

**KENTUCKY BOARD OF PHARMACY
23 MILLCREEK PARK
FRANKFORT KY 40601-9230
SEPTEMBER 14, 2005 9:00a.m.**

Agenda

- I. CALL TO ORDER**

- II. MINUTES**
 - *A. JULY 6, 2005**
 - *B. JULY 10, 2005**

- III. APPEARANCES**
 - *A. Shannon Haycraft-9:15a.m.**
 - *B. Jill Jones-9:45a.m.**

- IV. INTERAGENCY**
 - *A. Automated Dispensing System for Controlled Substances in long term care**
 - *B. DEA clarification for existing requirements for Scheduled II Controlled Substances**

- V. BOARD REPORTS**
 - A. Board President**
 - 1. Board Retreat**
 - 2. Board Exam October 5, 2005**
 - 3. Changes in Statute/Regulation concerning Board Exam**
 - B. Board Members**
 - C. Board Executive Director**
 - *1. Telehealth Regulation**
 - *2. Map of new location**
 - D. Board Staff**
 - E. PRN Chairman**

- VI. CURRENT/PENDING CASES**
 - A. OAG – C. Lalonde**
 - B. Case Update**
 - Case No. 04-0102**
 - Case No. 05-0024A**
 - Case No. 05-0025**
 - Case No. 05-0031A**
 - Case No. 05-0041A**
 - Case No. 05-0042**

Case No. 05-0046A

Case No. 05-0048A

Case No. 05-0048B

Case No. 05-0058B

C. Case Review Committee

VII. RECIPROCITY/RELICENSURE/INTERNSHIP

***A. RajaKumar Donthi: Request for internship by research**

***B. Billy Ray Moore: Request to take Board examination**

VIII. CORRESPONDENCE/COMMUNICATIONS

***A. Dr. Trish Freeman: Request to purchase pharmaceuticals**

IX. NABP

A. Request for Executive Director to attend NABP Fall Educational Conference

X. LEGISLATION/REGULATIONS

XI. CONTINUING EDUCATION

A. Program Review

XII. FINES

A. Fines Report

XIII. OLD BUSINESS

XIV. NEW BUSINESS

****VAWD/NABP Model Rules Wholesalers/Manufactures**

***Information enclosed with this agenda**

****Information previously provided**

*****Old material with response**

MINUTES

KENTUCKY BOARD OF PHARMACY

Frankfort, Kentucky

September 14, 2005

CALL TO ORDER: A regular meeting of the Kentucky Board of Pharmacy was held at the Board Office at 23 Millcreek Park, Frankfort, Kentucky. President Edwards called the meeting to order at 9:08 a.m.

Members present: Mark Edwards, Becky Cooper, Georgina Jones, Greg Naseman, Peter Orzali, and Patricia Thornbury. Staff: Michael Burlison, 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. Pharmacy and Drug Inspector Steve Hart was absent. Guests: Michael S. Whitaker, Pharmacist Recovery Network Committee; Ralph Bouvette and Allison Cubit, APSC; Paula York, Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services; John Hawks, Leon Claywell and Susan Gitzinger, Kentucky Pharmacists Association; Jan Gould, Kentucky Retail Federation; Trish Freeman, University of Kentucky College of Pharmacy; Eric Vermillion, Kristina Wimpee, R. Jared Thornton, and Neal Slard, University of Kentucky College of Pharmacy PY4 students; Jill Jones; Shannon and Kasey Haycraft; and Mike Leake, new Board appointee. Melanie Curtis, Court Reporter, recorded the meeting.

MINUTES: On motion by Ms. Jones, seconded by Mr. Naseman and passed unanimously, the Minutes of July 6, 2005 were adopted as amended. On motion by Mr. Naseman, seconded by Mr. Orzali and passed unanimously, the Minutes of July 10, 2005 were adopted as amended.

APPEARANCES: Shannon Haycraft. Mr. Haycraft appeared before the Board to petition for reinstatement of his Kentucky pharmacist's license. Mr. Haycraft was placed under oath by Ms. Curtis, Court Reporter. Mr. Haycraft gave a brief overview of the cause leading to the loss of his pharmacist's license, his progress and his treatment. Mr. Naseman moved to reinstate with an Order of Reinstatement with stipulations as follows: 5 years probation; maximum hours of work: 40 hrs/wk or 80 hrs/2wk, with exceptions to be approved by PRN Committee chairman and notification provided to the Board; shall not serve as pharmacist-in-charge or have power of attorney during terms of probation; shall not be a preceptor; must provide copy of Agreed Order to all employers; must enter into an aftercare contract with PRN Committee, to include drug counselor if indicated; submission of signed release for Board access to all medical records; must attend NA/AA meetings no less than 3 times per week; submission to the Board of written monthly reports of all NA/AA meetings; submit to random observed urine/blood screens; shall be subject to quarterly inspections by the Board at all places of employment, with audits to

