KANSAS STATE BOARD OF PHARMACY MINUTES OF THE MEETING

March 7 & 8, 2006 KU School of Pharmacy 2056 Malott Hall Room 6056 Lawrence, Kansas 66054

Tuesday, March 7, 2006

MEMBERS PRESENT: Merlin McFarland, RPh., President; JoAnne Gilstrap, RPh., Vice President; Max Heidrick, RPh.; Dr. Shirley Arck, RPh.; Michael Coast, R.Ph., and Howard Paul, Public Member.

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

OTHERS PRESENT: See attached listing.

MEETING CALLED TO ORDER: Merlin McFarland called the meeting to order at 9:45 a.m.

APPROVAL OF AGENDA. A motion was made and seconded to approve an amended agenda with the addition of discussion regarding the pharmacy technician ratio. (Gilstrap/Paul) Motion carried 5-0.

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

APPROVAL OF FEBRUARY 2006 MINUTES: A motion was made and seconded to approve the February 2006 minutes (Heidrick/ Arck). Motion carried 5-0.

ADMINISTRATIVE PROCEEDINGS:

WALGREENS CO CASE NO. 05-67

Gary Peters, Attorney for Walgreens Co. and Julie Bickers, District Manager appeared on behalf of Walgreens Co. The Board appeared through its attorney, Randall Forbes. The proposed discipline was a Stipulation, which provided a fine of \$500 for failure to have an incident report on file. A motion was made and seconded to accept the Stipulation (Arck/Coast) Howard Paul recused himself from discussion and voting. Motion carried 3-0

WALGREENS CO **CASE NO. 06-02**

Gary Peters, Attorney for Walgreens Co. and Julie Bickers, District Manager appeared on behalf of Walgreens Co. The Board appeared through its attorney, Randall Forbes. The proposed discipline was a Stipulation which provided a fine of \$500 for failure to register technicians. A motion was made and seconded to accept the Stipulation. (Arck/Coast) Howard Paul recused himself from discussion and voting. Motion carried 3-0.

WALGREENS CO CASE NO. 06-08

Gary Peters, Attorney for Walgreens Co. and Julie Bickers, District Manager appeared on behalf of Walgreens Co. The Board appeared through its attorney Randall Forbes. The proposed discipline was a Stipulation which provided a fine of \$500 for failure to register technicians. They were also fined \$1,460.00 for operating a pharmacy for a period in excess of 30 days without a Pharmacist in charge. A motion was made and seconded to accept the Stipulation. (Arck/Coast). Howard Paul recused himself from discussion and voting. Motion carried 3-0.

WALGREENS CO CASE 06-09

Gary Peterson, Attorney for Walgreens Co. and Julie Bickers, District Manager appeared on behalf of Walgreens Co. The Board appeared through its attorney Randall Forbes. The proposed discipline was a Stipulation, which provided a fine of \$1340.00 for operating a pharmacy for a period in excess of 30 days without a Pharmacist in charge. A motion was made and seconded to accept the Stipulation. (Arck/Coast), Howard Paul recused himself from discussion and voting. Motion carried 3-0.

WALGREENS CO **CASE NO. 06-11**

Gary Peterson, Attorney for Walgreens Co. and Julie Bickers, District Manager appeared on behalf of Walgreens Co. The Board appeared through its attorney Randall Forbes. The proposed discipline was a Stipulation, which provided a fine of \$1740.00 for operating a pharmacy for a period in excess of 30 days without a Pharmacist in charge. A motion was made and seconded to accept the Stipulation. (Arck/Coast). Howard Paul recused himself from discussion and voting. Motion carried 3-0.

ADJOURNMENT:

The Board adjourned for five minutes.

RECONVENE: The Board reconvened at 10:25 a.m.

LORIE DILLEHAY

Continued to June Board meeting.

