

Kansas State Board of Pharmacy
Minutes of the December 2010
Board Meeting

800 SW Jackson
Basement Level, Conference room A
Topeka, KS 66612

Thursday, December 2, 2010

Meeting Called to Order: President Shirley Arck called the meeting to order at 9:01am. Introductions were made by those present.

Members Present: Shirley Arck, Pharm. D., President; Jim Garrelts, Pharm. D., Vice-President; Karen Braman, R.Ph.M.S; Michael Coast, R.Ph.; Nancy Kirk, Public Member; David Schoech, R.Ph.; and Frank Whitchurch, R.Ph.

Staff Present: Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph., Pharmacy Inspector; Carly Haynes, R.Ph., Pharmacy Inspector; Melissa Martin, Compliance Officer; Christina Morris, PDMP 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. (Schoech/Garrelts). Motion passed.

Approval of the September Minutes: The following amendments were made:
On page 6 in Ms. Braman's report: The name "Jonalon" should be "Jonalan"
A motion was made and seconded to approve the minutes as amended.
(Braman/Coast) Motion passed.

Approval of the November Minutes: The following corrections were made:
On page 1 near the bottom after the sentence "The Board members expressed their frustration that they had been working on an MOU for months and still could not come to an agreement with CHPA and Apriss" add: "Prior to making the initial decision to use Apriss the Board was provided a draft MOU by Apriss that did not contain the language restricting the tracking system to only those products manufactured by the donors to CHPA. The Board and the Board attorney spent many hours working with Apriss to refine this document to be mutually agreeable. After the Board made the decision to use Apriss they were informed by CHPA that they had received the wrong starting document and CHPA would not accept it. CHPA then provided a second draft MOU. This document has language that the Board's attorney advised is beyond the Board's scope and potentially violates state statute."

A motion was made and seconded to approve the minutes as corrected.
(Coast/Braman) Motion passed.

Administrative Proceedings:

- Jessica J. Duben (14-08854) **Case 10-65** – Mr. Rein presented the case. Ms. Duben was not in attendance and in November withdrew her request to appeal. A motion was made and seconded to revoke Jessica Duben's technician registration (Coast/Schoech). Motion passed.
- Marcus Ortiz (14-05003) **Case 10-84** – Mr. Rein presented the case. Mr. Ortiz was not in attendance. Mr. Ortiz's technician registration was revoked due to diversion of controlled substances from his employer.
- Coral Main (14-02268) **Case 10-57** - Mr. Rein presented the case. Ms. Main was not in attendance. Ms. Main's technician registration was revoked due to diversion of controlled substances from her employer.
- Gwendolyn Parks (14-00351) **Case 10-58** - Mr. Rein presented the case. Ms. Parks was not in attendance. Ms. Parks' technician registration was revoked due to diversion of controlled substances from her employer.
- John Dye (1-08412) **Case 10-28** – Mr. Rein requested the Board to go into executive session to receive privileged information. A motion was made and seconded to go into executive session to receive privileged information for a period of 20 minutes to include the Board, Ms. Billingsley, Mr. Forbes, Mr. Kinderknecht and Ms. Haynes, to reconvene the regular meeting at 9:40am (Coast/Garrelts). Motion passed. Dr. Arck reconvened the regular meeting at 9:40am. Mr. Dye arrived at the meeting and wanted to present privileged information to the Board. A motion was made and seconded to return to executive session for 10 minutes for all the same reasons and to include all the previous and Mr. Dye (Coast/Garrelts). Dr. Arck reconvened the meeting at 9:55am. Mr. Forbes told the Board he recommended the Board accept the Settlement and Final Order since it is a signed document. Mr. Dye may make application for reinstatement of his pharmacist's license as required since his license was not renewed during the renewal period. A motion was made and seconded to approve the final order as presented (Schoech/Braman). Motion passed.
- Stephanie Ketcher (14-05899) **Case 10-21** – Mr. Rein presented the case. Ms. Ketcher was not in attendance. Ms. Ketcher's technician registration was revoked due to diversion of controlled substances from her employer.

PMP Update:

Ms. Morris gave a brief update. K-TRACS has received 2 grants and this will continue funding until fall of 2012. Ms. Morris has mailed several thousand brochures to prescribing and dispensing providers explaining the program and has held one meeting; with many others scheduled. Ms. Morris received the updated PMP regulations from the Attorney General's office and will schedule the public hearing for March 2011. Ms. Morris said questions have arisen concerning the patient reports and how doctors retain those reports. The other question concerns hospice patients and the reporting from

pharmacies filling for hospice patients whether inpatient or outpatient. Ms. Morris will place a comment on the Policy page explaining that pharmacies filling prescriptions for hospice patients will need to report the outpatient prescriptions.

Recess: Dr. Arck declared a break to reconvene in 10 minutes.

