

Kansas State Board of Pharmacy
Minutes of the December 2, 2008
Board Meeting

Topeka Shawnee County Public Library
1515 SW 10th
Topeka, KS, 66604

Tuesday, December 02, 2008

Meeting Called to Order: President JoAnne Gilstrap called the meeting to order at 9:00am. Nancy Kirk was absent.

Members Present: JoAnne Gilstrap, R.Ph., President; Karen Braman, R.Ph., Vice-President; Shirley Arck, Pharm. D, Investigative Member; Michael Coast, R.Ph.; and Frank Whitchurch, R.Ph.

Staff Present: Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph., Pharmacy Inspector; Tom Frazier, R.Ph., Pharmacy Inspector; Carly Haynes, R.Ph., Pharmacy Inspector; Melissa Martin, Compliance Officer, Reyne Kenton, Compliance Officer; Christina Morris, Assistant Executive Director, and Randall Forbes, General Counsel.

Others Present: See attached listing.

Approval of the Agenda:

Ms. Gilstrap added the following to the 3:15pm time slot:

- o. Proposed Correction of K.S.A. 65-1636
- p. Faxing CII prescriptions for assisted living
- q. Epilepsy Drug Substitution
- r. e-Scrbing of CII drug

Ms. Gilstrap corrected "a." to read "Tech Check Tech in Hospitals"

Mr. Whitchurch added an Executive Session on December 2, 2008 at 11:30am.

A motion was made and seconded to approve the agenda as amended. (Braman/Coast) Motion passed.

Approval of the October Minutes

Corrections:

Page 2: Change Ms. Braman's arrival time to "11:19am"

Change the Recess time to "11:30am"

Page 3: Internet Pharmacy Issues change "bill" to "law" on the third line

PMP last line change "grants" to "grant applications"

Page 4: "c." second line change "regulation" to "statute"

"g." Add "legislative task force" to "A meeting has been...."

Page 5: Instymeds add "The Board open an investigation case on Instymeds."

A motion was made and seconded to approve the minutes as corrected. (Coast/Braman) Motion passed.

Administrative Proceedings

- Cindy Chambers – Case No. 08-50. Ms. Chambers' technician registration was revoked.

- CVS- Case No. 08-104 and Case No. 08-105. The Board reviewed the case. CVS had submitted a signed Summary Order and paid the fine for working a non-registered technician at two stores.
- Walgreens – Case No. 08-41 and 08-36. The Board reviewed the case. Walgreen had submitted a signed Summary Order and paid the fine for working non-registered technicians.

Discussion Regarding Immunizations

Representative Don Hill and Sam Boyajian, owner of Gardner Pharmacy, were present to discuss the proposed legislation concerning immunizations.

Recess: Ms. Gilstrap declared a break to reconvene in 7 minutes

Reconvene: Ms. Gilstrap reconvened the meeting at 10:00am.

Administrative Proceedings

- Walgreens – Case No. 08-33 – Mr. Chad Ullum R.Ph., district pharmacy manager, and Cyrus Tuttle, R.Ph., PIC, were present. Mr. Ullum said Walgreens management had looked into the incident and had discerned the events that led to the incident. Walgreens has changed the screen information to show an age under 1 year old in red to make the pharmacists more aware of an infant’s age. Walgreens had submitted a signed Summary Order and paid the fine. Mr. Forbes will write a letter to the Kansas Board of Healing Arts to inform them of the doctor’s involvement in the case.

Investigative Member Report – Closed Cases

Ms. Arck gave the report and the status of all the cases for the year. The Board discussed the variety of cases. Mr. Coast described the needs of Long Term Care Facilities and the need for quicker access to needed drugs. The Board may expect to see more of these types of cases in the future with more pharmacies providing service from further distances.

Executive Session

A motion was made and seconded to go into executive session for 8 minutes to discuss client/attorney privileged information and to reconvene at 10am in the same room. The executive session is to include Mr. Forbes, Board counsel. (Coast/Whitchurch) Motion passed. Ms. Gilstrap reconvened the meeting at 10:01am.

