

KENTUCKY BOARD OF PHARMACY
Holiday Inn University Plaza & Sloan Convention Center
1021 Wilkinson Trace
Bowling Green, KY 42103
November 1-2, 2013 (following Board Meeting on Nov. 1)

BOARD RETREAT

AGENDA

The Kentucky Board of Pharmacy serves the Commonwealth to promote, preserve, and protect the public health, safety, and welfare through effective regulation of the practice of pharmacy. The Kentucky Board of Pharmacy accomplishes this mission through the examination, testing, and credentialing of prospective pharmacists; regulation, discipline of all licensed pharmacists; and through appropriate communication of information and laws pertaining to the practice of pharmacy in Kentucky.

I. CALL TO ORDER

II. INTRODUCTIONS

III. ITEMS for discussion

- Scheduling gabapentin
- Set up exempt controlled substance when sold OTC be reported to KASPER
- Discharge Medication Reconciliation by pharmacists
- Kroger proposal
- Walgreen proposal
- Quality Assurance
- Formulary Compliance Approval
- DEA Policy to restrict sale of certain quantities to pharmacies and how it affects patient care

*** Casual dress attire**

SCHEDULE:

Friday, November 1, 2013

Time permitting Retreat Agenda items will commence on Friday afternoon

Saturday, November 2, 2013

8:30a.m.-12:00p.m.	Discussion of Agenda items
12:00p.m.-1:30p.m.	Lunch on your own
1:30p.m.-5:00 p.m.	Discussion of Agenda items

MINUTES
KENTUCKY BOARD OF PHARMACY
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Bowling Green, KY 42103

November 1-2, 2013

CALL TO ORDER: A regular meeting of the Kentucky Board of Pharmacy was held at the Holiday Inn University Plaza, Bowling Green, Kentucky. President Thornbury called the meeting to order at 9:08 a.m. President Thornbury congratulated Deborah Brewer, Brian DeWire and Scott Greenwell on being reappointed to the Board of Pharmacy.

Members present: Joel Thornbury, Deborah Brewer, Brian DeWire, Scott Greenwell, Larry Hadley and Cathy Hanna. Staff: Michael Burlison, Executive Director; Steve Hart, Pharmacy Inspections and Investigations Coordinator; Shannon Allen, Katie Busroe, Amanda Harding and Phil Losch, Pharmacy and Drug Inspectors; Cheryl Lalonde, Assistant Attorney General and Board Counsel; Brian Fingerson, Pharmacist Recovery Network Committee; and Lisa Atha, Executive Secretary. Guests: Trish Freeman, Karen Blumenschein, Amie Goodin, and Sarah Wixson, University of Kentucky College of Pharmacy; Lisa Smith, Walmart; Mike Wyant, Cardinal Health; Jeff Osman, VA; Chris Killmeier, Walgreens; Ralph Bouvette, APSC; Misty Stutz, Sullivan College of Pharmacy; Jan Gould; Kentucky Retail Federation; Robert McFalls, KPhA; Leon Claywell, Medica Pharmacy; Amber Kayse and Brody White, Kroger; and Lauren Christian, Taryn Howell, Lance Murphy and Ryan Timmons, College of Pharmacy students. Felicia Thomas, Court Reporter, recorded the meeting.

MINUTES: On motion by Ms. Brewer, seconded by Dr. Greenwell and passed unanimously, the Minutes of September 11, 2013 were approved.

**The Board received information from Change to Win via UPS delivery at 9:15 a.m. regarding the discussion of Walgreens Pharmacy new design and process in the pharmacy.

APPEARANCES: **Trish Freeman and Karen Blumenschein, University of Kentucky College of Pharmacy, Institute for Pharmaceutical Outcomes and Policy (IPOP).** The Cabinet for Health and Family Services engaged IPOP to evaluate the impact of HB1. The goals of the project are to evaluate the impact of HB1 on reducing prescription drug abuse and diversion, identify unintended consequences associated with the implementation of HB1 that impacts patients, providers and other stakeholders, and develop recommendations to improve effectiveness of HB1 and mitigate identified unintended consequences. Dr. Freeman and Dr. Blumenschein asked the Board members and staff a series of questions that were answered from the regulatory standpoint.

