

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

MARCH 4 & 5, 2008  
KU SCHOOL OF PHARMACY  
MALOTT HALL, ROOM 6056  
LAWRENCE, KS

**Tuesday, March 4, 2008**

**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, R.Ph., Pharmacy Inspector; Carly Haynes, R.Ph., Pharmacy Inspector; Melissa Martin, Compliance Officer; Reyne Kenton, Compliance Officer; Randall Forbes, General Counsel; Jamie Fitzhugh, Senior Administrative Assistant.

**OTHERS PRESENT:** See attached listing.

**MEETING CALLED TO ORDER:** President Michael Coast called the meeting to order at 9:30 a.m.

**WELCOME TO DEAN KEN AUDUS**

Dean Ken Audus, K.U. School of Pharmacy, welcomed everyone to the campus. The Board thanked Dean Audus for hosting the meeting at the School of Pharmacy.

**APPROVAL OF AGENDA:** A motion was made and seconded to approve an amended agenda by adding an executive session to the end of the meeting to discuss personnel issues, to add discussion regarding continuing education and to discuss the strategic planning meeting. (Arck/Braman). Motion carried 4-0.

**INVESTIGATIVE REPORT**

Presented by Shirley Arck, Pharm.D., - Vice-President and Investigative Member. The Board reviewed closed cases. A motion was made to accept the investigative report. (Gilstrap/Braman). Motion carried 3-0.

**DISCUSSION ON WHOLESALE DISTRIBUTION REGULATIONS**

The Board reviewed the wholesale distributor regulation draft of K.A.R. 68-14-9 through KAR 68-14-19. Amendments had been proposed by HDMA and by NACDS. Some of the changes will be incorporated into a new draft. KAR 68-14-14 will be amended to add the word "shall" related to controlled room temperatures. The Board discussed having the responsible party as someone who works at the warehouse who would be the contact

person for the Board. This language will be made consistent throughout the regulations. The Board removed the requirement that the deed or lease be required in order to be registered. KAR 68-14-10 will require social security numbers for all partners of non-publicly traded businesses. KAR 68-14-16 will make sure that when it states unfit for consumption that it refers to both human and animal and in (e) amend language so that products have to be kept until okayed for destruction so as to maintain evidence. The language was changed so that the Board could accept VAWD inspections or inspections from other states if their standards were the same or higher as those in Kansas. KAR 68-14-7 related to VAWD and will add that the limitation of the certification is three years. Non-VAWD accredited wholesalers will be inspected prior to registration and new inspections will be required at least every three years. The Wholesale Distributors shall document the continuous regulation of temperature and humidity. Changes were made to the educational requirements and deleted the continuing education for the responsible designee. The Board Attorney will draft the changes and an electronic draft will be provided to everyone. The Board may wish to have a phone conference to approve the final regulatory changes before it goes to the Department of Administration.

**RECESS:** President Coast recessed the meeting until 11:30 a.m.

**RECONVENE:** Michael Coast reconvened the Board meeting at 11:30. a.m.

#### **DISCUSSION ON PEDIGREE REGULATIONS**

The Board reviewed the change that was made to the pedigree regulation from the January meeting. The Board decided to strike section (b) and (c) of the 68-14-20 draft. The net result will be to allow paper or electronic at this time. Once track and trace becomes available the Board will review making it for all products and not just those outside the normal distribution chain. There is no current standardized system therefore the Board will require that criteria be met before a date is placed in the regulation. The change will be drafted and will be reviewed again when the Board reviews the distribution regulations.

#### **DISCUSSION ON NUCLEAR PHARMACY REGULATIONS**

The Board reviewed the nuclear regulations, KAR 68-10-4 through KAR 68-10-6. The Board reviewed what type of training was available to nuclear pharmacy technicians. There are currently three schools that provide certification for nuclear technician training. The nuclear pharmacies would like this certification to apply toward the technician ratio. The certification is a one time certification unlike the ICPT and PTCB where the certification must be renewed every two years. The Board discussed whether there would be a necessity to define nuclear pharmacy technician since the certification would only apply to that practice setting and should not be accepted as national certification for retail or hospital settings. The Board will continue to review this issue and will continue to get further information on the nuclear certification. The Board wants to check KAR 68-6-16 in relation to KAR 68-10-4 (f) and to place ratio and certification in KAR 68-10-4(f) to require annual training and CE. This issue may be part of a phone conference if one is held prior to the next meeting.

