KANSAS STATE BOARD OF PHARMACY

MINUTES OF THE MEETING

November 29 & 30, 2005 ClubHouse Inn & Suites 924 SW Henderson Topeka, Kansas

Tuesday, November 29, 2005

MEMBERS PRESENT: Merlin McFarland, RPh., President; JoAnne Gilstrap,RPh, Vice President; Max Heidrick, RPh.; Dr. Shirley Arck, Pharm D; and Michael Coast, RPh.

STAFF PRESENT: Debra Billingsley, Executive Secretary; Jim Kinderknecht, RPh., Pharmacy Inspector; Melissa Martin, Compliance Officer; LaTonyua Rice, RPh., Pharmacy Inspector; Reyne Kenton, 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: Merlin McFarland, President, called the meeting to order at 9:00 a.m.

APPROVAL OF AGENDA. A motion was made and seconded to approve the agenda as amended. The amendment moved the Tuesday, 9:30 topic regarding Patient Counseling to 9:30 on Wednesday. The Board also added Amira Kojan at 9:00 on Wednesday regarding the Test of Spoken English (TSE). (Arck/Coast). Motion carried 4-0.

APPROVAL OF MINUTES. A motion was made and seconded to approve the September 2005 minutes (Arck/Gilstrap). Motion carried 4-0.

ADJOURNMENT: Mr. McFarland adjourned the meeting to go into public hearing regarding K.A.R. 68-2-22 and K.A.R. 68-5-16.

MEETING CALLED TO ORDER. Merlin McFarland called the public hearing to order at 9:05 a.m.

K.A.R. 68-2-22 Electronic prescription transmission. There was no correspondence received by the Board. The floor was opened for public comment. John Kiefhaber, Executive Director of the Kansas Pharmacists Association commented that KPhA supported the regulatory change. Elaina Wolzak of Target Corporation commented that the Board might wish to change the language that required the transmission only be made to a pharmacist.

K.A.R. 68-5-16 Pharmacy Technician Ratio. The Board was provided all written communication that the Board received regarding the pharmacy technician ratio. John Kiefhaber, Executive Director of KPhA stated that they supported the regulation, as its intent was to put something in place since the statutory ratio was repealed. KPhA continues to support a 3 to 1 ratio in the future.

RECONVENE: Mr. McFarland called the regularly scheduled Board meeting to order at 9:15 a.m. A motion was made and seconded to adopt K.A.R. 68-2-22 and K.A.R. 68-5-16 as submitted. (Coast/Gilstrap). A roll call vote was taken: Max Heidrick – yes; Mike Coast – yes; Shirley Arck – yes; JoAnne Gilstrap – yes; and Merlin McFarland – yes. Motion carried.

DISCUSSION INVOLVING TARGET POLICY – The Board discussed a written policy that had been provided to Target Corporation employees titled, "Understanding Your Responsibilities in Sustaining Pharmacy Excellence". The Board had concerns that the policy permitted unregistered or unlicensed Target personnel into the pharmacy to help the pharmacists and pharmacy team. The policy stated that the pharmacy was not off limits and that any team member could integrate from the store into the pharmacy. The Board discussed whether this met the security and licensing requirements of Kansas Pharmacy law. Mike Stanley, District Manager and Elaina Wolzak, R.Ph. appeared on behalf of Target Corporation. Mr. Stanley advised the Board that as soon as he became aware of the Board's concern with the policy that he immediately notified corporate. It was not Target's intention to violate the spirit of Kansas's law. This policy was put into place to help pharmacists with staffing issues and to help managers understand the workings of the pharmacy department. Target intends to register all persons who would work in a technician capacity. Mike Stanley provided the Board with a new written policy as well as copies of emails he had written clarifying Target policy. The Board agreed that the changes resolved their concerns.

DISCUSSION REGARDING PRESCRIPTION SOLUTIONS VISIT: John Jones, Vice President of Government Affairs and Pharmacy Policy appeared on behalf of Prescription Solutions. Several of the Kansas Board members and staff made a site visit to the Overland Park location currently under construction. Since this is the first mail order facility of this size under the regulatory authority of the Kansas Board, the Board wanted to make sure that they were abreast of all issues and concerns. One of the issues that came up was whether the location should be licensed at this time. There are no drugs being dispensed but there are other activities that would potentially deem the location to be a pharmacy. The Board is in the process of getting the facility appropriately licensed. The facility will eventually be licensed as a distributor.