TERRACE PHARMACY 05-36

The Respondent did not appear. The Board was represented by its attorney Randall Forbes. The Board directed Board staff to report QuickMed to the state of Utah and to confirm their transfer policy. The proposed discipline for Terrace Pharmacy was a

Stipulation which provided a fine of \$500 for dispensing drugs in Kansas in a container that did not contain the pharmacy's toll free number. A motion was made and seconded to accept the Stipulation. (Heidrick/Coast) Motion carried 4-0.

JILL CHRISTINE CARRELL 05-38

The Respondent did not appear. This is an individual who holds licenses in MO and KS. She was previously disciplined in MO. Based on the Missouri conduct the Respondent entered into a Stipulation with the Board requiring 5 years in CIPP. The Respondent is no longer working in Kansas and requested that she be permitted to cancel the CIPP contract. The Board agreed to release the Respondent from the CIPP contract so long as she surrendered her Kansas license. She will also be required to meet the Vakas requirements should she request licensure in Kansas. She must meet the same criteria as if she had been revoked. A motion was made and seconded to accept the Stipulation. (Heidrick/Arck) Motion carried 4-0.

DEFEVER OSBORN CASE NO. 05-43

The Respondent, Steve Defever, appeared in person. The Board was represented by its attorney, Randall Forbes. The proposed discipline was a Stipulation which provided a fine in the amount of \$1000 for permitting the pharmacy to be open and unsecured and permitting a pharmacy technician to function in the prescription area without a pharmacist being present. The Stipulation also required each pharmacy technician to take the pharmacist technician test and answer all questions within 30 days. A motion was made and seconded to accept the Stipulation. (Heidrick/Coast). Motion carried 4-0.

CVS PHARMACY CASE NO. 05-48

Continued to June Meeting.

BRISCOE DRUG CASE NO. 06-65

Continued to June Meeting.

ALLEGRE DRUG CASE NO. 05-65A

Continued to June Meeting.

KYLE ALBRIGHT CASE NO. 05-60

Continued to June Meeting.

CVS PHARMACY CASE NO. 06-03

Continued to June Meeting.

RCR EAST, LLC PHARMACY CASE NO. 06-04

The Respondent did not appear. The Board was represented by its attorney, Randall Forbes. The proposed discipline was a Stipulation which provided a fine in the amount of \$500 for permitting a technician to work without being registered. A motion was made and seconded to accept the Stipulation. (Coast/Arck) Motion carried 4-0.

OSCO DRUG #5134 CASE NO. 06-12

The Respondent appeared through Paul Hartz. The Board appeared by and through its attorney, Randall Forbes. The proposed discipline was a Stipulation which provided a fine in the amount of \$1,780.00 for operating a pharmacy for a period in excess of 30 days without a pharmacist in charge. A motion was made and seconded to accept the Stipulation. (Coast/Arck) Motion carried 4-0.

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

RECONVENE: The Board reconvened at 1:00 p.m.

DISCUSSION REGARDING FEES FOR EXAMINATION AND LICENSURE AS A PHARMACIST – KAR 68-11-1

The Board reviewed the NABP increase of fees for the MPJE. The Board directed staff to draft a regulatory change to K.A.R. 68-11-1 so that it accurately reflects the fees that are made to NABP as opposed to those made to the Board.

DISCUSSION REGARDING RX REFILLS – KAR 68-7-19

The Board directed staff to draft an amendment to K.A.R. 68-7-19 to reflect that interns and pharmacy students may transfer prescriptions. The regulation should also reflect that the pharmacy intern/student and pharmacist should document their full name when transferring prescriptions. This regulation needs to be reviewed by the Board before it is sent to the Department of Administration.

DISCUSSION REGARDING SHARED SERVICE ISSUE:

Presented by: Mark Gagnon and Timothy Smith.

The Board discussed the intent of the shared service processing regulation as it related to providing pharmacy access for hospitals that are not open 24 hours a day. KAR 68-7-20 requires either a pharmacy to pharmacy arrangement that share a common electronic file or have a contractual agreement. The Board reviewed whether setting up an intermediary company (non-pharmacy) that contracts with a pharmacy would meet the requirements of the regulation and the Board determined that it would not be acceptable even for order processing. It must be a licensed pharmacy to licensed pharmacy.

