

**KENTUCKY BOARD OF PHARMACY
SPINDLETOP ADMINISTRATION BUILDING SUITE 302
2624 RESEARCH PARK DRIVE
LEXINGTON KY 40511**

**July 9, 2008
9:00a.m.**

Agenda

I. CALL TO ORDER

II. MINUTES

*A. May 14, 2008

III. APPEARANCES

IV. INTERAGENCY

V. BOARD REPORTS

A. Board President

*1. Pharmacist Recovery Network Committee Appointments

*2. USP 797 Responses

B. Board Members

1. Anne Policastri-New Pharmacist Reception-Update

C. Board Executive Director

*1. eMARS (May 08 and June 08)

2. Pharmacy Technician (HB 328)

3. Wholesaler/Pedigree (SB 118)

4. Board Retreat 2008

*5. NABP District III 2008

6. NABP District III 2009

7. Board Meeting: September 10, 2008

D. Board Staff

E. PRN Chair

VI. CURRENT/PENDING CASES

A. OAG-Cheryl Lalonde

*B. Case Update

*C. Case Review

VII. RECIPROCITY/RELICENSURE/INTERNSHIP

*A. Lee A. Martin

VIII. CORRESPONDENCE/COMMUNICATIONS

*A. Lincare-Dual PIC

*B. Joesph Hamm-Reduction of Inspections

IX. NABP

X. LEGISLATION/REGULATIONS

XI. CONTINUING EDUCATION

XII. FINES

XIII. OLD BUSINESS

XIV. NEW BUSINESS

***Information enclosed with this agenda**

****Information previously provided**

*****Old material with response**

**KENTUCKY BOARD OF PHARMACY
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**Agenda
Addendum**

- V. BOARD REPORTS**
 - 8. Executive Director-MPJE in October 8-12 in Chicago**
 - 9. Executive Director-NABP Executive Committee
November 5-7 in Chicago**

- VI. CURRENT/PENDING CASES**
 - B. Case Update: 08-0040**

- VIII. CORRESPONDENCE/COMMUNICATIONS**
 - *C. Dual PIC request-Michael Ingram**

- X. LEGISLATION/REGULATION**

- XI. CONTINUING EDUCATION**
 - *A. Programs 08-33 thru 08-36**

- XV. FYI**
 - *A. DEA Proposed Rules on e-prescribing**
 - *B. PRN overtime report**

***Information enclosed with this agenda**
****Information previously provided**
*****Old material with response**

MINUTES
KENTUCKY BOARD OF PHARMACY
Spindletop Administration Building, Suite 302
2624 Research Park Dr.
Lexington, Kentucky

July 9, 2008

CALL TO ORDER: A regular meeting of the Kentucky Board of Pharmacy was held at the Board Office at Spindletop Administration Building, 2624 Research Park Drive, Lexington, Kentucky. President Leake called the meeting to order at 9:09 a.m.

Members present: Mike Leake, Peter Orzali, Anne Policastri, Patricia Thornbury, Sandy Simpson and Catherine Shely. Staff: Michael Burleson, Executive Director; Jeffrey L. Osman, Pharmacy Inspections and Investigations Coordinator; Katie Busroe and Steve Hart, Pharmacy and Drug Inspectors. Guests: Brian Fingerson, Pharmacist Recovery Network Committee; Ralph Bouvette and Catherine Hanna, APSC; Jan Gould, Kentucky Retail Federation; Richard K. Stone and Brad Hall, Kentucky Pharmacists Association; Kim Morgan, Target; Scott Greenwell, Humana; Brandi Johnson, CVS Pharmacy; Ryan Crusier, K Mart Pharmacy; Mark Hollinden, Abbott Laboratories; and Candice Humphrey, UK College of Pharmacy student. Melody Curtis, Court Reporter, recorded the meeting. Phil Losch, Pharmacy and Drug Inspector; Lisa Atha, Executive Secretary; and Cheryl Lalonde, Assistant Attorney General and Board Counsel were not present.

MINUTES: On motion by Dr. Policastri, seconded by Mr. Orzali and passed unanimously, the Minutes of May 14, 2008 Board Meeting were adopted as amended.

BOARD REPORTS:

Board President. President Leake presented the list of names for the Pharmacist Recovery Network Committee (PRNC) to be appointed by the Board. Ms. Thornbury moved to have PRNC members sign a confidentiality statement. Mr. Orzali seconded, and the motion passed unanimously.

Mr. Orazli moved to table the election until the end of the Board meeting. Ms. Thornbury seconded, and the motion passed unanimously.