**RECESS:** President Mike Coast recessed the meeting for lunch to reconvene at 1:30 P.M.

**RECONVENE:** The Board reconvened at 1:30 p.m.

### **UNUSED MEDICATION ACT**

The Kansas Legislature passed HB 2578 which would create the Utilization of Unused Medications Act. The bill requires the Board of Pharmacy to establish and implement the program. It also requires that the Board adopt rules and regulations by December 1, 2008 to implement the act. Frank Whitchurch advised the Board that he had seen charitable drug regulations in other states such as Arkansas and Arizona and that the Board could pull those regulations to see how other states were implementing their programs. Board staff will search for regulations and then provide Frank Whitchurch and Joanne Gilstrap with copies to put together some draft regulations for the next Board meeting review in June.

### **CQI BILL AND REGULATIONS**

The CQI bill passed through the Senate and will now go to the House. Frank Whitchurch advised that he will continue to provide testimony to the committee when the bill comes up. The Board also reviewed the amendments to KAR 68-7-12b on Incident Reports. The Board discussed whether the report needed to be made as soon as practicable or whether a specific time limit should be added. The Board changed subsection (c) so that the pharmacy has 3 business days after discovery of the incident to prepare a report. The Board also discussed subsection (c) (8) so that incident reports can be provided to the Board upon 3 business days of request. The incident reports can be kept electronically so long as the pharmacy can provide the information to the Board within the regulatory time limits.

The Board directed that special thanks be sent to Sen. Vicki Schmidt for all of her help in getting this through the Senate. The Board would also like thank you notes to be sent to each Senator who voted in favor of passage.

### **PHARMACY CLASSIFICATIONS**

The Board discussed whether the Board needed to give some thought as to how the current pharmacy laws will apply to pharmacy currently and in the future. Frank Whitchurch reported that we should think about pharmacy practices and discuss this issue at the strategic planning meeting in April.

### **PMP STATUTE AND METH PRECURSOR ISSUE**

The Prescription Drug Monitoring Statute, SB 491, passed through the Senate and will now be heading to the House. The effective date will be July 1, 2009. There were some amendments made to the statute that would require the establishment of a methamphetamine Precursor Scheduling Task Force. Frank Whitchurch directed the Board Executive Director to send letters to the task force nine member organizations and ask that they provide the name of the designee so that a meeting could be scheduled as soon as possible. Karen Braman requested that the letters be sent after passage of the bill and its official publication so the statute can be referred to in the letter. The Executive

Secretary advised the Board that a grant had been requested through the Department of Justice and that the Board's budget would require a Governor's Amendment in case the grant went through during this fiscal year. A letter will be drafted and sent to Budget as soon as possible. The Executive Director also provided information regarding the KBI's request that "legitimate medical purpose" or "physician/patient relationship" be defined in the PMP statute. This will be discussed with Senator Schmidt to determine whether this is the best bill for this language.

#### **METH PRECURSOR STATUTE**

The Board's Executive Secretary provided information to the Board that indicated that a meeting had been held with software vendors who wanted to do a test market regarding the meth precursor statute. There has been interest in conducting a test in Kansas to see whether certain software systems would work in this area.

**RECESS:** President Mike Coast recessed for a break until 3:15 p.m.

**RECONVENED:** The Board reconvened at 3:15 p.m.

#### **APPROVAL OF 50 YEAR CERTIFICATES:**

A motion was made and seconded to approve the 50 year certificates and to thank these pharmacists for their years of service. (Arck/Whitchurch). Motion carried 4-0.

#### **APPROVAL OF NEW LICENSES AND REGISTRATIONS**

A motion was made and seconded to approve the new licenses and registrations. (Arck/Braman). Motion carried 4-0.

#### **PHARMACY AUTOMATION**

A motion was made and seconded to go into Executive Session with the Board members, the General Counsel, and the Executive Secretary for the purpose of attorney client discussion to reconvene in open session at 3:30 p.m. (Whitchurch/Arck). Motion carried 4-0.

The Board reconvened at 3:30 p.m. and extended the executive session until 3:45 p.m. (Whitchurch/Arck). Motion carried 4:00 p.m.

