

KANSAS STATE BOARD OF PHARMACY
Minutes of the March 8, 2018 Board Meeting

Meeting Location: Kansas Board of Healing Arts Board Room
800 SW Jackson, Lower Level
Topeka, KS 66612

Thursday, March 8, 2018

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: 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 Program Manager; Jackie Yingling, Assistant Director; Heidi Nelson, Administrative Specialist; Andrew Serrone, Law Clerk; Fan Xiong, Epidemiologist; Randy Forbes, JD, General Counsel; Michele Tunnell, JD, Administrative Law Judge.

Others Present: See attached listing.

Administrative Proceedings/Hearings

Case 17-154 Jason Marrs

- The Board was represented by Mr. Forbes.
- Jason Marrs represented himself and appeared without counsel.
- Ms. Tunnell swore in Mr. Marrs who gave testimony.
- Ms. Tunnell swore in Ms. Blasi who gave testimony.
- The Board entered into closed session for KAPA deliberations and included the Executive Secretary at 8:38am.
- Dr. Worden reconvened the proceedings at 9:14am.
- Motion made to deny the technician registration application. (Walden/Lonergan) Motion carries.

Case 17-237 Okwudili Okekearu

- The Board was represented by Mr. Forbes.
- Okwudili Okekearu represented himself and appeared without counsel.
- Ms. Blasi was still under oath.
- Ms. Tunnell swore in Okwudili Okekearu who gave testimony.
- The Board entered into closed session for KAPA deliberations and included the Executive Secretary at 9:30.
- Dr. Worden reconvened the proceedings at 9:34am.

- Motion made to approve the intern registration application. (Ullom/Worden)
Motion carries.

Meeting Called to Order: President John Worden called the open meeting to order at 9:53 am.

Board Discussion:

Board Meeting Content and Planning

The Executive Secretary attended training from the Federal Association of Regulatory Boards and offered suggestions for future Board meetings.

2018 Task List

The Executive Secretary and the Board reviewed the 2018 Task list which includes bringing many tasks to completion.

Board Delegations of Authority

The Executive Secretary proposed the creation of a formal guidance document to set forth the Board's delegation of authority to certain Board Members, the Executive Secretary, and staff to take actions on behalf of the Board. The Board's counsel agreed that this was a good plan and had probably been done in the past, but should be put in writing, updated, and formally approved by the Board. He recommended review on an annual basis when new officers are elected.

Investigation Cost Recovery

The Executive Secretary reviewed K.S.A 65-1658 with the Board which concerns civil fines for violations. The Board determined that the statute says the Board of Pharmacy Fee Fund shall/must keep the Board's actual costs from the fine with the balance being credited to the State General Fund.

Recess: John Worden recessed the open meeting to continue the Administrative Proceedings and Hearings.

Case 17-163 Jerry Spillman

- The Board was represented by Mr. Forbes.
- Jerry Spillman represented himself and appeared without counsel.
- Ms. Tunnell swore in Jerry Spillman who gave testimony.
- Ms. Blasi was still under oath.
- The Board entered into closed session for KAPA deliberations and included the Executive Secretary at 10:50am
- Dr. Worden reconvened the proceedings at 11:09am.
- Motion made to approve the pharmacist reciprocal license. (Ullom/Lonergan)
Motion carries.

Recess: John Worden recessed the administrative proceedings at 11:12 am

Reconvene: John Worden reconvened the administrative proceedings at 11:18 am

Case 15-109 Heartland Medical, LLC

- The Board was represented by Mr. Forbes.
- Heartland Medical did not appear.
- Ms. Tunnell swore in Carly Haynes who gave testimony.

- The Board entered into closed session for KAPA deliberations and included the Executive Secretary at 11:33am.
- John Worden reconvened the proceedings at 11:43am.
- Motion made to revoke the pharmacy registration, assess all pertinent fines against the owner, and have staff open an investigation into all registered pharmacies and owners associated with the facility. (Haneke/Lonergan) Motion carries.

Reconvene: John Worden reconvened the open meeting at 11:44am

Board Discussion cont.:

2018 Legislation

1. Cybersecurity & IT Consolidation

Staff was approached early on in the process by the CITO for assistance in understanding what legislation would mean for small agencies. After providing feedback, edits to bill language will allow the Board to provide supportive testimony to the legislature.