Another concern was whether the facility canceled prescriptions on the hard copy. KAR 68-20-19(e)(2) requires CII's to be canceled on the face of the prescription with the name of the pharmacist filling the prescription. This is an issue that is going to become more prevalent with all pharmacies since electronic prescribing is being used more frequently. The Board needs to review federal law on this issue.

Debra Billingsley and Jim Kinderknecht reported on their trip to California and their tour of the mail order facility in Carlsbad. California does not consider data entry to be a technician function so the data entry people are not registered. The Texas Board had the same problem so they have permitted electronic supervision of technicians rather than direct supervision. The Board reviewed K.S.A. 65-1663.

Another area of discussion was reducing oral prescriptions to hard copy in compliance with K.A.R. 68-20-18 (d)(1). California law is less restrictive in this area and the Board discussed this regulation. The Board will continue to review these issues.

DEA 222 ELECTRONIC TRANSFER UPDATE. A motion was made and seconded to interpret KAR 68-20-17 to mean that the process for filing of a DEA 222 form should conform with federal law. Therefore, a DEA 222 may be transferred electronically or by paper transfer. (Coast/Heidrick). Motion carried 4-0.

ADJOURNMENT: The Board adjourned for ten minutes.

RECONVENE: The Board reconvened at 10:40 a.m.

PRESENTATION BY SUPPLY SCAPE. Brenda Kelly, Vice President of Marketing presented a power point presentation regarding electronic pedigrees.

PEDIGREE DISCUSSION: The Board discussed pedigree requirements. The Board will continue to do a comparison of laws from other states as it relates to pedigrees.

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

ADMINISTRATIVE HEARINGS:

DAVID WENDOVER, CASE NO. 05-35

A Petition to Revoke, Suspend or Otherwise Discipline the license of David Wendover was filed on September 29, 2006. The Petition alleged that the Respondent diverted controlled substances from his employer. The Petition further alleged that the Respondent suffers from one or more mental conditions that render him incapacitated to such a degree that he is unfit to practice pharmacy. On October 17, 2005 the Respondent was noticed up for hearing on November 29, 2005. Pursuant to negotiations the Respondent was offered a Stipulation. The Respondent did not appear for hearing nor has he signed the Stipulation. A motion was made to find the Respondent in default and to revoke his license. The Board stayed the default for a period of 15 days in order to offer the Respondent an opportunity to sign the Stipulation. If the Respondent submits an executed copy of the Stipulation to the Board within 15 days the Default Order would be set aside. In the event that the Respondent fails to sign the Stipulation then the Default Order would become effective and the Respondent's license would be revoked. (Arck/Gilstrap). Max Heidrick recused himself from voting. Motion carried 3-0.

CVS PHARMACY #5257, CASE NO. 05-30

The Respondent appeared through Kelly Davis, Supervisor for CVS. The Board appeared through its attorney, Randall Forbes. The proposed discipline was a \$500 fine for having unregistered persons acting as technicians and a \$2,340 fine for operating the pharmacy in excess of 30 days without a pharmacist in charge.

A motion was made and seconded to accept the Stipulation (Coast/Arck). Motion carried 2-1. Max Heidrick voted no.

LINCARE, INC., CASE NO. 05-01

The Respondent appeared through Chuck Hatfield, STINSON MORRISON HECKER LLP. Shawn Schultz, Regional Manager for Lincare, Inc. also appeared. The Board was represented by its attorney, Randall Forbes. The proposed discipline was a \$500 fine for dispensing medications to an individual in Kansas without being registered with the Board as a pharmacy.

A motion was made and seconded to accept the Stipulation (Arck/Gilstrap). Motion carried 3-0.

INVESTIGATIVE REPORTS:

Presented by JoAnne Gilstrap.

