

Kansas State Board of Pharmacy
Minutes of the January 8 & 9, 2015
Board Meeting

Rasmussen College
620 SW Governor View, Rm #116
Topeka, KS 66606

Thursday, January 8, 2015

Meeting Called to Order: President Robert Haneke called the meeting to order at 9:04am.

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

Members Absent: Cheri Pugh, Public Member

Staff Present: Debra Billingsley, JD, Executive Secretary; 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; and Randall Forbes, General Counsel.

Others Present: See attached listing.

Introductions: Ms. Billingsley introduced Mitzi Dodds as the new Legal Assistant in the Board office. Dr. Garrelts introduced Rishonna Martin, PharmD, as a pharmacy resident for Via Christi Hospital.

Approval of the Agenda:

A motion was made and seconded to approve the agenda as amended. (Schoech/Worden) Motion passed. Added to the agenda was K.A.R.68-20-31 for adoption after the public hearings and an executive session to discuss personnel matters of nonelected officials at the end of the agenda on day one.

Approval of the October 16 & 17, 2014 Minutes:

A motion was made and seconded to approve the minutes as printed. (Schoech/Ullom) Motion passed.

Public Hearings for Proposed Regulations

Electronic Prescribing

K.A.R. – 68-2-22. Electronic transmission of a prescription

K.A.R. – 68-20-10a. Electronic transmission of a controlled substance

Dr. Haneke adjourned the regular meeting and opened the public hearing at 9:06am

Dr. Haneke asked for public comment.

Ms. Billingsley provided letters from ---

- Raney Gilliland, Director, Joint Committee on Administrative Rules and Regulations recommending that the Board consider adopting 21 CFR Part 1311 by reference.
- Janet Arndt, Assistant Attorney General, Attorney General's Office – No legal concerns with regulation.
- Lis Houchen, NW Regional Director, State Government Affairs with NACDS – National Association of Chain Drug Stores – supporting the amendments.
- Ken Whittemore, Senior Vice President, Professional Regulatory Affairs with Surescripts – supporting the amendments stating that the proposed changes would meet the federal requirement to allow Schedule II controlled substances to be electronically prescribed.
- Dale Masten, Director, Government Affairs, Genoa, a QoL healthcare company – supporting the amendments.
- Michelle Knowles, MSN,APRN, FNP-BC, and Merilyn Douglass, DNP, APRN-FNP-C, American Association of Nurse Practitioners – supporting the amendments.
- Kristin Powell, PharmD, Site Manager, Genoa Healthcare – supporting the amendments
- Dr. Eric Atwood, Medical Director, Family Service & Guidance Center – supporting the amendments.

Cancer Drug Repository Program – Revocation of Regulations

K.A.R. – 68-16-1. Same; Definitions.

K.A.R. – 68-16-2. Same; Requirements for participation by physicians, pharmacies, hospitals, and nonprofit clinics.

K.A.R. – 68-16-3. Same; Donation of cancer drugs.

K.A.R. – 68-16-4. Same; Dispensing requirements.

K.A.R. – 68-16-5. Same; Handling fees.

K.A.R. – 68-16-6. Same; Distribution of donated cancer drugs.

K.A.R. – 68-16-7. Same; Sale of donated drugs.

K.A.R. – 68-16-8. Same; Recordkeeping requirements.

K.A.R. – 68-16-9. Same; Forms.

Dr. Haneke asked for public comment.

Ms. Billingsley provided letters from ---

- Raney Gilliland, Director, Joint Committee on Administrative Rules and Regulations stating they had no comment on the proposed revocation of the regulations.
- Janet Arndt, Assistant Attorney General, Attorney General's Office – No legal concerns with revocation.

The cancer drug repository program statutory language was repealed by the legislature in the 2014 session necessitating the revocation of the regulations.

A motion was made and seconded to adjourn the public meeting. (Worden/Garrelts)
Motion passed.

Dr. Haneke closed the public hearing and reconvened the regular meeting at 9:15am.

