned the meeting at 11:47 am.