

**KENTUCKY BOARD OF PHARMACY
SPINDLETOP ADMINISTRATION BUILDING SUITE 302
2624 RESEARCH PARK DRIVE
LEXINGTON KY 40511
SEPTEMBER 12, 2007
9:00a.m.**

Agenda

- I. CALL TO ORDER**
- II. MINUTES**
 - *A. JULY 11, 2007**
- III. APPEARANCES**
 - *A. Billy Ray Moore**
- IV. INTERAGENCY**
 - *A. 906 KAR 1:160 Monitoring System for products containing ephedrine**
- V. BOARD REPORTS**
 - A. Board President**
 - B. Board Members**
 - C. Board Executive Director**
 - *1. eMARS (May 07, June 07, June 07-Final, July 07, August 07)**
 - *2. American Pharmacy Law**
 - *3. Board Dates 2008**
 - 4. Board Retreat Agenda 2007**
 - D. Board Staff**
 - E. PRN Chair**
- VI. CURRENT/PENDING CASES**
 - A. OAG-Cheryl Lalonde**
 - *B. Case Update**
 - Case No. 05-0108A, 06-0057, 06-0066, 06-0067B, 06-0121, 07-0051, 07-0056, 07-0053, 07-0046**
 - *C. Case Review**
- VII. RECIPROCITY/RELICENSURE/INTERNSHIP**
 - *A. Ronald J. Nix – Relicensure**
- VIII. CORRESPONDENCE/COMMUNICATIONS**
 - *A. Three Forks Apothecary-Daily Log Signature**
 - *B. Mary E. Scott Hatcher-Dual PIC Request**
- IX. NABP**
- X. LEGISLATION/REGULATIONS**

- *A. Pharmacy Technician (Amendment)**
- *B. Automated Medication System (New)**
- *C. Common Database (New)**
- *D. Centralized Processing of Prescription Drug Orders (New)**

XI. CONTINUING EDUCATION

XII. FINES

XIII. OLD BUSINESS

XIV. NEW BUSINESS

XV. FYI

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

**KENTUCKY BOARD OF PHARMACY
SPINDLETOP ADMINISTRATION BUILDING SUITE 302
2624 RESEARCH PARK DRIVE
LEXINGTON KY 40511
September 12, 2007 9:00a.m.**

**Agenda
Addendum**

- V. BOARD REPORTS**
- VII. CURRENT/PENDING CASES**
- VIII. CORRESPONDENCE/COMMUNICATIONS**
 - *C. Dual PIC-Thomas Bond**
- XII. CONTINUING EDUCATION**
- XIII. FYI**
 - *A. 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

September 12, 2007

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 Orzali called the meeting to order at 9:07 a.m.

Members present: Peter Orzali, Mike Leake, Anne Policastro, Catherine Shely, Sandy Simpson, and Patricia Thornbury. Staff: Michael Burlson, Executive Director; Jeffrey L. Osman, Pharmacy Inspections and Investigations Coordinator; Katie Busroe and Phil Losch, Pharmacy and Drug Inspectors; Lisa Atha, Executive Secretary; and Cheryl Lalonde, Assistant Attorney General and Board Counsel. Guests: Brian Fingerson, Pharmacist Recovery Network Committee; Ralph Bouvette, Catherine Hanna and Trey Hieneman, APSC; Chris Killmeier, Walgreens; Michael Wyant, Cardinal Health; Brad Hall, Kentucky Pharmacists Association; Brandi Johnson; CVS; Linda Asher; Bill R. Moore; Tobi Glasscock, Wal-Mart; Rod Presnell, Medco Health Solutions; Roxann Fry, Greater Louisville Inc.; Ram Wolf, Louisville Metro; Allison Aldred, James Mullins, Amy Mueller, Sarah Ratliff, Kevin Hong, Shannon McKeever; Matt Hume, Sam Bright and Yatin Patel, College of Pharmacy students. Melanie Curtis, Court Reporter, recorded the meeting. Steve Hart, Pharmacy and Drug Inspector, was absent because he was attending another meeting.

MINUTES: On motion by Mr. Leake, seconded by Dr. Policastro and passed unanimously, the Minutes of July 11, 2007 were adopted. Dr. Shely was not present for this vote.

APPEARANCES: **Billy Ray Moore** was sworn in by Melanie Curtis, Court Reporter. Mr. Moore appeared before the Board requesting permission to take the North American Pharmacist Licensure Exam (NAPLEX) and the Multistate Pharmacy Jurisprudence Exam (MPJE). Mr. Moore gave an overview of the events that led to the loss of his Kentucky pharmacist's license more than 10 years ago. After much discussion and questioning, Mr. Leake moved to grant Mr. Moore permission to take the NAPLEX and MPJE and if completed successfully place stipulations on his license. Motion died for lack of a second. After more discussion, Dr. Shely moved to deny Mr. Moore's request to take the NAPLEX and MPJE. The motion was seconded by Ms. Thornbury and passed with Dr. Shely, Ms. Thornbury, and Ms Simpson voting yes, Mr. Leake voting no, and Dr. Policastro abstaining.

