

**KANSAS STATE BOARD OF PHARMACY
MINUTES OF THE FEBRUARY 4 and 5, 2016
BOARD OF PHARMACY QUARTERLY MEETING**

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

Thursday February 4, 2016

Meeting Called to Order: Mr. Ullom called the meeting to order at 8:55 AM.

Members Present: Chad Ullom, R.Ph., 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; Jackie Yingling, Assistant Director; Jim Kinderknecht, R.Ph., Licensed Pharmacy Inspector; Carly Haynes, R.Ph., Licensed Pharmacy Inspector; Melissa Martin, Compliance Inspector; Reyne Kenton, Compliance Inspector; Mitzi Dodds, Legal Assistant; Kathleen Deeter, Administrative Specialist; KariAnn Wootan, Administrative Specialist; and Randall J. Forbes, JD, General and Disciplinary Counsel.

Others Present: See attached listing.

Omnicare of Wichita Pilot Project

Omnicare decided not to change their site location and was removed from the agenda without additional discussion

Thank you to Staff from Executive Secretary

Reports

Topics included: Administrative Specialists, Statistics: Licenses, Registrations and Permits, Budget, KTRACS, Grants, eLicensing, and NPLEx.

Licensing and Administrative Specialist Presentation by Kathleen Deeter

- Average of 40-60 applications per week for this time of year
- Majority of renewals are conducted online; Retail Dealers have the highest percentage of paper renewals
- Technicians have the highest number of licenses and lowest license renewal rate
- Based on the number of applications received from 2013-2015:
 - 95% of Pharmacists stay active in KS
 - 59% of Technicians stay active
 - Distributors 92%
 - Pharmacies 84%
- On the Board's website, KTRACS receives a lot of page views (more than 4000 a month for all of 2015)

- Summer – busy with annual renewals as well as pharmacist graduates and pharmacies needing technicians
- Renewal certificate colors are changing to be one color for each renewal period rather than different colors based on license type
- Staff
 - Respond to walk-ins, emails, faxes, and phone calls
 - Assist with KTRACS reports, questions, and assist data requesters with login and registration

Budget Report by Jackie Yingling

- Cash Balance for the end of January is \$1.3 million
- Revenues for fiscal year to date are approximately \$245,000 (last year \$283,000). Anticipated total revenues for 2016 are \$1 million.
- Expenses for fiscal year to date are approximately \$548,000. The fiscal year is 60% complete, and the Board has used 60% of the budget.
- Getting back on track for attorney costs
- Waiting on legislative approval of FY17 enhancement of \$208,431 for the KTRACS program. This is a one-time solution and not a viable long-term option.

K-TRACS Report by Executive Secretary

- The Board may obtain funding by accepting grants/donations but cannot charge users (distributors, dispensers or prescribers) without statutory change. KTRACS is currently funded through 6/30/16 by NABP Grant. The Board requested an FY17 budget enhancement of \$208,431 as a temporary fix, which includes a full-time salaried position for a KTRACS Director.
- Advisory Committee directed Board to pursue all possible funding sources to secure a long-term funding solution
 - Viable Ideas
 - KHIN integration
 - tax on controlled substances
 - adding nominal license fee to renewals (pharmacists, nurse practitioners, dentists and healing arts providers)
 - other appropriations of state general fund
 - fine revenues
 - Reaching out to other states to see how they fund
- Interconnect with other states is funded through 2018
- KTRACS program enhancements currently being pursued with other grant funding
 - Auto-enrollment in KTRACS through eLicensing
 - Patient Alert pop ups for threshold patients
 - Better reporting tools
- Total users – 9500 approximately. (50% of prescribers and 40% of dispensers)
- PMP Committee conducting pilot project referring prescribers to appropriate regulatory Board and revising recurring threshold letters

KDHE Grant from CDC

KDHE is eligible for a CDC grant and wants to apply with Board assistance/support. They are willing to provide the Board with a portion of the grant money. The purpose of the grant is to advance and evaluate state-level prevention for opioid overuse, misuse, abuse and overdose. Kansas applied last year but we were not awarded the grant. Board approved pursuing the grant opportunity.

eLicensing

Contract has been fully executed and the initial visit was Jan 5th-7th, 2016. Staff received a preliminary timeline which is conservative. The Board may need to delay the beginning of the renewal period in order to utilize the new system.

Related projects:

- Build a case management tool
- Forms update
- Website redesign
- Process checklists
- Real-time inspection checklists and reports

NPLEx

Salina is the top user. Crawford and Cowley County are high on the list. Inspectors indicate that the K-70 drug task force is more active in the Salina area and Franklin County may start appearing on the list.

