

Kansas State Board of Pharmacy
Minutes of the November 21 & 22, 2013
Board Meeting

Via Christi – St. Joseph Campus
3600 E. Harry
3rd Floor, Conference Room A
Wichita, KS 67218

Thursday, November 21, 2013

Meeting Called to Order: President David Schoech called the meeting to order at 9:02am.

Members Present: David Schoech, R.Ph., President; Bob Haneke, Pharm D., Vice President; Jim Garrelts, Pharm. D.; Michael Lonergan, Pharm. D.; Cheri Pugh, Public Member; Chad Ullom, R.Ph., Investigative Member; and John Worden, Pharm. D (9:18am – 1:42pm).

Staff Present: Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph., Pharmacy Inspector; Carly Haynes, R.Ph., Pharmacy Inspector; Melissa Martin, Compliance Officer; Reyne Kenton, Compliance Officer; Marty Singleton, Assistant Director, and Randall Forbes, General Counsel.

Others Present: See attached listing.

Approval of the Agenda:

A motion was made and seconded to approve the agenda as amended. (Garrelts/Haneke) Motion passed. Approval of New Pharmacists and New Registrants was added to the agenda.

Review of the September 2012 Minutes:

A discussion of the minutes of the Board's September 2012 minutes took place. It was noted that the Board took final action on July 19, 2012 to adopt K.A.R. 68-20-30. It was further noted that confusion has been caused by the comment in the Board's September 2012 Board minutes: "The Board needs the information indicating abuse potential before they approve an emergency scheduling." It was discussed that the adoption of K.A.R. 68-20-30 in July 2012 caused the substances described in the regulation to be classified as a Schedule I controlled substance. It was further discussed that in September 2012 the Board was interested if any further information of potential abuse existed before the Board made a scheduling report to the Legislature. As a result of the discussion, a motion was made, seconded and passed to amend the sentence in the September 2012 minutes: "The Board needs the information indicating abuse potential before they approve an emergency scheduling" by striking the words "they approve an emergency scheduling" and inserting in their place "it makes a report to the Legislature." As a result, the sentence should read: "The Board needs the information indicating abuse potential before it makes a report to the Legislature."

. (Haneke/Ullom) Motion passed.

Approval of the September 19 & 20, 2013 Minutes:

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

Requests

Sunny Lalli and Bob Dufour provided the Board with information on MedAvail. They presented the information for Board consideration. It is a pharmacist controlled remote dispensing solution. The company would like to market the technology in Kansas. The matter was taken under advisement.

Board Discussion

- **Automation and LTCF Automation Regulations**

The Board reviewed the automation regulations (K.A.R. 68-7-10; K.A.R. 68-9-2; K.A.R. 68-9-3) that have been drafted to update current automation rules as well as add additional language that would allow for automation of medications in long term care facilities. The primary concern should be centered on patient safety in all practice sites. The definition of “direct supervision” is defined in the statutes. Joan Kramer volunteered to help write/edit language to help ready the statute and regulations to proceed in the process. Mr. Haneke will reconvene the committee to address the concerns with the addition of any other stakeholders in automation of the pharmacy worksite.

National Certification of Pharmacy Technicians – (Participants via teleconference - Brian Caswell, Wolker Drug; Pete Stern, KPSC; Jeff Little, St Luke's Hospital; and Lesa Pastor, Natl Healthcareer Assoc.)

The Board was provided with information that had been reviewed by the Task Force working on national certification of pharmacy technicians as well as suggested legislative language. Mike Larkin, the Executive Director of KPhA, apprised the Board that the Task Force did not have a consensus. He suggested that it might be prudent to delineate the functions of technicians by work site.

Lindsay Massey, PharmD, (St. Lukes Hospital) a Task Force Member advised that the legislation was needed to protect the public health and safety and that it should be required in every practice setting.

Linda Radke, PharmD, (Salina Regional Health) provided additional information and recommended that national certification would provide optimal medication therapy outcomes for patients. It would also establish standards of quality for education and training in all practice settings. Ms. Radke also advised the Board that SB 155 required the State Board of Regents to establish a career technical education incentive program which would award \$1000, subject to appropriation, to a school district for each high school graduate who graduates from that district with an industry-recognized credential in a high-need occupation, as identified by the Secretary of Labor, in consultation with the State Board of Regents. High school students admitted to a vocational education course or program conducted by a community college, technical college or institute of technology may be charged fees, but not tuition. Ms. Radke explained that the

Pharmacy Technician was potentially a vocational area that could be considered under this bill.

Jeff Little, PharmD (St. Lukes Hospital) reiterated that the Task Force had discussed grandfathering, technician trainees, board exemptions, etc. in an effort to move forward with national certification in all practice areas and that he continued to support the language that the Task Force had worked toward.