Subsection (f) of K.A.R. 68-7-20 was added to permit flexibility to persons working outside the pharmacy who would be accessing their employer's system remotely. The question was whether an individual pharmacist not employed by a pharmacy, but with a contractual relationship, could access the system remotely. The Board stated that when the regulation was put into place that there was a compromise that this would be permitted but limited to order processing only and not order filling. The pharmacy contracting or employing the individual pharmacist would be responsible for the pharmacist.

DISCUSSION REGARDING KAR 68-1-1b and KAR 68-1-1d APPROVED SCHOOLS

The Board approved changing the language in the regulations from American Council on Pharmaceutical Education to Accreditation Council for Pharmacy Education. The Board directed staff to move forward with these changes.

DISCUSSION REGARDING FOREIGN GRADUATES KAR 68-1-1f AND INTERNET BASED TOEFL KAR 68-1-1h.

The Board approved amending KAR 68-1-1f and drafting 68-1-1h to change the TSE score to 50 as passing rather than 55. Effective June 1, 2006 the applicant must pass an Internet based TOEFL (iBT). KAR 68-1-1h gives authority for an Internet based TOEFL (iBT) with a score of not less than 24 in writing, 26 in speaking, 18 in listening, and 21 in reading in order to successfully qualify for licensure in Kansas.

DISCUSSION REGARDING SAMPLE DRUGS AND DRUGS FROM INDIGENT DRUG PROGRAMS

The Board reviewed the Department of Aging's interpretation of their regulations regarding sample drugs and drugs from indigent drug programs. A pharmacist consultant must review labeling. Any other interpretation permits a lesser standard of care for nursing home patients. Manufacturers are encouraged to send appropriately labeled product to the physician or send the medication to a pharmacy so that it can be properly labeled and packaged.

DISCUSSION REGARDING PHARMACY TECHNICIAN DUTIES

The Board discussed whether to require a specific list of duties regarding technicians. The Pharmacy Act requires that technicians perform no duties that are judgmental in nature. The Board made no decision at this time regarding drafting a comprehensive list of duties.

INVESTIGATIVE REPORT:

Presented by JoAnne Gilstrap, Vice President /Investigative Member The Board reviewed closed cases.

DISCUSSION REGARDING PSEUDOEPHEDRINE LAW VIOLATIONS

The Board discussed the penalties that should be assessed for violations of the pseudoephedrine laws. The Board noted that the investigative member should consider whether the violation was willful and whether it occurred on numerous occasions as opposed to a single incident.

DISCUSSION REGARDING PSEUDOEPHEDRINE LAW CHANGES

The Board discussed the passage of the Combat Methamphetamine Epidemic Act of 2005. To combat meth the law restricts the sale of pseudoephedrine, ephedrine and PPA

limiting the sale to 3.6 grams/day or 9 grams/month. The new law also requires purchasers of gelcaps and liquids to sign a logbook. The Board will update their website with information regarding these changes.

STRATEGIC NATIONAL STOCKPILING

The Board reviewed proposed Executive Orders regarding emergency medical response in Kansas. The Board has been working with KDHE and other stakeholders to develop a plan for emergency response and to provide a pharmacy volunteer corp. KU School of Pharmacy may be utilized to provide students and the Board will ask pharmacists on future license applications whether they would like to participate as a volunteer in case of emergency.

BUDGET

The Board of Pharmacy revised their 2006/2007 budget request asking for an additional \$50,000 to be used toward licensure software. The Board participated in an RFP with the Board of Nursing, Board of Cosmetology and Bank Commissioner's Office. The costs associated with software have increased and the Board would need additional money to be used in conjunction with the 111,000 that is currently encumbered. The Board also asked to use fee funds already collected to purchase a vehicle for 2006 and a vehicle for 2007.

