

**KENTUCKY BOARD OF PHARMACY
SPINDLETOP ADMINISTRATION BUILDING SUITE 302
2624 RESEARCH PARK DRIVE
LEXINGTON KY 40511
JANUARY 11, 2006 9:00a.m.**

Agenda

- I. CALL TO ORDER**
- II. MINUTES**
 - *A. December 14, 2005**
- III. APPEARANCES**
- IV. INTERAGENCY**
- V. BOARD REPORTS**
 - A. Board President**
 - 1. Pharmacy Technician Statute**
 - B. Board Members**
 - C. Board Executive Director**
 - D. Board Staff**
 - E. PRN Chairman**
 - 1. CAPTASA**
- VI. CURRENT/PENDING CASES**
 - A. OAG – C. Lalonde**
 - B. Case Update**
 - C. Case Review Committee**
- VII. RECIPROCITY/RELICENSURE/INTERNSHIP**
- VIII. CORRESPONDENCE/COMMUNICATIONS**
- IX. NABP**
- X. LEGISLATION/REGULATIONS**
- XI. CONTINUING EDUCATION**
 - A. Program Review**
- XII. FINES**
 - A. Fines Report**

XIII. OLD BUSINESS

XIV. NEW BUSINESS

***1 Student Pharmacist-Matt Martin**

***Information enclosed with this agenda**

****Information previously provided**

*****Old material with response**

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Agenda - Addendum

V. BOARD REPORTS

- *E. PRN Report**

VI. CURRENT/PENDING CASES

- *B. Case Update
Case No. 04-0105A; 05-0072; Case No. 05-0087A**

X. LEGISLATION/REGULATIONS

- *A. Prescription dispensing for formulary Compliance**
- *B. Wholesale Licensure & Prescription Medication Integrity Act**

XIV. NEW BUSINESS

- *2. Continuing Medical Education (CME) Credits**

***Information enclosed with this agenda**

****Information previously provided**

*****Old material with response**

MINUTES

KENTUCKY BOARD OF PHARMACY

Lexington, Kentucky

January 11, 2006

CALL TO ORDER: A regular meeting of the Kentucky Board of Pharmacy was held at the Board Office at Spindletop Administration Building, Suite 302, 2624 Research Park Dr., Lexington, Kentucky. President Naseman called the meeting to order at 9:13 a.m.

Members present: Greg Naseman, Becky Cooper, Mike Leake, Peter Orzali, Catherine Shely, and Patricia Thornbury. Staff: Michael Burleson, Executive Director; Jeffrey L. Osman, Pharmacy Inspections and Investigations Coordinator; Steve Hart, 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 and JD Hammond, APSC; Paula York, Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services; John Hawks, Kentucky Pharmacists Association; Chris Killmeier and Peter Cohron, Walgreens; Sue Gage, Target; Jan Gould, Kentucky Retail Federation; and Tony Tagavi and Matt Martin, University of Kentucky College of Pharmacy PY4 student. Juanita Toole, Court Reporter, recorded the meeting.

MINUTES: On motion by Dr. Shely, seconded by Ms. Cooper and passed unanimously, the Minutes of December 14, 2005 were adopted. Mr. Orzali was not present.

BOARD REPORTS: **President. 1. Pharmacy Technician Statute.** The Legislative Committee, made up of Mr. Naseman, Mr. Burleson, and Ms. Lalonde, met and suggested two changes to the statute. Mr. Leake moved to accept the changes to the Pharmacy Technician Statute as follows: Section 1 (2)(b) The person is in the employ of his son, daughter, spouse, father, mother, or legal guardian; and adding to Section 8(1) Failure to notify the Board office within fourteen (14) days of any change in home address, with the stipulation that failure to notify the Board of a change of address is not punitive in nature. Ms. Thornbury seconded, and the motion passed unanimously. Mr. Orzali was not present.

2. Dwaine Green resigned from the Pharmacist Recovery Network Committee, effective December 31, 2005. Ms. Thornbury moved to accept the recommendation of the PRN Committee to name Kenneth L. Kirsch to replace Mr. Green, effective immediately. Dr. Shely seconded, and the motion passed unanimously. Mr. Orzali was not present.

Board Members. Ms. Thornbury thanked Executive Director, Mr. Burleson, for the budget breakdown and explanation.

Board Executive Director. 1. MARS reports included for December and January. 2. Thanked Darla Sayre, administrative specialist, for all her hard work on getting online pharmacist's renewal active. From January 4, 2006 through January 10, 2006, there have been 1,104 pharmacists to renew online.

PRN Chairperson. Brian Fingerson encouraged everyone to attend the CAPTASA conference, January 28-29, 2006.

CURRENT/PENDING CASES:

Ms. Thornbury moved for acceptance and entry of the proposed Agreed Orders as written. Ms. Cooper seconded, and the motion passed unanimously. Mr. Orzali was not present.

