

**KENTUCKY BOARD OF PHARMACY
23 MILLCREEK PARK, BLDG 2
FRANKFORT KY 40601-9230
January 5, 2005 9:00AM**

Agenda

- I. CALL TO ORDER**
- II. MINUTES**
 - *A. December 6, 2004**
- III. APPEARANCES**
 - *A. Alesia Bernardo**
 - *B. David Hileman: Rx Crossroads and Medco Health**
 - *C. Dan Luce: Central Processing Technology**
- IV. INTERAGENCY**
- V. BOARD REPORTS**
 - A. Board President**
 - 1. Advisory Council**
 - 2. Board Exams January 22, 2005**
 - B. Board Members**
 - C. Board Executive Director**
 - D. Board Staff**
 - E. IPC Chairman**
- VI. CURRENT/PENDING CASES**
 - A. OAG – C. Lalonde-Mooney**
 - 1. Case update**
 - B. KBP CASE UPDATES**
 - C. Case Review Committee**
- VII. RECIPROCITY/RELICENSURE/INTERNSHIP**
- VIII. CORRESPONDENCE/COMMUNICATIONS**
 - *A. Rivendale: PIC request**
- IX. NABP**
- X. LEGISLATION/REGULATIONS**
- XI. CONTINUING EDUCATION**

A. Program Review

XII. FINES

A. Fines Report

XIII. OLD BUSINESS

XIV. NEW BUSINESS

***Information enclosed with this agenda**

****Information previously provided**

*****Old material with response**

KENTUCKY BOARD OF PHARMACY
23 Millcreek Park, Bldg. 2
Frankfort, KY 40601-9230
January 5, 2005- 9:00 a.m.

AGENDA ADDENDUM

VI. CURRENT/PENDING CASES

B. KBP CASE UPDATES

04-0045B

04-0081B

04-0085B

04-0088A

04-0088B

04-0089

04-0109

MINUTES
KENTUCKY BOARD OF PHARMACY
Frankfort, Kentucky
January 5, 2005

CALL TO ORDER: A regular meeting of the Kentucky Board of Pharmacy was held at the Board office, 23 Millcreek Park, in Frankfort, Kentucky. Becky Cooper made a motion to affirm Mark Edwards as President of the Board for the coming year, Peter Orzali seconded and it was passed unanimously. After being affirmed Mark Edwards was sworn in by Jeff Osman. President Edwards called the meeting to order at 9:10a.m.

Members present: Mark Edwards, Becky Cooper, Georgina Jones, Greg Naseman, Patricia Thornbury and Peter Orzali. Staff: Michael Burleson, Executive Director; Jeff Osman, Inspections and Investigations Coordinator; Katie Busroe, Steve Hart, and Phil Losch, Pharmacy and Drug Inspectors; and Cheryl Lalonde-Mooney, Assistant Attorney General and Board Counsel. Guests: Brian Fingerson, Pharmacist Recovery Network; Paula York, Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services; Karen Mankawski, Brian Pavue, Kevin Lamping, Randy Robinson, Scott Greenwell, Matt Miles, Rite Aid; Todd Downing, CVS; Chad Downing, Greg Baker, Walgreens; Mike Mayes, KPhA; Jan Gould, KRF; Ralph Bouvette, APSC; Vicki Yates Brown, Attorney; Kim Bottoms, Bobby Kron, Brad Ward, John Lewis, Amy Bowman, University of Kentucky College of Pharmacy intern students; Juanita Toole, Court Reporter.

MINUTES: Minutes of the December 8, 2004 Board meeting were corrected (Case No. 04-080A & Case No. 04-080B were corrected to read 10 tablets instead of 20). Becky Cooper made a motion to accept the Minutes as corrected, seconded by Georgina Jones and passed unanimously.

