

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

September 11 & 12, 2007
Hayden Office Building
212 SW 8th
Conference Room
Topeka, KS 66612

Tuesday, September 11, 2007

MEMBERS PRESENT: Michael Coast, RPh., President; Dr. Shirley Arck, Pharm.D., Vice President; JoAnne Gilstrap, R.Ph., Frank Whitchurch, R.Ph. (Arrived at 9:10 a.m.); Karen Braman, R.Ph., M.S., Nancy Kirk, Public Member.

STAFF PRESENT: Debra Billingsley, Executive Secretary; Jim Kinderknecht, RPh., Pharmacy Inspector; Carly Haynes, R.Ph. Pharmacy Inspector; Melissa Martin, Compliance Officer; Reyne Kenton, Compliance Officer; Tom Frazier, R.Ph., Pharmacy Inspector (Arrived at 1:00 p.m.); 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 an amended agenda by adding an Executive Session to the Wednesday Agenda related to personnel issues. Motion carried 5-0.

APPROVAL OF JUNE MINUTES A motion was made and seconded to approve amended June 2007 minutes by changing the Board member report of JoAnne Gilstrap, R.Ph. by replacing the acronym of CME to CE in the first two areas it is referenced in her report. Motion carried 5-0.

ADMINISTRATIVE HEARINGS

DONALD GARDNER, R.Ph. Case No. 07-27

The Respondent did not appear. The Board was represented through its counsel, Randall Forbes. This matter was continued until December Board meeting at request of counsel.

CVS PHARMACY 07-19

The Respondent appeared through its counsel, Richard Hayse, Attorney at Law. The Board was represented by Derenda Mitchell, Assistant Attorney General. Also appearing

were Ly Nguyen, Pharmacy Supervisor and Marius Maree, the Pharmacist in Charge. The Board was provided with a Consent Agreement. The Board did not approve the Consent Agreement. Randy Forbes will request additional information from CVS. Specifically, he will request that the Board be provided with 1) counseling sheets to be obtained by Melissa; 2) documents that show a complete trail to the identification of the pharmacist that verified the prescription; 3) documents that show CVS can determine the identity each of multiple pharmacists who worked on a prescription; 4) documents that show CVS can determine the identity of the pharmacist who verified the prescription even if another pharmacist accesses the system to enter information related to that prescription after the drug was dispensed; 5) documentation showing that after a transfer CVS can provide to an inspector information related to verification within 72 hours of the request; 6) documents reflecting an audit trail for all transactions that occurred the day of the incident; and 7) documents reflecting the policy changes that were made to respond to this incident and identifying when the policy changes were implemented. The Board also requested the appearance of the Pharmacist in Charge when the incident occurred at the December Board meeting. The case will be continued until December Board meeting.

MEDICINE SHOPPE PHARMACY Case No. 07-09

The Respondent did not appear. The Board was represented by Derenda Mitchell, Assistant Attorney General. The Board was provided with a Consent Agreement. The proposed discipline was a fine of \$500 for failing to record the name of the person who phoned in a prescription and a \$500 fine for failing to fill a prescription in strict conformity with directions of the provider. A motion was made and seconded to accept an amended Consent Agreement whereby the Agreement would reflect that the Respondent was not required to appear. Motion carried 4-0.

RICKY K. STONE CASE NO. 04-19

Ricky Stone did not appear. The Board appeared through its legal counsel, Randy Forbes. Mr. Stone asked that the restriction placed on his license be removed. A motion was made and seconded to approve the issuance of a Summary Order denying the request because the Respondent did not provide information regarding what factors have changed that would warrant lifting the restriction. Motion carried 5-0.

SHANNON LAYMON CASE NO. 07-06

The Respondent did not appear. The Board reviewed and approved an Agency Summary Order revoking the pharmacy technician registration of the Respondent. The basis of the order was theft of money from Respondent's employer. A motion was made and seconded to accept the Agency Order. Motion carried 4-0.