be conducted if necessary, the cost of each inspection not to exceed \$500; perpetual inventory of Scheduled II, III, and IV drugs to be required at each place of employment; shall not ingest any mood altering substances whether legend or nonlegend medications including alcohol; notification to the Board within 10 days of all legend and nonlegend drugs prescribed/ingested; Board or Board President to approve all pharmacies/worksites prior to employment; shall not dispense any drugs for himself or his family members; shall obtain all prescriptions and those of family members at pharmacy designated in writing to the Board; attendance at the University of Utah School on Alcoholism and Other Drug Dependencies or the South Eastern PRN meeting within one year; provide PRN Committee with a written self-performance evaluation monthly; shall make one appearance before the PRN Committee in 6 months; any violation of state and/or federal pharmacy or drug laws constitutes violation of Agreed Order and may result in an emergency suspension of pharmacist's license pursuant to KRS 315. The Agreed Order shall be reported to NABP. Order of Reinstatement to be drafted and forwarded to Mr. Haycraft for his signature and upon its return to be signed by President Edwards. Mr. Orzali seconded, and the motion passed with a vote of 4 to 1. Ms. Jones voted no.

Jill Jones. Ms. Jill Jones had appeared before the Board on July 6, 2005 to petition for reinstatement of her Kentucky pharmacist's license. Ms. Jill Jones was placed under oath by Ms. Curtis, Court Reporter. Ms. Georgina Jones moved to remove from table the original motion for reinstatement of Ms. Jill Jones' Kentucky pharmacist's license. Ms. Thornbury seconded and the motion passed unanimously. Ms. Thornbury moved to revisit Ms. Jones' request for reinstatement. Mr. Naseman seconded and the motion passed unanimously. After discussion, Ms. Georgina Jones moved to table any decision on reinstatement of Ms. Jill Jones' Kentucky pharmacist's license until Ms. Jill Jones has been evaluated by a PRN Committee approved addictionologist, substance abuse counselor, or psychologist. Ms. Thornbury seconded and the motion passed unanimously. The Board is to send a packet containing all materials related to Ms. Jill Jones, including but not limited to past Agreed Orders and transcripts of Board appearances, to the evaluator.

INTERAGENCY: Paula York, Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services. **A.** DEA has amended its regulation to allow, where state laws permit, for retail pharmacy installation of automated dispensing systems (ADS) at long term care facilities. Kentucky state law allows for the use of ADS at long term care facilities if the medication is patient specific, however 201 KAR 2:074 Section 4 (11) does not allow for floor stock in long term care facilities. Pursuant to 902 KAR 55:070, certain long term care facilities are allowed to store 2 doses each of three different injectable controlled substances in an emergency kit.

B. DEA has not changed the opinion that multiple Scheduled II prescriptions written on the same day with instructions to fill on different dates constitutes refilling of a Scheduled II drug. Instead of issuing multiple prescriptions at the same time, it is suggested that the prescriber write for larger quantities at a time or mail prescriptions to the patient or pharmacy at the appropriate time.

BOARD REPORTS: President. 1. The Board Retreat is scheduled for November 12-13, 2005 at the Cincinnati Marriott in Covington, Kentucky. Suggested agenda items include technician registration, Medicare Part D, and clinical pathways regarding hospitalized patients. The Board Retreat agenda will be finalized at the October 5, 2005 Board of Pharmacy meeting.

2. The Kentucky Operative Examination will be given on October 5, 2005 at the Board office in Lexington, Kentucky. There are 8 examinees. The exam will begin at 8 a.m., with one examinee beginning at 7:30 a.m.

3. After discussion, Mr. Naseman moved to proceed to change 201 KAR 2:020 Section 2 (3) to consist of the NAPLEX and jurisprudence examinations, eliminating the operative or practical examination. Ms. Jones seconded and the motion passed by a vote of 3 to 2. Ms. Cooper and Ms. Thornbury voted no.

4. An executive order was received appointing two new board members with terms beginning January 1, 2006, serving through December 31, 2009: Mike Leake to replace Mark Edwards and Catherine Shely to replace Georgina Jones.