APPEARANCES: **Alesia Bernardo** was sworn in by Juanita Toole. She asked for her license to be reinstated. After an overview of her progress and treatment, Greg Naseman made a motion, Becky Cooper seconded that her license be reinstated with the following conditions of the Agreed Order: 10 years probation, maximum hours of work: 40hrs/wk or 80 hrs/2wk, cannot be pharmacist-in-charge during terms of probation, cannot have power of attorney during terms of probation, must provide copy of Agreed Order to all employees, must have aftercare contract with IPC – to include drug counselor if indicated, must sign a release for Board to have access to all medical records, must attend NA/AA meetings no less than 3 times per week, must provide Board with written monthly reports of all NA/AA meetings for the first five years, then quarterly, must agree to random observed urine/blood screens, quarterly inspections by Board, perpetual inventory required for: C-II, C-III, C-IV for 5 year period, shall not ingest any mood altering substances including alcohol, notify Board within 10 days of any RX/OTC med prescribed/ingested, IPC Chair or President to approve all pharmacies/worksites prior to employment, cannot fill any RX's for self or immediate family, and must identify to the

Board one pharmacy for these RX's, has already attended SE-PRN, provide IPC with a written self-performance evaluation monthly for 10 years, shall make yearly appearance before the IPC as requested, any violation of state/federal pharmacy or drug laws constitutes violation of AO and may result in an emergency suspension of pharmacist license pursuant with KRS 315, all above is reported to NABP. The motion passed unanimously.

David Hileman Rx Crossroads was sworn in by Juanita Toole. Mr. Hileman requested permission for the mass transfer of prescriptions via disc from Medco Health to Rx Crossroads, after an in depth discussion. Greg Naseman made the motion that Mr. Hileman request be approved, Georgina Jones seconded, passed unanimously.

Dan Luce, Walgreens was sworn in by Juanita Toole. Mr. Luce made a presentation about central processing. Walgreens is piloting programs in WI, FL, AZ, CA.

INTERAGENCY: There was a copy of the letter sent to DEA in your extra packet, it's for your information only.

BOARD REPORTS: President. Mr. Mark Edwards thanked the Board for reaffirming his Presidency.

1. A list for possible advisory council members was passed out and each Board member was to vote for 8 (9th person is to be chair, Tim Armstrong, voted on at the last Board meeting). There was discussion of making sure the committee is a representation of the pharmacy profession. The Board members then voted on the list of names. The 8 names who received the most votes were presented to the Board. Greg Naseman made a motion that the list of 8 Advisory Council members be accepted, seconded by Georgina Jones, and passed unanimously to appoint the following to the 2005 advisory council: Kim Croley, Jan Gould, Melinda Joyce, Joel Thornbury, Ken Roberts, Ralph Bouvette, Trish Freeman, and Todd Downing. Hopefully voluntary staggering will take place, other wise they will serve 4 year terms according to the statutes.
2. Mike Burleson went over schedule for Board Exams on January 22, 2005, he will send a written copy all involved, as soon as possible. Georgina Jones made motion to have a special training meeting in Lexington on Friday evening January 21, seconded by Pete Orzali. Greg Naseman made a motion to ask Tim Armstrong to help with exam in case Patricia Thornbury can't be there, seconded by Georgina Jones, and passed unanimously. Greg Naseman made the motion to set January 14, 2006 as the Exam date for January 2006, seconded by Becky Cooper, and passed unanimously.

BOARD MEMBERS: Patricia Thornbury said the Board needs to make sure that they have checks and balances for the office; the Board is responsible for comp time. An internal policy manual with all Board decisions should be created; this should be done by Executive Director.

Pete Orzali said the new Board member manual was very good, but he would like bios for the Board members as well as the Board office staff. He would also like business cards as a Board member.

Greg Naseman said he is continuing to go through the regulations and at the March meeting will have a list of what needs to be updated.

Executive Director. Mike Burlson introduced Lisa Atha, the new Executive Secretary II. He asked that each Board member review the MARS report. He will begin gathering information for preparation of the budget. There was a discussion about new office space, Patricia Thornbury made a motion for Mike to pursue the new office space on Ironworks Pike, seconded by Pete Orzali, and passed unanimously. He reminded the Board that the March 9th Board meeting is at the UK Student Center, where the PY3 Class of about 90 students will be there. He showed the 50 page transcript for telepharmacy and will get copies to all Board members for their review for discussion at the next Board meeting.

