KANSAS STATE BOARD OF PHARMACY
MINUTES OF THE MEETING

December 17 & 18, 2007
US Bank Building
800 SW Jackson
Topeka, KS

Monday, December 17, 2007

MEMBERS PRESENT: Michael Coast, RPh., President; Dr. Shirley Arck, Pharm.D., Vice President; JoAnne Gilstrap, R.Ph.; Frank Whitchurch, R.Ph.; Karen Braman, R.Ph., M.S.

STAFF PRESENT: Debra Billingsley, Executive Secretary; Jim Kinderknecht, RPh., Pharmacy Inspector; Carly Haynes, R.Ph. Pharmacy Inspector; Melissa Martin, Compliance Officer; Randall Forbes, General Counsel; Derenda Mitchell, Assistant Attorney General; and Lori Thompson, Administrative Assistant.

OTHERS PRESENT: See attached listing.

MEETING CALLED TO ORDER: President Michael Coast called the meeting to order at 9:00 a.m.

APPROVAL OF AGENDA. A motion was made and seconded to approve the agenda (Whitchurch/Arck). Motion carried 4-0.

APPROVAL OF SEPTEMBER MINUTES A motion was made and seconded to approve the September 2007 minutes. (Arck/Gilstrap). Motion carried 4-0.

AVAILABILITY OF LEAF MARIJUANA FOR MEDICINAL PURPOSES.
Presented by Dr. Eric Voth, MD, FACP
Dr. Voth is the chairman of The Institute on Global Drug Policy. He presented a power point presentation related to the safety implications of using leaf marijuana for medicinal uses. The Department of HHS, including the FDA has previously concluded that no sound scientific studies support medical use of marijuana for treatment in the United States. Accordingly, the FDA and DEA do not support the use of smoked marijuana for medical purposes. Dr. Voth provided that there are safe and effective reliable medicines that do exist that are best for patients. He requested that the Board of Pharmacy pass a resolution taking the position that the Board of Pharmacy does not approve of leaf marijuana for medicinal purposes. A motion was made and seconded to pass a resolution that until approved by the FDA the Board of Pharmacy does not support the use of leaf marijuana for treatment of any medical condition. (Braman/Gilstrap). Motion carried 4-0.

ADMINISTRATIVE PROCEEDINGS

KATIE SUROWSKI, R.Ph. Case No. 07-52
The Respondent appeared in person. The Board was represented through its counsel, Assistant Attorney General Derenda Mitchell. The proposed discipline was a Consent Agreement which will provide for the standard CIPP requirements for a period of five years. A motion was made and seconded to accept a Consent Agreement and the Board directed the Assistant Attorney General to draft said agreement for signature by all parties. (Braman/Whitchurch). Motion carried 3-0.

WASHINGTON HEALTHMART Case No. 07-32
The Respondent did not appear. The Board was represented through its counsel, Assistant Attorney General Derenda Mitchell. The Board was provided with a Consent Order. The proposed discipline was a fine of $500 for failing to maintain a completed incident report. The Board requested that this matter be carried over to the next meeting and that the Respondent provide a copy of a completed incident report as well as a policy and procedure manual.

WALGREENS Case No. 07-20
The Respondent did not appear. The Board was represented through its counsel, Assistant Attorney General Derenda Mitchell. The Board was provided with a Consent Order. The proposed discipline was a fine of $500 for failing to maintain a completed incident report. A motion was made and seconded to accept the Consent Agreement. (Braman/Gilstrap). Motion carried 3-0.

INVESTIGATIVE REPORT
Presented by Shirley Arck, Pharm.D., Vice-President/Investigative Member
The Board reviewed closed cases.

DISCUSSION REGARDING EMERGENCY KITS
The Board had requested a legal opinion regarding the permissibility of the use of an Emergency Medication Kit ("E-Kit") in an assisted living facility. The Pharmacy Act permits an Adult Care Home to maintain an E-Kit. An assisted living facility falls under the definition of an Adult Care Home so they may utilize an E-Kit. However, the assisted living facility shall maintain the E-Kit in compliance with the following requirements: 1) Drugs in the E-Kit shall be maintained under the control of the pharmacist-in-charge of the pharmacy from which the kit came until administered to the patient upon the proper order of a practitioner. 2) Drugs may include controlled substances, but in such cases a pharmaceutical services committee shall be responsible for specifically limiting the type and quantity of controlled substances that are placed in the E-Kit. 3) Administration of controlled substances shall be in compliance with the Uniform Controlled Substance Act. 4) The consultant pharmacist shall be responsible for developing procedures, proper control and accountability for the E-Kit and shall maintain accurate records of the controlled substances. A periodic physical inventory of the kit is required.

