

Kansas State Board of Pharmacy
Minutes of the April 6, 2017
Board Meeting

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

Thursday, April 6, 2017

Meeting Called to Order: President John Worden called the meeting to order at 8:31am.

Members Present: John Worden, Pharm. D., President; Michael Lonergan, R.Ph., Vice President ; James Garrelts, Pharm. D.; Robert Haneke, Pharm D; Cheri Pugh, Public Member; David Schoech, R.Ph., Alternate Investigative Member; and Chad Ullom, R.Ph., 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 Program Manager; Jackie Yingling, Assistant Director; KariAnn Wootan, Administrative Specialist; Heidi Nelson, Administrative Specialist; Ashley Riley, Sr. Administrative Assistant; Andrea Haddad, Law Clerk; Andrew Serrone, Law Clerk; Randall Forbes, JD, General Counsel; Michele Tunnell, JD, Administrative Law Judge.

Others Present: See attached listing.

Administrative Proceedings

Case 14-100 Steven Stoecker

- The Board was represented by Mr. Forbes
- Steven Stoecker represented himself and appeared without counsel.
- The Board entered into closed session for KAPA deliberations, and included the Executive Secretary.
- Dr. Worden reconvened the open meeting.
- A motion was made to reinstate Mr. Stoecker's license on July 16, 2017 (Lonergan/Garrelts). Motion passed. Mr. Stoecker must notify the Board when changing employers or if he has any noncompliance issues with the Kansas Pharmacist Recovery Network, KsPRN.

Case 13-132 Angela Little

- The Board was represented by Mr. Forbes
- Angela Little represented herself and appeared without counsel, was sworn in by Ms. Tunnell, and gave testimony.

- Mr. Haneke requested a closed hearing to discuss confidential information relating to the KsPRN, to include the Executive Secretary and members of the CIPP staff and Committee.
- The Board entered into closed session for KAPA deliberations, and included the Executive Secretary.
- Dr. Worden reconvened the open meeting.
- A motion was made to reject early release from KsPRN and pre-approve preceptor or PIC status in January 2018 upon approval of CIPP (Ullom/Garrelts). Motion passed. Reappearance not required but must remain in compliance and complete five-year term in KsPRN.

Recess: Dr. Worden declared a break at 9:28 am

Reconvene: Dr. Worden reconvened the meeting at 9:37 am

Case 16-204 Kiara Hollins

- The Board was represented by Mr. Forbes
- Kiara Hollins represented herself, appeared without counsel, was sworn in by Ms. Tunnell, and gave testimony.
- The Executive Secretary was sworn in by Ms. Tunnell and gave testimony on behalf of the Board.
- The Board entered into closed session for KAPA deliberations, and included the Executive Secretary.
- Dr. Worden reconvened the open meeting.
- A motion was made to deny Ms. Hollins pharmacy technician application (Lonergan/Schoech). Motion passed.

Case 13-141 Leigh Angell

- The Board was represented by Mr. Forbes
- Leigh Angell represented herself and appeared without counsel, was sworn in by Michele Tunnell, and gave testimony.
- The Board entered into closed session for KAPA deliberations, and included the Executive Secretary.
- Dr. Worden reconvened the open meeting.
- A motion was made to reject early release from KsPRN and pre-approve PIC or preceptor status in January 2018 upon approval of CIPP (Ullom/Schoech). Motion passed. Reappearance not required but must remain in compliance and complete five-year term with KsPRN.

Case 16-170 Amtis Amani

- The Board was represented by Mr. Forbes
- Amtis Amani represented herself and appeared without counsel, was sworn in by Michele Tunnell, and gave testimony.
- The Executive Secretary, still under oath, gave testimony.
- Ms. Amani requested a closed hearing to discuss confidential health information, to include the Executive Secretary.

- The Board entered into closed session for KAPA deliberations, and included the Executive Secretary.
- Dr. Worden reconvened the open meeting.
- A motion was made to deny Ms. Amani's application for registration as a pharmacy technician after revocation for failure to demonstrate complete and consistent rehabilitation (Ullom/Garrelts). Motion passed. The Board encouraged Ms. Amani to continue her rehabilitation efforts and reapply in the future.

Recess: Dr. Worden declared a 5 minute break at 10:59 am

Reconvene: Dr. Worden reconvened the meeting at 11:05 am

Proteus Presentation

Rob Duck provided information on Proteus Digital Health's FDA-approved digital sensor containing an ingestible event marker.

The Board directed the Executive Secretary to pursue regulatory updates consistent with allowing repackaging of medications to include the FDA-approved IEMAP device.

Special Presentation

The Board and Staff recognized Mr. Schoech and Dr. Garrelts and thanked them for their eight years of outstanding service to the State as members of the Board of Pharmacy.

Recess: Dr. Worden recessed the meeting for lunch at 12:05 pm

Reconvene: Dr. Worden reconvened the meeting at 1:01 pm

Public Comment: There were no public comments.

