

KENTUCKY BOARD OF PHARMACY

Board Meeting

125 Holmes Street, Suite 102

Frankfort, KY 40601

July 12, 2017

9:00 a.m.

Agenda

I. CALL TO ORDER

II. MINUTES

- A. *May 10, 2017
- B. *June 28, 2017

III. APPEARANCES

- A. Cubex 09:15 am

IV. INTERAGENCY

V. BOARD REPORTS

- A. Board Executive Director
 - 1. *eMars- March and April
 - 2. MALTAGON meeting Board Members & Executive Director
October 22nd -25th Charleston, SC

VI. CURRENT/PENDING CASES

- A. *Case Review
- B. *Fines Report
- C. *Final Order
 - 1. 17-0006B

VII. RECIPROCITY/RELICENSURE/INTERNSHIP/PHARMACY TECHNICIANS

- A. *Derek A. Sapone Reciprocity
- B. *BrooksideRX Non-resident permit
- B. *Pharmacy Technicians

VIII. CORRESPONDENCE/COMMUNICATION

- A. *Johnna S. Neary CE
- B. * William B. Board CE
- C. *Derrick Browning Dual PIC
- D. * Matt Daniels Onsite Storage
- E. *Bernard Onyenze Relicensure

IX. NABP

X. LEGISLATION/REGULATION

- A. *Outsourcers (503b) Facilities
- B. *Third Party Logistics Facilities

XI. CONTINUING EDUCATION

- A. *CE Programs – 17- – 17-

XII. OLD BUSINESS

- A. *502 KAR 2:076 Written Comment
 - 1. Phillip Schwieterman
 - 2. Kentucky Retail Federation
 - 3. American Pharmacy Services Corporation
 - 4. KPhA

XIII. NEW BUSINESS

A.

XIV. FYI

- A. Expungement
 - 1. 04-0017B
 - 2. 12-0044
 - 3. 99-0079

XV. BOARD WORK SESSION

A. *Protocols

*Information enclosed with this agenda

MINUTES
KENTUCKY BOARD OF PHARMACY
125 Holmes Street
Frankfort KY 40601
July 12, 2017

CALL TO ORDER A regular meeting was held at Kentucky Board of Pharmacy, Frankfort, KY. President Greenwell called the meeting to order on July 12, 2017 at 9:01 am.

Members present: Scott Greenwell, Brian Dewire, Cathy Hanna, Ron Poole and Craig Martin. Staff: Steve Hart, Executive Director; Katie Busroe, Pharmacy Inspections and Investigations Supervisor; Shannon Garrett, Pharmacy and Drug Inspector; Amanda Harding, Pharmacy and Drug Inspector; Paul Daniels, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector; Rhonda Hamilton, Pharmacy and Drug Inspector; Cheryl Lalonde, General Counsel; and Melissa Hall, Administrative Specialist. Guests: Anne Policastri, KSHP; Brian Fingerson, KYPRN; Paula York, KY OIG; Brittany Reid, Walmart; Elizabeth Elliott, Kroger; Monica Roberts, Kroger; Cindy Stowe, SUCOP; Shannon Stiglitz; Lauren Craycraft, UKCOP Student; Amanda Lewis, UKCOP Student; Claire Stall, APSC/UK Community Resident; Chris Killmeier, Walgreens; Mike Wyant, Cardinal Health; Emma Turner, UKCOP Student; and Chris Harlow, KPhA. Court Reporter Terri Pelosi recorded the meeting. Board Member Deborah Brewer was absent.

MINUTES On motion by Dr. Martin, seconded by Mr. Poole and passed unanimously, the Minutes of May 10, 2017 and June 28, 2017 were approved.

APPEARANCES

Cubex - Karen Nishi, Director of Regulatory Affairs, presented a PowerPoint presentation on their product, MedBank, requesting that this automated dispensing system be allowed in Kentucky long term care facilities. After discussion regarding the allowance of automation in long term care facilities, Mr. Poole moved for Executive Director Steve Hart, Board Counsel Cheryl Lalonde, Inspections and Investigations Supervisor Katie Busroe and Karen Nishi meet and summarize this meeting at the next scheduled Board Meeting in September. Dr. Dewire seconded, and the motion passed unanimously.