Further, the assisted living facility would need to utilize the services of a pharmacist and the E-Kit would have to be approved by the medical staff composed of a duly licensed practitioner and a pharmacist. The Emergency Kit could only be used in cases of emergency and can only be accessed by a licensed registered nurse or nurses or licensed practitioner.

A related question was whether an assisted living facility could fax a C-II prescription the same as a long term care facility. They cannot. The Controlled Substance Act limits faxed schedule II prescriptions to long term care facilities only. The Board attorney was also asked whether drugs could be returned from an assisted living facility. KAR 68-12-2 specifically states that prescription drugs may not be resold, redispensed, or distributed unless the prescription drug is in a single unit dose package containing only one medication and in which the drug has not been dispensed to the final consumer or reached the patient. The package must also be intact. Since most patients in an assisted living facility maintain their own medications this regulation would not generally apply to their situation and their drugs could not be returned to the pharmacy.

The Board also discussed whether an infusion clinic met the requirements for an E-Kit. Infusion pharmacies are not always located on the premises of the clinic and there were concerns that a patient may find themselves in an emergency situation in which an E-Kit would be helpful. If the clinic were licensed as a Home Health agency they would fall under the provisions of K.S.A. 65-1659 and would be permitted to carry sterile water for injection or irrigation; sterile saline solution for injection or irrigation; heparin flush solution; diphenhydramine injectable; and epinephrine injectable. It is unlikely that they have been deemed to be a home health agency. Therefore, their options may be limited. The infusion clinic can call 911 in the case of an emergency or the physician can write an order for the patient ahead of time and have it filled and the patient can keep the drugs with them at all times. These are not particularly good solutions. The Board will contact KDHE, Aging and any other applicable licensing authority and schedule a meeting. It is possible that something could be worked out that would provide for better patient care. Steve Schwarm will also be notified of the meeting so that he can attend.

DISCUSSION REGARDING BOARD STRATEGIC PLAN

Frank Whitchurch provided the Board with a copy of the California State Board of Pharmacy Strategic Plan. It addressed that Board's vision and mission statement, strategic issues to be addressed such as costs of pharmaceutical care, aging population, pharmacists' ability to provide care, changing demographics, laws governing pharmacists, integrity of the drug delivery system, technology , internet issues, disaster planning, qualified staff and Board members and pharmacy health care in the 21st century. Frank suggested that the Kansas Board have a retreat sometime this spring and that they set goals in anticipation of planning for future events and issues. The Board agreed that this would be beneficial and directed the Executive Secretary to schedule a spring meeting specifically for strategic planning

DISCUSSION REGARDING JOINT MEETING OF KANSAS STATE BOARD OF HEALING ARTS (KSBHA) AND KANSAS BOARD OF NURSING (KSNB) RELATED TO PRESCRIPTIONS WRITTEN BY PHYSICIAN ASSISTANT (PA) AND ADVANCED REGISTERED NURSE PRACTITIONER (ARNP)

Shirley Arck advised the Board that she, Frank Whitchurch and Deb Billingsley attended the December 7, 2007 Joint Meeting of the KSBHA and the KSBN. The Board of Pharmacy addressed the two Boards regarding the statutes and regulations related to prescriptions written by PA's and ARNP's that require the name, address and telephone number of the responsible physician on each actual prescription. The KSBHA and KSBN both indicated that there was no patient safety issues that would require the responsible physician's name to be on the prescription. Therefore, they agreed to work with the Board of Pharmacy on making changes in their laws that would be consistent with each agency. The Board staff did subsequently contact the KSBHA and asked them whether a prescription would be valid if the PA failed to indicate the responsible physician's name, address and telephone number and the KSBHA said it would not be valid. Therefore, the Board of Pharmacy determined that it would not be beneficial to change the labeling requirements unless the KSBHA and KSBN change their statutory and regulatory requirements regarding the requirements of a valid prescription. The Board of Pharmacy will continue to work with KSBHA and KSBN on this issue.

RECESS: A motion was made and seconded to recess for lunch until 1:30 p.m. Motion carried 4-0.

BACKGROUNDING OF LICENSEES AND REGISTRANTS

The KSBHA and KSBN have both tried to get legislation passed that would permit backgrounding and fingerprinting of their licensees. This has been difficult to get passed in the legislature. KSBHA Executive Director, Larry Buening reported to his Board that Post Audit was recommending that licensing boards pass legislation that would require fingerprinting and backgrounding of licensees. The Board of Pharmacy would like to explore this option also but will wait to see whether the legislature is favorable toward KSBHA and KSNB. The Board of Pharmacy staff will get a copy of the Post Audit Report for the Board members.