DEBRA KRUEGER CASE NO. 07-11

The Respondent did not appear. The Board reviewed and approved an Agency Summary Order revoking the pharmacy technician registration of the Respondent. The basis of the order was diversion of controlled substances from her employer. A motion was made and seconded to accept the Agency Order. Motion carried 4-0.

WALGREENS CASE NO. 07-12

The Respondent did not appear. The Board reviewed and approved an Agency Summary Order fining the Respondent in the amount of \$500 for permitting an unregistered pharmacy technician to function in the prescription area of the pharmacy. A motion was made and seconded to accept the Agency Order. Motion carried 4-0.

CARLOS ARREOLA CASE NO. 07-17

The Respondent did not appear. The Board reviewed and approved an Agency Summary Order denying a pharmacy technician registration to the Respondent. The order was based on the Respondent's criminal history. A motion was made and seconded to accept the Agency Order. Motion carried 4-0.

DONNA S. MUNIZ CASE NO. 07-24

The Respondent did not appear. The Board reviewed and approved an Agency Summary Order revoking a pharmacy technician registration. The order was based on the Respondent's diversion of a controlled substance from her employer. A motion was made and seconded to accept the Agency Order. Motion carried 4-0.

CONSUMERS 07-40

The Respondent did not appear. The Board reviewed and approved an Agency Summary Order fining the Respondent in the amount of \$500 for permitting a pharmacy technician to function in the prescription area without being registered. A motion was made and seconded to accept the Agency Order. Motion carried 4-0.

COSTCO CASE NO. 07-42

The Respondent did not appear. The Board reviewed and approved an Agency Summary Order fining the Respondent in the amount of \$500 for permitting a pharmacy technician to function in the prescription area without being registered. A motion was made and seconded to accept the Agency Order. Motion carried 4-0.

STACY BURGESS CASE NO. 07-44

The Respondent did not appear. The Board reviewed and approved an Agency Summary Order revoking the pharmacy technician registration of the Respondent. The basis of the Order was that the Respondent diverted drugs and took merchandise from her employer. A motion was made and seconded to accept the Agency Order. Motion carried 4-0.

QUEEN'S PRICE CHOPPER CASE NO. 07-45

The Respondent did not appear. The Board reviewed and approved an Agency Summary Order fining the Respondent in the amount of \$3,040 for operating over 30 days without a pharmacist in charge. A motion was made and seconded to accept the Agency Order. Motion carried 4-0.

INVESTIGATIVE REPORT

Presented by Shirley Arck, Pharm.D., Vice-President/Investigative Member

The Board reviewed closed cases.

RECESS: A motion was made and seconded to recess for lunch until 1:00 p.m. Motion carried 5-0.

DISCUSSION REGARDING KAR 68-7-19 TRANSFER OF A PRESCRIPTION.

The Board reviewed a legal opinion related to the issue of whether a pharmacy student or intern can transfer a controlled substance. This issue began when the Board attempted to change the regulation so that pharmacy students and interns would clearly be permitted to transfer prescriptions. 21 CFR 1306.25 states that a transfer of a prescription for a controlled substance must be between two licensed pharmacists. A motion was made and seconded for the Board's counsel to request a legal interpretation from the DEA as to whether a pharmacy student or intern can transfer a controlled substance prescription. Motion carried 5-0.

INTERIM COMMITTEE ON ADMINISTRATIVE HEARINGS.

The Board received an update from the Executive Secretary on the Legislative Interim Committee on Administrative Hearings. The Board of Pharmacy participated with other administrative agencies in submitting a joint letter to the committee asking that KAPA remain in effect as written. Board staff will continue to monitor this bill.

DISCUSSION REGARDING AUTOMATED PRESCRIPTION SYSTEM.

Presented by: Susanne Hiland, Pharm.D. – Director, Pharmacy Professional Services and Government Relations.

A presentation was made related to automated will-call machines. The Board recommended that a regulation be written to require that the machine be a part of the pharmacy. The Board would like to review other state's language and the draft in advance of the December Board meeting. The Board continued the matter until December Board meeting.

RECESS: A motion was made and seconded to recess until 3:15 p.m.