Dr. Greenwell moved to go into Executive Session pursuant to KRS 61.810(1)(f) for discussion which might lead to the appointment, discipline, or dismissal of an individual employee, member or student without restricting that employee's, member's or student's right to a public hearing if requested. Mr. Hadley seconded, and the motion passed unanimously.

Dr. Greenwell moved to come out of Executive Session. Ms. Brewer seconded, and the motion passed unanimously.

Dr. Greenwell moved to ratify the voluntary resignation letter from Chris Frasure, dated September 23, 2013. Dr. Hanna seconded, and the motion passed unanimously.

Dr. Greenwell moved for Mike Burlison, Executive Director, and Steve Hart, Pharmacy Investigations and Inspections Coordinator, to present a plan at the December Board Meeting around the setting of expectations, the review and monitoring of staff so the Board can be aware of the level of set expectations in order for the Board to determine the oversight of staff needed. Dr. DeWire seconded, and the motion passed unanimously.

INTERAGENCY: KPhA. KPhA is hosting a Midyear Conference focusing on legislative processes and priorities at the Marriott in Lexington, November 15-16, 2013.

KSHP. KSHP is very interested in the Board's proposal to use funds for substance abuse education. Interested stakeholders will work on a more detailed proposal.

BOARD REPORTS:

Board Executive Director. 1) eMars for July, August, September FY 2014 and Financial Report Summaries were presented to the Board. 2) Mr. Hadley moved to accept the proposed budget for 2015-2016. Dr. DeWire seconded, and the motion passed unanimously. 3) Dr. Greenwell moved to approve travel for Mike Burlison to attend NABP Budget/Finance Meeting November 11-13, 2013, at no expense to the Board; travel for Cheryl Lalonde and Amanda Harding to attend the NABP Attorney/Compliance Officer Meeting, December 3-4, 2013, at no expense to the Board; and travel for Mike Burlison to attend the NABP Attorney/Compliance Officer/Executive Committee Meeting, December 3-6, 2013, at no expense to the Board. Ms. Brewer seconded, and the motion passed unanimously. 4) Dr. Greenwell moved to approve travel for the Executive Director and Board President to attend the APhA Annual Meeting, March 28-31, 2014, in Orlando, Florida. Dr. Hanna seconded, and the motion passed unanimously. 5) Dr. Greenwell moved to allow the Board President, up to four additional Board Members, the Executive Director, Brian Fingerson and one staff to attend the National Prescription Drug Abuse Summit, April 22-24, 2014, in Atlanta. Dr. Hanna seconded, and the motion passed unanimously.

CURRENT/PENDING CASES:

Case Updates: Mr. Hadley moved to accept Case Updates for Case Numbers 11-0148C; 11-0217B; 12-0037B; 12-0224B; 13-0017A; 13-0032; 13-0086; 13-0087A; 13-0087B; 13-0098B;

13-0110; 13-0114A; 13-0116A; 13-0117B; 13-0118A; 13-0118B; 13-0119A; 13-0120A; 13-0121A; 13-0121B; 13-0122A; and 13-0124B as written. Dr. DeWire seconded, and the motion passed unanimously.

RECIPROCITY/RELICENSURE/INTERNSHIP/PHARMACY TECHNICIANS:

William Wood. William Wood requested to reciprocate his pharmacist's license to Kentucky in order to serve as the Kentucky licensed pharmacist-in-charge of an out of state pharmacy permit. Mr. Wood had been disciplined by the Alabama Board of Pharmacy and the Florida Board of Pharmacy. Dr. DeWire moved to deny William Wood's request to reciprocate his pharmacist's license to Kentucky, and, therefore, deny his request to become a Kentucky licensed pharmacist-in-charge of an out of state pharmacy permit. Dr. Hanna seconded, and the motion passed unanimously.