Reconvene: Dr. Arck reconvened the meeting at 10:39am

Dr. Arck introduced Senator Vicki Schmidt and thanked her for her championship of the prescription-monitoring program. Ms. Braman recognized the PMP Advisory Committee.

RxSentry HID Presentation:

Steve Espy and Sheila McCoullough with Health Information Design presented the information about the web-based PMP portal HID will host for Kansas as the Kansas PMP vendor. Ms. McCoullough said that on December 20, 2010 pharmacies may sign up and begin sending test data. On February 1, 2011 mandated reporting begins and pharmacies will submit the prior 6 months to create a base of data. The deadline for retroactive data submission will be March 15, 2011. Physician and pharmacist access will go live March 29, 2011 with law enforcement access on April 19, 2011. Mr. Espy presented the information as found online, requirements, and reports that are available to different entities.

Recess: Dr. Arck recessed the meeting for lunch to reconvene at 1pm.

Reconvene: Dr. Arck reconvened the meeting at 1pm.

Administrative Proceedings

- Kansas Spine Hospital (2-09907) **Case 08-139A** – Mr. Forbes presented the case. Ms. Haynes answered questions for the Board. A motion was made and seconded to accept the Stipulation and Final Agency Order (Garrelts/Schoech) Motion carried.

Investigative Member Report – Closed Cases

Mr. Coast thanked the staff for the work on the cases.

Board Discussion

Electronic Logging System for PSE products – Dr. Arck outlined the parameters for the discussion and public participation. The Board discussed the options available to the Board for electronic tracking of methamphetamine precursors. Mr. Coast reiterated that all methamphetamine precursor products must be tracked per Kansas statute. Mr. Forbes worked on the language in the MOU with CHPA. Ms. Billingsley gave an update on one other vendor currently available. MethShield. Dr. Arck and the Board reviewed options if the MOU with CHPA and Appriss was not signed. Dr. Garrelts stated the Board should not enter into an agreement that has no exit clause for the Board. Ms. Kirk suggested we ask the Legislature to change the statute or go to the Attorney General to get an opinion on compliance.

Dr. Arck opened the discussion to public comments. Pat Hubbell, Pharma, addressed the Board. Mr. Hubbell encouraged the Board to go with Appriss since it will cost the state nothing. Cathy Nugent, MethShield, said they were presently in the state

operating and could cover the state of Kansas and have it up and running by March 2011 and could do so for one year with no cost to the State.

Bob Keller, Johnson County Law Enforcement, encouraged the Board to pursue the electronic tracking rather than scheduling or returning to the paper tracking method because it is a useful tool for law enforcement.

Jeff Bottenberg, CHPA, gave the states that are in the system and the manufacturers that are participating in the system. He advised that at least 99% of the manufactures will be captured with the Appriss system.

Public discussion was closed and the Board continued the discussion of the proposed MOU. Ms. Braman reiterated the lack of an exit clause and that it should be added to the MOU. Dr. Arck stated that for the system to comply with the legislature, must track all the drugs and not 99%. Mr. Whitchurch asked what the concerns would be if the Board signed the MOU and tracked 99% and asked the legislature to fix the statute to reflect what can be tracked or how to make any new manufacturer comply with the program. The Board consensus was to have Mr. Forbes continue to work with CHPA for 15 days until December 17, 2010, to get the MOU finalized with the exit clause and language reflecting that only 99% of the medications would be tracked. If not completed by December 17, 2010, the Board will pursue other options.

Recess: Dr. Arck declared a break to reconvene in 15 minutes.

Reconvene: Dr. Arck reconvened the meeting at 2:45pm

Synthetic Marijuana Legislation – Jeremy Morris and Valerie Kamb of the Johnson County Crime Lab brought proposed legislative language amending the law concerning synthetic marijuana. The draft amends K.S.A. 65-4105 for substances included in Schedule I. The amendment would restrict synthetic cannabinoids by class rather than each individual chemical compound. The synthetic cannabinoid class of drugs is expanding at a rapid pace with many new compounds being developed yearly and this would be an option the legislature could take to restrict these drugs in Kansas. The Board consensus was to support the legislation.

Formulary and Substitution for LTCF – Jason Syring and Ron Erker, NCS Healthcare of Kansas, appeared before the Board and requested the ability to develop a formulary for their long term care facilities when that facility requests. The formularies would allow the facility and the patient to save money. The Board agreed that a long-term care pharmacy could develop a formulary with the participation of the consultant pharmacist, the staff physician, and a formulary committee or its equivalent. The consultant pharmacy could also develop policies for therapeutic interchange so long as the prescriber approved the policy. The pharmacy would be responsible for filling or refilling medication orders according to the directions of the practitioner, however, the pharmacy could formulate broad professional policies regarding the evaluation, appraisal, selection, and procurement of medications within a long-term care facility using a formulary that was approved by the formulary committee.