RECONVENE: The President reconvened the meeting at 3:15 p.m.

DISCUSSION REGARDING PRESCRIPTIONS FROM OUT OF STATE/COUNTRY PHYSICIANS

The Board reviewed a written request from Prescription Solutions that pharmacies be permitted to fill prescriptions that are written in U.S. Territories. There is a Federal mandate that requires pharmacies in the U.S. to cover Medicare Part D patients who reside in U.S. Territories. The Board agreed that the prescriptions could be filled if the pharmacy verified the physician does exist, the appearance of the prescription is appropriate, and if there are any doubts the prescriber will be called. Nothing in the pharmacy act prohibits this practice but pharmacies would be cautioned to use the same precautions as for any other prescription. A motion was made and seconded to approve this practice. Motion carried 5-0.

DISCUSSION REGARDING FDA RESPONSE TO COMPOUNDING REGULATIONS

The Board was provided with a 56 page response from the FDA regarding the Board draft of their compounding regulations. The opinion may clarify the Board regulation providing more precision as to what the Board intent is. The Board wants to protect a pharmacy's right to compound but there is an interest in preventing manufacturing in the pharmacy. The Board requested that the information be run by the committee that worked on the compounding regulation to see if they would recommend the changes be made. The changes should be available for review at the December meeting.

FEES FOR DURABLE MEDICAL EQUIPMENT RETAILERS

A motion was made and seconded to implement a regulation requiring that the fee of \$300 be set for businesses selling durable medical equipment to the end user, in order to be consistent with the \$300 fee required of prescription drug distributors. Motion carried 5-0.

DISCUSSION REGARDING TAMPER RESISTANT PRESCRIPTION PADS

The Board reviewed the information provided by CMS requiring tamper resistant prescription pads for reimbursement to state Medicaid programs, as well as a provider notice sent to Kansas Medicaid providers by the Kansas Health Policy Authority regarding this new policy. CMS is requiring all state Medicaid programs to enforce this policy in their individual states. The Board will request that Kansas legislative delegation make efforts to delay implementation of the law since appropriate time was not given to licensees. The Board will provide a link on their website to the CMS policy notification and the Kansas Health Care Policy Authority provider notice regarding these prescription pads.

APPROVAL OF NEW LICENSES AND REGISTRATIONS

A motion was made and seconded to approve the new pharmacist's licenses and pharmacy registrations. Motion carried 5-0.

ADJOURNMENT: A motion was made and seconded to adjourn until 8:00 a.m. on Wednesday, September 12, 2007. Motion carried 4-0.

Wednesday, September 12, 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.; and Nancy Kirk, Public Member.

STAFF PRESENT: Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph., Pharmacy Inspector; Carly Haynes, R.Ph., Pharmacy Inspector; Tom Frazier, R.Ph., Pharmacy Inspector; Reyne Kenton, Compliance Officer; 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 Coast called the meeting to order at 9:00 a.m.

ADJOURNMENT: President Coast adjourned the Board meeting for public hearing at 9:00 a.m.

PUBLIC HEARING FOR PROPOSED REGULATION.

K.A.R. 68-7-21. INSTITUTIONAL DRUG ROOMS. The Board received a letter from the Joint Committee on Administrative Rules and Regulations. No other correspondence was received by the Board. The Board heard comments from Viola Riggins, Department of Corrections, and Sue Brun, Regional Director of Nursing with Correct Care Solutions.

MEETING CALLED TO ORDER

President Coast, R.Ph. called the Board meeting back into regular session. The regulation failed for lack of a motion. The Board's General Counsel was directed to redraft portions of the regulation based on the comments made by Board and the comments from the public.

PRESENTATION BY DUANE OLBERDING – ST. FRANCIS RECOVERY CENTER.

Mr. Olberding is the Clinical Coordinator for St. Francis Recover Center. He gave the Board educational information related to evaluations and how they can be utilized by the Board.

