

KENTUCKY BOARD OF PHARMACY

Board Meeting

125 Holmes Street, Suite 102

Frankfort, KY 40601

November 8, 2017

9:00 a.m.

Agenda

I. CALL TO ORDER

II. MINUTES

- A. *September 6, 2017
- B. *October 20, 2017

III. APPEARANCES

- A. * David Gregory Jones Reinstatement

IV. INTERAGENCY

V. BOARD REPORTS

- A. Board Executive Director
 - 1. *eMars- September and October 2017
 - 2. KYPRN- Appointments in December
 - 3. January Board meeting date

VI. CURRENT/PENDING CASES

- A. *Case Review and Fine Report
- B. *Final Order
 - 1. 15-0334B
 - 2. 17-0407
 - 3. 17-0439
 - 4. 14-0462
 - 5. 17-0468

VII. RECIPROCITY/RELICENSURE/INTERNSHIP/PHARMACY TECHNICIANS

- A. *Apex Pharmacy Non-Resident Pharmacy Permit
- B. *Ipharm Inc Wholesale Distributor License
- C. *Orenthal James Carter Reciprocity

VIII. CORRESPONDENCE/COMMUNICATION

- A. *Kevin Enzweiler Dual PIC
- B. *Zach Roberts Non-resident permit exemption
- C. *Dominic Pileggi Agreed Order exemption request

IX. NABP

X. LEGISLATION/REGULATION

- A. *201 KAR 2:390 and 2:400 written comment
 - 1. Healthcare Distribution Alliance (HDA)

XI. CONTINUING EDUCATION

- A. *CE Programs – 17-48 – 17-65

XII. OLD BUSINESS

- A. *USP 800 Task Force
- B. Election of Board Officers (discussion)

XIII. NEW BUSINESS

- A. *Advisory Council appointment

XIV. FYI

- A. Expungement

XV. BOARD WORK SESSION

- A. *Automation in Long Term Care

*Information enclosed with this agenda

KENTUCKY BOARD OF PHARMACY

BOARD MEETING

125 HOLMES STREET, STE 300

FRANKFORT KY

November 8, 2017

CALL TO ORDER A regular meeting was held in the Board office at 125 Holmes Street, Frankfort, Kentucky. President Greenwell called the meeting to order on November 8, 2017 at 9:10 a.m.

Members present: Deborah Brewer, Scott Greenwell, Craig Martin, Cathy Hanna and Ron Poole. Brian Dewire arrived at 9:12 a.m.

Staff present: Steve Hart, Executive Director; Rhonda Hamilton, Paul Daniels, and Jessica Williams, Pharmacy and Drug Inspectors; Cheryl Lalonde, General Counsel; and Darla Sayre, Executive Staff Advisor. Court Reporter Jolinda Todd recorded the meeting.

Guests present: Anne Policastri, KSHP; Chris Killmeier, Walgreens; Mark Glasper, KPHA; Chris Harlow, KPHA; Brian Fingerson, PRN Committee; Shannon Stiglitz, Kentucky Retail Federation; John Long, CVS Health; David Gresham, Pharmerica; Darren Parks, Omnicare; Joel Tjeedsma, Cubex; Scott Dilley, Pharmerica; John Carver, Baptist Health; Matt Martin; Paula York, OIG; Scott Anderson, Pharmerica; Steve Lariviere, Pharmerica; H. Andrew Wilsey; David Jones; Chris Kresnak, DOJ/DEA; Adam Parrish, Wal-mart; Joe Mashni, Medicare Pharmacy and Justina Egwnagu, Rite-aid Pharmacy.

MINUTES On motion by Dr. Martin, seconded by Dr. Hanna and passed unanimously, the Minutes of September 6, 2017 and October 20, 2017 were approved.

APPEARANCE David Gregory Jones was sworn in by the court reporter, Jolinda Todd. Mr. Jones appeared before the Board to request reinstatement of his Kentucky pharmacist license. Mr. Jones gave a brief overview of the events leading to his arrest, conviction and incarceration in federal prison. Mr. Jones signed an Agreed Order of Surrender as Revoked for no less than five years and one day from November 22, 2006. Mr. Jones admitted he had filled prescriptions knowing they were not legitimate for people seeking addictive pain medication.

Chris Kresnak, DOJ/DEA, was sworn in by the court reporter, Jolinda Todd. Mr. Kresnak was involved with Mr. Jones case and gave testimony regarding the case. Mr. Kresnak informed the Board of details that pertained to the federal prosecution of Mr. Jones. Mr. Kresnak stated that this was not just a case of a pharmacist filling prescriptions for bad physicians, but rather a bad pharmacist filling illegitimate, addictive prescriptions, written by bad doctors, and motivated by greed.

Mr. Poole moved to deny Mr. Jones petition for reinstatement. Dr. Hanna seconded, and the motion passed with one nay vote from Dr. Dewire.