IPC (Impaired Pharmacist Committee) Chairman, Brian Fingerson reported that it was voted by the IPC to change IPC to PRN (Pharmacist Recovery Network). Mike Burlson said that "committee" needed to be added (Pharmacist Recovery Network Committee) to the Statute that is to be changed. Greg Naseman made the motion, seconded by Patricia Thornbury, and passed unanimously.

It was ask if Cheryl Mooney should be part of Advisory Council. Patricia Thornbury moved she be in attendance to the Advisory Council meetings and that staff be in attendance as necessary, Becky Cooper seconded and it passed unanimously.

Mike Burlson said if we are changing statutes for PRNC, it would be a good time to change Advisory Council statute also to add the word "staggered" terms. Greg Naseman made the motion to add the word staggered to the Advisory Council term, Pete Orzali seconded and it passed unanimously.

CURRENT/PENDING CASES: KBP Case Updates: Patricia Thornbury moved for acceptance and entry of the proposed Agreed Orders as written. Georgina Jones seconded and it passed unanimously.

Case No. 04-0045B; Case No. 04-0081B; Case No. 04-0085B; Case No. 04-0088A; Case No. 04-0088B; Case No. 04-0089; Case No. 04-0109

CASE REVIEW COMMITTEE: Patricia Thornbury moved for acceptance of the Committee recommendation for the following case reports:

Case No. 02-0109RR Revisit. Special limited medical gas pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate without an active permit. The permit expired at the end of business on June 30, 2002. The Board office received the renewal application on July 10, 2002. The Case Review Committee

met on September 10, 2002, and recommended a 4, an attempt to resolve through an Agreed Order. The Kentucky Board of Pharmacy adopted the recommendation at the September 11, 2002, Board meeting. On October 25, 2002, a proposed Agreed Order was sent to the permit holder. The Agreed Order was never signed. The permit holder failed to renew permit in a timely manner and continued to operate without an active permit in 2003 also. That Agreed Order, Case No. 03-0096, was signed. Alleged violation of law: KRS 315.035 (1). CRC Recommendation: Case is dismissed. Greg Naseman seconded and it passed unanimously.

Case No. 04-0048 A. Pharmacy permit holder allegedly sold a misbranded product as the result of a medication error. A refill was presented to the pharmacist for folic acid 1mg with the directions of taking five (5) tablets daily. The prescription was filled with cyclobenzaprine 10 mg. Alleged violation of law: KRS 217.065(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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0048 B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. A refill was presented to the pharmacist for folic acid 1mg with the directions of taking five (5) tablets daily. The prescription was filled with cyclobenzaprine 10 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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0054 A. Pharmacy allegedly engaged in unprofessional conduct as the result of a medication error. The Board office received a Medical Professional Liability Insurance Claim from the Kentucky Department of Insurance. On or about June 21, 2002, a patient had medications filled, including one for Prinivil. On or about August 2002, the patient informed the pharmacy that he had received someone else's Prinivil, had taken it and been hospitalized. He wanted financial compensation. The pharmacist explained that he would not just give the patient money but he could go through his insurance. At this time the pharmacist confiscated the prescription vial. The patient did sue the pharmacy. At a meeting of the attorneys, the pharmacist, and the patient, the patient produced a second vial of Prinivil with someone else's name on the label. The pharmacist did not want to settle the case, but was advised that it was more cost effective to settle than to fight the claim. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Greg Naseman seconded and it passed unanimously.

Case No. 04-0054 B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. The Board office received a Medical Professional Liability Insurance Claim

from the Kentucky Department of Insurance. On or about June 21, 2002, a patient had medications filled, including one for Prinivil. On or about August 2002, the patient informed the pharmacy that he had received someone else's Prinivil, had taken it and been hospitalized. He wanted financial compensation. The pharmacist explained that he would not just give the patient money but he could go through his insurance. At this time the pharmacist confiscated the prescription vial. The patient did sue the pharmacy. At a meeting of the attorneys, the pharmacist, and the patient, the patient produced a second vial of Prinivil with someone else's name on the label. The pharmacist did not want to settle the case, but was advised that it was more cost effective to settle than to fight the claim. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Greg Naseman seconded and it passed unanimously.

