

**KANSAS STATE BOARD OF PHARMACY
MINUTES OF THE MEETING**

June 7-8, 2005
ClubHouse Inn & Suites
924 SW Henderson
Topeka, Kansas

Tuesday, June 7, 2005

MEMBERS PRESENT: Jeff Thompson, RPh., President; Frank Whitchurch, RPh., Vice President; Merlin McFarland, RPh.; Max Heidrick, RPh.; JoAnne Gilstrap, RPh.; Howard Paul, Public Member.

STAFF PRESENT: Debra Billingsley, Executive Secretary; Jim Kinderknecht, RPh., Pharmacy Inspector; Melissa Martin, Compliance Officer; Tom Frazier, R.Ph., Pharmacy Inspector; Randy Forbes, General Counsel and Karen Hollon, Administrative Officer

OTHERS PRESENT: See attached listing.

MEETING CALLED TO ORDER: Jeff Thompson called the meeting to order at 9:00

APPROVAL OF AGENDA. A motion was made and seconded to amend the agenda to add discussion regarding K.S.A. 65-1635a, K.A.R. 68-1-1b and K.A.R. 68-1-1d ; to discuss the calendar for 2006; to move the election of officers to Wednesday; and to move the time for the meeting on Wednesday to 8:30 a.m. (Paul/McFarland) Motion carried 5-0.

APPROVAL OF MARCH 2005 MINUTES A motion was made and seconded to approve the March 2005 minutes (Heidrick/McFarland). Motion carried 5-0.

DISCUSSION, CONSIDERATION, AND POSSIBLE ACTION REGARDING RENEWAL OF CONTRACT WITH KPhA TO IMPLEMENT CIPP PROGRAM: Jenith Hoover, Associate Director of KPhA presented a summary report of the past year's program and the 2005 expense report. The Board was introduced to Bill Bays, the CIPP Committee Chairman. Dr. Mary Carder also appeared and the Board discussed the increase in CIPP expenses. CIPP has not had a contract increase in a number of years. The Board advised that they would look at the possibility of increasing the contract amount based upon the Board's budget. After the budget is reviewed the Board will determine whether they have the ability to amend the CIPP contract. CIPP specifically requested a \$5000 a year increase. A motion was made and seconded to approve the current \$30,000 a year contract with KPhA to implement the CIPP program for the July 1, 2005 through June 30, 2006 period (McFarland/Paul). Motion carried 5-0.

KPhA Report:

John Kiefhaber, Executive Director of the Kansas Pharmacists Association provided an update on several issues. He advised the Board that KPhA would be holding their 125th Annual Meeting on September 15-17 in Lawrence, Kansas. Information was provided to the Board and John issued an invitation to everyone.

John expressed KPhA's appreciation in the Board of Pharmacy's participation in KPhA Board of Director meetings as well as other district meetings that are held around the state.

The BOP fee fund sweep was also discussed. KPhA had reviewed the two Attorney General opinions with their attorney. The Kansas Society of Association of Executives had taken the lead in determining whether various agencies would want to participate in a class action lawsuit. There is no clear answer as to whether funding would go back to the pharmacists if the pharmacists prevailed. Terri Roberts, the KSAE executive director, had indicated that there were monetary constraints for each association but that they would continue to review this issue. It did not look promising that any lawsuit would be initiated by KSAE.

John also reviewed the results of a poll that was taken among KPhA members regarding the technician to pharmacist ratio. John provided the results to the Board and reviewed some of the comments and concerns that had been made by his members. John asked that these results be considered by the BOP when they reviewed the topic as it related to implementing a regulation.

DISCUSSION REGARDING PSEUDOEPHEDRINE REGULATIONS RELATING TO INVENTORY/SECURITY MEASURES.

The new statute regarding sales of pseudoephedrine has raised many questions. One area of concern was that the Board does not register all retail dealers who may be selling these products. The Board suggested that efforts be made to ensure that all retailers in the state are in compliance with the law. Helpful information is on the website and additional information will be added, as it becomes available.

Dan Bellingham from HDMA wanted to know whether legitimate wholesalers could have an exemption regarding the schedule V storage requirements. There was discussion regarding current security at wholesale locations. Mr. Bellingham explained that volume of product was the problem as it related to storage and security. A motion was made a seconded to provide an exemption of this nature for drug wholesalers and to construct language in the regulations if that is necessary. (Whitchurch/McFarland) Motion carried 4-1. (Heidrick voted no.) There was also discussion on requiring wholesale distributors to segregate the CII - V on the retail invoices.

