

**KENTUCKY BOARD OF PHARMACY
SPINDLETOP ADMINISTRATION BUILDING SUITE 302
2624 RESEARCH PARK DRIVE
LEXINGTON KY 40511
NOVEMBER 16, 2007
9:00a.m.**

Agenda

I. CALL TO ORDER

II. MINUTES

- *A. October 8, 2007

III. APPEARANCES

- *A. Darrell Greenwalt
- *B. Philip Garber

IV. INTERAGENCY

- *A. 906 KAR 1:160 Monitoring system for products containing ephedrine, pseudoephedrine, or phenylpropanolamine

V. BOARD REPORTS

- A. Board President
 - 1. NABP Committee-December 2007
- B. Board Members
- C. Board Executive Director
 - *1. eMARS (September 07, October 07)
 - *2. 2008-2010 Budget
- D. Board Staff
- E. PRN Chair
 - *1. CAPTSA

VI. CURRENT/PENDING CASES

- A. OAG-Cheryl Lalonde
- *B. Case Update
 - Case No. 07-0022B, 07-0052B, 07-0055A, 07-0055B, 07-0058A, 07-0058B, 07-0059, 07-0060, 07-0069, 07-0066, 07-0070B, 07-0073, 07-0048, 07-0074
- *C. Case Review

VII. RECIPROCITY/RELICENSURE/INTERNSHIP

- *A. Herman Watford-Reciprocity

VIII. CORRESPONDENCE/COMMUNICATIONS

- *A. Brent Bridges-Dual PIC

IX. NABP

X. LEGISLATION/REGULATIONS

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

XI. CONTINUING EDUCATION

XII. FINES

XIII. OLD BUSINESS

XIV. NEW BUSINESS

- *A. False Claims Act (FCA)

XV. FYI

***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

November 16, 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 9:03 a.m.

Members present: Peter Orzali, Mike Leake, Anne Policastri, Catherine Shely, Sandy Simpson, and Patricia Thornbury. Staff: Michael Burlson, Executive Director; Jeffrey L. Osman, Pharmacy Inspections and Investigations Coordinator; Katie Busroe, Steve Hart 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; Jan Gould, Kentucky Retail Federation; Brandi Johnson, CVS; Karriann Wood, Omnicell; Kell Dixon and Scott Greenwell, Humana; Roxann Fry, Greater Louisville Inc.; Richard Ross; Philip Garber; Darrell Greenwalt; and Kristin Martin, Stacia Roser, Lindsey Settles, Stephanie Lemaster, and Jeff Ponatoski, College of Pharmacy students. Melanie Curtis, Court Reporter, recorded the meeting.

MINUTES: On motion by Dr. Policastri, seconded by Mr. Leake and passed unanimously, the Minutes of the Special Called Board Meeting October 8, 2007 were adopted as amended.

APPEARANCES: **Darrell Greenwalt.** Mr. Greenwalt was sworn in by Melanie Curtis, Court Reporter. Mr. Greenwalt appeared before the Board asking for reinstatement of his Kentucky pharmacist's license. Mr. Greenwalt gave an overview of the events that lead to the loss of his license. Mr. Greenwalt was convicted of selling physician samples in his pharmacy and was impaired. After discussion, Ms. Thornbury moved to reinstate Mr. Greenwalt's Kentucky pharmacist license with the stipulations as follows: 5 years probation; shall attend AA/NA meeting no less than 6 times per 2 week period or 12 meetings per calendar month; Board shall conduct semi-annually inspections at all locations of employment or practice as a pharmacist and all pharmacies owned, the cost of which not to exceed \$500 per inspection, shall be paid to the Board within 30 days of invoicing; continuing education requirements must be satisfied, renewal fees and any penalties must be paid, and a complete renewal application must be submitted; maximum hours of work: 45 hours/week or 90 hours/2 weeks, with a maximum of 50 hours in any 7 consecutive days and no overtime; shall provide a copy of this Agreed Order to all employers and pharmacists-in-charge; shall sign an aftercare contract, to include drug counselor if indicated, with the Pharmacist Recovery Network