INTERAGENCY

Paula York, Drug Enforcement and Professional Practices (DEPP) Branch of the Office of Inspector General in the Cabinet for Health and Family Services (CHFS). Ms. York provided an update on the regulatory changes at CHFS. Gabapentin became a Schedule V as of July 1, 2017. CHFS is in process of updating regulations to allow for partial fillings of Schedule II prescriptions in accordance with Federal law and the allowance of oral Schedule II prescription authorization in limited situations such as for long term care patients and end of life/Hospice patients. These two regulations are on track to become effective in the Fall of 2017.

BOARD REPORTS

1. Financial Reports and eMars were presented for May and June 2017. Year-end review of eMars will be provided at the September Board Meeting.
2. Mr. Hart stated there has been no date set for the reorganization.
3. Mr. Poole moved to approve travel for Mr. Hart and any Board Member interested to attend MALTAGON, October 22-25 in Charleston, South Carolina. Dr. Martin seconded, and the motion passed unanimously.
4. Dr. Martin moved to approve travel for Mr. Hart to attend the FDA 2017 Intergovernmental Working Meeting on Pharmacy Compounding, September 25-27, 2017 in Washington D.C. at no expense to the Board. Mr. Poole seconded, and the motion passed unanimously.
5. Mr. Hart is continuing to research limiting the number of times a candidate may take the NAPLEX.

CURRENT/PENDING CASES

Case Review: Mr. Poole moved to accept Case Review recommendations as presented:

CASE 17-0339A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. The pharmacy reported the loss of 1,216 units of various controlled substances over approximately 2 months due to employee pilferage. Alleged Violation[s] 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 17-0339B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. The pharmacy reported the loss of 1,216 units of various controlled substances over approximately 2 months due to employee pilferage. Alleged Violation[s] of Law: 201 KAR 2:105 Section 2 [3][b]. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

CASE 17-0339C. Pharmacy technician allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required without first receiving a prescription drug order for the drug. Alleged Violation[s] 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. Standard terms and status of 'Do Not Renew.'**

CASE 17-0340A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 76 hydrocodone/apap 10/325 tablets. Alleged Violation[s] 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 17-0340B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 76 hydrocodone/apap 10/325 tablets. Alleged Violation[s] of Law: 201 KAR 2:205. Section 2. (3) (b). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

CASE 17-0340C. Registered Pharmacy Technician allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without first receiving a prescription drug order for the drug. Alleged Violation[s] 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. Standard terms and revocation.**

CASE 17-0343A. Pharmacy permit holder allegedly had reason to know that a pharmacist had a mental or physical incapacity and was unable to engage in the practice of pharmacy with reasonable skill, competence, and safety to the public and failed to report relevant information to the Board of Pharmacy while the pharmacist continued to practice. Alleged Violation[s] of Law: KRS 315.121 [1][d]. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

CASE 17-0343B. Pharmacist allegedly has a mental or physical incapacity that prevents licensee from engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public. Alleged Violation[s] of Law: KRS 315.121 [1][b]. **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation; mental/physical evaluation and in-state evaluation direct from provider by August 15, 2017.**

CASE 17-0359A. Pharmacy permit holder allegedly engage in unprofessional or unethical conduct by employing a pharmacist-in-charge that failed to notified the Board of Pharmacy within 14 days of change in the Pharmacist-in-Charge. Alleged Violation[s] of Law: KRS 315.120 [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. Standard terms and \$500 administrative fine.**

CASE 17-0359B. Pharmacist-in-charge allegedly engaged in unprofessional or unethical conduct by failing to notify of a change in PIC with 14 days. Alleged Violation[s] of Law: 201 KAR 2:205

Section 2[3][d]. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

CASE 17-0359C. Pharmacist allegedly engaged in unprofessional or unethical conduct by refusing to fill a controlled substance prescription. Alleged Violation[s] of Law: KRS 315.121 [2][b]. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

CASE 17-0360A. Pharmacy permit holder allegedly sold a misbranded drug due to a medication error. Patient allegedly was dispensed a prescription of oxaprozin 600mg rather than the prescribed oxcarbazepine 600mg. Alleged Violation[s] 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 17-0360B. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public by dispensing the wrong medication to a patient. Pharmacist allegedly dispensed oxaprozin 600mg rather than the prescribed oxcarbazepine 600mg. Alleged Violation[s] 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. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention.**