Board Members: Ms. Thornbury stated that NACDS meeting in San Diego was very informative with Medicare Part D causing much discussion. She thanked Jeff Osman for attend the ARNP meeting in her place. Ms. Thornbury was previously approved to attend the NCPA meeting in Florida.

Ms. Georgina Jones excused herself for the rest of the Board meeting.

Board Executive Director:

1. Written comments were received on the proposed Telehealth Regulation, 201 KAR 2:290. Several concerned parties were present to discuss the proposed regulation. Leon Claywell and John Hawks from the Kentucky Pharmacists Association requested permission to be recognized. Mr. Claywell and Mr. Hawks were sworn in by Ms. Curtis, Court Reporter. Of primary concern was the vagueness of the regulation as written with no definition of an underserved area. Mr. Naseman moved to withdraw the Telehealth Regulation from the regulatory process but open the issue up for further discussion at the November Board Retreat. Mr. Orzali seconded the motion. The motion was unanimously defeated. At that time Ralph Bouvette and Allison Cubit from APSC requested permission to be recognized. Dr. Bouvette and Dr. Cubit were sworn in by Ms. Curtis, Court Reporter. It was argued that KRS 315.310 does not allow for an area out of which drugs are dispensed to be accessed electronically by a pharmacist in another location. After an in depth discussion, Mr. Naseman made a motion that the Telehealth Regulation be withdrawn from the regulatory process and be given further consideration. Ms. Cooper seconded and the motion passed unanimously.
2. The Board office is scheduled to move September 19-20, 2005 to the Spindletop Administration Building in Lexington, Kentucky.

3. Mr. Orzali move to send one member of the PRN Committee to the South Eastern PRN meeting in Atlanta, Georgia, November 11-13, 2005. Ms. Cooper seconded and the motion passed unanimously.

PRN Chairman. Mike Whitaker is representing Brian Fingerson for the PRN Committee.

CURRENT/PENDING CASES: Mr. Naseman moved for acceptance and entry of the proposed Agreed Orders as written. The motion was seconded by Ms. Thornbury and passed unanimously.

Case No. 04-0102; Case No. 05-0024A; Case No. 05-0025; Case No. 05-0031A; Case No. 05-0041A; Case No. 05-0042; Case No. 05-0046A; Case No. 05-0047A; Case No. 05-0047B; Case No. 0048A; Case No. 0048B; Case No. 0058A; Case No. 0048B

CASE REVIEW COMMITTEE: Mr. Naseman moved for acceptance of the Committee recommendations for the following case report; the motion was seconded by Mr. Orzali and passed unanimously:

Case 04-0075A (revisit) Pharmacy permit holder allegedly sold misbranded drug. Pharmacist allegedly purchased, acquired and dispensed physician samples at three pharmacies he owed. It is alleged that he did this independently without the knowledge of others employed by him. Alleged violation of law: Title 18 USC Section 371, Title 21 USC Section 331 (t), Title 21 USC Section 353 (c)(1), Title 21 USC Section 333 (b)(1)(B), KRS 217.055, KRS 217.065, KRS 315.121 (1)(c)(1), 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 04-0075B (revisit) Pharmacy permit holder allegedly sold misbranded drug. Pharmacist allegedly purchased, acquired and dispensed physician samples at three pharmacies he owed. It is alleged that he did this independently without the knowledge of others employed by him. Alleged violation of law: Title 18 USC Section 371, Title 21 USC Section 331 (t), Title 21 USC Section 353 (c)(1), Title 21 USC Section 333 (b)(1)(B), KRS 217.055, KRS 217.065, KRS 315.121 (1)(c)(1), 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 04-0075C (revisit) Pharmacy permit holder allegedly sold misbranded drug. Pharmacist allegedly purchased, acquired and dispensed physician samples at three pharmacies he owed. It is alleged that he did this independently without the knowledge of others employed by him. Alleged violation of law: Title 18 USC Section 371, Title 21 USC Section 331 (t), Title 21 USC Section 353 (c)(1), Title 21 USC Section 333 (b)(1)(B), KRS 217.055, KRS 217.065, KRS 315.121 (1)(c)(1), 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 04-0075D (revisit) Pharmacist allegedly sold misbranded drugs. Pharmacist allegedly purchased, acquired and dispensed physician samples at three of the pharmacies that he owned. It is alleged that he did this independently without the knowledge of others employed by him. The pharmacist subsequently plead to this felonious activity in the United States District Court on June 17, 2005. Alleged violation of law: Title 18 USC Section 371, Title 21 USC Section 331 (t), Title 21 USC Section 353 (c)(1), Title 21 USC Section 333 (b)(1)(B), KRS 217.055, KRS 217.065, KRS 315.121 (1)(c)(1), KRS 315.121 (2)(d)(e)(f). **Accepted** at January 5, 2005 Case Review.