INTERAGENCY: The Office of Inspector General filed 906 KAR 1:160 Monitoring system for products containing ephedrine, pseudoephedrine, or phenylpropanolamine. A public hearing on this administrative regulation shall, if requested, be held on September

21, 2007 with written comments being accepted until close of business on October 1, 2007. Mr. Burleson is to keep the Board informed of any developments regarding this proposed regulation.

BOARD REPORTS:

Board Members. Dr. Policastri thanked those that attended the University of Kentucky College of Pharmacy's White Coat Ceremony.

Mr. Leake made a request to attend the NABP Fall Legislative Conference in Washington D.C. September 16-18, 2007. Ms. Thornbury moved to approve Mr. Leake's attendance at the NABP 2007 Fall Legislative Conference with all expenses paid by the Board. Dr. Policastri seconded, and the motion passed unanimously.

Dr. Shely requested an update on the Advisory Council's progress regarding a plan for quality assurance in pharmacy. Mr. Burleson expects a draft from the Advisory Council in the near future. Dr. Shely inquired about the issue of unused patient medications being returned to the pharmacy for destruction. Dr. Bouvette stated that this was a tremendous OSHA, EPA, and DEA problem with no easy solution. Dr. Shely asked about licensure standards for pharmacists in the event of an emergency or disaster such as Hurricane Katrina. Mr. Burleson informed the Board that an emergency statute had passed the Legislature and all professional boards were working on regulations to handle emergency situations.

Board Executive Director. 1) Mr. Burleson is currently working on the budget for 2009/2010. Dr. Shely moved to send a request to Personnel at the appropriate time for up to a 5% salary adjustment for the inspectors. Dr. Policastri seconded, and the motion passed unanimously. 2) Dr. Shely moved to approve the Executive Director joining the American Society for Pharmacy Law with the Board paying the dues. Mr. Burleson is to inquire if the Board may join the Society or if it is for individual memberships only. Ms. Simpson seconded, and the motion passed unanimously. 3) Dr. Shely moved to accept the following dates for the 2008 Board Meetings:

January 9, 2008 – Board Room	September 10, 2008 – To Be Announced
March 12, 2008 – Board Room	November 14, 2008 – To Be Announced
May 14, 2008 – Board Room	November 15-16, 2008 – Retreat, To Be Announced
July 9, 2008 – Board Room	December 10, 2008 – Board Room

Dr. Policastri seconded, and the motion passed unanimously. 4) Dr. Policastri moved to set the Board Retreat agenda as Wholesaler Pedigree, Disaster Relief, and Criminal Background checks on licensees. Ms. Thornbury seconded, and the motion passed unanimously. The Board Retreat will be November 17-18, 2007 at the Marriott Griffin Gate in Lexington, Kentucky. 5) There was an error in the September Board Newsletter where it read Kansas instead of Kentucky. NABP will print a correction. 6) Mr. Burleson thanked the Board members for their support in his successful bid for District III representative on the NABP Executive Council.

PRN Chair. Brian Fingerson informed the Board that two pharmacists had their exit interviews with the Pharmacist Recovery Network at the September 11, 2007 meeting. Ms. Lalonde suggested that Mr. Fingerson periodically present anecdotal evidence of the success of the PRN program to the Board. Mr. Fingerson announced CAPTASA will be held January 25-26, 2008 in Lexington. He will be speaking at CAPTASA as well as the Southeastern PRN meeting in November 2007.

CURRENT/PENDING CASES:

CASE UPDATES:

Mr. Leake moved for acceptance and entry of the proposed Agreed Orders as written. Ms. Simpson seconded, and the motion passed unanimously. Case No. 05-0108A, Case No. 06-0057, Case No. 06-0066, Case No. 06-0067B, Case No. 06-0121, Case No. 07-0046, Case No. 07-0051, Case No. 07-0053, and Case No. 07-0056.

CASE REVIEW COMMITTEE:

Dr. Shely moved for acceptance of the Case Review Committee recommendations for the following case reports. Ms. Simpson seconded, and the motion passed unanimously. Mr. Leake recused because he attended the Case Review Committee meeting as President Elect.