Administrative Proceedings

- CVS – Case No. 07-19 Mr. Forbes discussed the reason CVS was called to the meeting. Mr. Duncan was present on behalf of CVS. CVS was asked to change the pharmacy system to provide better protection for the patients and pharmacists of the pharmacy. CVS has made the upgrade to the store involved in the incident plus one more, but not all stores in Kansas. Mr. Duncan said he would talk with CVS and obtain the timeline for the stores in Kansas.

A motion was made and seconded to go into executive session for 15 minutes to discuss client/attorney privilege information to include Mr. Forbes and Ms. Billingsley and to return to open session at 11am. (Braman/Coast). Motion passed.

Ms. Gilstrap reconvened the meeting at 11am.

The Board sent the case back to the Investigative Member for further review and investigation.

Board Discussion

Prescription Monitoring Program Update

Ms. Braman told the Board about the formation of a subcommittee to write the report to the legislature. The report to the legislature will be sent to the Board before it goes to the legislature. Virginia will be presenting their program on December 12 in the State Capital Room 143N at 10am. Open discussion and other business will follow the presentation. Ms. Braman has encouraged the chain and independents pharmacies to be present. Walgreens and Dillons are planning to attend.

Ms. Morris said the grant applications have been received. Ms. Braman suggested the Board retain someone with grant writing expertise to ensure a better chance of winning the grant. Draft regulations have been written and will be reviewed by the committee. The regulations will be held until funding is secured.

Ms. Braman will lead a phone conference of the subcommittee on December 8.

Meth Precursor Update

Mr. Coast reported on the October 7th meeting. MethWatch is not functioning in southeast Kansas as of yet. MethShield is functioning and the Salina police have made arrests off the data received. Mr. Coast told the Board that Oregon has not shown any increase in medicaid cost since pseudoephedrine was scheduled. Most states do not have the Board of Pharmacy responsible for the methamphetamine program. Currently funding is not available for the Board or the State. The next meeting will be Thursday, December 11, 1pm at KPhA. Mr. Coast will request a subcommittee prepare the Legislative Report.

Veterinarian Prescription Drug Monitoring Task Force Update

Ms. Arck said the task force is in the information gathering stage currently. The question was should veterinarians be required to report to the Prescription Monitoring Program. The task force believes the Veterinary Board is monitoring the dispensing logs of the veterinarian clinics and the cost would be prohibitive.

Executive Session

A motion was made and seconded to go into executive session for 30 minutes to discuss client/attorney privilege and to reconvene at noon in the same room. The session included Mr. Forbes. (Coast/Whitchurch) Motion passed.

Ms. Gilstrap reconvened the meeting at noon.

Recess: Ms. Gilstrap recessed the meeting for lunch at noon to reconvene at 1pm.

Reconvene: Ms. Gilstrap reconvened the meeting at 1pm.

Board Discussion

Hospital Telepharmacy Update

Mr. Coast reported on the meeting. There is a difference between what is needed in the Critical Access Hospitals and the mid size hospitals. The regulations written for the Retail Telepharmacy can be used with some modifications. The mileage will be removed but limited to in state. Mr. Forbes suggested changes be made in the technician regulations to allow technicians be allowed to function in a telepharmacy hospital setting. Regulation K.A.R. 68-7-11(n)(2) will need to be changed to allow technicians to access the pharmacy when the pharmacist is not present. Technician ratios and mileage need to be addressed. Mr. Forbes will draft regulations for the Board's review for February 2009.

Compounding Regulation

Ms. Arck said the regulations have been submitted to the Department of Administration. Some pages were approved and others are still waiting for substantive questions to be answered. Ms. Arck will collate information from the current proposed regulations and stakeholders, forward the information to Jeff Thompson for input. Mr. Forbes will receive the information, update the proposed regulation and forward them to the Department of Administration by February.

Unused Medication Regulation Forms

Ms. Gilstrap thanked Mr. Whitchurch for his work on the forms. Robert Stiles, Primary Care Clinic Coordinator, Office of Local and Rural Health, KDHE, was present to make comments and appreciates the Board's work on this issue. KDHE must develop methods to collect data required by statute and requests the Board and KDHE work together to make data collection easier. Mr. Stiles made suggestions of types of information to add to the forms Mr. Whitchurch developed. Ms. Gilstrap thanked Mr. Stiles for the time he has spent working with the committee. Ms. Braman suggested the Board allow electronic forms. Mr. Stiles said KDHE has set aside some money, \$53,000, for the start-up of a state repository. Mr. Whitchurch will update the forms to incorporate the proposed changes by December 3, 2008.