2. Industrial Hemp, CBD & Marijuana

Watching these various bills and how they could potentially affect the Board.

3. Senate Bill 312

This bill would create a dental therapist which is a step up from a dental hygienist, but would work under a dentist. The bill allows the dental therapist to administer and dispense certain drugs without counseling patients or taking a patient history. The Board submitted opposition testimony in regard to the dispensing language. The bill passed the Senate and is in the House where the Executive Secretary will offer opposition testimony. The Board discussed the potential dangers and ramifications of the administration and dispensing language in the bill and directed the Executive Secretary to continue pursuing opportunities to educate legislators about these issues and suggest amendments removing the concerning language.

4. Various Bills

Bills that the Executive Secretary is watching include those affecting transparency in government and how bills are introduced; an update to the tax code to define DME; telemedicine bill (dispensing language removed); and state contracts and net neutrality.

5. Senate Bill 421

This bill concerns the Board's ability to consider and review applicant and licensee criminal history, in addition to a new pre-application determination step based on the applicant's criminal history. The Executive Secretary offered testimony about the burden that it would put on the agency and the potential harm to the public of allowing licensure/registration for individuals with certain types of criminal history.

6. Controlled Substance Act Senate Bill 282

The bill was passed out of the Senate and is now in the House where the plant substance Kratom (adding to Schedule I) has become a topic of discussion.

7. Pharmacy Bills

Senate Bill 377 would allow pharmacists to administer drugs by injection. Senate Bill 387 would authorize the creation of statewide protocols like the naloxone

protocol. Both bills were introduced by pharmacy associations and received strong opposition from the medical community. It appears neither bill will pass the House this year.

Recess: John Worden recessed the meeting at 12:21 pm

Reconvene: John Worden reconvened the meeting at 1:02 pm

Public Comment:

There was no public comment.

Public Hearing on Administrative Rules and Regs*

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 March 5, 2018, which included no comments or questions on K.A.R. 68-21-7, 68-5-17, 68-13-2, or 68-13-3. The Joint Committee did suggest that the Board not adopt K.A.R. 68-13-4 and reevaluate it based on the public comments and pending changes to USP <797>.

K.A.R. 68-5-17

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. 68-21-7

The Executive Secretary provided a brief statement regarding the amendments and principle reasons for adopting the regulations. There were no public comments. Written comments were received from Ralph Holbrook of the Kansas Pharmacists Association.

K.A.R. 68-13-2, K.A.R. 68-13-3, K.A.R. 68-13-4

The Executive Secretary provided a brief statement regarding the amendments and principle reasons for adopting the regulations.

Written comments were received from:

- The University of Kansas Health System
- Richard L. Green, R.Ph BCNP of Cardinal Health Nuclear Pharmacy Services
- Katherine Miller, PharmD, Director of Government Affairs, Kansas Council of Health-System Pharmacy; Lindsay Massey, PharmD, President, KCHP; Emily Prohaksa, PharmD, President, Kansas Pharmacists Association; Aaron Dunkel, Executive Director, KPhA; and Chad Austin, Kansas Hospital Association Senior Vice President, Government Relations, KHA on behalf of the Kansas Council of Health-System Pharmacy, Kansas Pharmacists Association, and Kansas Hospital Association
- Cynthia Blankenship, Executive Vice President, International Academy of Compounding Pharmacists
- Ronna B. Hauser, Vice President, Pharmacy Affairs, National Community Pharmacist Association
- Mary E. Durham, Pharm D., M.S., BCPS, Truman Medical Centers
- Eric Everett, RPh, O'Brien Pharmacy

- Joseph M. Hill III, Director, Government Relations Division, American Society of Health-System Pharmacists
- Lawrence Memorial Hospital
- Julie Pellet, PharmD & Craig Campbell, RPh of Mercy Hospital Fort Scott
- Denis Wormington, RPh, BCNSP, CNSC
- Jason Syring, RPh, Director of Pharmacy Operations, JCB Laboratories & Fagron Sterile Services
- Michael Blaire, RPh, FIACP of Blaire Pharmacy Consulting.