Another issued that needed to be addressed was whether a retail pharmacy needed to conduct a beginning inventory and a biennial inventory for schedule V pseudoephedrine products. The consensus of the Board was that these products were scheduled and therefore there would be no exception regarding inventory.

The Board also reviewed whether a purchase could be made of a C-V at a separate cash register from the pharmacy cash register. The Board's interpretation of K.A.R. 68-20-21(a) indicates that the actual cash, credit, transaction, or delivery, may be completed by a non-pharmacist so it is inferred that the sale may take place somewhere other than the pharmacy cash register.

The Board discussed whether C-V products had to be behind the pharmacy shelf. The Board stated that security measures must be in place but they directed staff to look at all security requirements.

RECESS: The Board took a ten-minute break

RECONVENE: The Board meeting reconvened at 10:35 a.m.

DISCUSSION REGARDING INSTITUTIONAL DRUG ROOM REGULATIONS:

The Board reviewed a draft of proposed regulations regarding institutional drug rooms. Debra Billingsley, Jim Kinderknecht, R.Ph., and Dr. Norma Robinson, R.Ph. had worked on the initial draft. The Board indicated that they would want additional language regarding the requirement of a patient profile. They also discussed a requirement that the pharmacist check orders within 7 days. Max Heidrick and Merlin McFarland will continue to review the regulations and provide an updated version at the next meeting.

DISCUSSION REGARDING IMPLEMENTATION OF TECHNICIAN TO PHARMACISTS RATIO REGULATION.

A motion was made that the Kansas Board of Pharmacy find, that in light of the passage of HB 2156, establishing a ratio of pharmacy technicians to pharmacists in the prescription area is necessary to preserve the public health, safety, and welfare. The health, safety and welfare would be protected by adopting a temporary regulation with an effective date prior to the effective date that would result from complying with the otherwise applicable hearing and publication requirements for adopting regulations. Therefore, the motion was made to adopt the following temporary regulation: The ratio of pharmacy technicians to pharmacists in the prescription area of a pharmacy shall not exceed two to one (Gilstrap/Paul) Those voting yes were Thompson, Whitchurch, McFarland, Heidrick, Gilstrap and Paul.

The Board discussed implementing a permanent regulation. They discussed whether to continue to require a two to one ratio. The Board also discussed whether the ratio could be increased if all technicians were PCTB certified. There were some who thought that the ratio could be increased to three to one if the technicians were certified. There was also discussion that the permanent regulation should require all future changes in the ratio regulation to require a board majority vote. This issue will be reviewed further.

RECESS: The Board recessed for lunch until 1:30 p.m.

DISCUSSION REGARDING CANCER DRUG REPOSITORY REGULATIONS

The drug repository statute will go into effect upon publication in the statute book in July. The statute requires the Board to adopt regulations as it relates to standards and procedures for accepting, safely storing and dispensing donated cancer drugs; standards for inspecting donated cancer drugs; establishing a form that individuals receiving cancer drugs must sign; establishing a form that each donor must sign; develop a formula to determine the amount of a handling fee; develop a category of cancer drugs acceptable for use in program; and developing any other standards necessary to implement the program. The Board reviewed the Nebraska regulations. Max Heidrick and Frank Whitchurch agreed to start with the Nebraska model and devise a preliminary set of regulations. These will be presented to the Board at the next meeting for further review.

DISCUSSION REGARDING K.A.R. 68-20-17 AS IT RELATES TO ELECTRONIC TRANSFERS OF DEA 222 FORMS.

The Board had reviewed K.A.R. 68-20-17 at a previous meeting. The issue concerned the recent amendment to DEA regulations that now permit electronic transfers of DEA 222 under certain conditions. The Kansas regulation has incorporated 21 CFR 1305 (1999 version) by reference. In order for Kansas to permit electronic transfers the regulation would need to be changed. A motion was made and seconded that staff make the appropriate changes to the regulation to permit electronic transfers or its equivalent of the DEA 222 form (McFarland/Heidrick). Motion carried 5-0.