President Leake reported on the comments from KPhA, KSHP, and APSC concerning USP 797 "low volume" criteria for hazardous drugs preparations. Following the review of the comments, Mr. Orzali moved to make the minimum standard for low volume preparation of hazardous drugs not more than an average of five (5) preparations per week, calculated over any running six (6) week period. Ms. Thornbury seconded the motion. After discussion, Dr. Shely moved to amend the motion that the minimum standard of not more than an average of five (5) preparations be calculated over a two (2) week period. Mr. Orzali seconded, and the amendment passed unanimously. The motion to adopt the minimum standard for low volume preparation of hazardous drugs in regard

to USP 797 as not more than an average of five (5) hazardous drug preparations calculated over a two (2) week period, passed unanimously.

Board Members. Dr. PolICASTRI. Dr. PolICASTRI presented information on a date, time and place for the new licensee reception. Ms. Thornbury moved for the new licensee reception to be held on September 26, 2008 at the University of Kentucky Alumni House or other suitable facility from 5:00 p.m. until 7:00 p.m. Ms. Simpson seconded, and the motion passed unanimously.

Board Executive Director. 1) EMars monthly report for June 2008 was presented to the Board. 2) The Board Retreat will be in Louisville November 15-16, 2008. Currently there is one Agenda item for the Board Retreat, disciplinary action on medication errors when more than one pharmacist is involved in the prescription filling process, to include discussion regarding remote pharmacist approval. 3) NABP District III Meeting is scheduled to be in Sandestin, Florida, August 17-19, 2008. 4) 2009 NABP District III meeting will be August 2-4, 2009, in Lexington, Kentucky. 5) Dr. PolICASTRI moved to approve the travel for Mr. Burleson to attend the NABP MPJE review with Jeff, October 8-12, 2008, in Chicago and to attend the NABP Executive Committee meeting November 5-7, 2008, in Chicago. Dr. Shely seconded, and motion passed unanimously. 6) Ms. Thornbury moved to authorize the Executive Director to use the federal funds totaling up to \$37,000 to pursue the purchase of GPS systems for the inspectors, pill counters, reference materials and software for pharmacy technician registration. Mr. Orzali seconded, and the motion passed unanimously. 7) Brad Hall, Executive Director of KPhA, introduced Richard Sloan as President of KPhA and Scott Greenwell as Vice-Speaker of the House of Delegates of KPhA. 8) Mr. Orzali moved to approve the pharmacy technician application as amended by adding the driver's license and state of issuance. Ms. Simpson seconded, and the motion passed unanimously. 9) Mr. Burleson gave a summary of the July 1, 2008, meeting to discuss the wholesaler/pedigree regulation. Another meeting is set for August 22, 2008. 10) Mr. Burleson reminded the Board members and staff that the September Board meeting will be held on the University of Kentucky campus.

Board Staff. Ms. Busroe thanked the Board for allowing her to attend the DEA meeting in June 2008. One item discussed was the DEA's ruling that the waiver letter for Kentucky long term care facilities to use reverse distributors for the destruction of controlled substances was no longer valid. Mr. Orzali moved that the Executive Director send a letter to the DEA and United State Senators and Representatives from Kentucky discussing the issue of handling discontinued controlled substances in long term care facilities and urging a resolution to this problem. Dr. Shely seconded, and the motion passed unanimously.

CURRENT/PENDING CASES:

Case Updates: Ms. Thornbury moved for acceptance and entry of the proposed Agreed Orders as written. Dr. PolICASTRI seconded, and the motion passed unanimously.

Case No. 07-0020A; Case No. 07-0106A; Case No. 07-0106C; Case No. 08-0014; Case No. 08-0020; Case No. 08-0021A; Case No. 08-0021B; Case No. 08-0022B; Case No. 08-0023; Case No. 08-0024; Case No. 08-0025; Case No. 08-0027; Case No. 08-0028; Case No. 08-0029; Case No. 08-0031; Case No. 08-0032; Case No. 08-0033; Case No. 08-0037; Case No. 08-0040; Case No. 08-0042; Case No. 08-0044; Case No. 08-0045; Case No. 08-0047; Case No. 08-0048.

Case Review: Ms. Thornbury moved for acceptance of the Case Review Committee recommendations for the following case reports. Dr. Policastri seconded, and the motion passed unanimously.