Case No. 04-0083 B Revisit. Consultant pharmacist for special limited medical gas pharmacy permit holder allegedly allowed permit to move without notifying the Board of the move and was not inspected prior to the move. The Case Review Committee met on October 5, 2004, and recommended a 4, an attempt to resolve through an Agreed Order. The Kentucky Board of Pharmacy adopted this recommendation at the October 6, 2004, Board meeting. New information: at the time of the move the permit holder did not have any oxygen patients or tanks. Alleged violation of law: 201 KAR 2:205 Section 2 (3)(e). CRC Recommendation: There is sufficient evidence of a violation; however, the penalty shall be the issuance of a Letter of Reprimand. Greg Naseman seconded and it passed unanimously.

Case No. 04-0105 A. Pharmacy permit holder allegedly engaged in unprofessional conduct by failing to perform prospective drug utilization reviews; failing to have quality assurance monitors in place; failing to maintain hard copy prescriptions for a period of approximately 3 months; failing to be licensed as an out-of-state pharmacy in the 40 states into which medication is shipped; failing to have pharmacist print, review, and sign daily prescription logs; inability to print requested patient profiles and prescriptions; failing to have required pharmacy equipment and no exemption has been granted by the Board; having over 500 unlabeled vials of medications on the pharmacy shelves; and failing to comply with the generic substitution law by inappropriately dispensing trade name products. The Board office received a verbal, followed by a written complaint, in November 2004, from the Iowa Board of Pharmacy that this pharmacy had dispensed Cialis to a 17 year old, 198 pound, female that stated her medical condition to be erectile dysfunction. Two Kentucky Board of Pharmacy inspectors investigated the complaint and made further discoveries. The pharmacist stated that she was too busy to print the hard copy prescriptions since approximately September 15, 2004. The prescription is e-mailed to her from the physician and she enters the prescription from this e-mail. The pharmacist was also too busy to print the daily prescription logs. On this particular date, one pharmacist filled over 600 prescriptions. Further review of prescriptions revealed two additional female patients that received Cialis for erectile dysfunction on the same day as the Iowa complaint. When confronted with these 3 scenarios, the pharmacist stated that she "tries to catch these patients." There are not any hard halts in the

computer software or any type of computer quality assurance to alert the pharmacist to such errors. The pharmacist was unable to print a copy of the patient's profile. The prescription serial numbers are not identifiable on the patient invoice or profile. It was observed during the inspection that there were over 500 unlabeled vials of pre-counted medications throughout the pharmacy. The pharmacist had been educated as to the legality of this practice on July 7, 2004. There was none of the required prescription equipment, nor had an exemption granted. The pharmacy stocks both Ultram and tramadol. Ultram was being dispensed without any notation on the prescription that would prohibit the generic (tramadol) from being dispensed. The pharmacist indicated that the patient would request brand on the questionnaire that is review by the physician. However, the physician does not indicate any type of notation on the prescription that would prevent the pharmacist from dispensing the generic nor does the patient indicate to the pharmacy that brand name is requested yet brand was being dispensed. On July 7, 2004, the pharmacist was informed that out of state permits were needed for the states (approximately 40) into which medications are shipped. The pharmacy has failed to obtain these permits.