**RECONVENE:** The Board reconvened the meeting at 3:45 p.m.

#### **PHARMACY AUTOMATION**

Matt Sneller, Vice-President of Pharmacy Operations of Instymeds and Jeff Ellis of Lathrop and Gage appeared before the Board. Mr. Sneller provided the Board with information about how the Instymeds system would be used in Kansas. It is in 11 states and mostly leased to hospitals. They generally provide a 3 day supply or up to a full course of antibiotics. The company asked for a waiver or permission to do a pilot program but those are not statutorily permitted in Kansas. Many questions and concerns were brought up by the Board. Mr. Ellis requested that the Board provide a list of

specific concerns in writing so that InstyMeds may respond. The Board agreed to provide this in writing.

**ADJOURNMENT:** President Mike coast adjourned the meeting at 4:50 p.m.

**Wednesday, March 5, 2008**

**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; Carly Haynes, R.Ph., Pharmacy Inspector; Melissa Martin, Compliance Officer; Reyne Kenton, Compliance Officer; Randall Forbes, General Counsel; Jamie Fitzhugh, Senior Administrative Assistant.

**OTHERS PRESENT:** See attached listing.

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

**ADJOURNMENT:** The board meeting was adjourned and the meeting for public hearing regarding regulations was opened at 9:00 a.m.

**K.A.R. 68-7-21 INSTITUTIONAL DRUG ROOM REGULATIONS**

The Board received correspondence regarding this matter from the Kansas Legislative Research Department; Barry's & Dunne's Pharmacies; Kansas Association of Counties; Shawnee County Department of Corrections; Finney County Sheriff's Office; There was public comment from representatives from Franklin County, Douglas County, Shawnee County DOC, Sedgwick County, Riley County Police Department, and CCS-Topeka Three problems were identified with the regulation, i.e. labeling, bulk medications, and how medicines are dispensed. The Board requested that interested parties who would like to review a revised draft regulation and provide comments list their contact information, including e-mail address, on the meeting sign-in sheet. The Board further requested that the Board Executive Secretary send the revised regulation out to these interested parties so that we can work together to develop the final regulation. The public hearing was closed at 10:10 a.m.

**RECONVENE:** At 10:10 a.m. President Coast reconvened board meeting.

**ADJOURNMENT:** The Board meeting was adjourned at 10:23 a.m. and the meeting for public hearing regarding K.A.R. 68-20-23 was opened.

**K.A.R. 68-20-23 LIMIT ON AMOUNT OF CONTROLLED SUBSTANCE DISPENSED**

The Board staff provided information to the Board regarding comments they received from pharmacists attending the KPhA meeting in September of 2007. The Board staff also heard from Dr. Bob Twillman regarding the issue. The comments related to students, travelers abroad, and people on mission trips taking a larger supply of medications with them if they were going to be gone longer than 90 days. The mailing of medications via mail service abroad is not considered to be reliable. Comments were received that the PMP would take care of any concerns of over medicating patients.

The public hearing was closed at 10:31 a.m. Mike Coast asked for a motion to **not** pass the statute (Arck/Braman).

A motion was made and seconded that the amendment to KAR 68-20-23 fail and that the regulation not be passed. (Arck/Braman). A roll call vote was taken with the following votes: Braman – yes; Arck – yes; Gilstrap – yes; Whitchurch – yes; and Coast – yes.

**RECONVENE:** At 10:31 a.m. President Coast reconvened the Board meeting.

**ADJOURNMENT:** The Board meeting was adjourned at 10:34 a.m. and the meeting for public hearing regarding KAR 68-7-20 was opened.

**K.A.R. 68-7-20 SHARED SERVICES**

There was discussion as to what effect the regulation would have. There were questions about whether a pharmacist could hire a technician and work out of their home. Would this be called a pharmacy? The conclusion of the Board was that a pharmacist could not hire a technician and work out of their home as this would present the Board with a model of practice that resembled a pharmacy and this would require a pharmacy license. President Coast closed the public hearing at 11:19 a.m.

**RECONVENE:** Mike coast reconvened board meeting at 11:19 A.M. A motion was made and seconded to adopt the regulation (Arck/Whitchurch). Roll Call Vote was taken with the following votes: Braman-yes; Arck – yes; Gilstrap – yes; Whitchurch – yes; and Coast yes. Regulation adopted. The regulation will become effective 15 days after published in the Kansas Register.

The Board stated that “A technician cannot access a pharmacy computer from outside the pharmacy.”

**APPROVAL OF JANUARY MINUTES:**

A motion was made and seconded to accept the January minutes. (Arck/Gilstrap). Motion carried 4-0.