Board Discussion:

January 2017 Board Meeting Public Comment Follow Up

At Richard Couldry's request, case 16-114 was reviewed by another Board member. A similar determination was made and the Board did not pursue formal reconsideration.

At Richard Couldry's request, staff reviewed the process for notification of disciplinary actions. The Executive Secretary recommended that the Board remain in compliance with the Kansas Administrative Procedure Act by sending correspondence to the address of record and, as an additional courtesy, email disciplinary action directly to the Respondent (pharmacist or technician) or the PIC (pharmacy or technician). The Board agreed with the Executive Secretary's recommendation.

Unlicensed Personnel in Pharmacy

HIPAA - all persons with access to PHI shall have completed a HIPAA training program; no disclosure is intended for business associates (any disclosure is incidental).

DEA - facility will carefully screen all employees, provide adequate supervision, and have policies for guests, visitors, maintenance, and non-employee service personnel.

Kansas Requirements –

- Registered pharmacist on duty at all times the pharmacy is open
- Allows tech, nurse, or intern to be in pharmacy unsupervised in certain circumstances
- Maintain records for all training / education of pharmacy personnel
- Policies and effective controls for adequate accountability and security of drugs

Board discussed information above and consensus was that all unlicensed and licensed/registered individuals should only be allowed in the pharmacy at the PIC's discretion so long as they meet all federal and state requirements.

Pilot Project Request – Sedan Pharmacy / Myers Family Center

The Pilot Project Committee expressed concerns about the risks of having pharmacy technicians in a prominent role, with functions that verge on judgmental, without adequate supervision and controls. Staff identified issues with potential tele-pharmacy location ownership, licensing, and documents provided. The Committee recommended denying the pilot project request.

If the request is not approved, Sedan Pharmacy plans to buy clients from Myers Family Center rather than the pharmacy itself. Board requested that Sedan Pharmacy / Myers Family Center correct the ownership issues, update controlled substance policies, and change policies which prohibit inspectors from conducting inspections or deny them access to information required under current state regulations. The Board tabled the matter and upon receipt of requested changes and documents, will revisit the request at the next quarterly meeting.

Sabetha Guidance Document

Inspectors and the Executive Secretary reviewed the draft guidance document and expressed concerns about restating and summarizing current law/regulation in policy format. The Board determined there is no need to issue a guidance document to allow after-hours prescribing and pre-packed hospital dispensing discussed with the Sabetha prescribers at the February 2016 Board meeting.

KPhA Telepharmacy Workgroup

The Executive Director of KPhA, Aaron Dunkel, indicated that KPhA formed a tele-pharmacy workgroup due to several telehealth bills that were introduced during the 2017 legislative session and invited the Board to participate. He anticipates the workgroup will consider potential updates to Kansas law to be protective, facilitate expansion, and incentivize growth in telehealth within Kansas. Telemed, telementoring and telemonitoring will also be topics of discussion. The Board suggested Dr. Worden and Ms. Rosebrook participate in the workgroup.

Pharmacy Tech / Rural Nurse Task Force Update

Task Force had an initial meeting to talk about topics that they will look at for the next year or more. The Executive Secretary heard from the Board of Nursing and they would like someone from the staff to participate and will also get some nurses from the community to participate.

Remedial Pharmacy Ethics Course

The Board received a request to approve a remedial pharmacy ethics course. They indicated that it could be an option for disciplinary cases, and approved the request.

NABP Resolutions

NABP Resolutions for the 2017 Annual Meeting were provided to the Board. Mr. Ullom will be the Board's voting delegate on the resolutions next month and will be attending along with Mr. Kinderknecht.

2017 Tri-Regulator Symposium

The Executive Secretary requested to attend the 2017 Tri-Regulator Symposium, a collaborate meeting with all state pharmacy, nursing, and medical/healing arts boards. The Board agreed.

Regulation Review

The following topics will have a draft prepared and submitted through the administrative rules and regulations process. A final adoption likely wouldn't occur until August or November 2017.

68-7-12a Nonresident Pharmacies

- All pharmacists dispensing or providing pharmacy services to Kansas must be licensed in Kansas
- All PICs must be licensed in Kansas
- Each pharmacy must provide an inspection from the previous 12-month period from the resident state or, if none is available, a Board-approved organization at the pharmacy's expense.

68-7-20 Shared Services

- Pharmacist must be physically present in Kansas or the state where the pharmacy is located
- Nothing shall permit a pharmacy, physician, physician's assistant, or mid-level practitioner to utilize shared services to operate a requesting pharmacy that is not actively engaged in the practice of pharmacy

68-7-12b Incident Reports

- Allow electronic signatures from pharmacy employees involved in incident report
- Do not require license numbers on form

The Board decided not to pursue updates to this regulation.