Frances Tucker. Frances Tucker requested to sit for the NAPLEX for a seventh time. Ms. Tucker has previously failed the examination 6 times. NABP has a policy which states candidates are only permitted five attempts to pass the NAPLEX. There is nothing in the Kentucky Pharmacy Practice Act that limits the number of times a candidate may sit for the Kentucky Board examinations. Dr. Greenwell moved to accept Frances Tucker's request to sit for the NAPLEX examination. Dr. DeWire seconded, and the motion passed unanimously. Dr. Greenwell directed Executive Director Burlison to review the contract the Kentucky Board of Pharmacy has with NABP and reach out to NABP for discussion of NABP's policy limiting the number of times a candidate is eligible to sit for examinations being in conflict with Kentucky law.

Pharmacy Technician Registrant LS. Dr. Greenwell moved grant pharmacy technician registration to LS provided he signs an Agreed Order with probation for 2 years, 6 drug screens per year, and standard PRN language. Ms. Brewer seconded, and the motion passed unanimously.

Pharmacy Technician Registrant TI. Dr. Greenwell moved to grant pharmacy technician registration to TI without restriction. Dr. Hanna seconded, and the motion passed unanimously.

CORRESPONDENCE/COMMUNICATION:

Dual PIC/Angela Nicole Hotard. Pharmacist Angela Nicole Hotard requested permission to be dual pharmacist-in-charge of Monroe Clinic Pharmacy in Monroe, Louisiana, and Sterlington Village Pharmacy in Sterlington, Louisiana. Dr. Greenwell moved to conditionally approve Angela Nicole Hotard's request to be pharmacist-in-charge of Monroe Clinic Pharmacy and Sterlington Village Pharmacy provided the pharmacies are located at the same address, and Executive Director Burlison is directed to contact the Louisiana Board of Pharmacy regarding the pharmacies. Ms. Brewer seconded, and the motion passed unanimously.

PETNET Solutions/Tigran Sinanian. Tigran Sinanian requested an exemption for PETNET Solutions to not be permitted as an out of state pharmacy by the Kentucky Board of Pharmacy. PETNET produces Amyvid, a drug used in early Alzheimer's detection. There are no facilities in Kentucky that produce this drug. The only way for a patient in Kentucky to receive the drug is through the St. Louis, Missouri, facility. PETNET foresees a maximum of five doses needed in the next four months on an emergency need only. Mr. Sinanian made a similar request and was unanimously denied at the July 10, 2013, Board Meeting. Dr. Greenwell moved to deny Tigran Sinanian's request for an exemption so that PETNET Solutions would not need to be permitted as an out of state pharmacy by the Kentucky Board of Pharmacy. Dr. Hanna seconded, and the motion passed unanimously.

NABP: Mr. Burleson gave a brief overview of the meeting facilitated by NABP between various stakeholders and the American Medical Association (AMA), regarding the AMA resolution that inquiries from pharmacists regarding prescriptions, diagnoses and treatment plans are an interference with the practice of medicine and unwarranted.

LEGISLATION: STATUTE/REGULATION:

Statute: Wholesale Distribution. The Executive Director's plan of action is to approach the Attorney General to provide support for passage of KRS 315.400 to be amended to read: (7) A pharmacy shall not engage in selling or distributing prescription drugs to any entity that is a wholesale distributor. Mr. Burleson is directed to review the technical amendments made to KRS 315.400 previously in regards to whether a reverse distributor is considered a wholesaler, therefore, prohibiting Kentucky pharmacies from using reverse distributors. Mr. Burleson will keep the Board informed of the Attorney General's response and the technical amendments.

Statute: Pharmacy Technician on Advisory Council. Don Carpenter requested the Board consider a position for a pharmacy technician on the Advisory Council. The Advisory Council is composed of pharmacists and non-pharmacists. Dr. Greenwell moved to direct the Executive Director to respond to Mr. Carpenter by informing him of the process of submitting his name to be considered for appointment to the Advisory Council. Mr. Hadley seconded, and the motion passed unanimously.