BUDGET:

The Board reviewed the agency budget for FY 2006. The Division of Budget denied the agency supplemental requests. The agency made a request for a vehicle purchase in FY2006 and a vehicle purchase in FY2007. The moratorium on purchasing vehicles was lifted so the Board made the requests as the mileage is getting high on both vehicles. The agency views this as a safety issue and will appeal the denial of funding. The agency also made requests for supplemental amounts regarding the software that is being purchased. This request was based on actual expenditures other than estimates. The bids were a bit higher than the agency estimated so the agency is requesting additional money. The Board also asked for an increase in grant money allotted to the CIPP program. The Board has supplemented CIPP in the amount of \$30,000 for over ten years. Expenses have gone up and the Board would like to increase the grant available to CIPP by \$5,000. The Board will appeal the denial and take their supplemental request to the legislature.

INTERNET PRESCRIBING:

The Board reviewed language out of Colorado that prevents a pharmacist from dispensing a prescription drug if the pharmacist knows or should have known that the order was issued on the basis of an internet-based questionnaire, an internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship. No action was taken regarding this issue.

ELECTRONIC PRESCRIBING

In January the final rule on Medicare E prescribing goes into effect. The legislation is software neutral. This will preempt any provision in state law that conflicts with the

federal e prescribing rules. The Board would like a presentation by SureScripts at the next meeting if they are available.

RENAL DIALYSIS PHARMACY LICENSE:

In 1998 the legislature enacted a law that required medicare approved renal dialysis facilities to be licensed by the Board of Pharmacy. The Board's counsel advised that the current law set the license fee the same as all other pharmacies. To date, these facilities have not gotten licensed in Kansas. Stan Langhofer of Kansas Dialysis Services, LC appeared at the meeting and advised the Board that the facilities as a group have asked the legislature to repeal the law requiring licensure with the Board. Debra Billingsley advised the Board that she had heard from a few legislators advising that they were being asked to repeal the regulatory authority of the board to license these facilities. They are currently reviewed by Medicare and through KDHE. The Board discussed the fact that no specific regulations have been adopted regarding these facilities. The facilities would like the Board to give them time to go to the legislature to ask that the statute be repealed before moving forward with regulations. The Board agreed to wait and see what the legislature would want from the Board. The Board will review the issue again in March.

ADJOURN: The Board took a break for approximately ten minutes.

RECONVENE: The Board reconvened at 3:25 p.m.

PAUL CROUCH, CASE NO. 05-47

The Respondent, Paul Crouch, appeared in person. The Board was represented by its attorney, Randall Forbes. A stipulation and final agency order was provided to the Board for final approval. The proposed discipline in the Stipulation required a 5-year contract with CIPP and includes the typical language that respondent stay in compliance and that CIPP provide information to the Board. A motion was made and seconded to accept the Stipulation. (Arck/Coast). Motion carried 3-0.

PHARMACY TECHNICIAN RATIO:

The Board reviewed two letters. One was written by Kevin Nicholson, R.Ph., J.D. representing National Association of Chain Drug Stores. The letter expressed concerns of requiring the tech certification to coincide with an expanded ratio. They also expressed concerns that the Board might mandate PTCB certification as the only vendor choice. The Board also received a letter and attachments from Kenneth W. Schafermeyer, R.Ph.,Ph.D. representing the Institute for the Advancement of Community Pharmacy. He expressed similar concerns that the Board not name a single exam vendor should it place a certification requirement on technicians.

The Board discussed this issue at length. A motion was made and seconded to change the regulation requiring a 3 to 1 ratio so long as two of the three technicians have been certified by a vendor that has been approved by the Board. The motion further required the Board to seek a legislative change in the statute requiring a super majority before the ratio can be changed. A statutory change should also be sought permitting a technician

30 days before they have to take a test for registration other than having to take the test prior to registration. (Coast/Arck). Motion carried 4-0.

CANCER DRUG REPOSITORY:

The Board reviewed drug donation legislation from the 2005 legislative session of approximately 21 states. The Board discussed specifically the criteria that the statute required regulations to address. This matter will be continued on Wednesday, November 30, 2005.

ADJOURN: A motion was made to adjourn the meeting and to reconvene at 8:00 a.m.

Wednesday, November 30, 2005

MEMBERS PRESENT: Merlin McFarland, RPh., President; JoAnne Gilstrap,RPh., Vice President; Max Heidrick, RPh.; Dr. Shirley Arck, Pharm D; and Michael Coast, RPh.