Oral comments were received from:

- Travis Gratton, DVM of Kansas Veterinary Medical Association
- John McEniry, JCB Laboratories & Fagron Sterile Services with Jason Syring of JCB Laboratories
- Jason McGuire Vice President of Quality for Fagron Sterile Services
- Katie Peterson of Heritage Biologics
- Rick Couldry of University of Kansas Health System
- Jeff Kivett from Stark Pharmacy
- Denis Wormington of Central Admixture Pharmacy Services, but speaking on behalf of himself
- Jerrod Brown with Triad Isotopes
- Andrea Puyear, Cardinal Health Nuclear Pharmacy Services
- Eric Everett, O'Brien Pharmacy

John Worden shared a brief history of the attempt to regulate compounding in Kansas and discussed the regulations with a few of the attendees who had offered public comment.

The Executive Secretary requested the Board move on in the agenda to hear a previously scheduled presentation from the Idaho Board of Pharmacy and temporarily table consideration of the regulations.

Presentation on Pharmacy Technicians from the Idaho State Board of Pharmacy

Alex Adams, Executive Director, and Nicole Chopski, Chairman of the IBOP shared information about their less restrictive requirements for pharmacy technicians and increased discretion for supervising pharmacists.

Consideration of Administrative Rules and Regulations:

A motion was made and seconded to adopt K.A.R. 68-21-7 and 68-5-17.

(Ullom/Walden) Motion passed.

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

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

A motion was made and seconded to adopt K.A.R. 68-13-2 & 68-13-3. (Ullom/Brunswig) Motion passed.

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

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

68-13-4: The Joint Committee on Administrative Rules and Regulations recommended the Board table the regulation. Issues revolve around ceasing compounding as a result of microbial growth. Discussion was held about a proposed amendment that could mitigate the bulk of the concerns expressed in public comment.

A motion was made and seconded to amend 68-13-4 prior to adoption based on public comments. (Walden/Ullom) Motion passed.

Board Discussion cont.:

2018 Legislation cont.

The Board has provided many presentations to legislators about K-TRACS to ensure they have accurate information about the program.

8. House Bill 2574

This bill would mandate prescribers & dispensers register with K-TRACS. The bill would also allow K-TRACS access for impaired provider programs and reports to be provided to the DEA upon receipt of an administrative subpoena. Bill will probably not get a hearing this year.

9. House Bill 2759

This bill would mandate veterinarians report dispensing of controlled substances and drugs of concern to K-TRACS. Appriss says this is feasible. Not sure if it will get a hearing this year.

10. Funding

The Board was asked to make a wish-list for K-TRACS – if you had all the money in the world what would you want? The House Social Services Budget Committee voted to approve all wish-list enhancements and funded the requests from the State General Fund. The Committee's recommendation will be presented to the House Appropriations Committee in the coming weeks for their consideration.

Substance Use Disorder Task Force

The Governor signed Executive Order 18-09 creating a Substance Use Disorder Task Force. As a representative of the Board of Pharmacy, the Executive Secretary will be part of task force formed to address the growing substance use disorder problem in Kansas.

Offer for CBD presentation

The Attorney General recently issued an opinion indicating CBD is an illegal substance in Kansas. Some pharmacies (and other shops) were selling CBD but have ceased after the AG's opinion was released. Many groups are lobbying for legislative change. In the meantime, Cody Freeze, PharmD, offered to provide an education presentation to the Board about CBD and ECS if the Board is interested. The Board agreed to hear a 20-minute presentation at a future meeting, to be arranged by the Executive Secretary.

2018 NABP Annual Meeting – Delegate and Resolutions

Chad Ullom was elected by District 6,7,8, to the 2018 NABP Resolutions Committee. He and Jon Brunswig will be attending the 2018 Annual Meeting in May. A motion was made to appoint Mr. Ullom as the Board's voting delegate and Mr. Brunswig as the alternate delegate. (Hanake/Lonergan) Motion passes.

Regulations

Comments were submitted by the University of Kansas Health System regarding K.A.R. 68-7-15(b). The regulation was amended last year and hadn't been amended since the 1980s. The comments indicated that a previous understanding was that this regulation only applied to long-term care facility. The text and article of the regulation would not indicate such limited application. There is now a question about repackaging and distribution among the facilities in the University of Kansas Health System. It may be more of an FDA issue. Decision was made to re-address the issue at the next Board meeting.