Statute: Collaborative Care Agreement. Mr. Burleson is to work with Dr. Bouvette to encourage pharmacists to submit templates that illustrate the need for changing the Collaborative Care Agreement statute.

CONTINUING EDUCATION: Dr. Greenwell moved to approve continuing education programs 13-43 through 13-45 and 13-47 through 13-54 as recommended and not approve

programs 13-41, 13-42 and 13-46 until more information can be obtained. Mr. Hadley seconded, and the motion passed unanimously.

NEW BUSINESS:

- A. APRN: Multiple prescriptions of Schedule II.** Nathan Goldman, General Counsel for the Kentucky Board of Nursing, submitted a legal memorandum that in his opinion Psychiatric-Mental Health Advanced Practice Registered Nurses (APRN) may utilize 21 CFR 1306.12 to write multiple prescriptions of psychostimulants. Dr. Greenwell moved to disagree with Nathan Goldman, General Counsel for the Kentucky Board of Nursing. A Psychiatric-Mental Health APRN may write one prescription for up to a 30 day supply of a Schedule II psychostimulant and may not issue multiple prescriptions. Dr. Hanna seconded, and the motion passed unanimously.
- B. Request opinion on labeling.** Lynn Harrelson requested the Board's opinion on appropriate labeling. A 90 day supply of a medication was dispensed in 3 separate vials, each containing a 30 day supply, and placed in a box. The 3 vials were not labeled but the box was labeled. Dr. Greenwell moved that it is inappropriate labeling not to label individual vials. Mr. Hadley seconded, and the motion passed unanimously.
- C. Advisory Council Letter.** Chris Killmeier, Chair of Advisory Council, presented a letter to the Board regarding pharmacist consolidation of non-controlled substances refills to make a 90 day prescription without prescriber authorization. The Advisory Council requested the Board send the letter to the Kentucky Board of Medical Licensure and the Kentucky Board of Nursing for their opinions on this subject. Mr. Hadley moved to fulfill the request of the Advisory Council and send the letter regarding pharmacist consolidation of non-controlled substances refills to make a 90 day prescription without prescriber authorization to the Kentucky Board of Medical Licensure and the Kentucky Board of Nursing for their opinions on the subject. Dr. Greenwell seconded, and the motion passed unanimously.

President Thornbury recessed the meeting for lunch from 12:15 p.m. to 1:15 p.m.

BOARD RETREAT – November 1, 2013, began at 1:28 p.m.

Dr. Greenwell moved to come out of recess at 1:28 p.m. Mr. Hadley seconded, and the motion passed unanimously.

Court Reporter, Felicia Thomas, was not present for the Board Retreat.

Scheduling of Gabapentin. There was discussion regarding the scheduling of gabapentin. This is under the purview of Drug Enforcement and Professional Practices Branch of the Office of Inspector General. No other state controls gabapentin. Mr. Hadley moved to send a letter to Drug Enforcement and Professional Practices Branch of the Office of Inspector General to

consider scheduling gabapentin due to potential of abuse. Dr. Hanna seconded, and the motion passed unanimously.

Track Exempt Schedule V Cough Syrup through KASPER instead of a Log. There was discussion regarding tracking exempt Schedule V cough syrups through KASPER instead of a log. No action was taken.

Discharge Medication Reconciliation. There was discussion regarding medication reconciliation in the hospital setting. Practices vary greatly with some hospitals investing in pharmacists performing medication reconciliation and some hospitals having nursing perform this. Another issue is the lack of continuum of care from the hospital discharge to the community pharmacy. President Thornbury directed Executive Director Burleson to refer the issue of medication reconciliation and continuum of care from hospital discharge to the community pharmacy to Dr. Freeman and the Center for the Advancement of Pharmacy Practice.