Committee (PRNC) for the length of the Agreed Order; any violation of this Agreed Order or PRN contract shall be reported to the Board and PRN Chair within 24 hours of violation; shall notify Board of change of home address, telephone number, and/or email within 7 days of change; shall provide to the Board and PRNC a signed release granting the Board and PRNC access to all medical records; shall provide the Board and PRNC with written monthly reports of all AA/NA meetings; shall agree to provide observed urine, other body fluid, or hair samples for drug/alcohol screens at the direction of PRNC, the Board or any other monitoring body; provide copies of any results of any screens ordered to the Board and PRNC; provide notification to PRN Chair, Board and testing company of anything that may affect pharmacist's availability for screens prior to event, a missed screen shall be cause for reporting such to the Board, any positive screen that is a violation of the Agreed Order or PRN contract shall be communicated to the Board by the PRN Chair within 24 hours, a report indicating a presumptive presence shall constitute a conclusive basis, without the necessity of a hearing, for a determination that pharmacist is not in compliance with the terms of this Agreed Order of Reinstatement; shall agree to abstain from any and all mood-altering chemicals, except as prescribed by pharmacist's physician and only after consultation with PRN Chair; shall notify PRN Chair in advance if any mood-altering and/or potentially addictive medications are required or recommended by pharmacist's physician; shall provide documentation to PRN Chair of the need for the medication within 3 days; shall renew verification with PRN Chair every 90 days if need for medication is ongoing; shall give up the right to self medicate with the exception of single entity OTC NSAIDS and acetaminophen; shall be excluded from accepting a position of pharmacist-in-charge, power of attorney, or preceptor; shall advise Board at all times of place of employment and shall only practice at a location with a work schedule that has received prior approval of the Board or its President; shall obtain all prescriptions and those of family at a pharmacy designated in writing to the Board; prescriptions may not be filled by a family member or at any family owned pharmacy and shall not dispense any drugs for self or family; shall attend within 1 year of entry of this Agreed Order either the University of Utah School on Alcoholism and other Drug Dependencies, CAPTASA, or SE PRN meeting and shall provide a certificate of completion; shall provide monthly written self performance evaluation to the Board and PRN Chair and shall make all appearances before the PRN Committee as requested, including an annual appearance closest to the anniversary date of reinstatement; committing any act that results in violation of federal or state pharmacy or drug statute or regulation, may result in an emergency suspension of pharmacist's license, require an appearance before the Board, or result in a complaint against pharmacist's license with the Board imposing any applicable penalties; shall not seek to amend or modify this Agreed Order. Above information shall be reported to NABP and is subject to disclosure under the Kentucky Open Records Act. Mr. Leake seconded, and the motion passed unanimously.

Philip Garber. Mr. Garber was sworn in by Melanie Curtis, Court Reporter. Mr. Garber appeared before the Board requesting that he be allowed to sit for examination for a Kentucky pharmacist's license. Mr. Garber was sentenced to 41 months in a federal penitentiary after being convicted of three counts: theft from an organization receiving federal funds, engaging in monetary transaction in property derived from an unlawful

activity, and tax evasion. As a result, his Ohio pharmacist's license was permanently revoked by the Ohio Board of Pharmacy. Mr. Leake moved to deny Mr. Garber's request to sit for examination for a Kentucky pharmacist's license. Dr. Policastri seconded. A role call vote was taken and the motion passed unanimously.

INTERAGENCY: A draft of 906 KAR 1:160 Monitoring system for products containing ephedrine, pseudoephedrine, or phenylpropanolamine, from the Office of Inspector General was presented to the Board. Jan Gould stated that additional changes to the regulation would be forthcoming.

BOARD REPORTS:

Board President. Mr. Orzali was named to the NABP National Drug Task Force on Drug Diversion Committee. The committee meets in January 2008 at the NABP offices in Mount Prospect, Illinois. Dr. Shely moved for the Board to pay for any of Mr. Orzali's expenses incurred for the trip that are not covered by NABP. Mr. Leake seconded, and the motion passed unanimously.

Board Members. Ms. Thornbury reported that she attended the Kentucky Board of Nursing's Advanced Registered Nurse Practitioners Council meeting on October 16, 2007. The Council is working on writing statements of ethics for advanced registered nurse practitioners.

Board Executive Director. 1) EMars monthly reports for September and October were presented to the Board. 2) A copy of the 2008-2010 budget was presented to the Board. 3) Dr. Shely moved to approved the following out of state travel for 2008: Executive Director to attend NABP Legislation Committee, January 24-25, 2008; Executive Director, President and Ms. Thornbury to attend APhA Annual Meeting in San Diego, March 14-18, 2008; all Board Members, inspectors and Board attorney to attend NABP Annual Conference in Baltimore, May 17-21, 2008, and NABP District III Meeting in Alabama, August 2-6, 2008; Executive Director, Dr. Shely and staff to attend American Society of Health-System Pharmacists Meeting in Orlando, December 7-11, 2008; and President to attend National Community Pharmacists Association Annual Meeting in Tampa, October 11-15, 2008. Dr. Policastri seconded and the motion passed unanimously. 4) It has been confirmed that the September 10, 2008 Board Meeting will be at University of Kentucky Student Center for the PY3 students.