Board Discussion

Meeting Notices

The meetings that are currently required to be noticed under the Kansas Open Meetings Act (KOMA) include Board, PMP Advisory Committee, Collaborative Drug Therapy Management Committee, and CE Review Committee. KOMA only requires notice be given; notice on Board website would be sufficient. Staff requested discontinuing emailed meeting notices to members of the public and solely posting all notices, agenda and minutes on the Board website. Staff will notify everyone on the email lists about this change. The Board approved and requested that Board and Committee members continue to be notified via email.

Bankruptcy Filings

Staff requested the Board either identify the purpose of receiving bankruptcy notifications/filings and take action, or ask licensees to stop sending them to the Board office and shred any bankruptcy filings received. Staff noted one exception for notifications of change in ownership related to filings. The Board agreed to staff shredding bankruptcy filings sent to the Board office unless needed for change of ownership purposes.

2015 CE Audit

Over 47% of the CE Summary Orders have been dismissed for compliance. In the future, Board should consider penalty for failure to respond to Board requests for

documentation. There is an opportunity with eLicensing to provide proof of CE completion to the Board before renewal and interface real-time with the NABP CPE Monitor, but this would require regulatory change and could be implemented for by the 2017 renewal period. The Board approved moving forward with this approach.

CE Committee

Committee is composed of one Board member and three field experts that review and approve/deny CE courses. The Board previously discussed expanding the Committee's role to include review of CE for technicians. Committee is currently subject to KOMA. Mr. Forbes agreed that any committee approving/denying CE on behalf of the Board would be subject to KOMA, and suggested reformatting the process to allow experts to review CE independently (not subject to KOMA) and make recommendations to the Board for approval. Board agreed to dissolve the Committee and ask experts to make recommendations to the Board to approve/deny CE, which will be reviewed at quarterly meetings.

Mr. Ullom called a 15-minute break at 10:25 AM

Mr. Ullom reconvened the meeting at 10:45 AM

PMP Advisory Committee

The Executive Secretary reviewed the PMP Advisory Committee's statutory purpose and authority, membership, and current activity. The Committee is also tasked with developing CE programs in conjunction with:

- Agencies with oversight of prescribers and dispensers
- Kansas Bar Association for attorneys
- KBI for law enforcement

The PMP Advisory Committee should be composed of, at minimum, the following:

- 2 licensed pharmacists (KS Pharmacist Association)
- 1 licensed dentist (KS Dental Association)
- 2 licensed physicians (KS Medical Society and KS Association of Osteopathic Med)
- 1 KBI (Attorney General)
- 2 education (KU School of Med and Pharmacy both nominated by dean)
- 1 KHA (KS Hospital Association)

The Board may also appoint an unlimited number of individuals authorized to prescribe or dispense drugs, recognized experts, or representatives from law enforcement. Appointments to the Committee are currently expired except for one member. Mr. Schoech requested a balance of doctors and pharmacists.

The PMP Advisory Committee is subject to the oversight of the Board, making the Board responsible for operation the program. The Executive Secretary heard from legislators that there is some concern about the momentum of the committee. Legislators would like to see: plans of action, demonstrated evidence of cases being referred, statistics and analysis. At the most recent Committee meeting, members decided to invite CE groups for presentation about KTRACS and provide an opportunity

for collaboration. In addition, the Committee is pursuing a pilot project referral program for providers/dispensers to their respective regulatory Board. The Executive Secretary suggested considering regular status reports and review of PMP meeting minutes at each Board meeting.

Motion to reach out to all agencies for nominations on a staggered basis starting with non-attendees first (Haneke/ Garrelts). Motion passed.

Motion to appoint two new members to the Committee: Dr. Myron Leinwetter and Dr. Kimberly Templeton, recommended by and representative of the Board of Healing Arts (Lonegan / Garrelts). Motion passed.

Inspectors

- Mr. Kinderknecht: Inspectors could be a source of information for the PMP Committee. The rash of break-ins and armed robberies in NE Kansas is alarming.
- Ms. Haynes: Inspectors refer information to Dan Riley separate from the PMP data. DEA has become more active and we may see them on a fairly routine basis.
- Ms. Martin: She, like Mr. Kinderknecht, has been seeing break-ins and armed robberies in her territory. She was shadowed by the Executive Secretary; inspected Axelacare and Spring campus Walgreens.
- Ms. Kenton: She was shadowed by the Executive Secretary and they went on a tour of Hays Medical Center.
- The Executive Secretary indicated staff would be participating in Active Shooter Mitigation Training in March with the Kansas Highway Patrol.