Budget Report

Sheena Ward was unavailable at this time and the discussion was moved to Wednesday at 10am.

Regulation and Legislative Update

- a. Tech Check Tech in Hospital
- b. Nuclear Pharmacy Regulation
- c. Annual Inventory of Controlled Substances
- d. Legitimate Medical Purpose
- e. Valid Prescription
- f. Refills after One Year
- g. Continuing Education Regulation
- h. Length of Board Members Terms
- i. Number of Board members Serving on Board
- j. Criminal Background
- k. Dosage Form Substitution
- l. Display of Pharmacy Technician Registration
- m. Continuous Quality Improvement
- n. Telepharmacy(Retail)
- o. Proposed Statute Amendment K.S.A. 65-1636 – Cancer Repository Drugs
- p. Faxing CII statute change for Assisted Living
- q. Epilepsy Drug Substitution
- r. E-scribing of CII drugs

The Board separated items needing statute changes. They are f, h, i, j, k, l, o, and q.

f. Refills after One Year – Senator Schmidt will shepherd the statute K.S.A. 65-1637. In essence, all prescriptions written will expire one year from the date written. Ms. Billingsley will forward the language to Representative Don Hill by December 10, 2008.

h. Length of Board Members Terms. – K.S.A. 74-1603. The change would increase Board Member terms to 4 years.

i. Number of Board members Serving on Board – same statute. The change would increase the Board to an odd number of members. Mr. Forbes will check with the Reviser of Statutes to make sure the new language indicates six of the seven members will be pharmacists.

j. Criminal Background – The bill would allow the Board to perform criminal background checks on perspective licensees or registrants. Mr. Forbes will check with the Reviser of Statutes to obtain a draft copy of the bill.

k. Dosage Form Substitution – KMS listened and has not given a consensus on their position. They will take it to their membership about the statute change. Ms. Gilstrap asked for a consensus as to whether to proceed or not. A motion was made and seconded to support the bill. (Coast/Whitchurch). Vote was 3 – 1 (Arck). Motion passed.

l. Display of Pharmacy Technician Registration – K.S.A. 65-1663. The Board supports. Displaying the registration card will take the place of the on-duty board. Ms. Morris will consult with DISC to increase the size of the font of the expiration date on the Technician Registration Card.

o. Proposed Statute Amendment K.S.A. 65-1636 Cancer Repository Drugs – The Board supports the statute change. Mr. Forbes will follow.

q. Epilepsy Drug Substitution – The consensus is the pharmacy law has a “dispense as written” requirement that should prevent pharmacists from routinely substituting without physician approval. Pharmacy best practices would require pharmacists to counsel patients when any changes are made in the drugs they receive. Currently, there is no bill filed, but the drug companies are expected to have the bill filed. Ms. Billingsley will give an update on February 3, 2009.

The following items do not need statute changes.

a. Tech check Tech – There have been no meetings scheduled on this topic. Ms. Billingsley will contact Pat Parker and Kirk Star for policies and procedures, training, and input for presentation to the Board in March.

b. Nuclear Pharmacy Regulation – The draft language is awaiting Board consensus/approval. The Board asked questions to clarify some language. The regulation will be sent to Department of Administration as soon as possible. Mr. Kinderknecht will check the Topeka hospital and determine if they are selling nuclear products outside their facility.

c. Annual Inventory of Controlled Substances – The regulation has been approved by the Department of Administration

Recess: Ms. Gilstrap declared a break to reconvene in 15 minutes

Reconvene: Ms. Gilstrap reconvened the meeting at 2:55pm

d. Legitimate Medical Purpose – The language was taken from the Federal Statute. The Board will pursue a regulation on defining a “legitimate medical purpose”. Ms. Billingsley is to send a copy to Kansas Medical Society and Senator Schmidt as soon as possible.

e. Valid Prescription – Mr. Forbes and Ms. Billingsley stated that the Board does not need both “Legitimate Medical Purpose” and a regulation for a “Valid Prescription”. At this time the Board will pursue the “Legitimate Medical Purpose” regulation.

g. Continuing Ed – K.A.R.68-1-1b Ms. Billingsley said that Dean Audus wanted the continuing education to remain ACPE approved. Ms. Arck reiterated her reasons for leaving CE as ACPE approved. Ms. Barb Woods gave the Board her opinion on the proposed regulation. Ms. Gilstrap suggested the Board add an additional requirement for pharmacists that administer immunizations.