Alleged violations of law: 201 KAR 2:210 Section 1 (1)(d)(1); 201 KAR 2:210 Section 1(2)(f); 201 KAR 2:090 Section 2 (1)(a)(b)(c)(d)(e)(f)(g)(i); KRS 216.065(2)(a); KRS 315.121 (1)(d) and (j); KRS 315.121 (2)(d), (e), and (g); and KRS 217.822 (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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0105 B. Pharmacist-in-charge allegedly engaged in unprofessional conduct by failing to perform prospective drug utilization reviews; failing to have quality assurance monitors in place; failing to maintain hard copy prescriptions for a period of approximately 3 months; failing to ensure licensing as an out-of-state pharmacy in the 40 states into which medication is shipped; failing to print, review, and sign daily prescription logs; inability to print requested patient profiles and prescriptions; failing to have required pharmacy equipment and no exemption has been granted by the Board; having over 500 unlabeled vials of medications on the pharmacy shelves; and failing to comply with the generic substitution law by inappropriately dispensing trade name products. The Board office received a verbal, followed by a written complaint, in November 2004, from the Iowa Board of Pharmacy that this pharmacy had dispensed Cialis to a 17 year old, 198 pound, female that stated her medical condition to be erectile dysfunction. Two Kentucky Board of Pharmacy inspectors investigated the complaint and made further discoveries. The pharmacist stated that she was too busy to print the hard copy prescriptions since approximately September 15, 2004. The prescription is e-mailed to her from the physician and she enters the prescription from this e-mail. The pharmacist was also too busy to print the daily prescription logs. On this particular date, one pharmacist filled over 600 prescriptions. Further review of prescriptions revealed two additional female patients that received Cialis for erectile dysfunction on the same day as the Iowa complaint. When confronted with these 3 scenarios, the pharmacist stated that she "tries to catch these patients." There are not any hard halts in the computer software or any type of computer quality assurance to alert the pharmacist to such errors. The

pharmacist was unable to print a copy of the patient's profile. The prescription serial numbers are not identifiable on the patient invoice or profile. It was observed during the inspection that there were over 500 unlabeled vials of pre-counted medications throughout the pharmacy. The pharmacist had been educated as to the legality of this practice on July 7, 2004. There was none of the required prescription equipment, nor had an exemption granted. The pharmacy stocks both Ultram and tramadol. Ultram was being dispensed without any notation on the prescription that would prohibit the generic (tramadol) from being dispensed. The pharmacist indicated that the patient would request brand on the questionnaire that is review by the physician. However, the physician does not indicate any type of notation on the prescription that would prevent the pharmacist from dispensing the generic nor does the patient indicate to the pharmacy that brand name is requested yet brand is being dispensed. On July 7, 2004, the pharmacist was informed that out of state permits were needed for the states (approximately 40) into which medications are shipped. The pharmacy has failed to obtain these permits.

Alleged violations of law: 201 KAR 2:205 Section 2 (3)(a) and (b); 201 KAR 2:210 Section 1 (1)(d)(1); 201 KAR 2:210 Section 1(2)(f); 201 KAR 2:090 Section 2 (1)(a)(b)(c)(d)(e)(f)(g)(i); KRS 216.065(2)(a); KRS 315.121 (1)(d) and (j); KRS 315.121 (2)(d), (e), and (g); and KRS 217.822 (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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0107 A. Pharmacy permit holder allegedly engaged in unprofessional conduct as the result of a medication error. The Board office received a written complaint from the patient on October 21, 2004. The prescription was written for a compounded product, testosterone 2 mg/1 ml (0.2%) cream. The product compounded and dispensed was testosterone 2 % cream. The patient stopped the medication when she noticed facial hair growth. 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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0107 B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. The Board office received a written complaint from the patient on October 21, 2004. The prescription was written for a compounded product, testosterone 2 mg/1 ml (0.2%) cream. The product compounded and dispensed was testosterone 2 % cream. The patient stopped the medication when she noticed facial hair growth. 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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0108 A. Pharmacy permit holder allegedly engaged in unprofessional conduct as the result of a medication error. The Board office received a written complaint from the patient on October 25, 2004. The patient presented a prescription for nicotinamide 500 mg tablets, take 1 tablet 3 times daily. The prescription dispensed was niacin 500 mg tablets, take 1 tablet 3 times daily. The patient began the medication and experienced severe flushing and itching. She contacted the pharmacist about this reaction and that is when the error was discovered. 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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0108 B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. The Board office received a written complaint from the patient on October 25, 2004. The patient presented a prescription for nicotinamide 500 mg tablets, take 1 tablet 3 times daily. The prescription dispensed was niacin 500 mg tablets, take 1 tablet 3 times daily. The patient began the medication and experienced severe flushing and itching. She contacted the pharmacist about this reaction and that is when the error was discovered. 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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0110. Pharmacy permit holder allegedly closed the pharmacy without proper notification to the Board and the public and allegedly failed to identify a pharmacist-in-charge in a timely manner. The pharmacist owner passed away on July 9, 2004. The pharmacy was inherited by non-pharmacist family members. A pharmacist agreed to be pharmacist-in-charge until November 26, 2004. After November 29, 2004, the family was unable to find a pharmacist and closed the pharmacy from November 30, 2004, through December 8, 2004. A new pharmacist-in-charge was named on December 9, 2004. Alleged violations of law: KRS 315.121(2)(d), KRS 315.020 (1), and 201 KAR 2:106. 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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0111 A. Pharmacy permit holder allegedly closed the pharmacy without proper notification to the Board and the public. On October 28, 2004, the pharmacist-in-charge/ part owner had a motorcycle accident resulting in his being unable to work. The