BOARD REPORTS

1. eMars reports were presented for September 2017 and October 2017. Mr. Hart informed the Board that in an effort to reduce the Biennium Budget 2018-2020 the office will establish a method for all licenses, registration and permits to be self-printed directly from the website. This will reduce the cost of printing, paper and postage for the Board.
2. Mr. Hart informed the Board that a vote would be held at the December Board meeting for two appointments to the KYPRN Committee, a pharmacist member and a consumer member. Applications must be received in the office by November 30th.
3. 2018 Board Calendar – Mr. Hart requested that the January 10, 2018 meeting be moved to January 17, 2018 with Case Review on January 10, 2018. Dr. Hanna moved to accept this change. Mr. Poole seconded, and the motion passed with one nay vote from Dr. Dewire.
4. Mr. Hart reported to the Board that no Board member appointments have been received from the Governor's office. President Greenwell's, Ms. Brewer's and Dr. Dewire's terms will expire on December 30, 2017. Elections will be held at the December meeting to elect a Board President.
5. Mr. Hart reported to the Board that Mr. Hadley's appointment as Executive Director is under review at the Governor's office.

CURRENT/PENDING CASES Dr. Martin moved to accept Case Review Committee's recommendations:

16-0368A Revisit

Medical gas facility allegedly continued to operate after failing to renew special pharmacy permit in a timely manner; engaged in drug manufacturing by transfilling medical oxygen cylinders without obtaining a permit; failed to adequately track medical oxygen cylinders by lot number; and failed to have records reviewed quarterly by pharmacist-in-charge. Alleged Violation of Law: KRS 315.035(1), (3); KRS 315.036(1), (2), (3) and 201 KAR 2:320 Section 1 (1); KRS 315.121(1)(f) and 21 CFR 211.130; 201 KAR 2:225 Section 2 (1)(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/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.**

16-0368B Revisit

Pharmacist-in-charge allegedly failed to review records of medical gas facility each quarter. Alleged Violation of Law: 201 KAR 2:225 Section 2 (1)(b) and 201 KAR 2:205 Section 2 (3)(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. Standard terms and \$500 administrative fine, cannot serve as PIC of a medicinal gas or manufacturer permit.

17-0172 Revisit

Out of state pharmacy was allegedly convicted of a violation of pharmacy or drug Laws, rules or administrative regulations of another state. Alleged Violation of Law: KRS 315.121(1)(c)3. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

17-0239A Revisit

Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 2860 dosage units of various controlled substances over an eight month time period. 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.**

17-0239B Revisit

Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 2860 dosage units of various controlled substances over an eight month time period. Alleged Violation 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.**

17-0240A Revisit

Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 1723 dosage units of various controlled substances over an eight month time period. 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.**

17-0240B Revisit

Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 1723 dosage units of various controlled substances over an eight month time period. Alleged Violation 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.**

17-0297A Revisit

Pharmacy permit holder allegedly allowed prescription information for a non-controlled substance prescription to be transferred for the purpose of refill dispensing and the oral communication was not directly between two pharmacists. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by selling and dispensing 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: 201 KAR 2:165 and 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. Standard terms and voluntary surrender as revoked or transfer ownership within 60 day of Agreed Order. Combine with 17-0297B.

17-0297B Revisit

Pharmacist allegedly allowed a transfer of prescription information for a non-controlled substance prescription to be transferred for the purpose of refill dispensing and the oral communication was not directly between two pharmacists. Pharmacist allegedly engaged in unprofessional or unethical conduct by selling and dispensing 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: 201 KAR 2:165 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. Standard terms and voluntary surrender as revoked or transfer ownership within 60 day of Agreed Order. Combine with 17-0297A.**

17-0297C Revisit

Technician allegedly engaged in unprofessional or unethical conduct by transferring prescription information for a non-controlled substance prescription for the purpose of refill dispensing when the oral communication was to be directly between two pharmacists. 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.**

17-0297D Revisit

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. 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. Standard terms and revocation.**

17-0341B Revisit to Reconsider Charges

Letter received from attorney of respondent requesting reconsideration of the charges in the Agreed Order. **CRC Recommendation: Pending**

17-0341C Revisit to Reconsider Charges

Letter received from attorney of respondent requesting reconsideration of the charges in the Agreed Order.

CRC Recommendation: Pending

17-0341D Revisit to Reconsider Charges

Letter received from attorney of respondent requesting reconsideration of the charges in the Agreed Order.

CRC Recommendation: Pending

17-0341E

Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to maintain the security of confidential patient information. Patient information was left behind after the closure of the pharmacy. Alleged Violation of Law: KRS 315.121(1)(a).

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.