Case 04-0121 (revisit) Wholesaler permit holder allegedly did not renew permit in a timely manner and continued to operate, resulting in operating as a wholesaler without a current permit. Alleged violation of law: KRS 315.036(1). New Information: No response was received from the Agreed Order of Surrender; the wholesaler is not operating at this time. **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. 05-0006 (revisit). Pharmacy permit holder allegedly violated previous Agreed Order. Pharmacy entered into an Agreed Order with the Kentucky Board of Pharmacy on December 3, 2003. The Order required the hospital administrator to complete and have certified 6 hours of continuing education on Kentucky pharmacy law by December 3, 2004. A letter dated January 11, 2005, was sent to the administrator. The Board office received a telephone call from the administrator stating that the pharmacy had filed bankruptcy and was under new ownership. She expressed that she was unaware of the Agreed Order and felt it was not the new owner's responsibility. **New Information:** Continuing Education was received. Alleged violation of law: KRS 315.121(1)(i). **CRC Recommendation:** Case is dismissed.

Case 05-0035A Pharmacy permit holder allegedly filled an unauthorized prescription. The Board office received a complaint from a doctor stating that a prescription was refilled for a patient for alprazolam that was not authorized. Upon investigating it could not be confirmed from records that the prescription had been filled. Alleged violation of law: KRS 315.121(2)(f). **CRC Recommendation:** Case is dismissed.

Case 05-0035B Pharmacist allegedly filled an unauthorized prescription. The Board office received a complaint from a doctor stating that a prescription was refilled for a patient for alprazolam that was not authorized. Upon investigating it could not be confirmed from records that the prescription had been filled. Alleged violation of law: KRS 315.121(2)(f). **CRC Recommendation:** Case is dismissed.

Case 05-0049 Pharmacist practicing under the influence of alcohol or mind altering substance. Pharmacy Intern called the Board office to report the pharmacist on duty

appeared to be intoxicated. She also reported that he had left the pharmacy on several occasions this particular day. Police were called, pharmacist was asked to meet the inspector and police on the outside of the building where the pharmacist was having a difficult time standing. The police performed a breathalyzer test and no alcohol was detected, however when asked for a list of medications that the pharmacist was currently taking the following were listed: crestor, oxycontin, atenolol, cymbalta, tricor, clonazepam, lidoderm patch. The pharmacist refused to take a drug test, he wanted an attorney. After investigating it was found that the pharmacist did not list all medications he was taking. Alleged violation of law: KRS 315.121 (1)(b), 315.121 (2)(d), 315.121 (2)(e). **CRC Recommendation:** There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case 05-0050A Pharmacy permit holder allegedly committed a medication error by failing to dispense the correct quantity of generic Demerol. A complaint was received from a patient stating that his prescription was for 120 and he actually received 79 tablets. Alleged violation of law: KRS 315.121 (2)(d). **CRC Recommendation:** Case is dismissed.

Case 05-0050B Pharmacist allegedly committed a medication error by failing to dispense the correct quantity of generic Demerol. A complaint was received from a patient stating that his prescription was for 120 and he actually received 79 tablets. Alleged violation of law: KRS 315.121 (2)(d). **CRC Recommendation:** There is sufficient evidence of a violation; however, the penalty shall be the issuance of a Letter of Reprimand.

Case 05-0052A Pharmacy permit holder allegedly sold misbranded drug. Complaints have been received; the first and second complaints stated that physician samples were being sold. The third complaint was that the pharmacy allegedly re-dispensed returned prescriptions. The formal complaint stated: dispensing legend drugs without a prescription, filling/refilling duplicate therapy Rx's for patients with different MD's, refilling controlled substance Rx's early, giving employees other patient's prescriptions after they had returned them to the pharmacy, allowing pharmacy tech. to take new prescriptions from a Dr. by telephone, insurance fraud by billing insurance companies for prescriptions that were not dispensed, dispensing physician samples. A list of over 50 different drugs were identified. Alleged violation of law: KRS 315.121(2), 201 KAR 2:205 section 2 (3)(a)(b), 201 KAR 2:045 section 2 (3)(b)1,2; 201 KAR 2:190 section 1; 210 KAR 2:210 section 4 (1); 218.170 (2); 218A.180(2)(3)(4); 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 05-0052B Pharmacist allegedly sold misbranded drug. Complaints have been received; the first and second complaints stated that physician samples were being sold. The third complaint was that the pharmacy allegedly re-dispensed returned prescriptions. The formal complaint stated: dispensing legend drugs without a prescription, filling/refilling duplicate therapy Rx's for patients with different MD's, refilling controlled substance Rx's early, giving employees other patient's prescriptions after they had returned them to the pharmacy, allowing pharmacy tech. to take new