A motion was made and seconded to adopt the proposed regulation K.A.R. 68-2-22.
Electronic transmission of a prescription (Ullom/Worden)

Roll call: Dr. Garrelts – Yes, Dr. Haneke – Yes, Mr. Lonergan – Yes, Mr. Schoech – Yes, Mr. Ullom – Yes, and Dr. Worden – Yes.

The motion passed. The regulation will become effective 15 days after publication in the Kansas Register (February 13, 2015).

A motion was made and seconded to adopt the proposed regulation K.A.R.68-20-10a. Electronic transmission of a controlled substance (Ullom/Worden)

Roll call: Dr. Garrelts – Yes, Dr. Haneke – Yes, Mr. Lonergan – Yes, Mr. Schoech – Yes, Mr. Ullom – Yes, and Dr. Worden – Yes.

The motion passed. The regulation will become effective 15 days after publication in the Kansas Register (February 13, 2015).

A motion was made and seconded to revoke the Cancer Drug Repository Program regulations K.A.R. 68-16-1 through K.A.R. 68-16-9. (Worden/Garrelts)

Roll call: Dr. Garrelts – Yes, Dr. Haneke – Yes, Mr. Lonergan – Yes, Mr. Schoech – Yes, Mr. Ullom – Yes, and Dr. Worden – Yes.

The motion passed. The revocation will become effective 15 days after publication in the Kansas Register (February 13, 2015).

Pursuant to K.S.A. 77-436 the Board motioned to adopt K.A.R. 68-20-31 subsequent to the review of the Joint Committee on Administrative Rules and Regulations. (Schoech/Lonergan).

K.A.R.68-20-31. 2,5-dimethoxy-4-methyl-n-(2-methoxybenzyl)phenethylamine included in Schedule I.

Roll call: Dr. Garrelts – Yes, Dr. Haneke – Yes, Mr. Lonergan – Yes, Ms. Pugh – Yes, Mr. Schoech – Yes, Mr. Ullom – Yes, and Dr. Worden – Yes.

The motion passed.

Board Discussion and Reports

Drug Supply Chain Security – On November 27, 2014, Congress signed into law the Drug Quality and Security Act (DQSA) amending section 503(e) of the Federal Food, Drug and Cosmetic Act. Several key requirements go into effect on January 1, 2015. Some of the things that the Act requires is product tracing, licensing and pre-exemption. Ms. Billingsley provided the draft statutory language for discussion. Martha Russell, Assistant General Counsel – Regulatory, Cardinal Health made a presentation describing the changes to federal law and how they conflict with certain provisions of the Kansas Pharmacy Act. The Board will pursue statutory changes this legislative session to bring Kansas statutes and then regulations into federal compliance.

Recess: Dr. Haneke declared a 5 minute break at 10:13am.

Reconvene Dr. Haneke reconvened the meeting at 10:32am

Omnicare Pilot – Kara Tindal, Pharm D., PIC for Omnicare in Wichita made the presentation. Dr. Haneke recused himself from the discussion as he works with Omnicare. A motion was made and seconded to allow Omnicare to proceed with the proposed pilot in the two designated facilities and to report results quarterly after the pilot commences in the facilities. (Lonergan/Garrelts) Motion passed. The Board

requested Ms. Tindal to notify the Board office when the machines became operational in the two facilities.

Pharmacy Technician Education – David Schoech, RPh. and chairman of the Pharmacy Technician Education Task Force gave an update on the Task Force's progress. Draft regulations were provided and discussed by the Board. The draft regulations included proposed language that all pharmacy technicians take an examination that is accredited by the National Commission for Certifying Agencies (NCCA). There was a proposed exemption clause that would grandfather technicians meeting certain criteria. The proposed regulations included a definition of *Technician in Training* allowing time for a technician to become nationally certified within 2 years from the time a technician registration is obtained. The Board recommended revisions to the draft specifically as it related to technician trainee restriction on duties. The Committee is scheduled to meet again on February 6, 2015 and will continue revising the draft regulations.