PRN Chair. Brian Fingerson announced CAPTASA will be held January 25-26, 2008 in Lexington and presented the program.

CURRENT/PENDING CASES:

CASE UPDATES:

Mr. Leake moved for acceptance and entry of the proposed Agreed Orders as written. Dr. Shely seconded, and the motion passed unanimously.

Case No. 06-0068; Case No. 06-0115B; Case No. 06-0115D; Case No. 06-0115F;
Case No. 07-0007; Case No. 07-0009; Case No. 07-0022A; Case No. 07-0022B;
Case No. 07-0048; Case No. 07-0052B; Case No. 07-0055A; Case No. 07-0055B;

Case No. 07-0058A; Case No, 07-0058B; Case No. 07-0059; Case No. 07-0060; Case No. 07-0066; Case No. 07-0069; Case No. 07-0070B; Case No. 07-0073; and Case No. 07-0074.

CASE REVIEW COMMITTEE:

Mr. Leake moved for acceptance of the Case Review Committee recommendations for the following case reports. Ms. Simpson seconded, and the motion passed unanimously.

Case No. 05-0070. Pharmacist was allegedly charged with the theft of a legend drug. Alleged violation of law: KRS 217.182(7). 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. 07-0041. Pharmacist allegedly diverted phentermine and is impaired. Alleged violations of law: KRS 315.121(1)(b), (2)(d), and (2)(e). 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. 07-0054A. Pharmacy permit holder allegedly committed a medication dispensing error, changing the strength of medication and not the quantity. Alleged violation of law: KRS 315.121 (2)(d). CRC Recommendation: Case is dismissed.

Case No. 07-0054B. Pharmacist allegedly committed a medication dispensing error, changing the strength of medication and not the quantity. 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. 07-0065A. Pharmacy permit holder allegedly sold a misbranded drug as the result of a medication error. Alleged violation of law: KRS 315.121 (2)(d). CRC Recommendation: Case is dismissed.

Case No. 07-0065B. Pharmacist alleged committed a medication error by mislabeling the medication. 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. 07-0068A. Pharmacy permit holder allegedly sold a misbranded drug as a result of a medication error. Prescription was supposed to be Prednisone 50 mg, but was filled with Primidone 50 mg. Alleged violation of law KRS 315.121(2)(d). CRC Recommendation: Case is dismissed.

Case No. 07-0068B. Pharmacist allegedly committed a medication error. Prescription was supposed to be Prednisone 50 mg, but was filled with Primidone 50 mg. 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. 07-0075A. Pharmacy permit holder allegedly sold incorrect tablet count on a drug. A complaint was received that a customer received a prescription for Oxycodone and it was 10 pills short. Pharmacy permit holder was unable to produce record keeping requested by Board Inspector. 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. 07-0075B. Pharmacist allegedly committed a medication error. A complaint was received that a customer received a prescription for Oxycodone and it was 10 pills short. 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. 07-0076. Pharmacist allegedly engaged in unethical and unprofessional conduct by committing a medication error. Pharmacist allegedly filled a tramadol 50 mg prescription with trazodone 50 mg. The 91 year old patient experienced a setback on her recovery and was “out of it” for 2 to 3 days after taking the trazodone. 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. 07-0077A. Pharmacy permit holder allegedly sold a misbranded drug by giving the wrong prescription to the wrong person. 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. 07-0077B. Pharmacist allegedly committed a medication error by giving the wrong prescription to the wrong person. 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. 07-0077C. Pharmacist allegedly committed a medication error by giving the wrong prescription to the wrong person. 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. 07-0078A. Pharmacy permit holder allegedly sold a misbranded drug by labeling inappropriately. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: Case is dismissed.