Pete Stern of KPSC discussed the surveys that had been conducted and advised the Board that there was a definite split in opinion. He suggested that as a compromise that the language could exempt the first technician in every store. He suggested that the group leave as much flexibility with the Board so that they could assess the needs of pharmacy and would also be in the best interest of the public. He reminded the Board that there was a fiscal impact to the local pharmacies with a mandatory requirement.

Brian Caswell, R.Ph. (Baxter Springs) noted the overall struggle of the task force coming up with a consensus. He suggested that there would be value to those who opposed if the pharmacy knew that the technician to pharmacist ratio would increase to 4:1 if three were nationally certified. He suggested that a market driven rule would be more successful than a mandatory law across the board.

The Board's General Counsel advised the Board that the current language did not provide authority to the Board to revoke a trainee registration. That is an important piece that would need to be added. The Board discussed whether the current statute could be amended minimally so that the Board had flexibility through the regulations to identify the tests that would be required for pharmacy technicians.

A motion was made and seconded to draft language for a substitute bill for HB2127 deleting the current test language and allow the Board to set through regulation the tests approved and appropriate time frame. The intent would be to use the task force information to write new regulations encompassing the details. The Board should also develop a position statement regarding that support of national certification of all technicians. (Lonergan/Haneke). Motion Carried.

A motion was made and seconded to issue a Board resolution thanking and recognizing the hard work of the task force in their recommendation to the Board regarding the importance of pharmacy technician certification. (Garrelts/Ullom) Motion passed.

Recess: Mr. Schoech declared a break to reconvene in 10 minutes.

Reconvene: Mr. Schoech reconvened the meeting at 11:33am

Regulatory - continued

- **Pilot Projects** –

AlixRx - Blake Griese, PharmD,JD; and Amanda Stewart,PharmD were presented an updated on the AlixaRx pilot to the Board. They presented information and answered questions about the process and new information learned. AlixaRx has requested the ability to add more of the Golden Living facilities. A motion was made and seconded to expand the pilot to the remaining seven Golden Living sites. (Lonergan/Ullom) Motion failed. 3 Yes and 4 No.

Legislative and Regulatory - continued

1. **License and Permit Fees Regulation** – Ms. Billingsley presented the cash projections of lowering the fees by 20%. The fund will slowly decrease over time. Public hearing dates must be published 60-days before the hearing.

2. **Electronic Transmission of Prescriptions and Electronic Storage** – Ms. Billingsley needs dates to have the public hearings. We have not had 60 days from the last meeting.

3. **Controlled Substance Legislative Report** – The information was presented at the September meeting. The report will add additional drugs if any are scheduled federally.

4. **Notice of DEA Proposed Rulemaking Placing Tramadol into Schedule IV** – The DEA is asking for public comments on the scheduling of Tramadol. Tramadol is being reported through KTRACS as a drug of concern. Ms. Billingsley will draft a letter on behalf of the Board in support of scheduling tramadol. A motion was made to support the DEA recommendation in scheduling tramadol. (Worden/Ullom) Motion passed.

5. **Continuing Education Regulation** – Ms. Billingsley is in the process of drafting the regulation based on the policy change at the September meeting.

6. **Annual licensure / permit statute** – Ms. Billingsley presented the Board with a copy of 2012 SB 324. The change requires a statute change by the legislature. A motion was made and seconded to support the language as it appeared in SB 324 from 2012. (Ullom/Garrelts) Motion passed

7. **ePA legislation** – Ms. Billingsley reported the National Council for Prescription Drug Programs (NCPDP) has proposed five guidelines on electronic prior authorization standards. The Board staff was advised that they would be able to obtain some type of synopsis of their changes. The Kansas State Board of Pharmacy is not a member of NCPDP so we don't have access to all of their information unless they will share.

8. **Compounding** – Ms. Billingsley shared the Udall bill SB1667. The federal legislation will continue to place some of the regulatory responsibility on the state. An additional inspector was requested through the normal budget process and it was denied at the first level. The Board will need to make the request through the legislative budget process. In the meantime, the Board has been advised that they can make the request to the State Finance Council in December.

Recess: Mr. Schoech recessed the meeting for lunch at 12:45pm

Reconvene: Mr. Schoech reconvened the meeting at 1:24pm

Board Discussion

Future Board Meeting Dates –

January 16, 17, 2014 – Thursday and Friday in Topeka

February 28, 2014 – Friday at KU School of Pharmacy/Legislative

April 24, 25, 2014 – Thursday and Friday in Topeka

July 24, 25, 2014 – Thursday and Friday in Topeka

October 16, 17, 2014 – Thursday and Friday in Wichita

Set the meetings for the 2015 at the July 2014 meeting.