Pharmacist Discipline Statute – Ms. Billingsley presented a draft amendment of K.S.A. 65-1627 related to discipline of pharmacists in Kansas. The Board discussed the proposed language. Mr. Garrelts questioned the wording of number 19 (knowing or suspecting) strike “or suspecting”. Ms. Braman questioned number 24 and suggested adding “intentional” in front of “disclosure”. Ms. Billingsley will research the options and add the appropriate language.

Electronic Prescriptions Statute – Ms. Billingsley has identified which statutes will need to be changed to allow electronic controlled substance prescriptions. The changes will be drafted so that the Pharmacy Act will comply with the federal electronic prescription changes.

Compounding Regulations – Ms. Billingsley presented the proposed language and the changes needed to comply with the concerns with the Attorney General’s office. Ms. Billingsley will discuss the concerns with Camille Nohe at the Attorney General’s Office and make the needed changes.

Schedule V Samples Regulation – Ms. Billingsley provided an amendment to K.A.R. 68-20-15a regarding samples of certain Schedule V drugs. The Department of Administration has approved the language and it will be sent to the Attorney General’s Office.

Hard Copy Data Storage Regulations – Frank Whitchurch had requested that the Board review their requirements for hard copy data storage based on an NABP committee that Frank served on. Ms. Billingsley presented the information obtained from other states. Ohio has language that is very simple and would work well for Kansas. The Board approved staff to make the necessary change to the Kansas Pharmacy Act.

Registration of Persons behind the Pharmacy Counter – The Board discussed whether all persons behind the pharmacy counter should be registered or licensed as a security measure. Ms. Billingsley provided information as to what other states have done. Missouri registers and licenses everyone but the majority of states do not have this restriction. The Board determined that if there were security issues and drug diversion that rather than have everyone registered the Board staff should investigate the pharmacy and pharmacist for breach of security requirements.

Regulation Update

- Distributor Regulations – The regulations are in process.
- DME Regulations – The regulations are in process.
- Retail Telepharmacy Regulations – The Department of Administration made some grammatical changes and the regulations are still in review.
- Nuclear Regulations – The committee meeting has not been scheduled.
- Controlled Substance List – Ms. Billingsley has submitted the list per requirement and a bill is being drafted for the 2011 Session.
- Attorney Fees and Hearing Costs – These costs are in review.
- Veterinary Hospital Regulations – Dr. Arck said the committee of two has not made any proposals yet.

- Prescription Take Back Programs – Ms. Billingsley has been working with KDHE – Hazardous Wastes. A meeting is to be scheduled for sometime in December to begin the process of working toward a state wide drug take back system proposal.
- Shared Services – Mr. Coast asked the Board staff to look at the Shared Services regulations and the possibility of requiring the pharmacist in charge to be registered in Kansas.

Approval of New Pharmacists and New Registrants

A motion was made and seconded to approve the new licenses. (Coast/Braman)
Motion passed.

A motion was made and seconded to approve the new registrations. (Kirk/Coast)
Motion passed.

Board Member Reports

Shirley Arck – The Board and Board staff asked Dr. Arck about the news report of K-State Veterinary Teaching Hospital conducting cataract surgery on a wild mustang. Shirley gave details of what occurred and reported that the horse was able to see.

Nancy Kirk – questioned how pharmacists were being made aware of technician diversion and inappropriate access to computers.

Karen Braman – Ms. Braman stated her update included the PMP update Christina provided, and also wanted to make sure the Board was aware that NABP was pursuing a hub whereby state PMPs could exchange information.

David Schoech – gave a report on NABP District 6 meeting that he attended in September. Mr. Schoech stated that District 6 voted to hold their meetings with Districts 7 and 8 as a cost savings measure to all states. He discussed the resolutions that were made by District 6 to take to the annual NABP meeting.

Frank Whitchurch – asked the Board to consider a joint project with KU School of Pharmacy about addressing the needs of new pharmacists and meeting the needs of the state.

Staff Reports

Carly Haynes – gave the Board a continuing education article regarding the toxicity of acetaminophen to follow up on a Board discussion item from the September meeting. Ms. Haynes requested a ruling on an immunization protocol that lists only the chain's name and none of the pharmacists are identified. The Board advised that this would be handled by the investigative member and the Board Executive Secretary. The last item concerned a comment at the bottom of a prescription stating that it was not valid unless the patient sticker was affixed. The Board suggested the hospital remove the comment or the pharmacists would not be allowed to fill the prescription if it did not have the required sticker.

Melissa Martin – wished the Board a Merry Christmas.

Budget for FY2011, 2012, and 2013

Ms. Billingsley presented the information and stated the Agency would need to go to the legislators for any changes that are needed. The Board will be kept advised of budgetary issues throughout the year.

All business from the agenda was concluded and continuing the meeting on Friday would not be necessary.

Adjourn: Dr. Arck adjourned the meeting at 5:15pm.