

KENTUCKY BOARD OF PHARMACY
Board Meeting
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601
December 18, 2013
9:00 a.m.

Agenda

I. CALL TO ORDER

II. MINUTES

- *A. November 1-2, 2013

III. APPEARANCES

IV. INTERAGENCY

V. BOARD REPORTS

- A. Board Executive Director
 - *1. Emars October 2013 and November 2013 FY 2014 and financial reports
 - *2. Panasonic ToughPads Quote: Inspectors/Steve/Mike
 - *3. Dell Computers Quote: 10 computers all in office
 - 4. Travel: Washington DC: Stakeholders Meeting-AMA, DEA: Mike
 - 5. Travel: FARB Meeting: Cheryl
 - *6. Lexmark Printers Quote: 5 for office staff

VI. CURRENT/PENDING CASES

- A. OAG-Cheryl Lalonde
- *B. Case Update
- *C. Case Review

VII. RECIPROCITY/RELICENSURE/INTERNSHIP/PHARMACY TECHNICIANS

- *A. Nageena Ali Request Permission for Intern hours per research

VIII. CORRESPONDENCE/COMMUNICATION

- *A. Keith Bailey Dual PIC Request
- *B. NPS Pharmacy Request to Waiver Pharmacy Permit
- *C. Hepatitis C Treatment Center Request for compounding equipment

IX. NABP

X. LEGISLATION/REGULATION

XI. CONTINUING EDUCATION

- *A. CE Programs: 13-41 to 13-42, 13-46, 13-55 to 13-63

XII. FINES

XIII. OLD BUSINESS

- *A. Kroger Center for Excellence
- B. Reporting Policy/Evaluation Policy
- *C. Testing requirements from NABP

XIV. NEW BUSINESS

- *A. Resignation of Don Kupper, R.Ph. from Advisory Council
- *B. Federal Compounding Law: Drug Quality and Security Act of 2013
- *C. TB Reporting Regulation

XV. FYI

- A. Expungement of one Continuing Education
- *B. Article by Dr. Joe Fink: Legal Issues Surrounding the Number of Dosage Units Dispensed

*Information enclosed with this agenda

MINUTES
KENTUCKY BOARD OF PHARMACY

State Office Building Annex
125 Holmes Street
Frankfort, Kentucky 40601

December 18, 2013

CALL TO ORDER: A regular meeting of the Kentucky Board of Pharmacy was held at the Board Office at State Office Building Annex, 125 Holmes Street, Frankfort, Kentucky. President Thornbury called the meeting to order at 9:08 a.m.

Members present: Joel Thornbury, Deborah Brewer, Brian DeWire, Scott Greenwell, Larry Hadley and Cathy Hanna. Staff: Michael Burlison, Executive Director; Steve Hart, Pharmacy Inspections and Investigations Coordinator; Shannon Allen, Katie Busroe, Amanda Harding and Phil Losch, Pharmacy and Drug Inspectors; Cheryl Lalonde, Assistant Attorney General and Board Counsel; Brian Fingerson, Pharmacist Recovery Network Committee; and Lisa Atha, Executive Secretary. Guests: Chris Killmeier, Walgreens; Ralph Bouvette and Megan Pendley, APSC; Jan Gould, Kentucky Retail Federation; Anne Policastri, KSHP; Robert McFalls, KPhA; Amber Kayse and Brody White, Kroger; Yun Lee; and Monica Brooks and Bell Lee, College of Pharmacy students. Melanie Curtis, Court Reporter, recorded the meeting.

MINUTES: On motion by Ms. Brewer, seconded by Dr. Hanna and passed unanimously, the Minutes of November 1-2, 2013, were approved.

BOARD REPORTS:

Board Executive Director. 1) eMars for October and November FY 2014 and Financial Report Summaries were presented to the Board. 2) Mr. Hadley moved to use Federal Funds to purchase Panasonic ToughPads for Board staff at \$18,265, ten Dell computers for the Board Office at \$10,485, and five Lexmark printers for the Board Office at \$5,659. Dr. DeWire seconded and the motion passed 4 to 1 with Ms. Brewer, Dr. DeWire, Mr. Hadley and Dr. Hanna voting for the motion and Dr. Greenwell opposing the motion. 3) Dr. Greenwell moved to approve Executive Director Burlison's travel to Washington, DC for the AMA, DEA Stakeholders Meeting on December 19, 2013, at no expense to the Board. Dr. Hanna seconded, and the motion passed unanimously. 4) Dr. Greenwell moved to approve travel for Assistant Attorney General and Board Counsel, Cheryl Lalonde, to attend the Federation of Associations of Regulatory Boards Annual meeting January 24 – 26, 2014, in Austin, Texas. Mr. Hadley seconded, and the motion passed unanimously.