prescriptions from a Dr. by telephone, insurance fraud by billing insurance companies for prescriptions that were not dispensed, dispensing physician samples. A list of over 50 different drugs was identified. Pharmacy is closed 5/11/05. Alleged violation of law: KRS 315.121(2), 201 KAR 2:205 section 2 (3)(a)(b), 201 KAR 2:045 section 2 (3)(b)1,2; 201 KAR 2:190 section 1; 210 KAR 2:210 section 4 (1); 218.170 (2); 218A.180(2)(3)(4); 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 05-0053A Pharmacy permit holder allegedly sold misbranded drug as the result of medication error. The pharmacy allegedly dispensed fewer dosage units than prescribed and labeled on the container. A written complaint was filed alleging that the pharmacy shorted her prescription for Lortab 7.5mg. When the patient returned to the pharmacy with the bottle, it was determined that the patient was shorted and the additional units were given to the patient. Alleged violation of law: KRS 217.065 (1) and 201 KAR 2:210 section 1 (92)(e)(3). **CRC Recommendation:** Case is dismissed.

Case 05-0053B Pharmacist allegedly sold misbranded drug as the result of medication error. The pharmacist allegedly dispensed fewer dosage units than prescribed and labeled on the container. A written complaint was filed alleging that the pharmacy shorted her prescription for Lortab 7.5mg. When the patient returned to the pharmacy with the bottle, it was determined that the patient was shorted and the additional units were given to the patient. Alleged violation of law: KRS 217.065 (1) and 201 KAR 2:210 section 1 (92)(e)(3). **CRC Recommendation:** There is sufficient evidence of a violation; however, the penalty shall be the issuance of a Letter of Reprimand.

Case 05-0055A Pharmacy permit holder allegedly committed a medication error by dispensing Lordrane Liquid for Lodrane D Suspension. 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 05-0055B Pharmacist committed a medication error by dispensing Lordrane Liquid for Lodrane D Suspension. 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 05-0059A Pharmacy permit holder allegedly filled two different prescriptions without authorization from a physician. A complaint was received from the Division of Mental Retardation. Upon investigation it was determined that the patient had been previously been prescribed Zoloft and Risperdal, the two drugs in question, and that both prescriptions were filled legally. The confusion happened when the patient was transferred from one facility to another and their medications are administered

differently. Alleged violation of law: 201 KAR 2:185, section1 (1). **CRC Recommendation:** Case is dismissed.

Case 05-0059B Pharmacist allegedly filled two different prescriptions without authorization from a physician. A complaint was received from the Division of Mental Retardation. Upon investigation it was determined that the patient had been previously been prescribed Zoloft and Risperdal, the two drugs in question, and that both prescriptions were filled legally. The confusion happened when the patient was transferred from one facility to another and their medications are administered differently. Alleged violation of law: 201 KAR 2:185, section1 (1). **CRC Recommendation:** Case is dismissed.

Case 05-0060A Pharmacy permit holder allegedly committed a medication error by dispensing a compounded contaminated prescription. The prescription was delivered in an inappropriate labeled container. Alleged violation of law: KRS 315.121(2)(d), KRS 217.055 (1)(a), KRS 217.065. KRS 315.121 (1)(a) **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 05-0060B Pharmacist allegedly committed a medication error by dispensing a compounded contaminated prescription. The prescription was delivered in an inappropriate labeled container. Alleged violation of law: KRS 315.121(2)(d), KRS 217.055 (1)(a), KRS 217.065. KRS 315.121 (1)(a) **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 05-0060C Pharmacist allegedly committed a medication error by dispensing a compounded contaminated prescription. The prescription was delivered in an inappropriate labeled container. Alleged violation of law: KRS 315.121(2)(d), KRS 217.055 (1)(a), 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 05-0061A Pharmacy permit holder allegedly engaged in unprofessional conduct by employing and supervising a pharmacy technician that allegedly released confidential information regarding patient's healthcare and medication regimen to others in the community. A written complaint was received stating that the technician was releasing confidential information regarding oral contraceptives taken by a patient. Upon investigation it was found that both technician and patient are high school students with a history of feuding. Technician was on a work program which is over and no longer works there. Alleged violation of law: KRS 315.121 (2)(b). **CRC Recommendation:**