UPDATE ON ELECTRONIC INCIDENT REPORTS

At the March Board meeting a report was given regarding a paperless system being used by Walgreens to report incidents that occur in the store. The Board asked the inspectors to use the system for a period of three months and to report back whether this type of system could replace hard copies. Jim Kinderknecht and Melissa Martin reported that they had a few concerns such as being able to get more than one year of reports to view. There was discussion as to whether the Board inspectors could have their own sign on since a PIC was not always available during inspections. Mike Suwalski from Walgreens appeared at the Board and gave some additional information about the system. He offered to assist the Board in continuing to work within the confines of Walgreens system. The Board granted an additional three-month extension and asked that the matter be placed on the September agenda. For the record, Howard Paul abstained from any and all discussion related to this matter.

DISCUSSION REGARDING REPORTING OF DISCIPLINARY MATTERS IN NEWSLETTER

Jeff Thompson advised the Board that one of the issues that was discussed at the annual KSHP meeting was whether there was value in reporting disciplinary matters in the newsletter. Many of the pharmacists indicated that it was more of a punishment. The Board discussed whether the reporting provided any education to pharmacists. There is some value in letting pharmacists know what type of incidents the Board will discipline. The Board directed staff to continue reporting the incident in the newsletter but to omit the individual's name. The disciplinary information is available on the Board's website

and is a matter of public record. It is also discussed in the Board minutes so if pharmacists wish to have this information it is available.

DISCUSSION REGARDING DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL EXCLUSIONS.

The Board was provided with an informational bulletin from the Office of Inspector General regarding exclusions from participation in Federal health care programs. The Social Security Act authorizes the OIG to exclude individuals or entities based on particular circumstances. The Board asked staff to contact the OIG to see if they could attend a Board meeting to explain in more detail the triggers for an exclusion. A suggestion was made that something be put in the newsletter advising pharmacists that OIG can exclude health care providers from participating in Federal programs.

DISCUSSION REGARDING CONTINUING EDUCATION AUDIT PROCESS

The Board staff reviewed the continuing education audit process with the Board. At this point, the Board made no changes to the process but they would like this to be less burdensome to the pharmacists if staff determines an easier way to receive and review CE materials.

RECESS: The Board took a five-minute break.

RECONVENE: The Board reconvened at 3:08 p.m.

DISCUSSION REGARDING APPLICATION OF 1.5 FACTOR FOR KU INTERN HOURS

The Board discussed the 1.5 factor and the history related to the intern hours. The KU students will be required to do 60 affidavit hours with the 1440 hours that they receive from KU School of Pharmacy.

DISCUSSION REGARDING MANDATORY ON-LINE RENEWAL OF LICENSES/REGISTRATIONS

The Board discussed the cost effectiveness of having all license renewals accomplished on-line. Since the Board of Pharmacy is under budget constraints the Board felt that this was a positive direction. The executive director will work toward determining whether this would be a feasible cost saving mandate

DISCUSSION REGARDING K.S.A. 65-1635a; K.A.R. 68-1-1b and K.A.R. 68-1-1d.

A motion was made and seconded to change K.S.A. 65-1635a, K.A.R. 68-1-1b and K.A.R. 68-1-1d to reflect that ACPE stands for Accreditation Council for Pharmacy Education rather than American Council on Pharmaceutical Education (McFarland/Paul). Motion carried 5-0.

INVESTIGATIVE REPORTS:

Frank Whitchurch, Vice-President provided the Board with information regarding cases that he had reviewed and closed.

APPROVAL OF NEW LICENSES/REGISTRATIONS

A motion was made and seconded to approve the new pharmacist licenses and pharmacy registrations (Gilstrap/Whitchurch). Howard Paul abstained from voting on any Walgreens pharmacy license.

UPCOMING MEETINGS

The Midwest Pharmacy Conference will be meeting on July 27-29 at the Embassy Suites in Kansas City, Missouri. Board members are encouraged to attend. The KPHA 125th Annual Meeting will be held at the Holidome in Lawrence, Kansas September 15-18. The Board will have a panel discussion during the conference. The Board changed the December 2005 Board meeting date to November 29 and November 30, 2005 due to a conflict. The NACDS annual meeting will be held in San Diego, California on August 27-31, 2005. Howard Paul, Merlin McFarland and Max Heidrick expressed an interest in attending. The Board encouraged attendance at all meetings that further the education of Board members as it relates to the drug delivery system and enforcement.

STAFF MEMBER REPORTS

Debra Billingsley discussed an issue that came up at the KPhA Board of Director's Meeting regarding the year that a student is required to take the MPJE. The question was addressed to Ken Audus but Dean Audus advised that it was the Board of Pharmacy that dictated requirements of testing. The Board indicated that they had no problem with the MPJE portion of the pharmacy test be given during the 5th year. Debra will collect more information regarding this issue so that the Board can determine whether this will have a negative impact in areas unknown by the Board.