Case No. 07-0078B. Pharmacist allegedly committed a medication error by labeling inappropriately. 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. 07-0079A. Pharmacy permit holder allegedly engaged in unprofessional conduct by not dispensing prescriptions appropriately. Alleged violations of law: KRS 315.121(1)(a)(f), and 2(d)(h). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 07-0079B. Pharmacist allegedly engaged in unprofessional conduct by not dispensing prescriptions appropriately. Alleged violations of law: KRS 315.121(1)(a)(f), and 2(d)(h). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 07-0080. Pharmacist allegedly failed to complete 1.5 units of pharmacy continuing education. Pharmacist completed 1.4 of 1.5 units for 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. 07-0086. Pharmacist allegedly violated Agreed Order by not obtaining prior approval of worksites. Alleged violation of law: KRS 315.121(1)(i). 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. 07-0087. Pharmacy permit holder sold and closed business operations prior to notifying the Board office. Alleged violation of law: 201 KAR 2:106 Section 2(1)(c). 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. 07-0088. Manufacturer permit holder allegedly failed to renew permit in a timely manner and continued to operate, resulting in operating as a manufacturer without a current permit. Alleged violations of law: KRS 315.036(1) and KRS 315.020(2). 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. 07-0089. Manufacturer permit holder allegedly failed to renew permit in a timely manner and continued to operate, resulting in operating as a manufacturer without a current permit. Alleged violation of law: KRS 315.036(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. 07-0090. Special limited medical gas permit holder allegedly failed to provide complete documentation for a change of ownership in a timely manner and continued to operate, resulting in operating as a medical gas pharmacy without a current permit to reflect new owners and pharmacist-in-charge. Alleged violations of law: KRS 315.035(1)(5) and KRS 315.020(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. 07-0083. Pharmacist allegedly violated previous Agreed Order of Reinstatement by relapsing. Alleged violation of law: KRS 315.121(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. 07-0047. Pharmacist violated Kentucky Pharmacist Recovery Network agreement. Alleged violation of law: KRS 315.121(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.

RECIPROCITY/RELICENSURE/INTERNSHIP:

Herman Watford. Mr. Watford requested that he be allowed to reciprocate his Georgia pharmacist's license to Kentucky. His licensed has been disciplined in 1989 in Georgia as a result of impairment issues in California. Mr. Leake moved to allow Mr. Watford to proceed with reciprocating his Georgia pharmacist's license to Kentucky. Ms. Simpson seconded, and the motion passed unanimously.

CORRESPONDENCE/COMMUNICATIONS:

Brent Bridges. Dr. Bridges requested to be a dual pharmacist-in-charge at two locations, Methodist Hospital Pharmacy - inpatient and Methodist Hospital Pharmacy - outpatient. Dr. Shely moved to allow Dr. Bridges to be dual pharmacist-in-charge at Methodist Hospital Pharmacy – inpatient and Methodist Hospital Pharmacy - outpatient. Dr. Policastri seconded, and the motion passed unanimously.

LEGISLATION/REGULATIONS:

Scott Greenwell, Humana, and Roxann Frye, Greater Louisville, Inc., requested that the Board continue moving forward with the proposed regulations on Automated Medication Systems, Common Database, and Centralized Processing of Prescription Drug Orders. Ms. Simpson moved for the Board to have a structured workshop special meeting regarding Automated Medication Systems, Common Database, and Centralized Processing of Prescription Drug Orders at the Board office on February 13, 2008 at 9 a.m. Dr. Shely seconded, and the motion passed unanimously. Dr. Shely moved that the workshop special meeting agenda be to continue with the existing drafts of Automated Medication Systems, Common Database, and Centralized Processing of Prescription Drug Orders, letting interested parties review and comment on the drafts with the Board taking the comments into consideration as the Board continues to define the proposed regulations. Ms. Simpson seconded, and the motion passed unanimously.

CONTINUING EDUCATION:

Ms. Thornbury moved to accept the continuing education programs 07-39 through 07-44 and 08-01 as recommended. Dr. Policastri seconded, and the motion passed unanimously.

OLD BUSINESS:

Ms. Thornbury stated that any responses the Board directs the Executive Director to write need to be included in the FYI section of the Board packet for Board Members to review.

NEW BUSINESS:

Jim Guinn, Legislative Research Commission, requested a Board opinion on the False Claims Act (FCA). Mr. Leake moved for the Executive Director to send a written response stating that with the amount of information provided, the Board has no opinion at this time, but would like to review any copies of draft documents regarding FCA. Ms. Thornbury seconded, and the motion passed unanimously.

Ms. Thornbury had an inquiry from a veterinarian regarding any questions or complaints the Board had received regarding veterinary medications being substandard and if an out of state pharmacy could provide veterinary medication to residents of Kentucky. Mr. Burleson explained that out of state providers of veterinary medications were required to be licensed with the Kentucky Board of Pharmacy as an out of state pharmacy. There have been no complaints regarding substandard veterinary medications.

FYI:

At the December 12, 2007 Board Meeting, Mr. Burleson is to provide the Board with information regarding the pre-filed bill enhancing KRS 218A.202.

ADJOURNMENT: On motion by Dr. Shely, seconded by Ms. Thornbury, and passed unanimously, President Orzali adjourned the meeting at 2:48 p.m. The next regularly scheduled Board meeting is scheduled to begin at 9:00 a.m. on December 12, 2007 at the Board Office.

Michael Burleson, R.Ph.
Executive Director