Phone meetings dates available if necessary:

December 20, 2013 Friday, 9am

March 14, 2014 Friday, 9am

John Worden – left the meeting at 1:42pm

Reports

KTRACS – Mr. Singleton presented the information that was provided to NASCSA and answered questions on that information. Provider users can no longer consolidate patient information when multiple listings are in the PMP for the same patient. The requested patient consolidations can only be completed during business days due to constraints placed on the system by Appriss. The Board will take a tour on Friday to view how the doctors at Via Christi access the KTRACS information in real time that was partially funded by the Board of Pharmacy through federal grants.

- Annual Legislative Report is being revised to reflect the Appriss information. The report will be sent to the Board when completed. The regulations have been drafted and public hearings will be scheduled for the following proposed regulations.

- Regulations

- ❖ K.A.R. 68-21-1. Definitions

- ❖ K.A.R. 68-21-2. Electronic Reports

- ❖ K.A.R. 68-21-7. Drugs of concern. The change would add promethazine with codeine, all prescription only pseudoephedrine and ephedrine products.

NPLEx – Ms. Billingsley provided the information

- Annual Legislative Report draft
- Dashboard Reports
- Information from Appriss – Release Communication

Budget – Jackie Yingling, BOP Accountant, joined the meeting by phone. Ms. Yingling explained the budget reports in the packet for the current year.

Board Member Reports

Jim Garrelts – shared an article with the Board regarding the regulation of PBMs by the Board of Pharmacy.

Cheri Pugh – Thanked Mr. Singleton for providing an easy sign in to the Board Member agenda material for the meetings. She also thanked the Board for their continued patience as she learns the functions and terminology of pharmacy.

Executive Director Report

Debra Billingsley

- Pharmacy Webpage – Ms. Billingsley said the web site was much more user friendly and Mr. Singleton had led in the development of the new site.

- Ms. Billingsley requested a volunteer to serve on a committee with the Board of Healing Arts and the Board of Nursing to update the joint policy statement on the use of controlled substances for pain management. Mr. Schoech volunteered.

- Heartland PRN hosted a meeting of the impaired programs. Ms. Billingsley attended the meeting and did a presentation. In comparison, the impaired program in Kansas is operating well and is organized and better funded. Ms. Billingsley met with

other professional boards in Kansas and several have experienced problems. They were asking for information so that they could improve their programs. She reported KPhA is keeping the Board of Pharmacy office informed.

- Maltagon will be scheduled as soon as Board meeting dates are set in the member boards.
- Staff changes. Two additional administrative positions have been added to the office and they are in the process of cross training to increase efficiency and responsiveness of the agency.
- Ms. Billingsley told the Board she really appreciates Mr. Singleton. He has taken on a lot of roles and the office is beginning to run more smoothly. Once everyone is trained there should be many increased efficiencies.

Staff Reports

Jim Kinderknecht and Melissa Martin reported on their trip to NABP and the sterile compounding seminar they attended. Mr. Kinderknecht said the Virginia inspectors had a report that could be used as a guideline for Kansas. Ms. Martin also gave a brief report on the NASCSA Conference that all of the inspectors and Marty Singleton attended.

Reyne Kenton – thanked the Board for their kindness in the passing of her dad. Ms. Kenton reported on the sessions at NASCSA. There was a lot of information and the report on Suboxone was the most informative. Suboxone is being used by addicts to bridge from their last fix until they can obtain the next. The presenter encouraged states with PMPs to look at Suboxone use to help identify possible persons who may be getting controlled prescription drugs illegitimately.

Carly Haynes – reported on the Maltagon meeting. Maltagon is a great source of information and networking with other inspectors. Mr. Schoech said Maltagon members have agreed to accept continuing education that any of the members approve. Ms. Haynes also commented about the recent change in Oklahoma by the OBNDD not to allow refills on hydrocodone products. Oklahoma pharmacies cannot honor refills and the OBNDD has said prescribers cannot write for refills.

Meeting Reports

NASCSA Meeting – Kansas City, MO. October 22-25, 2013 – Marty Singleton, Carly Haynes, Reyne Kenton, Melissa Martin, and Jim Kinderknecht. – see above staff reports.

District 6 meeting – Colorado. Ms. Billingsley, Chad Ullom, and Dave Schoech attended the meeting. Marijuana was the major discussion of the meeting.

22nd Annual Heartland PRN Conference October 11-13 – Debra Billingsley

Recess: Mr. Schoech declared a break to reconvene in 10 minutes.