CURRENT/PENDING CASES:

Case Updates: Dr. Greenwell moved to accept Case Updates for Case Numbers 11-0150B; 13-055; 13-0082A; 13-0123A; and 13-0135C as written. Mr. Hadley seconded, and the motion passed unanimously.

CASE REVIEW SUMMARY:

Mr. Hadley recused himself from Case No. 13-0188 A, B and C. Dr. Hanna moved to accept Case No. 13-0188 A, B and C as recommended. Dr. Greenwell seconded, and the motion passed unanimously.

Case No. 13-0188A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Alleged violation of law: 201 KAR 2:100 Section 1. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0188B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. Alleged violation of law: 201 KAR 2:205 (3)(b). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0188C. Pharmacist allegedly engaged in unprofessional or unethical conduct by diverting controlled substances and ingesting a drug for which a prescription drug order is required without having first received a prescription drug order for the drug. Alleged violation of law: KRS 315.121(2)(f). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Dr. Greenwell moved to not accept the Case Review Committee recommendations on Case No. 13-0164 A, B and C but to conduct further investigation. Ms. Brewer seconded, and the motion passed unanimously.

Case No. 13-0164A. Pharmacy permit holder allegedly sold an incorrect medication as the result of a dispensing error. Alleged violation of law: 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0164B. Pharmacist allegedly committed a dispensing error. Patient requested metoprolol but was dispensed losartan. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0164C. Pharmacy technician allegedly assisted in the commission of a dispensing error. Patient requested metoprolol but was dispensed losartan. 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Mr. Hadley moved to accept remaining Case Review Committee recommendations as written. Dr. Hanna seconded, and the motion passed unanimously.

Case No. 08-0064A. Pharmacy allegedly provided misbranded compounded inhalation drugs in that they contained false and misleading labeling that misrepresented potency and strength of the active ingredients. The pharmacy also allegedly provided compounded inhalation products that were contaminated and non-sterile. Pharmacy allegedly fraudulently billed Medicare for commercially available products while dispensing compounded inhalation drugs from June 2006 through June 2008. Alleged violations of law: KAR 217.055(1)(a) and (b) and (4)(a) and KRS 315.121(1)(h). 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0064B. Pharmacist allegedly dispensed misbranded compounded inhalation drugs in that they contained false and misleading labeling that misrepresented potency and strength of the active ingredients. The pharmacist also allegedly provided compounded inhalation products that were contaminated and non-sterile. Pharmacist allegedly fraudulently billed Medicare for commercially available products while dispensing compounded inhalation drugs from June 2006 through June 2008. Alleged violations of law: KAR 217.055(1)(a) and (b) and (4)(a) and KRS 315.121(1)(h) and (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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 08-0064C. Pharmacist allegedly dispensed misbranded compounded inhalation drugs in that they contained false and misleading labeling that misrepresented potency