DISCUSSION REGARDING CE APPROVAL

The Board reviewed the administrative regulations regarding approval of continuing education. The Board advised Board staff that they want full compliance with K.A.R. 68-1-1b. The regulation does not grant approval of Category I CME or attendance at medical school. Therefore, the Board will no longer approve these programs. Further, all CE that is approved by the Board must be submitted at least 120 days in advance of the program presentation.

DISCUSSION REGARDING PHARMACY TECHNICIAN RATIO

The Board reviewed the regulation that was drafted regarding a change in the pharmacy technician ratio. The Board approved the language that permitted a 3 to 1 ratio so long as two of the three have been certified by a vendor approved by the Board. The Board directed staff to move forward with this regulation.

DISCUSSION REGARDING NAPLEX/MPJE TESTING PRIOR TO GRAUDATION.

Gene Hotchkiss addressed the Board regarding a couple of concerns that the school had. KU has information that other schools are permitting students to take NAPLEX and MPJE prior to graduation. Kansas regulation requires actual graduation. The authorization to test generally reflects the graduation date. Gene had requested something from NABP confirming that this was the correct and acceptable practice but he has not received a response regarding this issue.

INTERN STATUS FOR STUDENTS

Gene Hotchkiss advised the Board that there have been several instances in the last few years where students have withdrawn from school for a semester due to personal issues. If the student is going to be out for a short time and is in good standing when they leave, the school will hold their spot open and let them return to school. The question is whether the student can retain their intern status since they are not currently enrolled in school? The Board advised Gene that the school should send a letter to the Board notifying that the student is no longer enrolled. The Board will then review each situation on a case by case basis to determine whether they can retain their intern status. If the situation warrants the student should be permitted to retain their intern status.

PRECEPTOR QUALIFICATION CRITERIA

Gene Hotchkiss asked the Board whether an individual wishing to be a preceptor met the qualifications if the had been licensed for 2 years in good standing or whether he had to be licensed in Kansas for 2 years. The Board interpreted the regulation to mean two years experience as a pharmacist thus the individual does not have to have two years experience in Kansas.

ADJOURNMENT:

The Board adjourned at 5 p.m. The Board will reconvene at 9:00 a.m. on March 8, 2006.

Wednesday, March 8, 2006

MEMBERS PRESENT: Merlin McFarland, R.Ph., President; JoAnne Gilstrap, R.Ph., Vice-President; Max Heidrick, R.Ph., Dr. Shirley Arck, R.Ph., Michael Coast, R.Ph, and Howard Paul, public member.

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

OTHERS PRESENT: See Attached listing

MEETING CALLED TO ORDER:

Merlin McFarland called the meeting to order at 9:00 a.m.

LEGISLATIVE UPDATE

John Kiefhaber, Executive Director of KPhA gave the Board an update on current legislation. The Department of Revenue attempted to change the sales tax on OTC vitamins and food supplements even if the product was written as a prescription. Revenue had changed their definition of a drug in order to clarify and simplify drug codes. Revenue indicated that to alleviate problems that resulted in the change that they would amend their regulations so that Revenue does not require the collection of sales tax on these items.

The Secretary of Corrections sponsored legislation that would hold an inmate's medical costs to Medicaid rates as a way to save their agency money. Under federal law Medicaid rates cannot be used for a non-Medicaid population. Corrections withdrew their request for this legislation.

KPhA advised the Board that the PBM registration bill had made it through the Senate Committee. Express Scripts had some objections. It will be heard next in the House Committee on Insurance. The Insurance Commissioner also introduced legislation to register PDP's.

There was a bill introduced that outlawed mercury in vaccinations. This was controversial. KPhA did not take a position on the bill since there was no clear clinical research on this issue.

Debra Billingsley reported that HB 2830 permitting pharmacy technicians to take their test within 30 days of registration and the language requiring a super majority regarding the ratio had passed out of the House Health Committee. It would be before the Senate Health Committee on March 9th.