There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case 05-0061B Pharmacist in charge allegedly engaged in unprofessional conduct by employing and supervising a pharmacy technician that allegedly released confidential information regarding patient's healthcare and medication regimen to others in the community. A written complaint was received stating that the technician was releasing confidential information regarding oral contraceptives taken by a patient. Upon investigation it was found that both technician and patient are high school students with a history of feuding. Technician was on a work program which is over and no longer works there. Alleged violation of law: KRS 315.121 (2)(b). **CRC Recommendation:** There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case 05-0066A Medical Gas Pharmacy permit holder failed to renew prior to July 1, 2005. During routine inspection on July 26, 2005 it was found that the MG permit had not been renewed. Alleged violation of law: special limited medical gas pharmacy failed to renew prior to July 1, 2005. **CRC Recommendation:** There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case 05-0066B Pharmacist-In-Charge failed to renew Medical Gas Pharmacy permit prior to July 1, 2005. During routine inspection on July 26, 2005 it was found that the MG permit had not been renewed. Alleged violation of law: special limited medical gas pharmacy failed to renew prior to July 1, 2005. **CRC Recommendation:** There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case 05-0069A Special limited medical gas pharmacy permit holder allegedly failed to renew the permit in a timely manner and continued to operate, allegedly closed a facility without proper notification to the Board office, and allegedly failed to have a consultant pharmacist. Alleged violation of law: KRS 315.035, 201 KAR 2:106 section 2(1)(c), and 201 KAR 2:225 section 2(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 05-0071 Pharmacist allegedly failed to complete 1.5 CE Units of pharmacy continuing education in 2004. During a routine inspection it was found that the pharmacist had 15 hours CE for 2005, but not for 2004. He had submitted them to KPhA in December 2004; they counted them as 2005, not 2004. Alleged violation of law: KRS 315.065(2) 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 05-0072 Pharmacist allegedly violated previous Agreed Order (04-0067). Pharmacist allegedly failed to complete the required 15 hours of continuing education for 2004. Pharmacist entered into an Agreed Order on April 12, 2005 with the conditions that the pharmacist obtains six hours CE on Kentucky pharmacy law. The Pharmacist submitted a course for a program that was not approved for pharmacy continuing education. Alleged violation of law: KRS 315.065(2) and 201 KAR 2:015. **CRC Recommendation:** There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case 05-0073 Pharmacist allegedly violated previous Agreed Order (03-0037). Pharmacist entered into an Agreed order on May 5, 2004, with the conditions that the pharmacist obtain six hours of continuing education on Kentucky pharmacy law. Pharmacist failed to complete six hours on Kentucky pharmacy law within one year of the signing of his Agreed Order. The board did receive a letter from the pharmacist stating he had trouble finding CE on Kentucky pharmacy law. 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 05-0075 Pharmacist allegedly failed to complete the required 1.5 units of continuing education in 2004. During a routine inspection it was discovered that Pharmacist could only produce .95 units of continuing education in 2004. His license renewal application was marked as having completed 1.5 units of CE. Alleged violations of law: KRS 315.065 and 201 KAR 2:015 section 5(1)(a). **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 05-0076A Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. The PIC had given the renewal application to the owner to sign, and the owner was out sick and failed to send the application in on time. The permit was renewed on July 5, 2005. Alleged violation of law: KRS 315.035 (1) and (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 05-0076B Pharmacist allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. The PIC had given the renewal application to the owner to sign, and the owner was out sick and failed to send the application in on time. The permit was renewed on July 5, 2005. Alleged violation of law: KRS 315.035 (1) and (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 05-0077A Pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. PIC stated that it was an oversight on his part, the permit was renewed on July 11, 2005. Alleged violation of law: KRS 315.035 (1) and (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 05-0077B Pharmacist allegedly failed to renew permit in a timely manner and continued to operate as a pharmacy. PIC stated that it was an oversight on his part, the permit was renewed on July 11, 2005. Alleged violation of law: KRS 315.035 (1) and (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 05-0078A Special limited medical gas pharmacy permit holder allegedly failed to renew permit in a timely manner and continues to operate as a special limited medical gas pharmacy. Permit was renewed on July 8, 2005. Alleged violation of law: KRS 315.035 (1) and (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 05-0078B Pharmacist in charge allegedly failed to renew permit in a timely manner and continues to operate as a special limited medical gas pharmacy. Permit was renewed on July 8, 2005. Alleged violation of law: KRS 315.035 (1) and (4). **CRC Recommendation:** There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case 05-0079 Special limited medical gas permit holder allegedly changed locations without proper notification to the board office. A phone call was received on July 19, 2005 stating that the permit holder had moved on July 16, 2005 without submitting a change of address application to the Board office. The new facility was inspected on July 26, 2005 and a new permit was issued. Alleged violation of law: KRS 315.035(5) and 201 KAR 2:225 section 2 (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 05-0080 Pharmacist allegedly violated previous Agreed Order (04-0039). Pharmacist entered into an Agreed order on June 9, 2004 with the conditions that the pharmacist obtain six hours of continuing education on KY Pharmacy law. Pharmacist completed only 4 of 6 hours required on Kentucky Pharmacy law. Alleged violation of law: KRS 315.121(1)(i). **CRC Recommendation:** Case is dismissed.