68-20-19 Partial fills on C-II prescriptions. Updates recommended by Barb Woods at KU School of Pharmacy (not yet drafted). The Board directed the Executive Secretary to pursue updates consistent with federal law changes.

68-2-20 Pharmacists function in filling a prescription / telemedicine

- December 2013 Newsletter article on tele-health was retracted due to concerns
- Will strike telephonic consultation language regarding legitimate medical purpose

- Recommend statutory update to definition of authorized prescriber
- May need to mandate prescriber's state license number on the prescription

Automation Regulations

- CVS recommended changes as cleanup items but they are more substantive
- Many requested changes are designed to allow control by a non-resident managing pharmacy, which is controversial and poses regulatory oversight issues.
- Automation task force is forming and will discuss these issues and language changes.

Reports

2017 Legislative Session

The following bills were passed by the Kansas House and Senate and will be effective after approval by the Governor, and upon publication in statute book, July 1st, 2017 or 15 days after publication in the Kansas Registrar.

- Budget and K-TRACS PMP Funding
- HB 2055 – Pharmacy Practice Act and Biosimilars (amended into the bill)
- SB 51 – Controlled Substance Updates and Emergency Scheduling Authority
- HB 2217 – Emergency Opioid Antagonists
- HB 2030 – Expanded Pharmacist Authority for Immunizations

The Executive Secretary provided a brief overview of the session and provided copies of final, approved legislation. The next objective will be drafting and updating regulations consistent with new legislation.

Recess: Dr. Worden declared a break at 3:09pm

Reconvene Dr. Worden reconvened the meeting.

Board of Pharmacy Financial Report

- Cash balance for the end of March is \$1,104,475.03
- Fund balance is good and YTD revenues up \$77,000 compared to FY16
- Expenses on target with 75% of year completed and about 65.6% of budget year used including encumbrances
- Purchased a new vehicle as budgeted for the 2017 Fiscal Year, to replace vehicle with more than 140,000 miles.

Staffing

Teambuilding Day - Kansas Board of Pharmacy licensing staff, Ms. Nelson, Ms. Riley, and Ms. Wootan, presented on the Kansas Board of Pharmacy People Styles Teambuilding Session which occurred January 2017. The Teambuilding session included office staff, management, inspectors, and discussed the four primary people styles: Analytical, Driver, Expressive, and Amiable.

The Executive Secretary nominated Ms. Martin as the employee of the first quarter 2017 for her outstanding work on the new Inspection Forms and eLicensing compliance portal. The Board agreed.

Licensing

eLicensing Renewals

- Retail Dealers
 - Renewed January 17-Feb 28
 - Online – automatic approvals and self-printing option
 - Less than 50 (3%) retail dealers failed to renew
 - Currently registered: 1,519
- Pharmacists and Facilities
 - Renew May 1 – June 30
 - Postcard Reminder and Email
 - Online – auto approve and self-print if no discipline or changes
 - CPE pre-loaded by NABP and Board staff (not yet functional)

Elicensing compliance portal overview provided by Ms. Haynes.

K-TRACS Report by Ms. Kenton

- Rebranding – Staff came together to design and create new logo for KTRACS
- Introduced Dr. Stanley Wint as the new PMP Advisory Committee member nominated by the Kansas Dental Association.
- Discussed CDC grant and how it will help with statewide integration.
- PMP Interconnect map shows more than 40 active and pending participants.
- Ms. Kenton wanted to host a 50-state roundtable for all PDMP directors, and secured funding from the Bureau of Justice Assistance for one representative of each state to attend in August 2017 (Kansas City, KS).
- Funding/Stakeholder Group discussed continuing to pursue funding options

Inspector Reports

- Ms. Haynes – Attended DEA conference in Wichita and discussed update in inspections
- Ms. Rosebook – Received consumer product safety commission credentials for the poison prevention packaging act
- Ms. Martin – Updated Board on new process for questions for the MPJE. Due to changes in process, may need to go to Chicago next spring.
- Ms. Jones – Consumer product safety commission credentials on the way

NPLEx March 2017 report.

Board Member Reports

Board members thanked Dr. Garrelts and Mr. Schoech for service on Board. Dr. Garrelts and Mr. Schoech thanked remaining Board members and staff.

Approvals

1. Minutes from Quarterly Board Meeting – January 6, 2017
A motion was made and seconded to approve the Minutes. (Schoech/Garrelts)
Motion passed.

2. New Licensees and Registrants

A motion was made and seconded to approve the New Licensees and Registrants.
(Worden/Garrelts) Motion passed.

3. Stipulations/Consent Orders

13-002 Michael Fillmore

A motion was made and seconded to approve Stipulation 13-002.
(Schoech/Haneke) Motion passed.

4. Summary Disciplinary Actions

A motion was made and seconded to approve the Summary Orders.
(Schoech/Garrelts) Motion passed.

Adjourn: Dr. Worden adjourned the meeting at 4:00 pm