NABP Delegate and Scholarship Application

The Executive Secretary asked the Board to decide who was going to be the official delegate for the NABP Conference. The official delegate must be in attendance at all business sessions to qualify for the scholarship. The Board tabled this agenda item to the next day to allow members to check their calendars.

Non-US Pharmacy Application

Staff received an inquiry from a non-U.S. pharmacy interested in registering in Kansas. The Executive Secretary visited with Mr. Forbes to determine whether they could be licensed. Mr. Forbes indicated that it was addressed in the statute for a non-resident pharmacy but he could not find where "state" or "non-resident" are defined. While the section indicating that the non-resident pharmacy must be in good standing with the state of residence may be intended to prohibit applicants located outside the U.S. that is unclear. Staff will work with Mr. Forbes and do additional research before responding.

Optometry Board Drug vs Device Question

Mr. Forbes provided and discussed material that was received by the Kansas Board of Optometry from a skin and wound cleanser sales representative. The Board of Optometry indicated that they could only dispense medications in limited quantities. The issue was that the manufacturer wants to sell the product as a device. The Board of

Optometry requested the Board of Pharmacy provide an opinion as to whether the item was a device or drug. The Board indicated that FDA.gov would be a resource and agreed that based on their resources and knowledge, the product is a drug.

Mr. Ullom recessed the meeting for lunch at 12:00 PM.

Mr. Ullom reconvened the meeting at 1:04 PM.

Board Member Reports

No reports. The Executive Secretary indicated Dr. Worden would present on the compounding task force the next day.

2016 Legislation

HB 2540

Ms. Haynes and Mr. Kinderknecht headed to the House Committee on Corrections Juvenile Justice for the hearing on HB 2540: amendments to the Kansas Controlled Substances Act. Katie Whisman, Executive Officer for the KBI, contacted the Board with requested changes for law enforcement, security and public safety. KBI will be driving the changes and the Board will be a supporting partner. The changes were reviewed by Ms. Haynes, Mr. Kinderknecht, Mr. Lonergan, Dr. Worden, and Mr. Ullom, prior to introduction of the bill.

HB 2614

HB 2614: Amendments to the Pharmacy Practice Act was reviewed by the Office of the Revisor, and introduced by Representative Don Hill, RPh, into the House Committee on Health and Human Services on January 25, 2016. The bill will be read-in tomorrow and assigned to a committee for hearing. The Board expressed a concern about changing spellings of pharmacopeia and pharmacopoeia for consistency and asked the Executive Secretary to clarify any issues.

Antipsychotic Drugs

The Executive Secretary met with the Chair of the Senate Committee on Public Health and Welfare, who raised questions and expressed concerns about off-label use of antipsychotic drugs in long term care facilities. The Chair suggested an expansion of KTRACS to include off-label and over-prescribing of antipsychotics. The Board would need legislative input and statutory changes to consider adding such drugs to KTRACS in addition to funding. The Board consensus was that this is primarily a prescriber issue and would not be an effective use of KTRACS.

SB389 and HB2577 – FY 17 Appropriations

Expenditure limit for FY 17 increased to \$1,399,519 from \$1,138,888

- Add \$208,431 to fund KTRACS
- Add \$43,200 for maintenance, support, hosting charges (eSoftware Solutions)
- Add \$9,000 – increase in OITS rates

Regulation Update

Collaborative Practice

The double-stamped regulation was published in the Kansas Register on February 4, 2016. The public hearing is scheduled for 8:30 AM on April 21, 2016 at the KU School of Pharmacy.

Automation

The Attorney General's Office (AG) agreed to an unofficial review of another draft of these regulations. The AG indicated there was no cause for concern but noted there was no guarantee they would be approved in the formal process. Mr. Forbes and the Board discussed the definition of dispense, final dispensing and automated dispensing together with the definition of dispense. Mr. Forbes asked if people may try to interpret the verbiage so that a machine could dispense or deliver to the patient. The Executive Secretary shared that there is a section that requires the dispensing be in accordance the Board's rules and regulations, which should protect against a fully automated system that has no human point of intervention or verification.

On advice of counsel, the Board agreed to have the Executive Secretary take over the administrative rules and regulations process.

Public Comment

Mr. Forbes indicated that he attended the NABP Legal Meeting with Ms. Martin in Chicago. They had breakout sessions for the lawyers and one topic was the US Supreme Court Decision in the North Carolina Dental Board case, which held that if Board members are involved in the industry they are not immune from antitrust liability. Mr. Forbes does not see any threat to the Board based on current activities, but actions preventing interstate commerce may be a topic to be revisited.

Mr. Ullom called a 15-minute break at 1:47 PM.

Mr. Ullom resumed the meeting at 2:00 PM.