Case No. 04-0105A; Case No. 05-0072; Case No. 05-0087A

Dr. Shely moved for acceptance of the Case Review Committee recommendations for the following case reports. Mr. Leake seconded, and the motion passed unanimously. Mr. Orzali was not present.

Case No. 03-0120 (Revisit). Pharmacist allegedly engaged in unprofessional conduct by obtaining legend drugs including controlled substances without valid authorizations from a licensed practitioner. At the October 8, 2003, Kentucky Board of Pharmacy meeting, the Board decided to attempt to resolve this case through an Agreed Order. At the June 8, 2004 meeting it was recommended that Mr. Parker be followed by Brian Fingerson for one year concerning drug screens. After the one year point the case was reviewed again at the November 22, 2005 PRN meeting, where it was determined that further investigation should be conducted. **New Information:** Pharmacist's brother is a physician and occupies one half of the building where Pharmacist has his pharmacy. Upon visiting the doctor's office to review that pharmacist's patient chart, investigator was informed he did not have to have a chart on his brother; he was adamant that he authorized the prescriptions in question and ask the investigator to leave his office. The pharmacist stated that he had fulfilled his requirements as agreed upon with the PRN committee and the case should be dismissed. The Pharmacist was told that his urine drug screens would be screened for controlled substances. In April 2005, urine tested positive for Fioricet and Ultram, which are not controlled substances. When informed that he needed to present prescriptions for Fioricet and Ultram, pharmacist's brother wrote prescriptions and dated them March 21, 2005. These two prescriptions were faxed to PRN, but were never filled at a pharmacy. The prescriptions that were filled for Ultram and Fioricet were telephoned prescriptions from pharmacist's brother. CRC Recommendation: Case is dismissed.

Case No. 05-0068. (Revisit). Pharmacist allegedly diverted controlled substances. The Board office received information about the arrest of Pharmacist. After approximately 3 months of trying to contact Pharmacist, Pharmacist did surrender pharmacist's license. On or about November 7, 2005, pharmacist contacted KY Pharmacist Recovery Network chairperson indicating that the KYPRN agreement had been signed and forwarded to the chairperson. As of November 16, 2005 the agreement has not been received. Alleged violations of law: KRS 218A.1415, KRS 218A.1417, and KRS 218A.1418. **New Information:** On December 12, 2005 the final judgment regarding the above pharmacist from the circuit court. The court placed the pharmacist on probation for five years for theft of controlled substances. Two conditions of the probation included that the pharmacist could not work directly with drugs, unless permitted by the court and continues working the KYPRN. **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. 05-0088. Pharmacist self reported his impairment. The Pharmacist admitted refilling a prescription for Ambien early and obtaining it from friends. Primarily admitted to early refills on 90 count prescription from his doctor. Pharmacist surrendered his license and has attended Guesthouse and already has an agreement with PRN and is attending the require meetings. 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. 05-0103. Pharmacy permit holder allegedly failed to report change of PIC within 14 days of change. Upon investigation it was discovered that the pharmacy operated without a PIC from 8/29/05 until 12/20/05. Alleged violations of law: 201 KAR 2:205 Section 2 (3) (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. 05-0105A. Pharmacy permit holder allegedly transfilled oxygen tanks without a permit. Upon serving an administrative subpoena for prescription records on the permit holder it was discovered that the pharmacy was transfilling oxygen tanks and had been doing so for three and a half years. Alleged violations of law: KRS 315.036. **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. 05-0105B. Pharmacist in Charge allegedly transfilled oxygen tanks without a permit. Upon serving an administrative subpoena for prescription records on the permit holder it was discovered that the pharmacy was transfilling oxygen tanks and had been doing so for three and a half years. Alleged violations of law: KRS 315.036. 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. 05-0106. Pharmacist self reported to Pharmacist Recovery Network for impairment issues, but allegedly has not followed the agreement with the Pharmacist Recovery Network. Pharmacist violations of PRN contract include Pharmacist not being in contact with PRN, not providing urine drug screens, not submitting 12-step meeting logs, not sending monthly self reports and had ignored attempts to contact him, this was reported to the Board office. The investigator interviewed the Pharmacist and the pharmacist was shocked that he had not been following the PRN contract. He stated that he had not been attending 12-step meetings because of a sick grandfather. He thought that his urine drug screens were being sent, and he assured the investigator that he had not relapsed. Alleged violation of law: 201 KAR 2:250 Section 8 (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. 05-0107. Pharmacist allegedly failed to complete 1.5 units of pharmacy continuing education in 2004. Pharmacist could not produce any CE certifications. 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. 05-0108A. Medical gas permit holder allegedly transported oxygen cylinders improperly. Alleged violations of law: 201 KAR 2:225 Section 2(2)(a) and 49 CFR 177.834 Subpart 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. 05-0108B. Pharmacist in charge allegedly allowed transported oxygen cylinders improperly. Alleged violations of law: 201 KAR 2:225 Section 2(2)(a) and 49 CFR 177.834 Subpart B. CRC Recommendation: There is sufficient evidence of a violation; however, the penalty shall be the issuance of a Letter of Reprimand.