and strength of the active ingredients. The pharmacist also allegedly provided compounded inhalation products that were contaminated and non-sterile. Pharmacist allegedly fraudulently billed Medicare for commercially available products while dispensing compounded inhalation drugs from June 2006 through June 2008. Alleged violations of law: KAR 217.055(1)(a) and (b) and (4)(a) and KRS 315.121(1)(h) and (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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 12-0175A Revisit. Pharmacy permit holder allegedly failed to provide adequate security of controlled drugs. New information: Owner has been unable to find a buyer and attorney for owner is requesting to allow owner to sell to son, who is a physician that works in the building. Alleged violation of law: 201 KAR 2:100 Section 1. **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 12-0256B Revisit. Pharmacy permit holder is allegedly allowing a product to be compounded and sold that is commercially available. Alleged violation of law: KRS 315.121(1)(a). **CRC Recommendation:** There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 13-0018. Revisit. Physician/Pharmacist allegedly was indicted on seven counts of first degree trafficking in a controlled substance, each a Class C Felony. Alleged violation of law: KRS 315.121(1)(c). **CRC Recommendation:** There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0035. Pharmacist allegedly violated her Agreed Order of Reinstatement by testing positive for ethyl alcohol. Alleged violation of law: KRS 315.121(1). **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0104A. Revisit. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to deliver medication in a timely manner. New Information: More information has been received from the Ohio Board of Pharmacy regarding its case against the pharmacy. Alleged violation of law: KRS 315.121(1)(a). **CRC Recommendation:** There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0104B. Revisit. Pharmacist allegedly engaged in unprofessional or unethical conduct by transferring the incorrect medication. Pharmacist allegedly transferred Foradil instead of Perforomist. Alleged violation of law: 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0108A. Revisit. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by allowing controlled substance medication to be diverted from the pharmacy. Alleged violation of law: KRS 315.121(1)(a). **CRC Recommendation:** There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 13-0108B. Revisit. Pharmacist-in-charge allegedly engaged in unprofessional or unethical conduct by not ensuring the procurement, storage, security and disposition of drugs. Pharmacist allegedly engaged in unprofessional or unethical conduct by selling, dispensing and ingesting a drug for which a prescription drug order is required, without having first received a prescription drug order for the drug. Alleged violations of law: 201 KAR 2:205 Section 2 and KRS 315.121(2)(f). **CRC Recommendation:** There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 13-0132. Pharmacist allegedly did not complete the required continuing education for 2012. Pharmacist only completed one hour of required fifteen hours. Alleged violations of law: KRS 315.065(2) 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0139A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to have adequate procedures in place for compounding oncology drugs. Alleged violations of law: KRS 315.121(1)(a) and 201 KAR 2:076 Section 1(1). **CRC Recommendation:** There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0139B. Pharmacist allegedly engaged in unprofessional or unethical conduct by committing a medication error and allegedly failing to perform a drug utilization review. Physician ordered cisplatin at a dose of 20mg/m² equaling 400mg. Pharmacist allegedly failed to correct miscalculation and dispensed 400mg. This was administered twice over a two day period. Alleged violations of law: KRS 315.121(2)(d) and 201 KAR 2:210 Section 4(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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0139C. Pharmacist allegedly engaged in unprofessional or unethical conduct by committing a medication error and allegedly failing to perform a drug utilization review. Physician ordered cisplatin at a dose of 20mg/m² equaling 400mg. Pharmacist allegedly failed to correct miscalculation and dispensed 400mg. This was administered twice over a two day period. Alleged violations of law: KRS 315.121(2)(d) and 201 KAR 2:210 Section 4(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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0139D. Pharmacist allegedly engaged in unprofessional or unethical conduct by committing a medication error and allegedly failing to perform a drug utilization review. Physician ordered cisplatin at a dose of 20mg/m² equaling 400mg. Pharmacist allegedly failed to correct miscalculation and dispensed 400mg. This was administered twice over a two day period. Alleged violations of law: KRS 315.121(2)(d) and 201 KAR 2:210 Section 4(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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0139E. Pharmacist allegedly engaged in unprofessional or unethical conduct by committing a medication error and allegedly failing to perform a drug utilization review. Physician ordered cisplatin at a dose of 20mg/m² equaling 400mg. Pharmacist allegedly failed to correct miscalculation and dispensed 400mg. This was administered twice over a two day period. Alleged violations of law: KRS 315.121(2)(d) and 201 KAR 2:210 Section 4(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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0139F. Pharmacist allegedly engaged in unprofessional or unethical conduct by committing a medication error and allegedly failing to perform a drug utilization review. Physician ordered cisplatin at a dose of 20mg/m² equaling 400mg. Pharmacist allegedly failed to correct miscalculation and dispensed 400mg. This was administered twice over a two day period. Alleged violations of law: KRS 315.121(2)(d)