Case No. 07-0040 (Revisit). Pharmacist allegedly violated previous Agreed Order of Reinstatement by relapsing a second time. Alleged violation of law: KRS 315.121(1). Case Review Committee decision was the issuance of an emergency suspension. A Hearing was set for October 15, 2007 at 9:00 a.m. at the Board Office, Spindletop Administration Building, 2624 Research Park Drive, Lexington, Kentucky.

Case No. 06-0024. Pharmacist allegedly filled five hundred forged prescriptions without verifying legitimacy (one customer at least eight different patient names). Pharmacist allegedly added drug strengths to scheduled prescriptions without verifying with physician. Alleged violations of law: KRS 315.121(2)(d), (c), (j), (1)(a), 315.010 (10)(d), (19), 201 KAR 2:210 Section 4(2), (f), (g). **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. 06-0068. Pharmacist was arrested for diversion and received a felony conviction. Alleged violations of law: KRS 315.121(1)(b)(c) 1 and (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. 07-0022A. (Revisit). Pharmacy permit holder allegedly failed to provide adequate security of controlled substances. Alleged violation of law: 201 KAR 2:100 Section 1. 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. 07-0024B. (Revisit). Pharmacist is allegedly impaired. New Information: Pharmacist had a multi-day assessment performed and was diagnosed with substance dependence. Alleged violations of law: KRS 315.121(1)(b) and (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. 07-0027 (Revisit). Kentucky permitted wholesaler allegedly failed to comply with the U.S. Drug Enforcement Administration (DEA) regulations that has resulted in the immediate suspension of their DEA registration. NEW INFORMATION: A plea agreement with DEA has been reached and fulfilled. Alleged violation of law: 201 KAR 2:105 Section 2 (4)(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. 07-0028. Pharmacy permit holder allegedly committed Medicaid fraud by billing Medicaid for various hydrocodone/acetaminophen prescriptions and also charging the patient full price for the prescriptions. Alleged violation of law: KRS 315.121 (2)(h). CRC Recommendation: Case is dismissed.

Case No. 07-0049. Pharmacist was arrested for diversion. Alleged violations of law: KRS 315.121(1)(a), (2)(f), 218A.140(a), and 218A.282. CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 07-0063. Pharmacist allegedly failed to perform a drug utilization review on controlled substances dispensed to patient. Alleged violation of law: 201 KAR 2:210 Section 4. 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. 07-0064. Special limited medical gas permit holder allegedly failed to renew permit in a timely manner and continued to operate as a special limited medical gas pharmacy. Alleged violation of law: KRS 315.035. 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. 07-0066. Pharmacist allegedly diverted phentermine, hydrocodone/acetaminophen and is impaired. Alleged violations of law: KRS 315.121 (1)(b) and (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. 07-0067A. Pharmacy permit holder allegedly allowed a person without a Kentucky pharmacist's license to engage in the practice of pharmacy by transferring a prescription. Alleged violations of law: KRS 315.030(2), KRS 315.121(1)(g), and 201 KAR 2:165 Section 1(1)(a). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 07-0067B. Pharmacist was in the process of reciprocating pharmacist's license from another state to Kentucky, and allegedly engaged in the practice of pharmacy in Kentucky without a Kentucky pharmacist's license by transferring a prescription. Alleged violations of law: KRS 315.030(2), KRS 315.121(1)(g), and 201 KAR 2:165 Section 1(1)(a). CRC Recommendation: There is sufficient evidence of a violation; however, the penalty shall be the issuance of a Letter of Reprimand.

Case No. 07-0069. Pharmacist allegedly failed to complete 1.5 units of pharmacy continuing education. Pharmacist completed 1.2 units in 2006. Alleged violations of law: 201 KAR 2:015 Section 5(1)(a) and KRS 315.065. 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. 07-0070A. Pharmacy permit holder allegedly sold a misbranded prescription as a result of a medication error. A patient received a prescription of gabapentin 600mg instead of gemfibrozil 600mg. Alleged violation of 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. 07-0070B. Pharmacist allegedly committed a medication error by filling a prescription with gabapentin 600mg instead of gemfibrozil 600mg. Alleged violation of 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. 07-0071. Pharmacist allegedly dispensed medications to herself that were not properly authorized and also purchased large amounts of pseudoephedrine over a period of time. Alleged violations law: KRS 315.121 (2)(d)(e)(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. 07-0072. Pharmacy permit holder allegedly failed to have a pharmacist in charge from August 1 through August 27, 2007. Alleged violations of law: KRS 315.020(1) and 201 KAR 2:205. 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. 07-0073. Special limited medical gas pharmacy permit holder allegedly failed to renew special limited medical gas pharmacy permit in a timely manner and continued to operate. Alleged violation of law: KRS 315.035. 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. 07-0074. Pharmacy permit holder allegedly failed to renew pharmacy permit in a timely manner and continued to operate as a pharmacy. Alleged violation of law: KRS 315.035. 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.