DISCUSSION REGARDING PEDIGREE AND WHOLESALE LICENSURE

The Board was provided with draft regulations related to wholesale distributors. The Board counsel drafted the regulations based on discussions from the previous task force of stakeholders related to wholesale distribution. The Board discussed some specific issues related to confidentiality and open records with the Board General Counsel. They advised Randy Forbes to move forward with the regulations.

The Board also reviewed the language of the Illinois Pedigree statute that was recently passed in that state. The Board directed the Board attorney to use the Illinois language as a model toward drafting additional pedigree regulations. The Board will meet again on January 9 to discuss the draft regulations.

DISCUSSION REGARDING COMPOUNDING REGULATIONS

Shirley Arck, Pharm.D. reported that she had participated in a phone call with Pat Parker, R.Ph., Jeff Thompson, R.Ph. Debra Billingsley, Randy Forbes and Lane Hemsley on November 19, 2007 to review the latest draft of the compounding regulations. Since that phone conference the USP revised various areas of Chapter 797. Pat Parker advised the Board of the specific changes that had been made to Chapter 797 and he suggested that the Board consider making revisions to their Compounding draft. The Board agreed and recommended that Randy Forbes reference the USP 797 changes in the draft regulations. The group agreed to have another phone conference to review the amendments made to the draft. All Board members will be notified when the phone conference will be held. As soon as the committee approves the changes to the draft it can be sent to the Dept. of Administration for their approval.

RECESS: A motion was made and seconded to recess until 3:42 p.m.

RECONVENE: The President reconvened the meeting at 3:42 p.m.

DISCUSSION REGARDING TECH CHECK TECH PROGRAM

The Board was addressed by Pat Parker, R.Ph., of Lawrence Memorial Hospital, Eugene Dedonder, R.Ph. of Newman Memorial County Hospital, and Kirk Starr of St. Francis Health Center regarding their use of the tech check tech program as it relates to filling the pyxis machine and other automation systems. The Board was considering whether regulations needed to be written that would actually permit this function. The Board was given statistical information related to errors, advised how data was collected, and how the technicians were monitored for accuracy. The Board determined that this was something that needed to be in the medical facility pharmacy regulations and they directed the Board attorney to draft language. Once the language is drafted it will be sent to interested parties and the Board Executive Secretary will discuss whether the regulations will meet the needs of hospital pharmacists.

DISCUSSION REGARDING AUTOMATED PRESCRIPTION SYSTEM PARATA SYSTEMS

Bill Holmes of Parata Systems attended the Board in order to provide additional information that had been requested at the last Board meeting. This system was requested by Wal-Mart pharmacy and the automation would be located in the pharmacy used only for refills. It would not contain any controlled substances. It was suggested that this should only be used when the actual pharmacy is open for business otherwise it will be closed. Mr. Holmes provided the Board with a written resolution and asked that the Board approve the system. The Board will have their attorney review the resolution. The Board needs to determine whether policies can be put in place that would address this type of automation. This matter should be carried to the January 9, 2008 meeting for further discussion and possible approval.

INSTYMEDS SYSTEM

Matt Sneller, Pharm.D., Vice President of Pharmacy Operations for InstyMeds, Martie Ross of Lathrop and Gage Law Firm, Christy Keating, RN, Craig Campbell, R.Ph. and Jay Allen, MD of Mercy Health Center in Fort Scott, Kansas asked the Board for approval of the Instymeds System in Kansas. Particularly, Mercy Hospital in Fort Scott would like to use the system in their hospital. The machine would be located in the emergency room and contains mostly generic acute medications. It would contain controlled substances. It would allow the physician to write a prescription and the physician would counsel the patient. The patient would then pay retail through the automation and would receive no more than a 30 day supply. The group discussed the needs of the hospital and the safety features of the machine. The Board did not make a decision on whether to approve Instymeds. The Board needed additional time to study the issue and to determine whether the telepharmacy regulations would assist the hospital with their particular problems. This matter would be discussed at the next available Board meeting.

ADJOURNMENT: A motion was made and seconded to adjourn until 9:00 a.m. on Tuesday, December 18, 2007. Motion carried 4-0.

Tuesday, December 18, 2007

MEMBERS PRESENT: Michael Coast, R.Ph., President; Shirley Arck, Pharm.D., Vice-President; JoAnne Gilstrap, R.Ph., Frank Whitchurch, R.Ph., Karen Braman, R.Ph.,M.S.

STAFF PRESENT: Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph., Pharmacy Inspector; Carly Haynes, R.Ph., Pharmacy Inspector; Melissa Martin, Compliance Officer, Lane Hemsley, General Counsel; and Lori Thompson, Administrative Assistant.