Case 05-0081 Pharmacist was allegedly arrested for DUI on 2/27/05. He was under an Agreed order 99-0215 that was in effect until 5/17/05. AO 99-0215 specifies failure to comply will result in immediate suspension of license, or license is revoked and the pharmacist may not apply for reinstatement for five years. Pharmacist pleaded guilty on DUI charge and served 3 days in jail. Alleged violation of law: **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 05-0082 Special limited medical gas pharmacy permit allegedly changed ownership without proper notification to the Board office and failed to renew permit in a timely manner. On or about April 14, 2005 this MG pharmacy was bought, but it was not reported to the Board Office. On July 5, 2005 the board office received an application for a new special limited medical gas pharmacy permit for the purchasing pharmacy with d/b/a of old facility. We contacted them to say it is not a new facility but it is a change of ownership, change of address and a late renewal. Alleged violation of law: KRS 315.035 (4) and (5) and 201 KAR 2:225. **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 05-0084 Facility had medical oxygen tanks on site without being permitted by the Kentucky Board of Pharmacy. Alleged violation of law: KRS 315.035(1) and 201 KAR 2:225 Sections 1 and 2(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 05-0085A Pharmacy permit holder allegedly changed location without a prior inspection by the Board inspector. From August 8, 2005 until a new permit was issued legend drugs including controlled substances were delivered to the pharmacy permit holder who did not have a permit for the new location. Alleged violation of law: KRS 315.035 (5), 201 KAR 2:205 Section 2 (3)(e), and 201 KAR 2:105 Section 3(3)(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 05-0085B Pharmacist-in-charge allegedly changed locations and operated a pharmacy without prior inspection by the Board inspector. During a regular inspection of the pharmacy, it was stated that they were building a new building, at that time it was explained to the pharmacist what the process was and the time frame, however from August 8, 2005 until a new permit was issued legend drugs including controlled substances were delivered to the pharmacy permit holder who did not have a permit for the new location. Alleged violation of law: KRS 315.035 (5), 201 KAR 2:205 Section 2

(3)(e), and 201 KAR 2:105 Section 3(3)(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 05-0085C Wholesaler allegedly delivered legend drugs including controlled substance to a pharmacy that did not have a permit for the new location. Alleged violation of law: KRS 315.035 (5), 201 KAR 2:205 Section 2 (3)(e), and 201 KAR 2:105 Section 3(3)(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.

RECIPROCITY/RELICENSURE/INTERNSHIP:

RajaKumar Donthi. Mr. Donthi requested that he be allowed to accumulate 400 hours internship credit for research he is conducting at the University of Louisville Hospital Pharmacy. Ms. Thornbury moved to allow up to 400 of Mr. Donthi's research hours be credited for internship pursuant to 201 KAR 2:040 Section 3(2) and Section 4 (a)(3). Mr. Orzali seconded and the motion passed unanimously.

Billy Ray Moore. Mr. West, attorney for Mr. Moore, submitted clinical assessment information regarding Mr. Moore that had previously been requested by the Board. Mr. Naseman moved to direct Mr. Burluson to correspond with Mr. Moore's attorney for Mr. Moore to make an appearance before the Board at either the October or December 2005 Board meeting. Mr. Orzali seconded and the motion passed unanimously.

Terry Coyle. Mr. Coyle requested approval to be pharmacist-in-charge for two separate permit holders. The decision was postponed until the October 5, 2005, Board meeting because the inspector for the area, Steve Hart, was not available for comment.