CASE 17-0379A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public and allegedly failed to provide references relevant to the professional practice of pharmacy. Alleged Violation[s] of Law: KRS 315.121 (1)(a) and 201 KAR 2:090 Section 1 (2) **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

CASE 17-0379B. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public. Pharmacist allegedly failed to offer counseling to a patient upon the presentation of an original prescription order. Alleged Violation[s] of Law: KRS 315.121 (2)(d) and 201 KAR 2:210 Section 2 (1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

CASE 17-0414. Registered pharmacy technician allegedly engaged in unprofessional or unethical conduct by ingesting a drug for which a prescription drug order is required, without having first received a prescription drug order for the drug. Pharmacy technician allegedly had prescriptions filled for herself and for her child that had not been authorized by a prescriber.

Alleged Violation[s] 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. Standard terms and revocation. Standard terms and revocation.**

CASE 17-0415. Pharmacist allegedly engaged in grossly negligent professional conduct, with or without established proof of actual injury, by refusal to dispense prescriptions for a patient. Pharmacist allegedly refused to fill prescriptions for clindamycin and fluconazole for a patient that were phoned in by a prescriber, thus delaying treatment. Alleged Violation[s] of Law: KRS 315.121 [2][e]. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

CASE 17-0418A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by not filling a patient's prescription. Alleged Violation[s] 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 17-0418B. Pharmacist allegedly failed to exercise appropriate professional judgement in determining whether a prescription drug order is lawful. Alleged Violation[s] of Law: KRS 315.121 [2][j]. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

CASE 17-0420A. Pharmacy permit holder allegedly sold a misbranded drug due to a medication error. Pharmacy processed a verbal prescription that resulted in a patient receiving a mislabel prescription with incorrect directions. Patient was allegedly dispensed a prescription of Zylet eye drops to be applied to both eyes four times a day when the prescriber stated only the right eye. Alleged Violation[s] 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 17-0420B. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Pharmacist allegedly received a verbal prescription from a prescriber that resulted in a patient receiving a mislabel prescription with incorrect directions. Patient was allegedly dispensed a prescription of Zylet eye drops to be applied to both eyes when prescriber stated only right eye. Alleged Violation[s] 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 17-0420C. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury

by committing a medication error. Pharmacist processed a verbal prescription that resulted in a patient receiving a mislabel prescription with incorrect directions. Patient was allegedly dispensed a prescription of Zylet eye drops to be applied to both eyes when prescriber stated only right eye. Alleged Violation[s] 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 17-0422A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to dispense a lawful prescription drug order. Alleged Violation[s] 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 17-0422B. Pharmacist allegedly engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful. Alleged Violation[s] of Law: KRS 315.121 (2)(j). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

CASE 17-0423A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Patient was allegedly prescribed topiramate 100mg, one tablet twice a day and received a prescription for topiramate 100mg, two tablets twice a day. Alleged Violation[s] 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 17-0423B. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Patient was allegedly prescribed topiramate 100mg, one tablet twice a day and received a prescription for topiramate 100mg, two tablets twice a day. Alleged Violation[s] 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. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention.**

CASE 17-0444A. Permit holder allegedly failed to provide written notification to the Kentucky Board of Pharmacy 15 days prior to permanent closure. Alleged Violation[s] of Law: 201 KAR

2:106 Section 2[1][c]. **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

CASE 17-0444B. Pharmacist-in-charge allegedly did not notify the Kentucky Board of Pharmacy of a closure of the medical gas facility. Alleged Violation[s] of Law: 201 KAR 2:106 Section 2[3][e]. **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

CASE 17-0447A. Special pharmacy permit holder allegedly closed facility without prior notification to the Board of Pharmacy. Alleged Violation[s] 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. Standard terms and \$1000 administrative fine.**

CASE 17-0447B. Pharmacist-in-charge allegedly did not notify the Board of Pharmacy of closure of medical gas permit location. Alleged Violation[s] of Law: 201 KAR 2:105 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/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$1000 administrative fine.**

CASE 17-0449. Pharmacy permit holder allegedly failed to report change of pharmacist-in-charge within 14 days of change. The pharmacy has operated without a pharmacist-in-charge from 12/30/2016 through June 2017. Alleged Violation[s] of Law: 201 KAR 2:205 Section 2[3][d]. **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$5000 administrative fine.**