and 201 KAR 2:210 Section 4(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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0149A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Alleged violation of law: 201 KAR 2:100 Section 1. **CRC Recommendation:** There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0149B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. Alleged violation of law: 201 KAR 2:205 (3)(b). **CRC Recommendation:** There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0149C. Pharmacy technician allegedly engaged in unprofessional or unethical conduct by diverting controlled substances. Alleged violation of law: KRS 315.121(2)(f). **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0151A. Revisit. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Alleged violation of law: 201 KAR 2:100 Section 1. **CRC Recommendation:** There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 13-0151B. Revisit. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. Alleged violation of law: 201 KAR 2:205 (3)(b). **CRC Recommendation:** There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 13-0151C. Revisit. Pharmacy technician allegedly engaged in unprofessional or unethical conduct by diverting controlled substances. Alleged violation of law: KRS 315.121(2)(f). **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0155A. Pharmacy permit holder allegedly allowed a drug to be dispensed which was adulterated. Patient received chipped medication. Alleged violation of law: KRS 217.055 (3). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0155B. Pharmacist allegedly engaged in unprofessional or unethical conducted by dispensing a drug which was adulterated. Patient received chipped medication. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0156. Pharmacist allegedly did not complete the required continuing education for 2012. Pharmacist only completed five hours of the required 15 hours of CE. Alleged violations of law: KRS 315.065(2) 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0157A. Pharmacy permit holder allegedly sold a misbranded product as the result of a medication error. Patient was prescribed hydrocodone/acetaminophen, quantity 30 and pharmacist allegedly dispensed hydrocodone/acetaminophen, quantity 90. Alleged violation of law: KRS 217.065(1). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0157B. Pharmacist allegedly engaged in unprofessional or unethical conduct by committing a medication error. Patient was prescribed hydrocodone/acetaminophen, quantity 30 and pharmacist allegedly dispensed hydrocodone/acetaminophen, quantity 90. 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0158A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by employing a pharmacist who allegedly failed to conduct a drug utilization review for the dose of guanfacine for a child. Alleged violation of law: KRS 315.121(1)(a). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0158B. Pharmacist allegedly engaged in unprofessional or unethical conduct by failing to conduct a drug utilization review for the dose of guanfacine for a child. Alleged violations of law: KRS 315.121(2)(d) and 201 KAR 2:201 Section 4. CRC Recommendation: There is sufficient evidence of a violation to warrant

disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0159. Pharmacist self-reported alleged failure to complete the required 15 hours of continuing education for license renewal for 2012. Pharmacist successfully completed no hours before January 1, 2013. Alleged violation of law: 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0160. Wholesale permit holder allegedly closed permit location without proper notification to the Board of Pharmacy. Alleged violation of law: 201 KAR 2:106 Section 2(1)(c). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0161A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Alleged violation of law: 201 KAR 2:100 Section 1. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0161B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. Alleged violation of law: 201 KAR 2:205 (3)(b). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0161C. Pharmacy technician allegedly engaged in unprofessional or unethical conduct by diverting controlled substances. Alleged violation of law: KRS 315.121(2)(f). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0162A. Home medical equipment permit holder allegedly engaged in unprofessional or unethical conduct by not practicing within the standards of the Kentucky Board of Respiratory Care. Alleged violation of law: KRS 315.121(3)(a).

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

Case No. 13-0162B. Home medical equipment permit holder allegedly engaged in unprofessional or unethical conduct by not practicing within the standards of the Kentucky Board of Respiratory Care. Alleged violation of law: KRS 315.121(3)(a). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0163. Home medical equipment permit holder allegedly closed without proper notification to the Board of Pharmacy. Alleged violation of law: 201 KAR 2:106 Section 2 (1)(c). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0167. Wholesale permit holder allegedly closed permit location without proper notification to the Board of Pharmacy. Alleged violation of law: 201 KAR 2:106 Section 2(1)(c). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0168A. Pharmacy permit holder allegedly sold a medication that was misbranded as a result of a medication error. Patient received a metformin ER 500mg tablet in their risperidone 1mg prescription vial. Alleged violation of law: KRS 217.065(1). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0168B. Pharmacist allegedly engaged in unprofessional or unethical conduct by dispensing a medication that was misbranded. Patient received a metformin ER 500mg tablet in their risperidone 1mg prescription vial. 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0169A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Alleged violation of law: 201 KAR 2:100 Section 1. CRC Recommendation:

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

Case No. 13-0169B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. Alleged violation of law: 201 KAR 2:205 (3)(b). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0169C. Pharmacy technician allegedly engaged in unprofessional or unethical conduct by diverting controlled substances. Alleged violation of law: KRS 315.121(2)(f). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0171A. Pharmacy permit holder allegedly sold a misbranded medication. Patient received hydrocodone/homatropine syrup instead of the prescribed tablets. Alleged violation of law: KRS 217.065(1). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0171B. Pharmacist allegedly engaged in unprofessional or unethical conduct by dispensing a misbranded medication. Patient received hydrocodone/homatropine syrup instead of the prescribed tablets. 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0173A. Complainant alleged that a nonresident pharmacy permit holder is in violation of the pharmacist-in-charge regulation and in violation USP 797 in regards to an FDA inspection in March 2013. Alleged violation of law: KRS 315.121(1)(a). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0173B. Complainant alleged that a nonresident pharmacy permit holder is in violation of the pharmacist-in-charge regulation and in violation USP 797 in regards to an FDA inspection in March 2013. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0174A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Alleged violation of law: 201 KAR 2:100 Section 1. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0174B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. Alleged violation of law: 201 KAR 2:205 (3)(b). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0174C. Pharmacy technician allegedly knowingly made or caused to be made a false, fraudulent, or forged statement or misrepresentation of a material fact in securing issuance or renewal of a license and allegedly engaged in unprofessional or unethical conduct by diverting controlled substance. Alleged violations of law: KRS 315.121(1)(e) and KRS 315.121(2)(f). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0175A. Pharmacy permit holder allegedly allowed a medication error by dispensing fentanyl 75 mcg patches for an Rx written for 25 mcg patches. Alleged violation of law: KRS 315.121(1)(a). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0175B. Pharmacist allegedly committed a medication error by dispensing fentanyl 75 mcg patches for an Rx written for 25 mcg patches. 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0176A. Pharmacy permit holder allegedly provided improper drug utilization review (DUR) that resulted in the dispensing of Vyvanse 70mg when the patient had been receiving 20mg previously. Alleged violation of law: KRS 315.121(1)(a). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0176B. Pharmacist allegedly failed to provide proper drug utilization review that resulted in the dispensing of Vyvanse 70mg when the patient had been receiving 20mg previously. Alleged violations of law: KRS 315.121(2)(d) and 201 KAR

2:210 Section 4. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0177. Pharmacy allegedly moved location without prior approval from the Board and operated as a pharmacy at a non permitted site. Alleged violation of law: KRS 315.035(5). 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0178. Pharmacist allegedly failed to complete the required 15 hours of continuing education for 2012. Pharmacist allegedly completed 11 hours. Alleged violations of law: KRS 315.065 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0180A. Pharmacy permit holder allegedly engaged in unethical or unprofessional conduct due to patient not receiving the entire quantity of his prescription. Alleged violation of law: KRS 315.121(1)(a). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0180B. Pharmacist allegedly engaged in unethical or unprofessional conduct by engaging in conduct likely to deceive, defraud, or harm the public by not dispensing a patient's prescription in the entirety. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0181A. Pharmacy permit holder allegedly sold a misbranded product as a result of an incorrect quantity. Patient allegedly received 63 tablets of hydrocodone/acetaminophen 7.5mg/325mg instead of the prescribed 90 tablets. Alleged violation of law: KRS 217.065(2)(b). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0181B. Pharmacist allegedly engaged in unprofessional or unethical conduct by committed a medication error, dispensing the incorrect quantity. Patient allegedly received 63 tablets of hydrocodone/acetaminophen 7.5mg/325mg instead of the prescribed 90 tablets. Alleged violation of law: KRS 315.121(2)(d). CRC

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

Case No. 13-0182. Pharmacy permit holder allegedly failed to place a pharmacist-in-charge of the pharmacy from September 10, 2013 to October 23, 2013. Alleged violation of law: KRS 315.020(1). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0183A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Alleged violation of law: 201 KAR 2:100 Section 1. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0183B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. Alleged violation of law: 201 KAR 2:205 (3)(b). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0183C. Pharmacy technician allegedly engaged in unprofessional or unethical conduct by diverting controlled substances. Alleged violation of law: KRS 315.121(2)(f). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0184. Home medical equipment permit holder allegedly did not renew its permit by the required September 30, 2013 deadline. Alleged violation of law: KRS 315.520(4). CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 13-0185A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct. A compound of clarithromycin 100mg/rifampin 100mg suspension was dispensed to 7 foals that developed gastrointestinal distress, resulting in the death of one foal. Alleged violation of law: KRS 315.121(1)(a). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0185B. Pharmacist allegedly engaged in unprofessional or unethical conduct by committing a medication error. A compound of clarithromycin