Reconvene: Mr. Schoech reconvened the meeting at 3:13pm

Executive Session:

A motion was made and seconded to recess into executive session for 30 minutes to discuss matters pertaining to security measures pursuant to K.A.A. 75-4319(2)(13) in order to protect public safety with the meeting resuming at pm to include the Board, Randy Forbes, Debra Billingsley, Marty Singleton, the Board inspectors, the Board Pharmacy intern, Ann Rule, and Richard Widup. (Ullom/Lonergan) Motion passed. Mr. Schoech reconvened the meeting at 3:44am.

Executive Session:

A motion was made and seconded to go into executive session pursuant to K.S.A. 75-4319(b)(2) in order to discuss privileged information deemed to be in the attorney client relationship for 10 minutes to include Mr. Forbes and Ms. Billingsley. (Haneke/Ullom) Motion passed. The meeting will resume at 3:56pm
Mr. Schoech reconvened the meeting at 4:06pm.

Adjourn: Mr. Schoech adjourned the meeting at 4:06pm.

Friday, November 22, 2013

Meeting Called to Order: President David Schoech called the meeting to order at 9:00am.

Members Present: David Schoech, R.Ph., President; Bob Haneke, Pharm D., Vice President; Jim Garrelts, Pharm. D.; Michael Lonergan, Pharm. D.; Cheri Pugh, Public Member; and Chad Ullom, R.Ph., Investigative Member.
Members Absent: John Worden, Pharm D.

Staff Present: Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph., Pharmacy Inspector; Carly Haynes, R.Ph., Pharmacy Inspector; Melissa Martin, Compliance Officer; Reyne Kenton, Compliance Officer; Marty Singleton, Assistant Director, and Randall Forbes, General Counsel.

Others Present: See attached listing.

Administrative Proceedings:**Hearings:**

- Bill Poulos (1-14493) **Case 9-27.** Request for Early Release from probation. Mr. Poulos was present without counsel. A motion was made and seconded to enter executive session for 30 minutes to discuss records regarding peer review pursuant to K.S.A. 65-4915 and to include Mike Larkin, KPhA; Vicki Whitaker, KsPRN; Ralph Holbrook, Chairperson of CIPP; Mr. Forbes; Ms. Billingsley, the inspectors, and pharmacy intern to return to open session at 9:35am. (Haneke/Ullom) Motion passed. Ms. Whitaker and Mr. Holbrook joined the session by phone.
Mr. Schoech reconvened the meeting at 9:36am.

A motion was made and seconded to leave the order in place. (Ullom/Haneke)
Motion passed.

- Jerry Franklin, Case 13-113. Mr. Franklin was present via phone connection. The Board consensus was that CE must be obtained from July 1 to June 30th and that there was no grace period for CE. A motion was made and seconded to require the four hours of CE per hour not obtained during the allowed calendar period and to amend Mr. Franklin's fine to \$500 based on mitigation provided by Mr. Franklin. (Garrelts/Haneke) Motion passed. Ms. Billingsley will follow up with the Order.
- Ronald Hiles **Case 13-115**. Mr. Hiles was present via phone connection. Mr. Ullom and Mr. Schoech recused themselves from the discussion/decision as they are employees of Walgreens. A motion was made and seconded to approve the Summary Order with Mr. Hiles. (Lonergan/Haneke) Motion passed – 4 Yes and 2 recused.

Summary Orders

Case 13-108 CE

Case 13-111 CE

Case 13-112 CE

Case13-114 CE

Case13-119 CE

Case13-122 CE

Case13-124 CE

Case13-126 CE

Case13-127 CE

Case13-128 CE

A motion was made and seconded to approve the Summary Orders as listed
(Ullom/Garrelts) Motion passed

Case 13-136 Alicia Ray Walker. A motion was made and seconded to approve the Summary Order of denial of pharmacy technician registration. (Ullom/Garrelts)
Motion passed

Closed Cases

The Board reviewed the closed cases presented by Chad Ullom,RPh, Investigative Member.

KTRACS Access

The Board discussed the Board policy of access to KTRACS by the inspectors. A motion was made and seconded to allow pharmacy inspectors that are licensed or registered to access KTRACS for investigations. (Lonergan/Garrelts) Motion passed.

Direction of Attorneys

A motion was made and seconded to grant the Board's Executive Director continuing authority to direct the Board's attorneys in defending any cases challenging K.A.R. 68-20-30. (Haneke/Ullom) Motion passed.

Biosimilars 2013 – Ms. Billingsley asked the Board for their opinion related to the recent biosimilar legislation that is being filed in other states. The Board has concerns over legislation and advised Ms. Billingsley to keep Board informed if any bills are filed.

Approval of New Pharmacists and New Registrants

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

Tour of KTRACS / Via Christi Hospital Project

Adjourn: Mr. Schoech adjourned the meeting at 11:10am.