The Executive Secretary anticipated that the automation (rural nurse) regulation amendments and revocation of K.A.R. 68-13-1 will soon go out for public comment. K.A.R. 68-2-23 & 68-7-25 were presented to the Board for review and consideration prior to sending them out for public comment. These new regulations concern proactive reporting of discipline, criminal offenses, and suspected theft, loss, or diversion of controlled substances to the Board by licensees and registrants. The Board was supportive of these additions.

The next group of regulations to be written include epinephrine kits, DSCSA regulations, and possibly moving forward with a Collaborative Practice Agreement regulation update.

Board Member Reports

John Worden requested that the Board put together a sterile compounding task force including members from KPhA and KPAC.

Bill Walden wanted to thank the Executive Secretary and inspectors for allowing him to participate in the presentation to the law class at the University of Kansas.

50 State Survey on Prescription Limitations

Jason Brozek, J.D., PharmD candidate presented a report on the opioid prescribing limitations for different states. The Board was very impressed, commended Mr. Brozek for his work and encouraged him to seek publication.

Recess: John Worden recessed the meeting at 3:54 pm

Reconvene: John Worden reconvened the meeting at 4:07 pm

Staff Reports

K-TRACS

Fan Xiong, Data-Driven Prevention Initiative Epidemiologist, presented on the opioid epidemic.

Compliance/Legal Forum

Randy Forbes attended the NABP Compliance & Legal Forum and reported that it had lots of breakout sessions and different points of view. Discussion topics included PMPs,

opioid prescription guidelines, diversion, prescribing in collaborative practices, cannabis, USP 800, and sterile compounding by physicians and nurses in clinics. Melissa Martin also attended the conference on behalf of the inspectors and provided a report in writing.

Compliance

Jim Kinderknecht reported that he enjoyed having Jason Brozek with him on the road for a few days during Jason's internship with the Board.

Committee Reports:

- Pilot Project-The approved pilot project has not started yet.
- Pharmacy Tech/Rural Nurse-This committee hasn't met recently.
- CE Review-The CE Review Committee now has a secure website for them to access and review applications.
- Collaborative Practice-This committee met recently and had a good discussion about protocols.

NABP

Staff requested NABP quantify member benefits to pass along to the legislatures. In response, NABP put together a Member Benefit Statement for all states. The Board pays an annual fee of \$250 and receives approximately \$327,095 worth of benefits, including free participation in PMPi.

Executive orders

The Governor has issued several Executive Orders. Staff is taking necessary steps to respond and comply as appropriate.

- Special PMP Advisory Committee Meeting was held on February 16th.
- Staff and recognition: Fan Xiong and Jackie Yingling were named Employees of the Quarter. Megan Alford joined the staff as a senior administrative assistant specializing in facilities in January.
- Office space: The Executive Secretary and Assistant Director are actively looking into expanding or renovating if we add more positions. The agency is growing and potentially in need of more space.
- A reminder that the mandatory Statement of Substantial Interests will be sent out to the Board in a few weeks for completion.
- Small agency meetings: The Executive Secretary continues to meet with other small agency heads to stay on top of things.
- Other business is included in the packet.

Approvals*

1. PMP Advisory Committee Appointments – all are nominations for reappointments
2. Stipulation and Consent Orders
3. Summary Disciplinary Actions
4. Minutes from Special Board Meeting – December 20, 2017
5. New Licensees and Registrants

A motion was made and seconded to approve the PMP Advisory Committee Appointments, Summary Disciplinary Actions, Minutes of the December 20, 2017 Special Board Meeting, and New Licensees and Registrants. (Ullom/ Lonergan) Motion passed.

A motion was made and seconded to approve the Stipulation and Consent Orders. (Walden/ Lonergan) Motion passed.

Executive Session

A motion was made and seconded at 4:49 pm to enter into executive session per K.S.A. 75-4319(b) to discuss personnel matters of nonelected personnel to reconvene at 5:00 pm and to include the Executive Secretary. (Ullom/Walden) Motion passed.

John Worden reconvened the meeting at 5:00 pm.

Adjorn: John Worden adjourned the meeting at 5:00 pm.