Kroger. At the November 2012 Board Meeting, Kroger Pharmacy requested approval on three options that would result in a new work flow for Kroger Pharmacies. Option 1, Pharmacy Call Center was approved at the November 2012 Board Meeting. Brody White and Amber Kayse appeared to answer questions regarding option 2, remote pre-verification and drug utilization review at the Center of Excellence. A technician at the local Kentucky Kroger Pharmacy enters the prescription in the computer system, then a Kentucky licensed pharmacist at the Center of Excellence in Ohio verifies the prescription information entered such as patient, prescriber, drug name and strength, directions, quantity, refills, and date written and performs the drug utilization review. The prescription is sent back to the local Kentucky Kroger Pharmacy where that pharmacist verifies the product in the vial. The Kroger proposal states, "Since the database records which pharmacist complete each step of work flow, we feel that responsibility should fall to the pharmacist that complete that process." After much discussion, most Board members were not comfortable pre-assigning responsibility in the case of a medication error.

Walgreens. Additional information was presented at the Board Retreat from Walgreens and Chance to Win, therefore, this Agenda item was tabled until the December 2013 or January 2014 Board Meeting.

The Retreat recessed at 4 p.m. on November 1, 2013.

BOARD RETREAT – November 2, 2013

Ms. Brewer moved to come out of recess at 8:37 a.m. on November 2, 2013. Dr. DeWire seconded, and the motion passed unanimously.

Members present: Joel Thornbury, Deborah Brewer, Brian DeWire, Larry Hadley and Cathy Hanna. Staff: Michael Burleson, Executive Director; Steve Hart, Pharmacy Inspections and Investigations Coordinator; Shannon Allen, Katie Busroe, Amanda Harding and Phil Losch, Pharmacy and Drug Inspectors; Cheryl Lalonde, Assistant Attorney General and Board Counsel; and Lisa Atha, Executive Secretary. Guests: Robert McFalls, KPhA; Ralph Bouvette, APSC; Jan Gould, Kentucky Retail Federation; Anne Policastri, KSHP; Chris Killmeier, Walgreens; Jeff Osman, VA; Misty Stutz, Sullivan College of Pharmacy; Leon Claywell, Medica; and Taryn Howell, College of Pharmacy student. Board Member Scott Greenwell was not present.

Quality Assurance. The Medication Errors Council Report from the Kentucky Board of Pharmacy Advisory Council, dated October 29, 2008, and resubmitted January 14, 2009, was discussed. President Thornbury directed Executive Director Burleson to begin conversations with Legislators to gauge the attitude toward the Quality Assurance subject.

Formula Compliance Approval. Discussion centered on how to promote 201 KAR 2:280, prescription dispensing for formula compliance. President Thornbury directed Executive Director Burleson to send an email blast to pharmacists and to work with the Kentucky Board of Medical Licensure and the Kentucky Board of Nursing to promote the use of 201 KAR 2:280.

DEA Policy to Restrict Sale of Certain Quantities to Pharmacies and how it affects Patient Care. There was discussion regarding wholesale distributors imposing quotas on pharmacies limiting the amount of controlled substances sold to pharmacies and how pharmacists are to determine which patients receive the limited amount of controlled substances available. Executive Director Burleson is to take the issue to NABP to attempt to initiate a discussion with DEA, wholesale distributors, and interested stakeholders.

Provider Status. Robert McFalls gave a brief update on the initiative for pharmacists to obtain provider status.

Physician Dispensing. After discussion, Executive Director Burleson was directed to ask Drug Enforcement and Professional Practices Branch of the Office of Inspector General for the latest opinion regarding physician dispensing. Mr. Burleson is to work with Kentucky Board of Medical Licensure to educate physicians on dispensing responsibilities.

ADJOURNMENT: On motion by Ms. Brewer, seconded by Dr. Hanna and passed unanimously, President Thornbury adjourned the Board Meeting and Retreat at 10:45 a.m. The next regularly scheduled Board Meeting is scheduled to begin at 9:00 a.m. on December 18, 2013 at the Board Office, Frankfort, Kentucky.

Michael Burleson, RPh