**CE CREDITS**

The Board received two letters related to the Board approving continuing education. One letter was from Todd Schroeder, Pharm.D. of Via Christi Regional Medical Center. The second letter was from Jim Garrelts, Pharm.D., FASHP, R.Ph. of Via Christi. Latonyua

Rice and Carly Haynes also provided information related to the Wichita Academy's use of continuing education. They all requested that the Board continue to support high-quality continuing education that has raised the level of practice in various pharmacy settings. The Board discussed whether there was as much scrutiny of continuing education as that required of ACPE. The Board determined that they needed to come up with some criteria that would be similar to that of ACPE before the Board approved Continuing Education. Mike Coast, Karen Braman and Carly Haynes will work on selecting criteria for Continuing education.

## **BOARD REPORTS**

Karen Braman and Shirley Arck spoke about the three day accreditation process that they had observed at the KU School of Pharmacy. They were both impressed with the validity and the integrity of the process.

Karen brought it to the attention of the Board that the District of Columbia was now requiring pharmaceutical dealers to be licensed by the Board of Pharmacy.

JoAnne Gilstrap requested information regarding the due date of the tamper resistant pads. Ms. Billingsley advised that the new date was April 1, 2008. Reimbursement will not be made on Medicaid prescriptions unless the prescription is executed on tamper resistant pads after that date unless the prescription meets one of the exceptions.

Ms. Gilstrap asked about the status of HB 2907 related to epileptic medications. The bill was withdrawn by the Epilepsy Association. They would like an opportunity to meet with the pharmacists and other interested parties after the session so that they can discuss problems they are having related to Brand and generic drugs. Ms. Gilstrap asked about the law books. Ms. Billingsley stated they had met with KPhA and that they will send out a supplement to fix the major errors and that the Helpful section will be brought before the Board before future publication. KPhA will remove sections not sued. JoAnne also asked

Ms. Gilstrap asked the Executive Secretary whether a meeting had been scheduled regarding the issue of emergency kits. The Board had discussed the issue in December. Due to time constraints the meeting has not been scheduled at this time.

Frank Whitchurch requested that the Board staff get more information about Instymeds including the principle operating officers list, and in what state it is a non-resident pharmacy or wholesaler. This would be in addition to the information that Instymeds provides to the Board based on the Board's letter to the company with their concerns.

Mr. Whitchurch wanted to schedule the Strategic Planning meeting for April. He suggested the dates of Sunday and Monday of April 6 & 7, 2008. Board members are to check their calendars to determine whether this weekend will work.

Frank Whitchurch asked whether the Board's software permitted it to make reports similar to an example he had from the State of Arkansas. The Board is currently using Access and it will not make these reports. Frank suggested that the Board invest in software that will duplicate the type of report that is being done in Arkansas. It is a report that keeps track of probations, etc.

### **STAFF REPORTS**

Debra Billingsley has bought 2007 law books for the Board members. The Board's website has been updated regarding the laws and regulations. They should now be correct and should be able to be downloaded.

The NABP National meeting will be in May in Baltimore. Information was provided to the Board regarding attendance at this meeting.

Carly Haynes advised the Board that the DEA is requiring recertification regarding their Sudafed training. Each pharmacy must go online on the DEAdiversion website and make sure that they have certified or recertified their training. Recertification is done every two years. Carly is reminding all of her pharmacies that she inspects to do this.

Reyne Kenton advised that she has been having problems with LPN's entering the pharmacy at hospitals when the pharmacist is not present and getting patient medications. The Board discussed that the LPN had no authority to enter the pharmacy and that it had to be done by a registered nurse. Once the medication has been removed by the RN it can be put in the medication cabinet for administering to the patient by the LPN.

### **BOARD MEETING:**

The next Board meeting will be held on June 10 and 11, 2008. It will be at Landon State Office Building in Room 106. The Board asked that the Board staff provide information about whether a hotel could be used for future board meetings. Everyone should bring their calendars so that future board meetings can be determined.

Motion was made at 1:11 p.m. to have an executive session for 20 minutes for the purpose of discussing personnel issues. In attendance is Debra Billingsley and Board members. (Whitchurch/Arck). Motion carried 4-0.

**RECONVENE:** Mike Coast reconvened the Board meeting at 1:30 p.m.

### **ADJOURNMENT**

Michael Coast adjourned meeting at 1:30 p.m.