Executive Session to Discuss a Personnel Matter

Motion to recess into Executive Session to discuss a personnel matter of non-elected personnel for the purpose of discussing position vacancies and supervision, and to return to open session at 3:00 PM (Haneke/Schoech). Motion passed.

Mr. Ullom reconvened the meeting in open session at 3:04 PM.

Approval of New Licensees and Registrants

Motion to approve new licensees/registrants (Haneke/Schoech). Motion passed.

Approval of Minutes

Motion to approve November 5-6, 2015 and December 15, 2015 minutes as written (Schoech/Haneke). Motion passed.

Disciplinary Actions

Stipulation and Consent Agreements

- Case 14-110 Dennis Nguutu (1-15353). Motion to accept the stipulation order (Garrelts/Lonegran). Motion passed.
- Case 15-005B Kelly Siebert (1-14651). Motion to accept the stipulation order (Haneke/Schoech). Motion passed.
- Case 15-050A Stevens County Retail Pharmacy (2-13046) Motion to accept the stipulation order (Schoech/Garrelts). Motion passed.
- Case 15-089 Ronald D. Satterfield (1-15821). Mr. Ullom recused himself from discussion and voting. Motion to accept stipulation (Garrelts/Schoech). Motion passed.
- Case 15-093B Tabia L. Norris (1-16506). Motion to accept the stipulation order (Pugh/Garrelts). Motion passed.

The Board discussed possible methods of notification of actions in other states.

Summary Orders

- 15-114 Deric Perkins
- 15-116 Gema Paola Munguia
- 15-118 Shaina Roberson
- 15-119 Sarah K. West
- 15-120 Dennis B. Dutton, Jr.
- 15-124 Richard W. Trowbridge
- 15-247 Jamie Martin

Motion to approve all summary orders (Haneke/Lonegran). Motion passed.

Adjourn: Mr. Ullom adjourned the meeting at 4:30 PM.

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BOARD OF PHARMACY QUARTERLY MEETING**

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

Friday February 5, 2016

Meeting Called to Order: Mr. Ullom called the meeting to order at 8:46 AM.

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, Executive Secretary; Mitzi Dodds, Legal Assistant; KariAnn Wootan, Administrative Specialist; Randall J. Forbes, JD, Disciplinary Counsel and Michele Tunnell, JD, General Counsel.

Others Present: See attached listing

Administrative Proceedings/Hearings

- Case 14-128A Walgreens #03069 (2-13084). Walgreens representative required to appear and is present. Mr. Ullom recuses himself from discussion and voting. Motion to accept the Stipulation and Consent Agreement (Lonergan/Garrelts). Motion passed.

Final Orders

- Case 9-058 William Pollard (1-12224). Motion to issue to revoke pharmacist license (Worden/Schoech). Motion passed.
- Case 15-026 Kyle Jones (3-06291 and Applicant). Motion to revoke intern license (Garrelts/Schoech). Motion passed.

NABP Delegate and Scholarship Application

Motion to designate Dr. John Worden as the Board's official delegate (Schoech/Garrelts). Motion Passed. Executive Secretary will serve as alternate delegate if allowed by NABP.

Administrative Proceedings/Hearings

Case 15-097 Cory Behnke (3-1336) – Hearing

- The Board was represented by Mr. Forbes. Mr. Behnke was pro se.
- Mr. Kinderknecht served as a witness for the Board.
- Mr. Behnke had no objections to the exhibits and they were all deemed admitted.

- Motion to close hearing at 9:40 AM to discuss private health information (Worden/Schoech). No objection from Mr. Behnke. Motion passed. Hearing reconvened at 9:47 AM.
- The Board went into deliberations at 10:28 AM, and reconvened at 10:40 AM.
- Mr. Ullom called for a 10-minute break at 10:40 AM.
- Hearing will be continued to July.

Board Member Reports – John Worden

Compounding Task Force: Dr. Worden stated that after completing a compilation of the comments and a final conference call with the task force, he would bring a final product to the next Board meeting. The Board indicated that USP 800 was released February 1st and deals with Hazardous Materials and made changes made to USP 797. Dr. Worden said we could consider additional regulations that addresses hazardous compounding but he would still propose that they continue with the basics for sterile and non-sterile compounding. Based on the update to USP 800 compounding pharmacies may have until 2018 to enact them. Dr. Worden and the Executive Secretary indicated that they would like to get the current regulations passed and then address the hazardous drugs compounding. The Executive Secretary indicated that HB 2614 makes amendments to the Pharmacy Practice Act that would grant the Board more authority to regulate compounding. The Board agreed to continue pursuing actions proposed by Dr. Worden.

Strategic Planning Session

Adjourn: Meeting adjourned by Mr. Ullom at 3:30 PM.