The Board consensus was to strike any continuing education that is not preapproved by the Board or ACPE approved. Mr. Forbes will revise the regulation and resubmit to the Department of Administration

m. Continuous Quality Improvement – Ms. Billingsley discussed with the Board the Department of Administration's recommended changes. The consensus of the Board is to proceed to public hearing.

n. Telepharmacy (Retail) - Lincoln County Pharmacy requested that controlled substances and mileage should be reconsidered in the Telepharmacy (Retail) regulation. The Board consensus was to proceed to public hearing.

p. Faxing CII status change for Assisted Living – This requires a change in statute and legislator Scott Schwab will introduce. According to the DEA, a registered nurse is not considered an agent of the physician in long-term care or assisted living facilities. The pharmacies must call the physician for the prescription. Mr. Coast said we should allow the faxing of the CII prescriptions. The Board consensus was to testify in favor of the bill depending on the total language. Ms. Billingsley will call Mr. Schwab to inform him the Board is not opposed but requests a copy of the bill before it is introduced.

r. e-Scribing of C II drugs – The DEA is in review of e-scribing comments and the regulation will be delayed for quite awhile.

Review of Action Items for the Board

Ms. Morris quickly reviewed the agenda items that require action by a specified individual and the date the action is due.

Adjourn: Ms. Gilstrap adjourned the meeting at 4:15pm.

Wednesday, December 03, 2008

Meeting Called to Order: President JoAnne Gilstrap called the meeting to order at 8:00am. Ms. Kirk and Ms. Braman were absent

Members Present: JoAnne Gilstrap, R.Ph., President; Karen Braman, R.Ph.(8:04am), Vice-President; Shirley Arck, Pharm. D, Investigative Member; Michael Coast, R.Ph.; Frank Whitchurch, R.Ph.; and Nancy Kirk, public member.

Staff Present: Debra Billingsley, Executive Secretary; Jim Kinderknecht, R.Ph., Pharmacy Inspector; Tom Frazier, R.Ph., Pharmacy Inspector; Carly Haynes, R.Ph., Pharmacy Inspector; Melissa Martin, Compliance Officer, Reyne Kenton, Compliance Officer; Christina Morris, Assistant Executive Director, and Randall Forbes, General Counsel.

Others Present: See attached listing.

Ms. Braman arrived at 8:04am(during the Administrative Proceeding).

Administrative Proceeding

- Lori Dillehay

Ms. Dillehay and Jessica Travis, Attorney, were present. Ms. Travis addressed the Board. They were requesting clarification of permissible employment options.

A motion was made and seconded to go into executive session to included Mr. Forbes, Ms. Billingsley, and Ms. Morris for client/attorney discussion for 20 minutes to return to open session at 8:25am.

Ms. Gilstrap reconvened the meeting at 8:25am.

The consensus of the Board was that they would consider allowing her to dispense provided:

1. CIPP be in communication with Ms. Arck, Investigative Member. A mental health professional must be consulted and an opinion given to Ms. Arck for her approval or disapproval.
2. Practice in non-dispensing site per agreement with Board or
3. May dispense if a mentor is secured, would be present during dispensing, and with Board approval. The Board will determine what would be required of the mentor once a mentor is secured.

The date given in the Agreement stands. If Ms. Dillehay would choose to modify the order she would need to file a petition.

Agenda Amendment

Ms. Braman requested the Board add time to the agenda to discuss Immunizations and Mr. Coast requested additional time for Dosage Form Substitution. A motion was made and seconded to add Immunizations and Dosage Form Substitution to the agenda. (Coast/Braman) Motion passed.