Collaborative Practice Report – Dr. James Garrelts and chairman of the Collaborative Practice Advisory Committee presented an update of the Committee's work. Dr. Garrelts reported the committee has held two meetings and is awaiting the Board of Healing Art's appointment of the physician members as required by statute. The committee has reviewed the collaborative agreement statute, discussed the need for collaborative practice, similarities to MTM (medication therapy management), and discussed how CDTM would be used in different health settings. The committee discussed keeping the regulations short and simple and to use educational documents to provide guidance. The committee discussed drug therapy co-management and the protocol between a doctor and a pharmacist as opposed to a store or corporation. They also discussed training and continuing education, internships, emergency situations, and licensing requirements.

Recess: Dr. Haneke recessed the meeting for lunch at 11:46am to reconvene at 12:45pm.

Reconvene: Dr. Haneke reconvened the meeting at 12:51pm.

Board Discussion and Reports - continued

Continuing Education – Ms. Billingsley presented the information concerning the reporting and auditing of continuing education for the pharmacists renewal in 2014. Ms. Billingsley asked the Board to review the Continuing Education Policy and determine if changes were needed. The Board consensus was to continue to support the Continuing Education Policy.

Budget – Ms. Yingling presented the budget report. The pharmacy fee fund has decreased as expected with the reduction of fees. The budget continues to be on target for the year.

NPLEx Report – Ms. Billingsley provided the statistics and information. Ms. Billingsley has prepared the report for the legislature. The pharmacies have adjusted to using the NPLEx system as well as the patients. It is a valuable tool in detecting criminal activity. The Board recommends continued support of the NPLEx system for purchases of over the counter methamphetamine precursors.

KTRACS – Jackie Yingling presented the report to the Board. The reporting problems appear to be corrected with the latest software upgrade. Fourth quarter threshold letters are in the process of being mailed. Oklahoma will soon be able to share their PMP data with neighboring states through the PMPi Interconnect. Ms. Yingling said she is in the process of learning KTRACS and will be going to Appriss for training in the next few weeks.

Approval of New Pharmacists and New Registrants

A motion was made and seconded to approve the new licenses and registrations. (Worden/Lonergan) Motion passed.

Board Discussion and Reports - continued

Investigative Member Report – Closed Cases. Mr. Lonergan presented the closed cases and asked for any questions. Mr. Lonergan suggested the Board form a committee to look at the KsPRN contract and make a proposal on how the program can be restructured to meet the needs of the Board. Those areas would include how to gather and report data, success metrics, guidelines as to how recommendations are made and presented. The committee will discuss the legal requirements for information needed at hearings and proposals of action if a licensee fails to comply. The Board set the committee to include: Mike Lonergan, Randy Forbes, Mike Larkin, and Ralph Holbrook.

Board Member Reports

Bob Haneke, PharmD – reported on the NABP yearly meeting. Dr. Haneke presented information from the sessions he attended.

- Medical marijuana was a big discussion regarding types of dispensing options.
- Unions are pursuing regulations controlling working conditions, as in number of hours, number of prescriptions per hour
- Boards using yearly retreats to introduce and mentor new Board members. The retreats are used to train Board members in regulatory procedures. The meeting allows for Board and staff to discuss direction and strategic planning needs.

John Worden – inquired as to the progress of the compounding regulations. The regulations have been transferred to legal for completion.

Executive Director Report

Ms. Billingsley –

- Tele-doc. Many employers are encouraging their employees to call their insurance doctor for prescriptions covered through the employee plan. The patient tells the doctor their symptoms and the doctor calls or faxes a prescription to the pharmacy. Many pharmacists question the doctor-patient relationship and are declining to fill the prescriptions. The Kansas Board of Healing Arts informed Ms. Billingsley that physicians engaged in this type of business model must be registered to practice medicine and surgery in the State of Kansas for the prescriptions to be legitimate. Ms. Billingsley encouraged pharmacists to use professional judgment and if necessary to call KBoHA.