CASE 17-0455A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by not selling syringes over the counter. Alleged Violation[s] 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 17-0455B. Pharmacist engaged in unprofessional or unethical conduct by refusing to sell syringes over the counter. Alleged Violation[s] 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 17-0456A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by refusing to fill a prescription. Pharmacy permit holder allegedly received authorization by the prescriber to refill a patient's prescription yet told the patient the authorization had not been received. Alleged Violation[s] 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 17-0456B. Pharmacist allegedly engaged in unprofessional or unethical conduct with or without established proof of actual injury by refusing to fill a prescription. Pharmacist allegedly received authorization by the prescriber to refill a patient's prescription yet told the patient the authorization had not been received. Alleged Violation[s] 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 17-0460A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by refusing to fill a prescription then refusing to return the prescription to the patient. Pharmacy permit holder allegedly refused to fill a patient's prescription for Vyvanse and also refused to return the prescription to the patient when asked for it back. Alleged Violation[s] 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 17-460B. Pharmacist allegedly engaged in unprofessional or unethical conduct with or without established proof of actual injury by refusing to fill a prescription then refusing to return the prescription to the patient. Pharmacist allegedly refused to fill a patient's prescription for Vyvanse and also refused to return the prescription to the patient when asked for it back. Alleged Violation[s] 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 17-0462A. Permit holder allegedly failed to provide written notification to the Kentucky Board of Pharmacy 15 days prior to permanent closure. Permit holder allegedly closed the medical gases facility on May 1, 2017 and did not notify the Board until May 18, 2017. Alleged Violation[s] 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. Standard terms and \$500 administrative fine.**

CASE 17-0462B. Pharmacist-in-charge allegedly failed to provide written notification to the Kentucky Board of Pharmacy 15 days prior to permanent closure of medical gases facility. The medical gases facility allegedly closed on May 1, 2017 and the Board was not notified until May 18, 2017. Alleged Violation[s] of Law: 201 KAR 2:205 Section 2 [e]. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

CASE 17-0472A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. The pharmacy reported the loss of 528 tramadol tablets over a period of approximately 2.5 years. Alleged Violation[s] 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 17-0472B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. The pharmacy reported the loss of 528 tramadol tablets over a period of approximately 2.5 years. Alleged Violation[s] of Law: 201 KAR 2:105 Section 2 [3][b]. **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

CASE 17-0472C. Pharmacist allegedly engaged in the following unprofessional or unethical conduct: engaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in the conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist, with or without established proof of actual injury; 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; willfully or knowingly failing to maintain complete and accurate records of all drugs dispensed in compliance with federal and state laws, rules, or administrative regulations. Alleged Violation[s] of Law: KRS 315.121 [2][d][f] and [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. Standard terms and revocation.**

CASE 17-0472D. Registered pharmacy technician allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required without first receiving a prescription drug order for the drug. Alleged Violation[s] of Law: KRS 315.121 [2][f]. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

CASE 17-0472E. Registered pharmacy technician allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required without first receiving a prescription drug order for the drug. Alleged Violation[s] of Law: KRS 315.121 [2][f]. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Dr. Hanna seconded, and the motion passed unanimously.

Final Orders. Dr. Martin moved to accept the Hearing Officer's Recommended Order, and issue the Final Order for Case 17-0006B as presented. Mr. Poole seconded, the motion passed unanimously.

RECIPROCITY/RELICENSURE/INTERNSHIP/PHARMACY TECHNICIAN

Derek A. Sapone – Reciprocal Applicant. Mr. Poole moved to allow licensure without restrictions. Dr. Martin seconded, the motion passed unanimously.

BrooksideRX. Mr. Poole moved to deny the request for a non-resident permit until the North Carolina Board of Pharmacy suspension is resolved. Dr. Martin seconded, and the motion passed unanimously.

Pharmacy Technician Registrant, Case 17-0471. Mr. Poole moved to approve the application for pharmacy technician registration with no restrictions. Dr. Hanna seconded, and the motion passed unanimously.

CORRESPONDENCE/COMMUNICATION

Johnna Neary. Ms. Neary requested a waiver of the 2016 CE requirements. Mr. Poole moved to approve the request for a deferral and dismiss the Agreed Order. Ms. Brewer seconded, and the motion passed unanimously.

William Board. Mr. Board requested a deferral of the 2016 CE requirements. Dr. Martin moved to approve the request for a deferral and dismiss the Agreed Order. Dr. Dewire seconded, and the motion passed unanimously.