non-pharmacist part owner attempted to continue the operation of the pharmacy with relief pharmacist, but closed the pharmacy on December 2, 2004. The Board office did not receive written notice until December 9, 2004, that the pharmacy was closed and the prescription files had been transferred to another pharmacy on December 6, 2004. The legend drugs, including controlled substances, were to be transferred on December 15, 2004. Alleged violations of law: KRS 315.121(2)(d) and 201 KAR 2:206. 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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0111 B. Pharmacist-in-charge/owner allegedly closed the pharmacy without proper notification to the Board and the public. On October 28, 2004, the pharmacist-in-charge/ part owner had a motorcycle accident resulting in his being unable to work. The non-pharmacist part owner attempted to continue the operation of the pharmacy with relief pharmacist, but closed the pharmacy on December 2, 2004. The Board office did not receive written notice until December 9, 2004, that the pharmacy was closed and the prescription files had been transferred to another pharmacy on December 6, 2004. The legend drugs, including controlled substances, were to be transferred on December 15, 2004. Alleged violations of law: KRS 315.121(2)(d), 201 KAR 2:106 and 201 KAR 2:205. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Greg Naseman seconded and it passed unanimously.

Case No. 04-0112 A. Pharmacy permit holder allegedly sold a misbranded product as the result of a medication error in the form of a miscounted prescription. The Board office received a written complaint from a patient. The patient presented a prescription for Percocet 10/325 mg, number 120. The patient alleges that when he counted his tablets at home he was 9 tablets short. He further alleges that the prescriptions in the will call bin are not secure. The pharmacist stated that it is policy for controlled substance prescriptions to be either double or triple counted. When the patient informed him of the alleged miscount, the pharmacist checked the inventory of both the brand and generic drug. The inventories were correct. The prescriptions in the will call bin are maintained in the pharmacy with no patient access. The pharmacist stated that he trusts his employees completely and feels that there is proper security throughout the day. Alleged violation of law: 216.065 (1). CRC Recommendation: Case is dismissed. Greg Naseman seconded and it passed unanimously.

Case No. 04-0112 B. Pharmacist allegedly engaged in unprofessional conduct by committing a medication error in the form of a miscounted prescription. The Board office received a written complaint from a patient. The patient presented a prescription

for Percocet 10/325 mg, number 120. The patient alleges that when he counted his tablets at home he was 9 tablets short. He further alleges that the prescriptions in the will call bin are not secure. The pharmacist stated that it is policy for controlled substance prescriptions to be either double or triple counted. When the patient informed him of the alleged miscount, the pharmacist checked the inventory of both the brand and generic drug. The inventories were correct. The prescriptions in the will call bin are maintained in the pharmacy with no patient access. The pharmacist stated that he trusts his employees completely and feels that there is proper security throughout the day. Alleged violation of law: 216.065 (1). CRC Recommendation: Case is dismissed. Greg Naseman seconded and it passed unanimously.

Case No. 04-0113 A. Pharmacy permit holder allegedly failed to provide proper security of controlled substances. The Board office received a DEA 106 Theft/Loss report from the pharmacy. From November 23, 2003, through August 4, 2004, a pharmacy technician had diverted more than 37,500 dosage units of 4 drugs: Lortab 10/500, Lortab 10/650, Xanax 0.5 mg, and Xanax 1 mg. Upon further investigation it was discovered that during the year 2004, 17 DEA 222 forms were not properly completed and the daily prescription logs were not always being verified and signed by each responsible pharmacist. Alleged violations of law: 201 KAR 2:100; KRS 315.121 (2)(d)(e); 201 KAR 2:205 Section 2 (3)(a)(b) and KRS 315.121 (1)(h) and (2)(g). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Greg Naseman seconded and it passed unanimously.