- Ms. Billingsley and Carly Haynes will be attending the NABP Inspection Blueprint meeting in Chicago next week. The goal is to update the Kansas inspection report and for the states to identify commonality and documentation needs.
- TALKOM2 – will be meeting February 14, 2015 in Dallas, Texas. Ms. Billingsley will attend. The group is primarily the NABP District 6 (Texas, Arkansas, Louisiana, Kansas, Oklahoma, Mississippi, and Missouri). The discussion items will include: Diversion, Compounding, Technician Issues, and other items of interest of the group.
- The Board of Pharmacy has budgeted for installation of professional licensing and disciplinary software. The state has purchased a license with Systems Automation and the Board staff has met with the vendor to begin the process of data conversion.
- As part of a Legislative Post Audit report, the Board of Pharmacy is participating in a financial and security audit. The recommendation was that each agency conducts an audit at least once every three years. The Board is in the process of providing information for the audit.
- Drug Destruction – The Board of Pharmacy has collaborated with KDHE regarding the Medication Disposal Program. Since the DEA updated their rules related to how a controlled substance may be destroyed the Board is working with KDHE to incorporate the recent changes in requirements and allowances from the DEA.

Staff Reports

Reyne Kenton – informed the Board of the passing of Jim Cleland, Wakeeney.
Ms. Billingsley told the Board of the passing of Karla Kneebone, Neodesha.

Executive Session:

A motion was made and seconded to enter into executive session for 15 minutes after a 5 minute break to discuss matters pertaining personnel and to reconvene the meeting in the Board room at 2:45pm to include Mr. Forbes. (Worden/Garrelts) Motion passed. The Board reconvened at 2:45pm and a motion was made and seconded to extend the executive session for 15 minutes to reconvene the regular meeting at 3pm (Worden/Garrelts) Motion passed.

Dr. Haneke reconvened the meeting at 3pm

Adjourn: Dr. Haneke adjourned the meeting at 3pm.

Friday, January 9, 2015

Meeting Called to Order: President Robert Haneke called the meeting to order at 8:57am.

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

Members Absent: Cheri Pugh, Public Member

Staff Present: Debra Billingsley, JD, Executive Secretary; Jim Kinderknecht, R.Ph., Licensed Pharmacy Inspector; Carly Haynes, R.Ph., Licensed Pharmacy Inspector;

Melissa Martin, Compliance Inspector; Reyne Kenton, Compliance Inspector; Randall Forbes, Disciplinary Counsel; and Michele Tunnell, Board Counsel.

Others Present: See attached listing.

Administrative Hearings

- Gregory Misse, R.Ph. (1-12547) **Case 14-17.** Mr. Misse was present with counsel, Dudley Smith. Mr. Forbes presented the case to the Board with the proposed resolution to include: probation for 2 years, \$2,500 fine, not being a preceptor or pharmacist in charge for 2 years, to take and pass the PARE test, and to appear in front of the Board. Mr. Forbes recommended approval. Mr. Smith stated Mr. Misse was not terminated but had resigned. Mr. Misse denies to the allegation of destruction of records.
A motion was made and seconded to approve the resolution as proposed by Mr. Forbes. (Lonergan/Worden) Motion passed.
- Darin Rohr, R.Ph. (1-15399) **Case 14-11B.** Mr. Rohr was present with counsel, Don Hoffman. Mr. Schoech recused himself from the discussion due to employment with Wal-Mart. Mr. Forbes presented the case to the Board with the proposed resolution to include a fine on \$1000. Mr. Forbes recommended approval.
A motion was made and seconded to approve the resolution as proposed by Mr. Forbes. (Ullom/Garrelts) Motion passed (Schoech – recused)
- Walmart Pharmacy #10-0664 (2-09515) **Case 14-11A.** Walmart was represented by Shelley Tustison and Debbie Mack with counsel, Mark Sappington. Mr. Schoech recused himself from the discussion due to employment with Wal-Mart. Mr. Forbes presented the case to the Board with the proposed resolution to include a fine on \$5000.
Ms. Tustison and Ms. Mack answered questions posed by the Board. The Board requested a copy of the policy and procedures on Incidents and CQI, continuous quality improvement. They/Walmart plans to use this case as a case study in educating Walmart pharmacists as to proper procedures.
Mr. Forbes recommended approval.
A motion was made and seconded to approve the resolution as proposed by Mr. Forbes. (Ullom/Garrelts) Motion passed (Schoech – recused).