HB 2831 changing ACPE language will also be heard on March 9th. There was no opposition to either bill.

The Renal Dialysis bill that repealed the Board's authority over dialysis facilities had passed through the House and Senate Health Committees. It is expected to pass and the statute will be repealed. There was no opposition to this language.

The Pedigree bill was heard in the House Health Committee. Pfizer and NABP were the only proponents. The Board testified neutrally although we pointed out numerous problems we had with the requirements of this particular bill. NACDS and HDMA testified as opponents. The bill will be worked on March 9th.

The Board has sent several regulatory changes to the Department of Administration. The compounding regulations have been revised and will probably go through several more revisions before they are completed. A draft is on the Board's website and will be replaced when there are revisions made.

The Institutional Drug Regulations and Cancer Drug Repository Regulations are both with the Department of Administration. These will be placed on the agenda for public hearing once they have gone through the system.

BOARD REPORTS:

Howard Paul recommended that the Board communicate with NABP that before they take a position against the Board legislatively that they should advise us and get our input. Conflicting testimony will impact on the Board's credibility with the legislature so we should be exchanging information in order to provide a unified message to the legislature.

Mr. Paul requested that the Executive Secretary review all job descriptions so that we look at the duties of each employee. It would be helpful to have some type of descriptive materials for each job associated with the Board.

Max Heidrick discussed requiring a pharmacy to conduct an inventory whenever there is a change in PIC or change of ownership. This requirement needs to be added to stipulations when the PIC changed. The staff should review whether this should be included in a regulation or whether a policy would be sufficient.

Mr. Heidrick also discussed the case load of the Board. It was suggested that in order to streamline cases that staff send notification of those individuals who need to appear before the Board and that if they do not respond in a timely manner that the case be forwarded for hearing at the next Board meeting.

Mike Coast advised the Board that he had attended the fall educational conference sponsored by NABP. One of the topics of interest was on telepharmacy. Mike has asked Board staff to work with him so that he can make a recommendation to the Board on regulations regarding telepharmacy.

JoAnne Gilstrap asked that a reminder be placed in a future Board newsletter regarding Pharmacy Technician registration. It is the PIC's responsibility to make sure everyone is properly registered before they let the technician work.

Ms. Gilstrap also discussed whether the Board staff could notify pharmacies whenever a physician is having problems with forged prescriptions, etc. The Board discussed whether a flash email could be sent out so that as many entities could watch for problem prescriptions.

Ms. Gilstrap also recommended that the Board review whether they would want to limit the supply for narcotics C-II drugs for patients. Currently, Kansas has no restriction and it might be helpful to limit the amount to a 90 day supply . Staff will provide Ms. Gilstrap with draft language and this can be discussed at the next meeting.

Shirley Arck discussed the transfer of prescriptions by Interns. Ms. Arck suggested that staff work on the regulatory language and bring it back to the Board so that the Board can see the language before it goes to the Department of Administration. It was questioned as to whether an intern could transfer a controlled substance. The statute indicates that interns can do everything a pharmacist can do so long as they are supervised.

Merlin McFarland offered to work with Frank Whitchurch on setting up a task force to change the statutes to classify pharmacies and distributors. This is something that the Board has discussed in the past and it would be helpful to separate the types of pharmacies out by statute.

APPROVAL OF 50 YEAR CERTIFICATES

A motion was made and seconded to approve the 50-year certificates. (Coast/Gilstrap). Motion carried 5-0.

APPROVAL OF NEW LICENSES AND REGISTRATATIONS (Gilstrap/Arck)

A motion was made and seconded to approve the new pharmacists licenses and pharmacy registrations. (Gilstrap/Arck). Howard Paul recused himself from voting on the approval of any Walgreen's license or registration. Motion carried 5-0.

ADJOURNMENT: The Board adjourned at 11:30 a.m.