DISCUSSION REGARDING CIPP CONTRACT

The Board attorney and Jenith Hoover, KPhA both provided the Board with amendments to the CIPP contract. The Board agreed with the amendments and directed the General Counsel to make these changes to the contract. A motion was made and seconded to amend the current CIPP contract to reflect the changes discussed. Motion carried 5-0.

RECESS: The Board recessed until 10:35.

RECONVENE: President Coast called the meeting back to order at 10:35 a.m.

BOARD MEMBER REPORTS:

JoAnne Gilstrap, R.Ph. thanked the Board members and staff for attending the telepharmacy meeting and providing input. She also commented that she felt it was good that NABP had addressed the problems the Board had with the timing of cases filed by the Office of Inspector General.

JoAnne asked where the Board was with Internet Pharmacy regulations. Randy Forbes advised that he had drafted an amendment to KAR 68-2-20 which was provided to the Board and that the amendment is moving through the process.

Mike Coast, R.Ph. discussed the telepharmacy regulation. Board members determined that they would like to have some preliminary meetings scheduled so that they could work on some of their projects at a later date. The CQI Meeting will be held Wednesday, October 10 in the morning and the Pedigree Meeting will be held October 10 in the afternoon at the Board office. This will give Board members an opportunity to have drafts finished by the legislative session.

Shirley Arck, Pharm.D. advised the Board that NABP had suspended the NAPLEX and that it might be November at the earliest before it can be put back into place.

Shirley thanked the inspectors and compliance officers for their assistance as she serves as investigative member of the Board.

Frank Whitchurch, R.Ph. wanted to know if there was any way that pharmacies could donate drugs that had been returned sealed from a patient to a pharmacy. The Board will look at the pending bill drafted by Rep. Kay Wolf that is related to drug donations to determine if it will meet the needs of pharmacy.

Frank also commented that the room we were using echoed and that he often had trouble hearing. The Board staff may need to make arrangements for other accommodations.

Nancy Kirk reported that she enjoyed being on the Board and that she was learning a lot.

Mike Coast reiterated that the Board would need to continue working on classifications of pharmacy.

The District VI Meeting will be held in Kansas City on October 24-26 at the Embassy Suites near the Plaza. Information will be forthcoming as the conference is developed.

STAFF REPORTS

Randy Forbes provided a copy of KAR 67-8-14 regarding prescription labels. He had drafted new language and had it available for everyone to review. It was determined that the new regulation with the new language was in conflict with Board of Healing Arts laws for prescriptions. The Board requested that the Board office arrange for a meeting with the Board of Healing Arts to discuss having them change their law so their law and this BOP regulation would not conflict. Karen Braman offered to contact Larry Buening with the Board of Healing Arts and let him know what the Board of Pharmacy discussed and that the office will be scheduling a meeting to discuss how we can work together to ensure that our laws and regulations can be congruent.

Randy also provided language to the Board that would require a nonresident pharmacy PIC to be licensed in Kansas. Randy advised the Board that this may need to be put in the form of a statute rather than a regulation. This action will be taken.

Randy also discussed KAR 68-2-20 related to a pharmacist's function in filling a prescription. No formal action was taken but the matter will be continued until the December meeting.

Randy also explained a potential motion related to automated will call machines. There were several issues raised that related to the drop station law found at KAR 68-2-16 and how the deployment of these machines would affect automated dispensing machines that are also available.

Reyne Kenton, Compliance Officer advised the Board of some areas of concern that related to medication in schools. The example provided was a school district that was stocking epi-pens in schools without a prescription for a specific child. Carly worked with Reyne on this issue as well as school officials to assist them with compliance to state pharmacy law.

Jim Kinderknecht, R.Ph., Board Inspector welcomed two new Board employees. They are Lori Thompson who took Karen Hollon's position and Jamie Fitzhugh who is the new Board receptionist. The Board welcomed both employees to the Board staff.

A motion was made and seconded to go into executive session to discuss personnel issues. The Board reconvened at 12:30 p.m.

RECONVENE: The Board reconvened into public meeting at 12:30.

A motion was made and seconded to adjourn the meeting at 12:35 p.m.

ADJOURN.