Immunizations

The Board discussed the Immunization legislation. Ms. Gilstrap stated she believed that age 12 was the better lower age across the bill. Ms. Arck suggested the Board be more open and approve the legislation without placing an age restriction on the bill. The consensus was to support the legislation.

Cancer Repository Forms

Mr. Whitchurch did the modifications and emailed the new forms to the Board and Ms. Billingsley.

Public Hearings for Proposed Regulations

K.A.R. 68-16-3 – Donation of Cancer Drugs

Ms. Gilstrap adjourned the meeting and opened the public hearing at 9:00am

Ms. Gilstrap ask for public comment – Ms. Billingsley provided the letter from Celgene. Celgene supports the regulation. Collene Chawla, Celgene representative spoke in favor of the regulation. Ms. Chawla asked that if any Thalidomid was sent into the repository that they call Celgene directly and not to return to donator.

Ms. Gilstrap closed the public hearing and called the meeting to order at 9:04am.

A motion as made and seconded to adopt the proposed regulation. (Coast/Whitchurch)

Roll call: Mr. Coast – Yes, Mr. Whitchurch – Yes, Ms. Braman – Yes, Dr. Arck - Yes
A motion passed. The regulation will become effective 15 days after published in the Kansas Register.

Recess: Ms. Gilstrap declared a break to reconvene in 7 minutes

Reconvene: Ms. Gilstrap reconvened the meeting at 9:15pm

K.A.R. 68-18-1, K.A.R. 68-18-2, and K.A.R. 68-18-3 -

Transferring, Accepting and Recall of Unused Medications

Ms. Gilstrap adjourned the meeting and opened the public hearing at 9:15am.

Ms. Gilstrap ask for public comment – Ms. Billingsley provided the letter from Celgene and a letter from Rules and Regs.

Marilyn Page, Director of Marion Clinic, spoke in favor of the proposed regulation.

Robert Stiles, KDHE, spoke in favor of the proposed regulation.

Ms. Gilstrap closed the public hearing and called the meeting to order at 9:18am

A motion as made and seconded to adopt the proposed regulations. (Coast/Braman)

Roll call –Mr. Coast – Yes, Mr. Whitchurch – Yes, Ms. Braman – Yes, Dr. Arck - Yes

A motion passed. The regulation will become effective 15 days after published in the Kansas Register.

Recess: Ms. Gilstrap declared a break to reconvene in 9 minutes

Reconvene: Ms. Gilstrap reconvened the meeting at 9:30am

K.A.R. 68-7-14 - Prescription Labels

Ms. Gilstrap adjourned the meeting and opened the public hearing at 9:30am

Ms. Gilstrap ask for public comment- Ms. Billingsley provided a letter from Fred Brinkley, Jr., Medco. Mr. Brinkley and Medco were not in support of the regulation.

Ms. Gilstrap closed the public hearing and called the meeting to order at 9:31am.

The Board discussed the proposed regulation and ability of pharmacies to comply.

A motion as made and seconded to adopt the proposed regulation. (Braman/Arck)

Roll call –Mr. Coast – No, Mr. Whitchurch – No, Ms. Braman – No, Dr. Arck – Yes, Ms. Gilstrap - No

A motion failed. The Board will reassess the regulation and language needed to accomplish allowing only the name of the prescriber on the prescription.

Board Discussion

Wholesale Distributor Rules Clarification of SB 11

Dan Bellingham, HDMA, Healthcare Distribution Management Association, addressed the Board concerning Senate Bill 11. He discussed how the Board addresses Repackagers. If Repackagers are considered wholesalers then it would require more documentation increasing time and cost, but if treated as manufacturers then the extra steps are not required.

Mr. Bellingham provided language that would alleviate the problem in the draft rules. The current definition of manufacturer includes repackagers. The Board consensus was to change the proposed language to maintain repackagers with manufacturers to be consistent with the definition. Mr. Forbes will make the changes.

Recess: Ms. Gilstrap declared a break to reconvene in 18 minutes

Reconvene: Ms. Gilstrap reconvened the meeting at 10:15am.

Board Discussion

Dosage Form Substitution – Mr. Coast requested the Board clarify the intent of the proposed statute change. The Board discussed the changes, what they anticipate the changes to effect, and if that will produce the desired results. The Board will seek other input before proceeding with the proposed changes. The Board will revisit the issue on February 3, 2009. Mr. Forbes will pull the bill from the Reviser's Office.