100mg/rifampin 100mg suspension was dispensed to 7 foals that developed gastrointestinal distress, resulting in the death of one foal. Alleged violation of law: KRS 315.121(2)(d). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0186A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by the circulation of false, misleading, or deceptive statement concerning the practice of pharmacy. Alleged violation of law: KRS 315.121(2)(a). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0186B. Pharmacist allegedly engaged in unprofessional or unethical conduct by the circulation of false, misleading, or deceptive statement concerning the practice of pharmacy. Alleged violation of law: KRS 315.121(2)(a). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

Case No. 13-0187. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by dispensing a medication to a patient without the patient's knowledge or consent. Alleged violation of law: KRS 315.121(1)(a). CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 13-0191A. Pharmacy permit holder allegedly aided or abetted an employee to assist in the practice of pharmacy without having a current pharmacy technician registration. Alleged violation of law: KRS 315.121(1)(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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0191B. Pharmacy technician allegedly assisted in the practice of pharmacy without a current pharmacy technician registration from 3/31/2012 to 4/12/2013. Alleged violation of law: KRS 315.138(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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0192. Wholesale distributor allegedly shipped legend drugs into the Commonwealth prior to licensure with the Board. Alleged violations of law: KRS 315.402(1) and KRS 315.121(1)(h). 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/or, if unsuccessful, to

proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0193. Pharmacist allegedly violated her KYPRN monitoring agreement. Alleged violations of law: KRS 315.121(1)(i) and KRS 315.126(8). 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

Case No. 13-0197A. Pharmacy permit holder allegedly failed to provide adequate security of controlled substances. Alleged violation of law: KRS 201 KAR 2:100 Section 1. CRC

Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

Case No. 13-0197B. Pharmacist-in-charge allegedly failed to provide adequate security, procurement and disposition of controlled substances. Alleged violation of law: 201 KAR 2:205 Section 2 (3)(b). CRC **Recommendation:** There is sufficient evidence developed and the investigator is directed to conduct further investigation.

RECIPROCITY/RELICENSURE/INTERNSHIP/PHARMACY TECHNICIANS:

Nagena Ali. Nagena Ali requested up to 400 hours of internship credit be granted for research. Dr. Greenwell moved to allow Nagena Ali to earn up to 400 hours internship credit for research. Dr. Hanna seconded, and the motion passed unanimously. Dr. Greenwell requested information be provided in the Board packet when a pharmacist intern completes the research and submits the 500 word essay describing the research experience.

CORRESPONDENCE/COMMUNICATION:

Dual PIC/Keith Bailey. Pharmacist Keith Bailey requested permission to be dual pharmacist-in-charge of ADiO Pharmacy and AllCare Pharmacy both located at the same address in Elizabethtown, Kentucky. Dr. DeWire moved to approve Keith Bailey's request to be pharmacist-in-charge of ADiO Pharmacy and AllCare Pharmacy located at the same address in Elizabethtown, Kentucky. Ms. Brewer seconded, and the motion passed unanimously.

NPS Pharmacy/Stephen Webb. Stephen Webb requested an exemption for NPS Pharmacy to not be permitted as an out of state pharmacy by the Kentucky Board of Pharmacy. NPS Pharmacy is located in Nashville, Tennessee. NPS Pharmacy would like to mail prescriptions to patients in Kentucky. Dr. Greenwell moved to deny Stephen Webb's request for an exemption so that NPS Pharmacy would not need to be permitted as an out of state pharmacy by the Kentucky Board of Pharmacy. Dr. Hanna seconded, and the motion passed unanimously.

Hepatitis C Treatment Center/Tami Goodbub. Tami Goodbub requested an exemption for Hepatitis C Treatment Center to not have compounding equipment. Dr. Greenwell moved to approve Tami Goodbub's request for Hepatitis C Treatment Center be exempt from having compounding equipment, but if the practice changes the exemption will be reconsidered. Ms. Brewer seconded, and the motion passed unanimously.

