

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

December 5 & 6, 2006
Hayden Office Building
Conference Room
212 W. 8th
Topeka, Kansas 66612

Tuesday, December 5, 2006

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

STAFF PRESENT: Debra Billingsley, Executive Secretary; Jim Kinderknecht, 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: Max Heidrick, President called the meeting to order at 9:00 a.m.

APPROVAL OF AGENDA: A motion was made and seconded to approve the amended agenda. (Coast/Gilstrap) Motion carried 5-0.

APPROVAL OF SEPTEMBER MINUTES A motion was made and seconded to approve the September 2006 minutes. (McFarland/Coast). Motion carried 5-0.

APPROVAL OF OCTOBER MINUTES A motion was made and seconded to approved the October 2006 minutes. (McFarland/Gilstrap). Motion carried 5-0.

ADMINISTRATIVE HEARINGS

ROBERT C. SIMS Case No. 06-93

The Respondent appeared in person. The Board was represented by its attorney, Randall Forbes. The matter was before the Board on an application for reinstatement of a pharmacist license. A motion was made and seconded to go into executive session not to exceed 15 minutes in order to review CIPP information. (Coast/Paul) Motion carried 5-0. The Board reconvened at 9:30 a.m. A motion was made and seconded to go into executive session not to exceed 15 minutes in order to deliberate. (McFarland/Coast). Motion carried 5-0. The Board reconvened at 9:50 a.m. A motion was made and seconded to deny the Respondent's request for reinstatement. (Coast/Gilstrap). Motion carried 5-0.

DONALD GARDNER, R.Ph. Case No. 06-55

The Respondent appeared in person. The Board was represented by its attorney, Randall Forbes. The matter was before the Board on a Petition to Revoke, Suspend or Otherwise Limit the License of the Respondent. A motion was made and seconded to adjourn into executive session not to exceed 25 minutes to review confidential information. (McFarland/Coast). Motion carried 4-0. The Board reconvened at 11:00 a.m. A motion was made and seconded to indefinitely suspend the license of the Respondent until such time as he is in compliance with the Consent Agreement requiring CIPP participation. (Arck/Paul) Motion carried 4-0.

ADJOURN The Board took a 15 minute recess.

LORIE DILLEHAY, R.Ph. Case No. 05-39

The Respondent appeared in person and with her attorney Jessica Travis. The Board was represented by its attorney, Randall Forbes. A Stipulation and Final Agency Order had been provided to the Board for review. A motion was made and seconded to adjourn into executive session not to exceed 5 minutes for the purpose of deliberation. (McFarland/Coast). Motion carried 4-0. The Board reconvened at 11:40 a.m. A motion was made and seconded not to accept the Stipulation and Final Agency Order, that there be no finding entered regarding a violation and that the case should be dismissed. (Arck/Coast). Motion carried 4-0.

WALGREENS #5539 Case No. 06-49

The Respondent was represented by pharmacist in charge, Christine Mondt and the District Manager, Julie Bickers. 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 fine in the amount of \$500 for failure to report a consumer complaint on an incident report. A motion was made and seconded to accept the Stipulation. (McFarland/Coast) Motion carried 3-0. Howard Paul recused himself from discussion and voting.

DOUGLAS HIGBIE, R.Ph. Case No. 06-53

The Respondent 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 was a fine in the amount of \$1000 and the Respondent was required to retake the PIC exam based on evidence that prescriptions were partially filled for controlled substances in violation of K.A.R. 68-20-19©. A motion was made and seconded to accept the Stipulation (Paul/Coast). Motion carried 4-0.

NOEL MCBRIDE, R.Ph. Case No. 06-45

The Respondent appeared in person. The Board was represented by its attorney, Randall Forbes. The Respondent made a request for modification of the Stipulation and Final

Order that was authorized in September 2006. Specifically, the Respondent requested that the restriction preventing him from dispensing be lifted. A motion was made and seconded to adjourn into executive session for 10 minutes. (Coast/McFarland). Motion carried 5-0. The Board reconvened at 12:30 p.m. The Board tabled the matter until they receive additional information from HAPN.

ADJOURN: The Board adjourned for lunch until 1:30 p.m.

RECONVENE: The Board reconvened at 1:45 p.m.

PRICE CHOPPER CASE NO. 06-57

The Respondent did not appear. The Board was represented by its attorney, Randall Forbes. The Board was provided with a Stipulation and Final Agency Order. The proposed discipline was a fine in the amount of \$500 for failure to complete an incident report. A motion was made and seconded to accept the Stipulation as written. (Coast/McFarland). Motion carried 4-0.