OTHERS PRESENT: See Attached Listing.

MEETING CALLED TO ORDER:
President Coast called the meeting to order at 9:00 a.m.

ADMINISTRATIVE PROCEEDING:

JAY PARKER, R.Ph. Case No. 07-81
The Respondent appeared in person and through his counsel, Darin Conklin of Alderson, Alderson, Weiler, Conklin, Burghart, & Crow, LLC. The Board was represented by Lane Hemsley of Frieden and Forbes, LLC. The matter was before the Board on an application for a pharmacist reinstatement. A motion was made and seconded to go into executive session to deliberate until 10:45 a.m. (Whitchurch/Arck). Motion carried 4-0. The Board reconvened and a motion was made and seconded to go into executive session to deliberate until 10:50. (Whitchurch/Arck). Motion carried 4-0. The Board reconvened at 10:50 a.m. A motion was made and seconded to enter an Order issuing the Respondent a pharmacist license with the restrictions that he be placed on probation for 2 years

beginning December 18, 2007. During the probationary period the Respondent will continue his criminal case probation and provide a statement from his probation officer that he has successfully completed the requirements upon completion. The Respondent will be restricted and cannot be a Pharmacist in Charge or a pharmacy owner. The Board will receive quarterly reports from the therapist for the next two years. The Board directed Lane Hemsley to draft the Order with the above stated conditions. (Braman/Gilstrap). Motion carried 4-0.

DISCUSSION REGARDING CLASSIFICATION OF PHARMACIES

a. Nuclear Pharmacy Regulations

Frank Whitchurch reported that he had met with interested stakeholders and discussed the different varieties of pharmacies that the Board licenses. As part of the discussion it was determined that a definition for consultant pharmacist needed to be added to K.S.A. 65-1626. Oversight of the newer pharmacy practice modalities is largely dependent upon the inspector's application of current statutes and regulations that were designed for typical retail or medical care facilities. Regulations need to be written for the newer practice modalities such as nuclear pharmacy, Methadone clinics, long term care pharmacy, same day surgery centers, non-drug pharmacy or consultant pharmacies, and mail order pharmacy.

The group worked on nuclear regulations that are similar to Oklahoma regulations. The Board discussed the issue of nuclear pharmacy technicians and whether the regulations should address the ratio issue. The question was whether the nuclear training certification has a standard not below that of PTCB. Becca Baugher offered to obtain information on nuclear pharmacy technician training so that the Board could review whether this certification would allow for the three to one ratio.

b. Prescription vs. Medical Order requirements

Frank Whitchurch further advised the Board that while reviewing the classifications of pharmacy issue that it was apparent that medical facilities had exempted themselves from requirements without having anything in the regulations so stating. The Board reviewed the useful information and directed the Executive Secretary to ask KPhA to remove the statement in the law book that relates to prescriptions versus medical orders as there is no legal authorization for the statement. The Board has not taken the position that medical facilities are exempt and the law book should not have a statement in it that states otherwise. Staff will continue to work on classification of pharmacy and will submit a plan to the Board for approval.

DISCUSSION REGARDING CQI

The CQI Committee met in October and November. They worked on a draft statute and regulation related to incident reports. The group discussed the current requirements for an alleged or real error in filling or dispensing. They were able to define an incident as a preventable medication error resulting in the incorrect dispensing of a prescription as a result of a series of risks. The series of risks were included in the proposed regulation. They also determined by regulation what should be in the incident report. The Committee recommended that the Board move toward an enabling statute and regulation

related to CQI. Once that is in place then the current incident report regulation should be amended. A motion was made and seconded to move toward taking the necessary steps to implement CQI. (Whitchurch/Gilstrap). Motion carried 4-0.

DISCUSSION REGARDING PRESCRIPTION DRUG MONITORING PROGRAMS AND SUDAFED PRODUCT MONITORING

The Controlled Substance Task Force has been meeting periodically. They have draft legislation for both a prescription drug monitoring program and a Sudafed tracking program. The group will be meeting again at 2:00 on December 18. Mike Coast went to a meeting in Washington D.C. that was sponsored by the Dept of Justice and the Model Drug Laws. He was able to get a lot of information regarding these programs and the grant money that is available.

DISCUSSION REGARDING DONATED DRUGS

The Board reviewed HB 2578 related to donating drugs. This language was taken from Oklahoma but their pharmacies are government owned. The Board decided that it would best to amend the Cancer Drug Repository statute and to submit it as a substitute bill. The Board would like Rep. Kay Wolf notified so that she will know that the substitute bill is in support of donating drugs. It would permit donations within a model that works in Kansas rather than the one in Oklahoma which does not support any model in this state. The Board supports the bill in theory but have problems with implementation.