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

OTHERS PRESENT: See attached listing.

MEETING CALLED TO ORDER: Merlin McFarland, President, called the meeting to order at 8:00 a.m.

CANCER DRUG REPOSITORY:

The Board drafted specific regulations. The Board will attempt to have the regulations approved on a temporary basis so that they can be implemented as soon as possible. As soon as the draft is completed and changes are made the Board will hold a phone conference approving the final regulation that can be sent to the Department of Administration.

DISCUSSION REGARDING TSE:

Amira Kojan presented information to the Board regarding her specific problems with the TSE. She provided letters of support as well as other documentation regarding the test and what other states have done. A motion was made to permit Amira the ability to take the NAPLEX since she provided proof to the Board's satisfaction that she could reasonably communicate verbally in English. It was further motioned that K.A.R. 68-1-1f be changed to require a score of not less than 50 on the TSE. (Hedrick/Coast). Motion carried 4-0.

PATIENT COUNSELING:

Juan Toledo, Pharm.D., is a community pharmacist and he provided information to the Board regarding patient counseling as it related to non-English speaking patients. He

showed the Board educational materials that are required to be posted in California. He suggested that the Kansas Board provide similar information to Kansas pharmacists regarding posters and brochures that would be available on the website. The Board will explore putting these type of educational items on their website.

BOARD REPORTS:

Max Heidrick discussed expanding the use of emergency kits to hospice locations. Max requested that counsel review whether this would necessitate a statutory change or regulatory change. The Board discussed safety issues involved with putting e-kits in hospice but it was determined that there is a need in this area.

Max advised the Board that the institutional drug regulations were almost complete. Randy is working with Deb and Max and will get this out to the Department of Administration.

Shirley Arck reported that she and Jeff Thompson have worked toward finalizing the compounding regulations. They are addressing the last of a series of questions and hope to have the final draft forwarded to the Department of Administration very soon.

JoAnne Gilstrap discussed whether the Board should come up with a list of technician duties. This issue has come up numerous times and it might be better to come up with some guidelines. This will be put on the agenda for the next meeting and the staff is encouraged to provide suggestions on what they would like to see as the list of approved duties.

JoAnne also suggested that the Board require all stipulations for persons who have diverted drugs to contain a requirement that a beginning inventory be conducted at their place of employment. The Board members agreed and this will be added to our stipulations.

A letter had been sent to the A.G.'s office regarding Canadian drug violations. JoAnne asked whether the A.G. had responded to the Board and Deb advised that they had not heard from the A.G.

Merlin McFarland expanded on JoAnne's thought of making a technician list. He thinks it might be helpful to differentiate between the clerk duties also. He suggested that this be put in the format of policy rather than regulation since technology is changing so quickly the list would certainly be outdated.

Mike Coast is attending the NABP educational fall meeting in Florida. They have numerous areas that they are discussing that are pertinent to our Board such as telepharmacy.

STAFF REPORTS:

LaTonyua Rice suggested that we add an inventory requirement whenever there is a change of PIC. This should be something that they are doing anyway but many aren't so it should be required.

Jim Kinderknecht advised the Board that Kaw Valley Pharmacy in Perry, Kansas had turned in their license. The Board asked about whether the previous fine had been paid and Jim advised that Tom Holroyd had paid the \$10,000 fine.

Debra Billingsley advised the Board that she would be meeting with Kyle Smith at the KBI to work on a report for the legislature regarding the Sudafed bill. The statute required a report by February. Deb is also going to discuss the grant regarding a prescription drug-monitoring program.

Reyne Kenton with be attending the Methamphetamine Summit in Salina, Kansas the first part of December.

MEETING DATES:

The Board scheduled the following dates for meetings: September 12-13, 2006 December 5-6, 2006

The NABP spring meeting will be held April 8-11 in San Francisco.

APPROVAL OF LICENSES AND REGISTRATIONS:

A motion was made and seconded to approve the pharmacist licenses issued by the Board since the September meeting. (Gilstrap/Coast). Motion carried 4-0. A second motion was made and seconded to approve pharmacy registrations issued by the Board since the September meeting. (Gilstrap/Coast). Motion carried 4-0.

ADJOURNMENT:

The Board adjourned at 10:50 a.m.