ADDLEMAN PHARMACY CASE No. 06-59

The Respondent did not appear. The Board was represented by its attorney, Randall Forbes. The Board was provided with a Stipulation and Final Agency Order. The proposed discipline was a fine in the amount of \$500 for failing to have a pharmacist conduct a final check which resulted in a misfill. The Board also required the Respondent to amend their written policy and provide said copy to the Board within 10 days. A motion was made and seconded to accept the Stipulation and Final Agency Order (Coast/Paul). Motion carried 4-0.

RAYMOND PERRENOUD CASE No. 06-67

This matter was continued to the March agenda.

SARA J. WORLEY CASE No. 06-22

The Respondent did not appear. The Board appeared through its attorney, Randal Forbes. The proposed discipline was a Stipulation assessing a fine of \$500 for failing to inform the Board that she was no longer the PIC at her place of employment. A motion was made and seconded to approve the Stipulation as written (Arck/McFarland) Motion carried 4-0.

JAMES CAVE Case No. 06-61

This matter was continued to the March agenda.

DISCUSSION REGARDING KAR 68-7-14(a)(2) Prescription Labels

John Jones, Vice-President of Government Affairs and Pharmacy Policy and Frank Whitchurch, Pharmacist in Charge, both with Prescription Solutions requested an opinion from the Board regarding an interpretation regarding prescription labels as it related to mid-level practitioners. Specifically, the question was whether a label had to reflect the name of the supervising physician for a mid-level practitioner when the prescription was written in a state where the law did not require said supervision. The Board attorney

advised that when K.A.R. 68-7-14 was drafted the Board was not contemplating filling out of state prescriptions. The recommendation was that the regulation should be amended to reflect that the supervising physician would not be required on the label if the prescription was written in a state that did not require a protocol with a supervising physician. The law regarding labels for prescriptions written by mid-level practitioners in Kansas would remain the same. The Board would still require the supervising physician's name to be placed on the label. This exception only applies to prescriptions written in a minority of states that do not require supervision. The Board staff will draft an amendment to the regulation.

PEDIGREE AND WHOLESALE DISTRIBUTOR LICENSING

Carey Potter of NACDS and Donovan Pepper of Walgreens addressed the Board in reference to the latest draft regarding pedigrees and wholesale distributor licensing. They discussed some discrepancy in the language regarding the definition of pedigree and the normal distribution chain. They also discussed their opinion related to having a date certain for compliance. The Board discussed the lawsuit filed by RxUSA Wholesale v. HHS to prohibit the FDA from implementing a regulation that requires that certain information be included in a pedigree, which documents the custody of prescription drugs in the drug supply chain. The US Federal Court in the Eastern District of New York was asked to issue a preliminary injunction. The Board discussed the directive by the legislature to conduct a study regarding pedigree by January 2007. The Board determined that they would proceed with a bill requiring wholesale distributor licensing and separate it from the pedigree issue. The Board proposed that they would try to have a meeting prior to the legislative session so that they could review proposed bill language.

ADJOURN The Board took a 10 minute recess.

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

IMMUNIZATION REQUIREMENTS

Sam Boyajian of Gardner Pharmacy appeared before to Board requesting the Board's endorsement of a change to K.S.A 65-1635a. Specifically, he requested that the Board endorse eliminating the patient age requirement for receiving an immunization or vaccine from a pharmacist. The Board agreed to support a change with a limitation beginning at five years of age. The also agreed to add language that would permit a pharmacy student to immunize so long as they had completed the training in their pharmacy class.

Immunizations by students would be done under the supervision of a pharmacist. The statute would also state with specificity that anyone administering a vaccine should have up to date CPR training.

NOEL MCBRIDE

The Board continued this matter until Wednesday, December 6, 2006.

ADJOURNMENT:

A motion was made and seconded to adjourn the meeting until 8:30 a.m. Wednesday, December 6, 2006. (Arck/Coast). Motion carried 5-0.

Wednesday, December 6, 2006

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

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

OTHERS PRESENT: See Attached listing.

MEETING CALLED TO ORDER:

President Max Heidrick called the meeting to order at 8:30 a.m.

EXECUTIVE SESSION:

A motion was made and seconded to adjourn into executive session not to exceed 15 minutes to discuss personnel issues. (Coast/McFarland). Motion carried 3-0.