Debra also reported that she was working on selecting a computer software vendor along with the Board of Nursing and Board of Cosmetology. This project is on a fast track since the money was budgeted for 2005.

Jim Kinderknecht provided the Board with information received from Osco Stores. This was based on a request from the Board at a previous meeting.

Jim also discussed with the Board a new DEA interpretation that compounded medications that contained a controlled substance would no longer be sent directly to the physician's office. It would be given directly to the patient and the patient would have to deliver it to the physician's office for administration. The Board had grave concerns regarding this issue because the integrity of the medication could become compromised when a patient handled the medication directly. There would be no safeguards in how the product was transported, etc. Further, the opportunity for diversion would be greater. The Board requested that the Executive Secretary prepare a comment to this proposal advising the DEA that the Kansas Board of Pharmacy had concerns with this proposed practice.

Melissa reported that she had participated in the MPJE writing workshop at the NABP office in Chicago. It was an in-depth review for Melissa and was a continuation of work she had Tom Frazier had begun on in January.

Randy Forbes, General Counsel, reported that he had reviewed the previous minutes requesting that a regulation be drafted establishing a fee for a renal dialysis pharmacy. Randy stated that his review of the statutes indicated that all pharmacies were required to pay the same fee and he did not believe a regulation was necessary. The fee is in place and these facilities should pay \$140 for a beginning license and \$125 for all renewals.-

Randy asked for a motion that the Board adjourn into an executive session to discuss matters pertaining a physical and/or mental examination until 4:25 p.m. A motion was made and seconded that all Board members along with Debra Billingsley and Tom Frazier adjourn into an executive session until 4:25 (Heidrick/McFarland). Motion carried 5-0.

RECONVENE: A motion was made to issue an order in Case No. 05-27 ordering a physical or mental examination based on information received in executive session. (Heidrick/McFarland). Motion carried 5-0.

ADJOURNMENT:

The Board adjourned at 4:40 p.m. The Board will reconvene at 8:30 a.m. on June 8, 2005.

Wednesday, June 8, 2005

MEMBERS PRESENT: Jeff Thompson, R.Ph., President; Frank Whitchurch, R.Ph., Vice-President; Merlin McFarland, R.Ph., Max Heidrick, R.Ph., JoAnne Gilstrap, R.Ph., Howard Paul, Public Member.

STAFF PRESENT: Debra Billingsley, Executive Director; Jim Kinderknecht, R.Ph., Pharmacy Inspector; Melissa Martin, Compliance Officer; Reyne Kenton, Compliance Officer; Tom Frazier, Pharmacy Inspector; Randall Forbes, General Counsel.

OTHERS PRESENT: See Attached listing

MEETING CALLED TO ORDER:

Jeff Thompson called the meeting to order at 8:30 a.m.

BOARD REPORTS:

Jeff Thompson advised the Board that he, Merlin, Max and Debra went to the National NABP meeting in New Orleans. The meeting was informative and many issues of mutual concern were addressed. Jeff and several others participated in the KSHP spring meeting in April. The Board of Pharmacy presented a forum discussion regarding new laws and regulations. Jeff advised the Board that he was continuing to work on the Compounding regulations. Randy had done another draft and it is in the process of review.

Merlin McFarland wanted to discuss the issue of whether those individuals with space restrictions could store PSE containing medications in a secure area separate from the

pharmacy. The statutes indicate that the medications shall be secure and that when the pharmacist is not on duty the premises shall be enclosed and secure, K.S.A. 65-1637. The Board reviewed the issue and determined that that if the statute regarding security permits this type of situation then the Board would have no objection to the product being in a separate locked area. Staff will review the security laws to make sure that this would not violate any law or regulation

Max Heidrick advised the Board that the NABP annual meeting had a presentation on pedigrees. Although Florida and California are moving forward with pedigree requirements it is clear that the current technology is not in place. CA and FLA are restricting the pedigree requirement to about 20 products. There are many advances in RFID technology but the companies that were represented indicated that there are still many things to work out.

Merlin McFarland and Max Heidrick would like to take a trip to Utah or Texas to see how well the telepharmacy technology is working. We have reviewed numerous regulations from other states but Merlin and Max would like to study the impact on pharmacy before we move further with our regulations.