Case No. 04-0113 B. Pharmacist-in-charge allegedly failed to provide proper security of controlled substances. The Board office received a DEA 106 Theft/Loss report from the pharmacy. From November 23, 2003, through August 4, 2004, a pharmacy technician had diverted more than 37,500 dosage units of 4 drugs: Lortab 10/500, Lortab 10/650, Xanax 0.5 mg, and Xanax 1 mg. Upon further investigation it was discovered that during the year 2004, 17 DEA 222 forms were not properly completed and the daily prescription logs were not always being verified and signed by each responsible pharmacist. Alleged violations of law: 201 KAR 2:100; KRS 315.121 (2)(d)(e); 201 KAR 2:205 Section 2 (3)(a)(b) and KRS 315.121 (1)(h) and (2)(g). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Greg Naseman seconded and it passed unanimously.

Case No. 04-0115. Wholesaler allegedly changed ownership without proper written notification to the Board office in a timely manner. The Board office received an application for a new wholesaler on December 3, 2004. The wholesaler was not new but

had been purchased by another entity on October 15, 2004. Alleged violations of law: 201 KAR 2:050 Section 1(13), KRS 315.036(1), and KRS 315.121. 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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0116. Wholesaler allegedly did not renew permit in a timely manner and continued to operate, resulting in operating as a wholesaler without an active permit. The permit expired at the close of business on September 30, 2004. The Board office received the renewal application on October 18, 2004. The wholesaler did continue to operate during this time period. The permit holder did pay a late fee. 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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0117. Manufacturer allegedly did not renew permit in a timely manner and continued to operate, resulting in operating as a manufacturer without an active permit. The permit expired at the close of business on September 30, 2004. The Board office received the renewal application on October 6, 2004. The manufacturer did continue to operate during this time period. 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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0118 A. Special limited medical gas pharmacy permit holder allegedly did not renew permit in a timely manner and continued to operate, resulting in operating as a special limited medical gas pharmacy without an active permit. The permit expired at the close of business on June 30, 2004. The Board office received an incomplete renewal application on September 30, 2004. The application was returned and the completed application was received on October 19, 2004. The special limited medical gas pharmacy did continue to operate during this time period. The permit holder did pay a late fee. Alleged violation of law: KRS 315.035(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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0118 B. Consultant pharmacist for a special limited medical gas pharmacy permit holder allegedly did not renew permit in a timely manner and allowed permit holder to continue to operate, resulting in operating as a special limited medical gas pharmacy without an active permit. The permit expired at the close of business on June 30, 2004. The Board office received an incomplete renewal application on September 30, 2004. The application was returned and the completed application was received on October 19, 2004. The special limited medical gas pharmacy did continue to operate during this time period. The permit holder did pay a late fee. Alleged violation of law: 201 KAR 2:205 Section 2(3)(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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0119. Wholesaler allegedly did not renew permit in a timely manner and continued to operate, resulting in operating as a wholesaler without an active permit. The permit expired at the close of business on September 30, 2004. The Board office received the renewal application on October 29, 2004. The wholesaler did continue to operate during this time period. 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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0120. Wholesaler allegedly did not renew permit in a timely manner and continued to operate, resulting in operating as a wholesaler without an active permit. The permit expired at the close of business on September 30, 2004. The Board office received the renewal application on October 12, 2004. The wholesaler did continue to operate during this time period. 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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0121. Wholesaler allegedly did not renew permit in a timely manner and continued to operate, resulting in operating as a wholesaler without an active permit. The permit expired at the close of business on September 30, 2004. The Board office received the renewal application on October 19, 2004. The wholesaler did continue to operate during this time period. 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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0122. Manufacturer allegedly moved without a prior inspection. The Board office received an application for a change of location on September 3, 2004. The Board office responded with a letter indicating the new site must be inspected and approved prior to the relocation. On December 15, 2004, an inspection was conducted at the new site after the manufacturer had already moved. Alleged violation of law: 201 KAR 2:105 Section 4 (3)(b). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Greg Naseman seconded and it passed unanimously.