Recess: Dr. Haneke declared a 15 minute break at 9:55am.

Reconvene Dr. Haneke reconvened the meeting at 10:10am

- Milka Goodlett, R.Ph. (1-15036) **Case 14-11.** Ms. Goodlett was present with counsel, Kurt James. Mr. Schoech recused himself from the discussion due to employment with Wal-Mart. Mr. Forbes presented the opening statements to the Board followed by opening statements from Mr. James. Exhibits were introduced and Reyne Kenton testified to the investigation of the case.
Please see the court reporter transcript.

Recess: Dr. Haneke declared a 10 minute break at 12:06pm.

Reconvene Dr. Haneke reconvened the meeting at 12:19pm

Case continued....

A motion was made and seconded to enter into executive session for quasi-judicial deliberations to include Ms. Tunnell, Board Counsel. (Ullom/Lonergan) Motion passed.

Dr. Haneke reconvened the meeting at 1:22pm

A motion was made and seconded to fine Ms. Goodlett \$2000, complete the 18 hour Continuing Education program from Oregon State University (Management & HR Skills for Pharmacists) and to pay the cost of the hearing prior to the April meeting. (Ullom/Worden) Motion passed (Schoech – recused).

- Chris Henington, R.Ph. (1-13153) **Case 14-55.** Mr. Henington was present with counsel, Randy Debenham. Mr. Forbes requested the session be closed to receive confidential information. A motion was made and seconded to enter into executive session to receive and discuss records regarding peer review pursuant to K.S.A. 65-4915. The session included Mr. Henington, Randy Debenham, Michele Tunnell, Debra Billingsley, Randy Forbes, and the KsPRN representatives - Vicki Whitaker, Mike Larkin, and Ralph Holbrook. (Worden/Schoech) Motion passed.
A recess was declared at 2:30pm and the executive session resumed at 2:40pm.
Mr. Larkin left at 3:30pm
Dr. Haneke reconvened the meeting at 3:50pm.
A motion was made and seconded to suspend Mr. Henington's license to practice pharmacy for 6 months, Mr. Henington is to remain in strict compliance with the pharmacist impairment program. He is to return to the Board in July 2015. (Ullom/Worden) Motion passed. The Board suggested Mr. Henington to prepare himself to take the PARE test and to seek employment outside pharmacy.
- David Neil, R.Ph. (1-09830) **Case 14-34.** Mr. Neil was present without counsel. Mr. Forbes requested the Board close the session to receive confidential information. Dr. Haneke closed the session to receive and discuss records regarding peer review pursuant to K.S.A. 65-4915. The session included Mr. Neil, Michele Tunnell, Debra Billingsley, Randy Forbes, and the KsPRN representatives - Vicki Whitaker, Mike Larkin, and Ralph Holbrook.
Dr. Haneke reconvened the regular meeting at 4:30pm
A motion was made and seconded to accept the recommendation from KsPRN in a step approach, to report time worked to CIPP and any dispensing errors to the Board office. KsPRN will report back to the Board as to compliance. (Lonergan/Ullom) Motion passed.
- Josh Tersinar (14-01742) **Case 14-102.** Mr. Tersinar was not present. Mr. Forbes presented the case to the Board. A motion was made and seconded to revoke the technician registration of Mr. Tersinar. (Ullom/Garrelts) Motion passed.
- ElKan Drug (2-10231) **Case 14-25.** ElKan had no representation present. Mr. Forbes presented the case. A motion was made and seconded to approve the Consent Order with ElKan Drug with a fine of \$1000. (Ullom/Lonergan) Motion passed.

- Genoa Pharmacy (2-10388) **Case 14-28.** Genoa Pharmacy had no representation present. Mr. Forbes presented the case. A motion was made and seconded to approve the Stipulation and Final Agency Order with Genoa Pharmacy with a fine of \$2500. (Ullom/Lonergan) Motion passed.

Summary Orders

- Health Partnership Clinic (applicant) **Case 14-115.**
- Damon Gardner (14-03457) **Case 14-116.**

Adjourn: Dr. Haneke adjourned the meeting at 4:40pm.