Case No. 05-0109A. Permit holder allegedly changed ownership without proper notification and maintained legend drugs at an unlicensed location. Alleged violations of law: 201 KAR 2:205 and KRS 315.035. CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 05-0109B. Pharmacist in charge allegedly did not get proper permits after pharmacy ownership change and maintained legend drugs at an unlicensed location. Alleged violations of law: 201 KAR 2:205 and KRS 315.035. CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 05-0109C. Permit holder allegedly changed ownership without proper notification and maintained legend drugs at an unlicensed location. Alleged violations of law: 201 KAR 2:205 and KRS 315.035. CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 05-0109D. Permit holder allegedly changed ownership without proper notification and maintained legend drugs at an unlicensed location. Alleged violations of law: 201 KAR 2:205 and KRS 315.035. CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 05-0109E. Pharmacist in charge allegedly did not get proper permits after pharmacy ownership change and maintained legend drugs at an unlicensed location. Alleged violations of law: 201 KAR 2:205 and KRS 315.035. CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 05-0109F. Pharmacist in charge allegedly did not get proper permits after pharmacy ownership change and maintained legend drugs at an unlicensed location. Alleged violations of law: 201 KAR 2:205 and KRS 315.035. CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Mr. Orzali arrived at 10:00 am.

NABP: President Naseman is to serve as Kentucky's voting delegate for the annual NABP meeting.

LEGISLATION / REGULATIONS: Jan Gould appeared before the Board to present suggested changes to 201 KAR 2:280, prescription dispensing for formulary compliance. Mr. Gould presented a draft of guidelines that make therapeutic substitution automatic by default for the Medicaid program. There would be appropriate safeguards in place to protect the patient. Mr. Gould asked the Board for a willingness on the part of the Board to work with the Medicaid program to change the regulation and ideally be ready within 2 months to institute the automatic formulary substitution program. Mr. Orzali moved to direct the Executive Director to draft and file the amendments to 201 KAR 2:280, with language to allow for prescribers to have exclusion criteria based on clinical information. Mr. Leake seconded, and the motion passed unanimously.

University of Kentucky PY4 student, Tony Tagavi, representing Senator Roeding's office, presented the Wholesale Licensure and Prescription Medication Integrity Act that is being considered before the legislature. After much discussion, Ms. Thornbury moved to notify Senator Roeding that the Board was not in favor of the Wholesale Licensure and Prescription Medication Integrity Act or the Proposed State Model Legislation Relating to the Distribution of Prescription Drugs for numerous reasons. Mr. Orzali seconded, and the motion passed unanimously.

CONTINUING EDUCATION: Mr. Orzali moved to accept the continuing education programs 06-01, 06-03 and 06-04 as recommended, and deny continuing education credit for program 06-02. Dr. Shely seconded, and the motion passed 4 to 1, with Ms. Thornbury voting no.

OLD BUSINESS: The Orientation Manual will be updated to include being a delegate to NABP as one of the duties of the President of the Board of Pharmacy.

NEW BUSINESS: **Matt Martin**, University of Kentucky College of Pharmacy PY4 student, appeared before the Board. Mr. Martin is a student representative serving on American Pharmacists Association's (APhA) National Standing Committee on Policy. The Committee is advocating the use of a universal title for pharmacy students, "student pharmacist," to be used by all state Boards of Pharmacy. The Board was not opposed to the use of "student pharmacist" and will continue to take the information under advisement.

Matt Martin also brought before the Board a policy from the APhA Student Pharmacist House of Delegates asking that the Kentucky Board of Pharmacy accept Continuing Medical Education (CME) credits in addition to Pharmacy Continuing Education (CE) credits. After discussion, Mr. Orzali moved to deny the request. Ms. Thornbury seconded, and the motion passed unanimously.

Mr. Orzali moved to go into closed session based on a personnel disciplinary action pursuant to KRS 61.810 1 (c)(f). Ms. Thornbury seconded and the motion passed unanimously.

Mr. Leake moved to go back into open session. Dr. Shely seconded, and the motion passed unanimously. President Naseman requested the establishment of an evaluation committee to evaluate the Executive Director as well as review staff evaluations to determine if changes need to be made. The members of the evaluation committee will be determined at the March Board meeting.

ADJOURNMENT: On motion by Ms. Thornbury, seconded by Dr. Shely, and passed unanimously, President Naseman adjourned the meeting at 2:05 p.m. The next regularly scheduled Board meeting is scheduled to begin at 9:00 a.m. on March 8, 2006 at the University of Kentucky student center.

Michael Burleson, Executive Director

MB:lha