E SIGNATURES ON PRESCRIPTIONS

The Board discussed computer generated and rubber stamped signatures on prescriptions. The question was whether this practice met the statutory requirements of the Pharmacy Act. The Board determined that computer generated or rubber stamped signatures were never acceptable for prescriptions handed directly to the patient. This would apply to both controlled and noncontrolled substances. Therefore, all prescriptions handed to the patient must be signed by the practitioner or mid-level practitioner in his or her own handwriting. Prescriptions for schedule III through V or non-scheduled prescriptions that are faxed or submitted electronically from the practitioner's office directly to the pharmacy may be signed with an electronic or rubber stamped signature. Faxes don't have to have any signature so long as the practitioner's identifying information is on the fax.

BUDGET

The Board reviewed the Budget for 2007. The Board discussed seeking additional revenue through legislation that would require the Board staff to have additional duties.

INVESTIGATIVE MEMBER REPORT

JoAnne Gilstrap, R.Ph. reported on the cases that had been closed. She asked that the inspectors follow-up to determine whether there was compliance with the Stipulations that were being issued.

2007 LEGISLATION UPDATE/REGULATION UPDATE

K.A.R. 68-5-16 Technician Ratio is scheduled for Public Hearing at the March Board meeting.

K.A.R. 68-20-17 Order Forms. Attorney General requested a revision. It has been revised and will probably be ready for the March Board meeting.

K.A.R. 68-20-23 Limitation on Controlled Substances. Approved by the Dept. of Administration and sent to the Attorney General.

K.A.R. 68-7-11 & 68-7-12 Requiring an inventory by the PIC. Dept of Administration requested a revision. Still with the DOA.

K.A.R. 68-7-19 Transfers by Interns. Rejected by the Attorney General. Revisions will need to be made and the regulation will be sent back to DOA.

K.A.R. 68-13-1 through 68-13-5 Compounding. The Class II Laminar Flow Biosafety Cabinetry Standards from NSF and the USP 797 were sent to DOA. They should be able to sign off on the regulations now and they will be sent to the AG as soon as we get the okay from DOA.

K.S.A. 74-1606 and K.S.A. 74-1608 have been sent to the Revisor's Office and the changes have been put into bill form.

BOARD MEMBER REPORTS

Merlin McFarland reported that he had been working with Sedgwick County Medical Society toward implementation of a state-wide prescription drug monitoring program. Merlin met with KMS, the Osteopathic Association, KPhA and KPSC to discuss how to go about drafting legislation.

Merlin also provided a copy of a standing order type prescription that had preprinted information that was patient specific for hospice patients. The Board reviewed the specific order and determined that it met the spirit of the law and could be filled.

There was also discussion regarding the new requirements for selling over the counter Plan B. There were questions as to whether the sale had to be recorded in a log book. Nothing has been presented from the FDA that would indicate that a log needs to be completed.

Max Heidrick reported that Dr. Mary Carder had submitted her resignation regarding her employment from HAPN. John Childers, LMSW is the new Executive Director of

HAPN. Max requested that John be invited to the March meeting so that everyone could meet him.

Max also requested that the Board staff draft some type of an information sheet for respondents appearing before the Board. It would be helpful to the Respondents to have information that would let them know what their rights are and what the procedures are for appearing before the Board.

JoAnne Gilstrap, R.Ph. requested an update on whether the Board was changing the regulation regarding a 90 day supply limitation on narcotics. The regulation has been drafted and has been submitted for approval.

Shirley Arck discussed the compounding inspections that are going to be conducted by the Board. She suggested that the Missouri Board be contacted to see what type of inspections and checks they are conducting and whether they just check for certification.

STAFF REPORTS

Debra Billingsley advised the Board that Peter Forrester had requested that they reconsider the denial of his license. A motion was made and seconded to deny the request for reconsideration and to let the denial stand. (Arck/Coast) Motion carried 5-0.

The Board was provided with a letter from the Optometric Association regarding use of DEA numbers. The Board determined that until NPI numbers are accepted by the industry that they will continue using whatever is necessary for reimbursement of claims.

Reyne Kenton advised the Board that she had been conducting numerous Sudafed checks with retail stores. Many of them are keeping logs. The Board requested that the inspectors check to see who the suppliers are and get their names and addresses so that they can be checked for licensure.

Jim Kinderknecht advised the Board that the office was seeing a lot more license requests from entities that were manufacturing. These entities want to be licensed as pharmacies and are producing drugs that are not patient specific. The Board requested that these types of licenses should not be issued without a thorough review.

APPROVAL OF NEW LICENSES AND REGISTRATIONS

A motion was made and seconded to approve the new pharmacist's licenses and pharmacy registrations. (Coast/Gilstrap). Motion carried 4-0.

ADJOURN: The Board adjourned at 12:00.