Max stated that the new emergency refill has been working well in his pharmacy. He said that it has turned out to be a good service to patients particularly during holiday weekends.

Max publicly thanked Jeff Thompson for providing good leadership as President this past year. He also commended Frank Whitchurch for all of the effort he put into his position as vice president.

Frank Whitchurch advised the Board that should he be reappointed he would like to work toward classifying all pharmacies. He thought that classifications would regulate the practice of pharmacy better.

Frank also indicated that telepharmacy needs to move forward. We need to have something on the books that we can regulate and he suggested that the Board go ahead and implement regulations.

Frank also asked that the Board provide guidance regarding new prescriptions vs. new drug therapy. He thought the Board should review whether we want the patient counseled when the drug therapy is different.

Frank also suggested that the Board discuss whether supervisors of pharmacists should be pharmacists. While the ultimate decisions need to be made by the PIC there are instances where the District Manager has intervened or tried to override the pharmacist. Missouri has a law which requires pharmacy to be accessed by pharmacist only. After the Board discussed this issue staff was directed to look at other state laws and report their findings to the Board. There was some thought that the manager should be able to step into the shoes of the pharmacist and take over in cases of emergency.

BUDGET REPORT

Julie Thomas, the Board's budget analyst was invited to provide updated information regarding the Board's budget. The legislature will be returning to Topeka on June 22 for a special session related to school finance. It is possible that the legislature could remove the 2 ½ percent pay raise that was given to classified employees. (It is actually 1.75 for whole year.) The legislature could also cut each state agency by a percentage. The legislature did take an additional \$4000 from Pharmacy from the savings that was made on the COLA.

After reviewing the finances after the \$850,000 sweep it appears that the agency is in better fiscal shape than first thought. If there isn't a dip in what we collect it would be best to wait until after the special session to determine whether there is a necessity for a fee increase. The agency did not bring in as much for FY04 as they did in FY05 but we are unsure why this happened. Budget will continue to watch our numbers.

The Board questioned Ms. Thomas about K.S.A. 74-1609 and whether it was proper for the legislature to take an additional \$850,000 when the agency had already given 20 percent. Julie advised that this was not a decision made by Budget. The Board also discussed the issue of inspector's and executive secretary pay being less than surrounding states. The Board discussed whether to seek reclassification or whether to consider having the inspectors as unclassified positions. The Board also discussed the difficulty of projecting expenses for automobiles based on the Board's inability to retain their fee funds. Julie advised the Board that post audit was currently conducting a study regarding the motor pool situation. The Board will need to keep abreast of mileage and age of the cars so that they can ask for a budget enhancement in order to purchase new vehicles in the future.

BOARD REPORTS, CONTINUED:

JoAnne Gilstrap reminded staff to check technician pocket cards to make sure that both cards have the registration number, and other significant information

JoAnne also asked that the Board make attempts to change the statute so that the Board can recoup costs associated with hearings. The Board did try to get a bill through the legislature in 2005 but they did not get a hearing on the bill. It is similar to the language of that in the Board of Healing Arts law.

There was a brief discussion on whether electronic prescriptions were treated as faxes regarding signatures. They are treated the same as a facsimile and do not have to be countersigned.

JoAnne asked whether the new emergency supply statute applied to birth control pills. There was brief discussion but the consensus was that the law did apply to a month supply of birth control.

JoAnne wanted to publicly thank Frank Whitchurch and Jeff Thompson for their time and work given to the Board of Pharmacy.

ANNUAL ELECTION OF OFFICERS:

A motion was made and seconded that Merlin McFarland be nominated as President of the Board of Pharmacy. (Heidrick/Gilstrap). Motion carried 5-0.

A motion was made and seconded that JoAnne Gilstrap be nominated as Vice-President of the Board of Pharmacy. (Heidrick/Paul). Motion carried 5-0.

NEW BUSINESS:

Howard Paul requested that the President and Vice-President write a letter to budget and to the Governor requesting an increase in the Executive Director's salary. He also directed the Board's General Counsel to assist in providing some language that sets forth the Board's authority to set the salary pursuant to K.S.A. 74-1608 and 1609.

Mr. Paul also requested that the Executive Secretary draft a letter to Legislative Post Audit asking them to make a determination as to whether the Board is in compliance with K.S.A. 74-1608 as it relates to the Board's providing over the 20 percent statutory amount to the legislature regarding the fee sweep.

ADJOURNMENT: The Board adjourned at 10:30 a.m.