RECIPROCITY/RELICENSURE/INTERNSHIP:

Ronald J. Nix let his Kentucky pharmacist's license lapse and requested that his Kentucky pharmacist's license be reinstated. Ms. Thornbury moved to allow Mr. Nix's license to be reinstated upon successful completion of the Multistate Pharmacy Jurisprudence Exam. Dr. Policastri seconded, and the motion passed unanimously.

CORRESPONDENCE/COMMUNICATIONS:

Three Forks Apothecary requested to be allowed to use a daily signature log for pharmacist verification of each day's dispensing activities. Dr. Shely moved to allow Three Forks Apothecary to use a daily signature log with the standard language of, "I attest to the fact that I have filled the following prescriptions on this date" on the log. Ms. Thornbury seconded, and the motion passed unanimously.

Mary Hatcher requested to be a dual pharmacist-in-charge at two locations, CertaCare Pharmacy – retail and CertaCare Pharmacy – home infusion. Ms. Simpson moved to allow Ms. Hatcher to be dual pharmacist-in-charge at CertaCare Pharmacy – retail and CertaCare Pharmacy – home infusion. Dr. Policastri seconded, and the motion passed unanimously.

Thomas Bond requested to be a dual pharmacist-in-charge at two locations, Gould’s Medical Pharmacy and Cook’s Pharmacy #3. Mr. Leake moved to allow Mr. Bond to be dual pharmacist-in-charge at Gould’s Medical Pharmacy and Cook’s Pharmacy #3. Ms. Thornbury seconded, and the motion passed unanimously.

LEGISLATION/REGULATIONS:

201 KAR 2:045. Technician (Amendment). Mr. Leake moved to direct Mr. Burleson to notify any company utilizing a system in which a prescription is presented and scanned into the computer system at Pharmacy A, entered into the computer system by a technician at Pharmacy B, data entry and drug utilization review verified by a pharmacist at Pharmacy C, then the final product verified and dispensed to the patient by a pharmacist at Pharmacy A, to cease and desist as this is in violation of KRS 315.010. Ms. Thornbury seconded, and the motion passed unanimously.

Dr. Shely moved to strike “the Nuclear Pharmacy Technician Program at the University of Tennessee” and replace it with “an accredited university affiliated nuclear pharmacy technician program” in 201 KAR 2:045 Section 1 (2) and to add the same language in Section 3 (1). Mr. Leake seconded, and the motion passed unanimously.

Mr. Leake moved to authorize Mr. Burleson to bring forward any information in any form that Mr. Burleson deems appropriate as long as he is directed to do so by the Board or its President. Ms. Thornbury seconded, and the motion passed unanimously.

Mr. Leake moved to have a special called board meeting with an agenda of the three proposed regulations, Automated Medication System, Common Database, and Centralized Processing of Prescription Drug Orders on September 26, 2007 at the Board Office, Spindletop Administration Building, 2624 Research Park Drive, Lexington, Kentucky, at 9:00 a.m. Ms. Simpson seconded, and the motion passed unanimously.

Automated Medication System (New). Dr. Shely moved to have the Executive Director and Board Counsel, if necessary, insert language and other changes from this discussion and present another draft of the Automated Medication System regulation at the special called meeting on September 26, 2007. Mr. Leake seconded, and the motion passed unanimously.

CONTINUING EDUCATION:

Ms. Thornbury moved to accept the continuing education programs 07-29 through 07-38 as recommended. Ms. Simpson seconded, and the motion passed unanimously.

OLD BUSINESS:

Mr. Burlison is to review the July 11, 2007 Board Meeting Minutes to clarify the decision made on communicating with Questhouse regarding the policy of bringing items to guests at Questhouse.

NEW BUSINESS:

When a person has made multiple appearances before the Board, President Orzali requested that transcripts, Minutes, and/or previously supplied Board packet information from the previous appearance(s) be included in the Board packet.

Mr. Leake moved to direct Mr. Burlison to update 201 KAR 2:040 Registration of pharmacist interns, removing all references to the University of Kentucky College of Pharmacy and using more generic terminology. Ms. Simpson seconded, and the motion passed unanimously.

ADJOURNMENT: On motion by Mr. Leake, seconded by Dr. Shely, and passed unanimously, President Orzali adjourned the meeting at 4:30 p.m. There will be a special Board Meeting on September 26, 2007 at the Board Office at 9:00 a.m. to discuss three new regulations, Automated Medication System, Common Database, and Centralized Processing of Prescription Drug Orders. The next regularly scheduled Board meeting is scheduled to begin at 9:00 a.m. on November 16, 2007 at the Board Office.

Michael Burlison, R.Ph.
Executive Director