Case No. 07-0049. Revisit. Pharmacist was arrested for diversion. NEW INFORMATION: Pharmacist pleaded guilty pursuant to a diversion agreement to one count of forgery of a prescription for a controlled substance. Alleged violations of law: KRS 315.121(1)(a) and (2)(f), KRS 218A.140(1)(a), and KRS 218A.282. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 07-0081. Pharmacist-in-charge allegedly failed to maintain adequate security and control of controlled substances and allegedly engaged in unprofessional and unethical conduct by dispensing a drug for which a prescription is required without having received authorization from a prescriber. Alleged violations of law: 201 KAR 2:100 Section 1 and KRS 315.121(2)(f). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 07-0082A. Pharmacy permit holder allegedly failed to provide adequate security and control of controlled substances. Alleged violations of law: 201 KAR 2:100 Section 1 and 201 KAR 2:205 Section 2(3)(b). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 07-0082B. Pharmacist-in-charge allegedly failed to provide adequate security and control of controlled substances. Alleged violations of law: 201 KAR 2:100 Section 1 and 201 KAR 2:205 Section 2(3)(b). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0034. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. Pharmacist dispensed an expired Humalog Pen. Alleged violations of law: KRS 315.121(1)(a) and (2)(d). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0036. Pharmacist allegedly engaged in unprofessional conduct by filling a prescription for Lortab 7.5 for which there was no authorized prescription. Alleged violation of law: KRS 315.121(2)(f). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0038A. Pharmacy permit holder allegedly sold a misbranded product by filling a prescription for Adderall 2.5mg with Adderall XR 25mg. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 08-0038B. Pharmacist allegedly committed a medication error by filling a prescription for Adderall 2.5mg with Adderall XR 25mg. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0039A. Pharmacy permit holder allegedly sold a misbranded product by filling a prescription for Hyzaar 12.5/50mg with Hyzaar 25/100mg. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 08-0039B. Pharmacist allegedly committed a medication error by filling a prescription for Hyzaar 12.5/50mg with Hyzaar 25/100mg. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0050A. Pharmacy permit holder allegedly allowed a pharmacy technician to engage in the practice of pharmacy on at least two occasions, failed to maintain proper security and control of drugs by allowing a technician in the pharmacy without a pharmacist present and allowed refills of non-controlled prescriptions for greater than one year. Alleged violations of law: KRS 315.121(1)(a) and (g), 201 KAR 2:100 Section 1, and 201 KAR 2:185 Section 3. CRC Recommendation: There is sufficient evidence of a

violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0050B. Pharmacist allegedly engaged in unprofessional and unethical conduct by allowing a pharmacy technician to engage in the practice of pharmacy, failing to maintain proper security and control of drugs by allowing a technician in the pharmacy without pharmacist present and allowing refills of non-controlled prescriptions for greater than one year. Alleged violations of law: KRS 315.121(1)(a) and (g), 201 KAR 2:100 Section 1, and 201 KAR 2:185 Section 3. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0054. Pharmacy allegedly opened without a Kentucky licensed pharmacist present. Alleged violation of law: 201 KAR 2:100(1). CRC Recommendation: Case is dismissed.

Case No. 08-0055A. Pharmacy permit holder owner/pharmacist has been charged with nine felony counts of trafficking in a controlled substance. Alleged violations of law: KRS 315.121(1)(c), KRS 218A.1411, KRS 218A.1412 and KRS 218A.1413. CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 08-0055B. Pharmacist has been charged with nine felony counts of trafficking in a controlled substance. Alleged violations of law: KRS 315.121(1)(c), KRS 218A.1411, KRS 218A.1412 and KRS 218A.1413. CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 08-0056. Pharmacist allegedly failed to complete 1.5 continuing education units for 2007. Alleged violations of law: KRS 315.065(2) and 201 KAR 2:105. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0057A. Pharmacist alleged received and dispensed physician drug samples from a pharmacy and committed insurance fraud. Alleged violations of law: KRS 315.121(1)(a) and (f), KRS 315.121(2)(d),(e) and (g), KRS 217.055(1)(b) and KRS 217.065. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0057B. Pharmacist alleged received and dispensed physician drug samples from a pharmacy and committed insurance fraud. Alleged violations of law: KRS 315.121(1)(a) and (f), KRS 315.121(2)(d),(e) and (g), KRS 217.055(1)(b) and KRS 217.065. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0058A. Special medical gas permit holder allegedly filed a change of address application, had an inspection by the pharmacy drug inspector, was issued a new permit with a new address, but failed to move and failed to notify the Board office of not moving. Therefore, oxygen and oxygen records were stored at an unlicensed location. Alleged violation of law: KRS 315.035(5). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0058B. Special medical gas pharmacist-in-charge allegedly filed a change of address application, had an inspection of the facility by the pharmacy drug inspector, was issued a new permit with a new address, but failed to move and failed to notify the Board office of not moving. Therefore, oxygen and oxygen records were stored at an unlicensed location. Alleged violation of law: KRS 315.035(5). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0059A. Pharmacy permit holder allegedly engaged in unprofessional and unethical conduct. Alleged violations of law: KRS 315.121(1)(a), KRS 315.121(2)(b) and (d) and 201 KAR 2:165 Sections 2 and 3. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 08-0059B. Pharmacist allegedly engaged in unprofessional and unethical conduct. Pharmacist allegedly refused to refill a prescription for a controlled substance, refused to transfer the prescription and violated confidentiality by discussing the situation in front of others. Alleged violations of law: KRS 315.121(1)(a) and KRS 315.121(2)(b) and (d) and 201 KAR 2:165 Sections 2 and 3. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 08-0060. Pharmacist allegedly failed to complete 15 hours of continuing education for 2007. Pharmacist reported completing all continuing education requirements on 2008 Kentucky pharmacist's license renewal, however pharmacist only completed 14.5 hours. Alleged violations of law: KRS 315.065 and 201 KAR 2:015. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an

Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0061. Pharmacist allegedly violated his Agreed Order with unprofessional conduct. Pharmacist was terminated from employment after confessing to taking non-controlled drugs from the pharmacy. Alleged violation of law: KRS 315.121(2)(f). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 07-0030A. Pharmacy permit holder's pharmacist-in-charge and pharmacist allegedly engaged in unprofessional and unethical conduct by failing to conduct a prospective drug utilization review and dispensing large quantities of alprazolam for one patient. Alleged violations of law: KRS 315.121(1)(a) and KRS 315.121(2)(d). CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 07-0030B. Pharmacist-in-charge allegedly engaged in unprofessional and unethical conduct by failing to conduct a prospective drug utilization review and dispensing large quantities of alprazolam for one patient. Alleged violations of law: KRS 315.121(1)(a), KRS 315.121(2)(d) and 201 KAR 2:210 Section 4. CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 07-0030C. Pharmacist allegedly engaged in unprofessional and unethical conduct by failing to conduct a prospective drug utilization review and dispensing large quantities of alprazolam for one patient. Alleged violations of law: KRS 315.121(1)(a), KRS 315.121(2)(d) and 201 KAR 2:210 Section 4. CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 08-0062. Pharmacist allegedly practicing under the influence of alcohol or mind altering substance. Alleged violations of law: KRS 315.121(1)(b) and KRS 315.121(2)(d), and (e). CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

RECIPROCITY/RELICENSURE/INTERNSHIP: Lee A. Martin. Ms. Martin requested to have her Kentucky pharmacist's license reinstated. Her license lapsed in 1994. She has not practiced pharmacy or been licensed in any state since 1996. Dr. Policastri moved to allow Ms. Martin to sit for the NAPLEX and MPJE and upon successful completion, have her Kentucky pharmacist's license reinstated. Dr. Shely seconded, and the motion passed unanimously.

CORRESPONDENCE/COMMUNICATIONS:

Lincare/Jami Cain. Ms. Cain requested to be a dual pharmacist-in-charge for Lincare Infusion Pharmacy in Lexington and Lincare Infusion Pharmacy in Somerset, Kentucky.

Ms. Thornbury moved to allow Ms. Cain to be dual pharmacist-in-charge at Lincare Infusion Pharmacy in Lexington and Lincare Infusion Pharmacy in Somerset for a 90 day period beginning July 9, 2008. Ms. Simpson seconded, and the motion passed unanimously.

Joe Hamm. Mr. Hamm requested that the number of inspections per year be reduced from quarterly to semi-annually per his Agreed Order. Ms. Thornbury moved to reduce the number of inspections from quarterly to semi-annually for Joe Hamm. Dr. Shely seconded, and the motion passed unanimously.

Fleming County Hospital/Michael Ingram. Dr. Ingram requested to be a pharmacist-in-charge at Fleming County Hospital Inpatient Pharmacy (P05087), Fleming County Hospital Outpatient Pharmacy (P06707), Fleming County Hospital – Home Medical Supplies (M00894), and Fleming County Hospital medical gas pharmacy (MG0129). Ms. Thornbury moved to allow Dr. Ingram to be pharmacist-in-charge at Fleming County Hospital Inpatient Pharmacy (P05087), Fleming County Hospital Outpatient Pharmacy (P06707), Fleming County Hospital – Home Medical Supplies (M00894), and Fleming County Hospital medical gas pharmacy (MG0129). Ms. Simpson seconded, and the motion passed unanimously.

CONTINUING EDUCATION:

Ms. Thornbury moved to accept the continuing education programs 08-33 through 08-36 as recommended. Dr. Policastri seconded, and the motion passed unanimously.

PHARMACIST RECOVERY NETWORK COMMITTEE APPOINTMENTS:

Ballots were passed out to the Board members to vote on the appointments. Dr. Osman, Ms. Busroe, and Mr. Hart tallied the votes. The following individuals were appointed to the Pharmacist Recovery Network Committee: Jared Combs, Gene Farley, David Jaquith, Ken Kirsch, James Liebetrau, Mark Taylor, Michael Whitaker, and Michael Wyant.

ADJOURNMENT: On motion by Ms. Simpson, seconded by Ms. Thornbury and passed unanimously, President Leake adjourned the meeting at 12:44 p.m. The next regularly scheduled Board meeting is scheduled to begin at 9:00 a.m. on September 10, 2008 on the University of Kentucky Campus.

Michael Burleson, R.Ph.
Executive Director