Derrick Browning. Mr. Browning requested dual pharmacist-in-charge for Twelvestone Pharmacy and their infusion pharmacy, Twelvestone Medical, located in the same building. Dr. Martin moved to approve the request for Derrick Browning to serve as dual pharmacist-in-charge of Twelvestone Pharmacy and Twelvestone Medical. Dr. Hanna seconded, and the motion passed unanimously.

Matt Daniels. Mr. Daniels requested approval for an on-site storage area. Dr. Martin moved to approve the request. Mr. Poole seconded, and the motion passed unanimously.

Bernard Onyenze. Mr. Onyenze's Kentucky pharmacist's license lapsed in 2009. He requested a waiver to not take the NAPLEX for reinstatement of his Kentucky pharmacist's license. Dr. Martin moved to deny the request based on the fact the statute does not allow the Board to

grant a waiver from the NAPLEX if a pharmacist's license has been inactive for over 5 years. Dr. Hanna seconded, and the motion passed unanimously.

LEGISLATION/REGULATION

Outsourcing Facility Regulation, 201 KAR 2:400. Mr. Hart presented a draft of 201 KAR 2:400, Outsourcing facility.

Third-Party Logistics Provider Regulation, 201 KAR 2:390. Mr. Hart presented a draft of 201 KAR 2:390, Third-party logistics provider.

Dr. Hanna moved to file both regulations, 201 KAR 2:400 and 201 KAR 2:390 and set a hearing date of August 30, 2017, at 8 a.m. EST at the Board office. Mr. Poole seconded, and the motion passed unanimously.

CONTINUING EDUCATION

Dr. Martin moved to approve continuing education programs 17-30 through 17-41. Dr. Hanna seconded, and the motion passed unanimously.

OLD BUSINESS

201 KAR 2:076. The Board received written comments from Phillip Schwieterman, Kentucky Retail Federation, American Pharmacy Services Corporation, and Kentucky Pharmacists Association. After discussion of the written comments, Mr. Poole moved to accept the Statement of Consideration prepared by Board Counsel Lalonde and file regulation 201 KAR 2:076 as presented. Dr. Hanna seconded, and the motion passed unanimously.

NEW BUSINESS

President Greenwell will be appointing a Task Force, chaired by Katie Busroe, to discuss implementation of USP Chapter 800 in Kentucky.

BOARD WORK SESSION

The Board held a work session following the regular business to discuss protocol regulation. During the discussion drafts from the Advisory Council, the Board staff and Board were reviewed. After discussion, Dr. Hanna moved to file 201 KAR 2:380, as follows with a hearing date of August 30, 2017, at 8 a.m. EST at the Board office:

- a. a protocol to be signed by any prescriber;
- b. pharmacists to initiate the dispensing of medications or other professional services under certain conditions:
 - a. the protocol meets the minimum standards set forth by the Board;
 - b. the protocol has been approved by the Board;
 - c. the pharmacist documents the dispensing in the pharmacy management system;
- c. minimum requirements include:
 - a. criteria for identifying persons eligible;
 - b. a list of medication to be dispensed;
 - c. procedures for how the medication is to be initiated and monitored;
 - d. education to be provided;

- e. procedures for documenting all medications dispensed and notification to prescriber;
 - f. length protocol is in effect;
 - g. date and signature of prescriber approving protocol; and
 - h. dates and signatures of pharmacists involved in protocol; and
- d. pharmacist must receive education and training in the subject matter of the protocol before participating in a protocol.

Mr. Poole seconded, and the motion passed unanimously.

EXECUTIVE SESSION

Mr. Poole moved that the Board go into closed session pursuant to 61.810(1)(f) to discuss possible discipline of a Board employee. The motion was seconded by Dr. Martin and the motion passed unanimously.

Mr. Poole moved to come out of closed session with Dr. Martin seconding the motion and it passed unanimously.

No further action was taken.

ADJOURNMENT

Dr. Martin moved to adjourn. Mr. Poole seconded, the motion passed unanimously. President Greenwell adjourned the meeting at 1:20 pm. The next regularly scheduled meeting begins at 9 am on September 6, 2017 at the University of Kentucky, Lexington, Kentucky.

B. Steven Hart, R.Ph.
Executive Director