Case No. 04-0123 A. Special limited medical gas pharmacy permit holder allegedly moved without a prior inspection. The Board office received an application for a change of location on September 3, 2004. The Board office responded with a letter indicating the new site must be inspected and approved prior to the relocation. On December 15, 2004, an inspection was conducted at the new site after the special limited medical gas pharmacy had already moved. Alleged violations 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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0123 B. Consultant for a special limited medical gas pharmacy permit holder allegedly allowed the permit holder to move without a prior inspection. The Board office received an application for a change of location on September 3, 2004. The Board office responded with a letter indicating the new site must be inspected and approved prior to the relocation. On December 15, 2004, an inspection was conducted at the new site after the special limited medical gas pharmacy had already moved. Alleged violations of law: 201 KAR 2:205 Section 2(3)(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. Greg Naseman seconded and it passed unanimously.

Case No. 04-0124 A. Pharmacy permit holder allegedly engaged in unprofessional conduct by selling legend drugs that were obtained from illegal sources and physician's samples. An FDA agent is conducting an investigation of pharmacies selling physician's samples. This pharmacy was selling physician's samples from two different sources as well as selling legend medications that were being diverting from a pharmacy in Texas. The FDA agent has requested that he be allowed to complete all subsequent investigations before the Kentucky Board of Pharmacy take any action against pharmacists or pharmacies. Alleged violations of law: KRS 217.055; KRS 217.065; KRS 217.175(1)(3); KRS 315.121(1)(j); and KRS 315.121(2)(d)(e)(g)(h). CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Greg Naseman seconded and it passed unanimously.

Case No. 04-0124 B. Pharmacist allegedly engaged in unprofessional conduct by selling legend drugs that were obtained from illegal sources and physician's samples. An FDA agent is conducting an investigation of pharmacies selling physician's samples. This pharmacy was selling physician's samples from two different sources as well as selling legend medications that were being diverting from a pharmacy in Texas. The FDA agent has requested that he be allowed to complete all subsequent investigations before the Kentucky Board of Pharmacy take any action against pharmacists or pharmacies. Alleged violations of law: KRS 217.055; KRS 217.065; KRS 217.175(1) and (3); KRS 315.121(1)(j); and KRS 315.121(2)(d)(e)(g)(h). CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Greg Naseman seconded and it passed unanimously.

Case No. 01-0071. Revisited. Pharmacist allegedly engaged in unprofessional conduct by transferring and/or ingesting a drug for which a prescription order is required, without having first received a prescription drug order for the drug. On September 7, 2001 CRC committee recommended the Complaint with attempt to resolve through A.O. January 5, 2004 CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Greg Naseman seconded and it passed unanimously.

CORRESPONDENCE/COMMUNICATIONS: Rivendale sent in a dual PIC request. Greg Naseman made the motion to deny the dual PIC. Patricia Thornbury seconded and it passed unanimously.

NABP: The Executive Director reminded everyone that the NABP Meeting is May 21-25 in New Orleans, LA and that the Board handle registration, but everyone is responsible for their own hotel.

LEGISLATION/REGULATIONS: Jan Gould gave a brief report on legislative activity, he said the main focus would be on the budget, he also said there would be a ½ - 1 billion dollar deficit for Medicaid; Pharmacy community is seeking legislation on PBM

CONTINUING EDUCATION: Georgina Jones made the motion to accept the continuing education program 05-01 program as recommended. Becky Cooper seconded and it passed unanimously.

NEW BUSINESS: The Board discussed what to send to the Advisory Council and what they should begin work on. It was decided to ask them to begin work on Technician Registration. Pete Orzali made the motion that we gather information from NABP and other states regarding this issue and give to the Advisory Council, Patricia Thornbury seconded and it passed unanimously.

ADJOURNMENT: On motion by Patricia Thornbury, seconded by Georgina Jones and passed unanimously, President Edwards adjourned the meeting at 2:34p.m. The next Board meeting is scheduled for Jan. 21, 2005.

Michael Burleson, Executive Director

MB:lha