Staff Member Reports

Policy and Procedure Manual – Ms Billingsley reported that a Policy and Procedure Manual has not been established. The office is working on it and will present it in March. The P&P for Board Meetings is also in process. Most information for this Board Meeting was in the office in an appropriate time for packet preparation with only a few straggling pieces. Ms. Billingsley will provide a paper copy of the Policy and Procedure Manuals of what has been accomplished.

Tom Frazier – Mr. Frazier told the Board them about the recent trip to China and the Chinese officials and their families. The Chinese wanted to see an American doctor and they demanded full body scans. Many of the Chinese have diabetes and hypertension. The doctors would write prescriptions that the Chinese officials took to the pharmacy to be filled. The Chinese officials would not take drugs made in China – they only wanted the drugs made in the United States. The interpreter explained that most Chinese Officials do not trust products made in China. Ms. Gilstrap gave Mr. Frazier accolades for his many mission trips and that he sets a good example for the rest of us. Mr. Whitchurch asked if he knew about the Starfish project. Mr. Whitchurch commended Mr. Frazier for his work.

Randy Forbes – Mr. Forbes discussed medicated contact lenses. The Optometry Board is concerned that optometrist will be limited in the dispensing of these contact lenses because of the regulations. Most pharmacies do not routinely keep contact lenses. The Optometry Board has not adopted any regulations at this time and wanted the Pharmacy Board to be aware that these contact lenses will be available in the future.

Board Discussion

Budget – Sheena Ward was not available. Ms. Billingsley discussed with the Board the financial situation of the State of Kansas and that all agencies have been asked to cut their budgets. There will be further cuts and restrictions on how current funds can be spent. Ms. Billingsley has talked with Nancy Kirk on funds that are encumbered and Ms. Kirk said that encumbered money is at risk of being swept. The office is ordering the laptops for the Board Members and in the process of doing an RFP on new software. The office will inquire into new phones for the inspectors/compliance officers and phones that work better in Western Kansas. The state budget rules will drastically change in the near future. The Board was encouraged to get the needs purchased quickly. Ms. Gilstrap asked for the budget figures to be presented in paper/electronic form for review.

Board Member Reports

Mike Coast – Mr. Coast asked about pharmacists doing chart reviews that are not Kansas licensed. He believes that any pharmacist doing chart checks in Kansas must be licensed. Mr. Forbes said the law states they must be licensed to practice pharmacy in the State of Kansas. The Board told him if he found a pharmacist practicing and not licensed in Kansas to file a complaint so a case could be opened.

Frank Whitchurch – Mr. Whitchurch is headed to Tucson for an NABP meeting on disposal of drugs. The hope is to develop protocols and procedures. Mr. Whitchurch complimented the Board on the handling of hard issues.

Karen Braman – Ms. Braman said the PMP is beginning the work to prepare the report to the legislature. The grant will be in process.

Shirley Arck – Dr. Arck thanked the staff for the help in all the cases.

JoAnne Gilstrap – Ms. Gilstrap thanked the board members for the hours they have put in on their various projects.

She requested the Board receive the electronic newsletter 2 weeks before it is released.

The strategic plan needs to be finalized in February.

Can nurse practitioners self prescribe? Ms. Billingsley is to find out the answer.

Ms. Gilstrap asked about reimbursements. Ms. Billingsley said A&R has mailed them. Ms.

Billingsley does not know what they have mailed but she will inquire.

Ms. Gilstrap asked about the pharmacist survey, classification of pharmacies, law books. She would like follow up at the March meeting.

Ms. Gilstrap wants to discuss technician functions at the February or March.

Approval of New Pharmacists and New Registrants

A motion was made and seconded to approve the new licenses and registrations.

(Braman/Arck) Motion passed.

Discuss the June Board meeting date conflict – Mr. Coast says there is a conflict. Move to June 9 &10.

Review of Action Items for the Board

Ms. Morris quickly reviewed the agenda items that require action by a specified individual and the date the action is due.

Adjourn: Ms. Gilstrap adjourned the meeting at 11:40am.