SHARED SERVICES

The Board reviewed the shared services regulation and how this would work for those pharmacists working from home. The Board staff was directed to put their concerns about licensing and regulating persons from their home. The Board would also like to know how other states are handling the issue of consultant pharmacists and whether they are licensing them as a separate classification. Board staff will report back to the Board on this particular issue.

BOARD MEMBER REPORTS:

Shirley Arck, Pharm.D. recommended that the Board look into going electronic for their Board packets. The Board of Nursing is using laptop technology and it would cut down on the amount of paper that is currently dispersed. This would also permit the Board to implement a cut off date for submitting information that could be downloaded to the Board packet. The Board agreed that this should be pursued.

Shirley also thanked the inspectors for their hard work on developing the cases. She appreciated the efforts that they put into their disciplinary cases.

JoAnne Gilstrap, R.Ph. recommended that the Board report the DEA rule regarding the issuance of multiple prescriptions for schedule II controlled substances in the next newsletter. This should also be on the agency website.

Ms. Gilstrap also reported that there were many epileptic drugs that were going to become generic. Many drug companies are going to state legislatures to ask for more restrictions. Before you can substitute you would have to go through extra steps. She recommended that the Board watch for this issue and to make sure that the Board provided information to the legislature regarding this issue should it arise.

The December Board meeting was canceled due to the weather and Ms. Gilstrap advised the Board that she felt that this was the right thing to do. However, she would like to make sure that in the future we try to schedule the December Board meeting in late November or early December to avoid holiday conflicts.

Ms. Gilstrap asked if the Board office was approving Continuing education. The Board staff has continued to review CE requests on a case by case basis.

Michael Coast, R.Ph. advised the Board that he, Carly Haynes, R.Ph. and Deb Billingsley attended the KPhA annual meeting in Hutchinson, Kansas. The KPhA members provided feedback that they felt that more board members should try to attend the meeting if possible. Mike agreed and stated that KPhA's next annual meeting would be the September 28, 2008 and that everyone should try to attend.

Mr. Coast also thanked the Board inspectors for all of their hard work.

EXECUTIVE SESSION – PERSONNEL
The Board adjourned into executive session to discuss personnel issues until 1:00 p.m.

STAFF REPORTS
Carly Haynes, R.Ph. advised that she had been reviewing other states regulations. Almost all states require nonresident pharmacies to be licensed before they can ship into their state. She also thought it was interesting how each state viewed the job of the inspector. Many states permit the inspector to issue a ticket related to minor offenses such as violation of the technician ratio.

Debra Billingsley reviewed the current status of regulations that the Board is working on.

KAR 68-2-20 related to a pharmacists function in filling a prescription.
The Attorney General rejected the language. Randy Forbes wrote a letter to the AG disputing the AG's position. We are waiting to hear from the Attorney General's Office on their position.

KAR 68-7-14 Prescription Labels
The Board met with the Nursing Board and with the Board of Healing Arts. The Board of Healing Arts believes that before a prescription is valid that is must contain all information related to the PA/ARNP and their responsible physician. Therefore, the Board can change the labeling requirement but it will prevent a prescription from being

filled if the correct information is not on the actual prescription. The Board will meet again with the KSBHA and the KSBN.

KAR 68-7-19 Transfer of a refillable prescription
Randy Forbes sent a letter to the DEA asking for a legal opinion. He is waiting for that decision.

KAR 68-7-21 Institutional Drug Rooms
Scheduled for March meeting for public hearing.

KAR 68-11-2 Fees for DME Providers
Regulation has been drafted and sent to the Dept of Administration

KAR 68-13-1 through KAR 68-13-4 Compounding Regulations
The compounding task force will make revisions from latest USP changes. Amendment will be sent to the Dept of Administration.

KAR 68-7-1 through KAR 68-7-11 Telepharmacy Regulations
Regulations are under review at the Dept. of Administration

KAR 68-2-16 Branches Agents Pick Up Stations
Regulations are under review at the Dept. of Administration

KAR 68-20-23 Limit on Controlled Substances Dispensed
Scheduled for Public Hearing at March meeting.

The Board reviewed a letter from Senator Derek Schmidt on behalf of a constituent. The question has been raised by other patients also regarding putting the diagnosis on the prescription label. The Board advised that this would need to be something that the physician directed be on the label. We should refer this to the Board of Healing Arts and ask for their assistance.

ADJOURN. The Board adjourned their meeting at 1:45 p.m.