CORRESPONDENCE/COMMUNICATIONS:

Trish Freeman. Dr. Freeman, coordinator for the Contemporary Aspects of Pharmacy Practice (CAPP) course sequence at the University Of Kentucky College Of Pharmacy requested a letter from the Board stating that the CAPP laboratory is exempt from the requirement of a pharmacy license therefore allowing Dr. Freeman to purchase specific pharmaceuticals from wholesalers to use in the practice laboratory. Using real prescription products makes the laboratory experience more realistic. After much discussion, Ms. Thornbury moved to provide Dr. Freeman with a letter stating that Dr. Freeman was a person in charge of a laboratory and therefore is allowed to purchase legend drugs from a wholesaler pursuant to 201 KAR 2:105 Section 3 (3)(f). The letter would further state that the Board reserves the right to inspect the laboratory. The motion died due to the lack of a second. This was discussed earlier in the meeting and Ms. Jones was present.

After more discussion, Mr. Orzali moved to license the CAPP laboratory as a wholesaler. The motion died due to the lack of a second. After further discussion, Ms. Thornbury moved to recognize Dr. Freeman as a person in charge of a laboratory and therefore is allowed to purchase legend drugs from a wholesaler pursuant to 201 KAR 2:105 Section 3 (3)(f). Mr. Orzali seconded and the motion passed unanimously.

Katherine Ladd. Ms. Ladd requested an exemption to 201 KAR 2:205 Section 2(b) that requires a pharmacist-in-charge be present at the pharmacy for a minimum of 10 hours per week. She requested that the VET Pharmacy be allowed to be open for only 5 hours per week. Ms. Thornbury moved to deny the request. Ms. Cooper seconded and the motion passed unanimously.

NABP: Ms. Thornbury moved that the Executive Director, Mr. Burleson, be allowed to attend the NABP Fall Meeting in Florida. Mr. Naseman seconded and the motion passed unanimously.

CONTINUING EDUCATION: Mr. Orzali moved to accept the continuing education programs 05-30 through 05-39 as recommended. Mr. Naseman seconded, and the motion passed unanimously.

NEW BUSINESS: VAWD/NABP Model Rules Wholesalers/Manufacturers. After discussion, it was decided that this topic be considered for an agenda item at the November Board Retreat. Mr. Burleson was directed to resend the power point presentation regarding VAWD to all Board members for their review prior to the Retreat.

Hospice Care Center/Barbara Ross. Dr. Ross requested that the Hospice Care Center be allowed to use automated dispensing systems in the facility to store non-patient specific legend medications. Ms. Thornbury moved to direct the Executive Director, Mr. Burleson, to correspond to Dr. Ross explaining that the request is not allowed pursuant to 201 KAR 2:074 Section 4 (11) and 902 KAR 55:070. Ms. Cooper seconded and the motion passed unanimously.

Generic Substitution. It was brought to the attention of the Board that allegedly Medicaid was requiring pharmacies to dispense brand name Duragesic Patches to patients even though the pharmacies have a lower priced generic in stock and neither the physician nor the patient is requesting brand name, thus violating KRS 217.822(1). Mr. Orzali moved to direct Dr. Osman to correspond with Medicaid requesting clarification regarding the generic substitution of Duragesic Patches. Ms. Cooper seconded and the motion passed unanimously.

Case Review Committee. After discussion, Ms. Thornbury moved that Case Review Committee Sessions be closed meetings. Mr. Naseman seconded and the motion passed unanimously.

Mr. Naseman made the motion to go into closed session pursuant to KRS 61.810(1)(c)(j), which may involve litigation. Mr. Orzali seconded and the motion passed unanimously.

The Board was then in closed session.

Ms. Thornbury moved to go back into open session. Mr. Orzali seconded and the motion passed unanimously.

Mr. Orzali moved to reject proposal 02-0122 as stated. Mr. Naseman seconded and the motion passed unanimously.

Mr. Naseman made the motion to approve the notice of complaint and to consult with attorney to see if Nov. 15 or 22 is okay for a hearing. Seconded by Mr. Orzali and the motion passed unanimously.

ADJOURNMENT: On motion by Ms. Thornbury, seconded by Mr. Orzali, and passed unanimously, President Edwards adjourned the meeting at 5:37 p.m. The next regularly scheduled Board meeting is scheduled to begin at 9:00 a.m. on October 5, 2005 at the Board Office at Spindletop Administration Building, Suite 302; 2624 Research Park Dr; Lexington, KY 40511.

Michael Burleson, Executive Director

MB:lha