LEGISLATION: STATUTE/REGULATION:

Statute: Wholesale Distribution. The Attorney General is willing to support the passage of KRS 315.400 to be amended to read: (7) A pharmacy shall not engage in selling or distributing prescription drugs to any entity that is a wholesale distributor.

Statute: Collaborative Care Agreement. Jan Gould, Kentucky Retail Federation, reported a meeting was held with the KMA lobbyists regarding the collaborative care agreement. Language was clarified and it was to be presented to the KMA leadership.

CONTINUING EDUCATION: Mr. Hadley moved to approve continuing education programs 13-41, 13-42, 13-46 and 13-55 through 13-64 as recommended. Dr. DeWire seconded, and the motion passed unanimously.

OLD BUSINESS:

A. Kroger Center for Excellence. Dr. Greenwell moved to approve Kroger's request for a prescription to be brought to a Kentucky Kroger pharmacy, a technician at the Kentucky pharmacy input the prescription information into the computer system, a Kentucky licensed pharmacist at the Hamilton, Ohio facility check the information entered by the technician in Kentucky and perform drug utilization reviews, with the pharmacist at the Kentucky Kroger pharmacy performing the product verification. Mr. Hadley seconded, and the motion passed 4 to 1 with Ms. Brewer, Dr. DeWire, Dr. Greenwell and Mr. Hadley voting for the motion and Dr. Hanna opposing the motion.

B. Reporting Policy/Evaluation Policy. Dr. Hanna moved to approve the following plan: at the end of each month inspectors will submit a monthly report, which will include inspections, investigations and Agreed Order inspections for each day and work activities completed at home; staff will inform Executive Director of any comp days, vacation days, or sick days taken/requested; Executive Director is required to evaluate each inspector in April, August and January, at a minimum, with the evaluation including review of number of completed inspections and completed cases and work schedule review if necessary. Dr. Greenwell seconded, and the motion passed unanimously.

- C. Testing Requirements from NABP.** Executive Director Burlison is directed to discuss with NABP the rationale for limiting the number of times a candidate may attempt the NAPLEX to five times.

NEW BUSINESS:

- A. Resignation of Don Kupper, R.Ph. from Advisory Council.** With one year remaining on his term, Don Kupper resigned from the Advisory Council due to moving out of state. Executive Director Burlison is directed to send out a notice of application to fulfill Mr. Kupper's term, to be returned to the Board office by January 14, 2014, for consideration at the January 2014 Board Meeting.
- B. Federal Compounding Law: Drug Quality and Security Act of 2013.** Dr. Greenwell moved to direct Mr. Burlison to send a mass email to pharmacists regarding the Drug Quality and Security Act of 2013, and that if a pharmacy is compounding for office use the pharmacy must be registered as an outsourcer with the FDA. Dr. DeWire seconded, and the motion passed unanimously.
- C. TB Reporting Regulation.** The Department of Public Health is proposing to amend 902 KAR 2:020 to include pharmacists among the healthcare providers who are required to report TB cases within one business day. Dr. Hanna moved to support the Department of Public Health's proposed amendment to 902 KAR 2:020 to include pharmacists among the healthcare providers required to report TB cases within one business day. The final draft of the regulation will be presented to the Board. Dr. Greenwell seconded, and the motion passed unanimously.
- D. Wholesale Distributor/Pharmacy Issues.** After discussion, President Thornbury is considering appointing a committee to address wholesale distributors limiting drug supply to pharmacies. The issue was tabled.
- E. Exempt Controlled Substances.** Any controlled substance not listed in 902 KAR 55:045 and 902 KAR 55:090 are controlled substances in Kentucky even if the drug is on the DEA exempt list. Drug Enforcement and Professional Practices is discussing options regarding exempt controlled substances including but not limited to mirroring the Federal DEA exempt list or abolishing the exempt list.

FYI:

- A.** Expungement of one Continuing Education violation.
- B.** Article by Dr. Joe Fink: Legal Issues Surrounding the Number of Dosage Units Dispensed, was distributed.

ADJOURNMENT: On motion by Dr. Greenwell, seconded by Mr. Hadley and passed unanimously, President Thornbury adjourned the Board Meeting at 11:40 a.m. The next regularly scheduled Board Meeting is scheduled to begin at 9:00 a.m. on January 22, 2014, at the Board Office, Frankfort, Kentucky.

Michael Burleson, RPh