17-0343B Revisit to Reconsider Charges

Letter received from respondent requesting reconsideration of the charges in the Agreed Order. **CRC Recommendation: Leave as is.**

17-0446A

Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 449 Codeine Phosphate 30 mg tablets, 63 Alprazolam 0.25 mg tablets, 439 Alprazolam 0.5 mg tablets, 3272 Alprazolam 1 mg tablets, 757 Diazepam 10 mg tablets, 5 Diazepam 2 mg tablets, 15 Diazepam 5 mg tablets, 34 Lorazepam 0.5 mg tablets, 91 Lorazepam 1 mg tablets, 4 temazepam 15 mg capsules, 26 temazepam 30 mg capsules, 138 tramadol 50 mg tablets, and 219 Zolpidem 10 mg tablets over a period of 378 days. 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.**

17-0446B

Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 449 Codeine Phosphate 30 mg tablets, 63 Alprazolam 0.25 mg tablets, 439 Alprazolam 0.5 mg tablets, 3272 Alprazolam 1 mg tablets, 757 Diazepam 10 mg tablets, 5 Diazepam 2 mg tablets, 15 Diazepam 5 mg tablets, 34 Lorazepam 0.5 mg tablets, 91 Lorazepam 1 mg tablets, 4 temazepam 15 mg capsules, 26 temazepam 30 mg capsules, 138 tramadol 50 mg tablets, and 219 Zolpidem 10 mg tablets over a period of 378 days. Pharmacist also allegedly engaged in unprofessional or unethical conduct by selling, transferring,

dispensing, ingesting, or administering drugs for which prescription drug orders are required, without first receiving prescription drug orders for the drugs. Pharmacist allegedly engaged in unprofessional or unethical conduct by knowing or having reason to know that pharmacy technicians had engaged in or aided and abetted the unlawful distribution of legend medications, and failing to report any relevant information to the Board. Alleged Violation of Law: 201 KAR 2:205 Section 2 (3) (b); KRS 315.121 (2) (f); KRS 315.121 (1) (j). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

17-0446C

Pharmacist allegedly engaged in unprofessional or unethical conduct by knowing or having reason to know that a pharmacy technician had engaged in or aided and abetted the unlawful distribution of legend medications, and failing to report any relevant information to the Board. Alleged Violation of Law: KRS 315.121 (1) (j). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

17-0446D

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 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.**

17-0446E

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 of Law: KRS 315.121 (2) (f). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

17-0446F

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 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.**

17-0446G

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 of Law: KRS 315.121 (2) (f). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

17-0446H

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 of Law: KRS 315.121 (2) (f). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

17-0448A Revisit

Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 58 ml of Dyanavel XR 2.5mg/ml suspension, and 584 ml Guaiaatussin AC Liquid over a period of 14 days. Alleged Violation of Law: 201 KAR 2:100 Section 1, KRS 315.121 (1)(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 \$1000 administrative fine.**

17-0448B Revisit

Pharmacist in charge knew that a pharmacist had engaged in the unlawful distribution of legend medications, and failed to report any relevant information to the board. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 58 ml of Dyanavel XR 2.5mg/ml suspension, and 584 ml Guaiaatussin AC Liquid over a period of 14 days. Alleged Violation of Law: KRS 315.121 (1) (d), 201 KAR 2:205, Section 2 (3)(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 \$5,000 administrative fine, additional 6 hours of continuing education on pharmacy law, 6 hours of continuing education on addiction/ impairment.**

17-0448C Revisit

Pharmacist 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. Alleged Violation of Law: KRS 315.121 (1)(a), 315.121 (2)(d)(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 voluntary surrender as revoked or 5 years plus one day of probation with scrupulous compliance of KYPRN.

17-0449 Revisit

Pharmacy operated without a pharmacist-in-charge from 12/30/16 to 6/23/2017. Alleged Violation of Law: KRS 315.020(1) and KRS 315.121(1)(a) and (h). **CRC Recommendation: Leave as is or surrender as revoked.**

17-0481A

Pharmacy permit holder allegedly sold a misbranded drug due to medication error. Patient allegedly had a written prescription for trazodone 50 mg tablets, but the prescription was dispensed as 150 mg with a prescription bottle that contained 150 mg 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.**

17-0481B

Pharmacist allegedly engaged 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 allegedly had a written prescription for trazodone 50 mg tablets, but the prescription dispensed as 150 mg with a prescription bottle that contained 150 mg 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. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention.**

17-0484A Pharmacy permit holder allegedly engaged in unethical or unprofessional conduct by allowing confidential information to be communicated against a patient's direction. 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.**

17-0484B Pharmacist allegedly engaged in unprofessional or unethical conduct by communicating confidential information to a patient exiting the pharmacy following the patient's refusal of medication counseling. Alleged Violation of Law: KRS 315.121 (2)(d) and 201 KAR 2:210 Section 3 (2)(b). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

17-0485A Pharmacy permit holder allegedly sold a misbranded drug due to a medication error. Patient allegedly received 120 alprazolam 0.5mg tablets instead of the labeled 180 tablets. Alleged Violation of Law: KRS 217.065 (1). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

17-0485B Pharmacist allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Patient allegedly received 120 alprazolam 0.5mg tablets instead of the labeled 180 tablets. 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.**

17-0497A

Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to dispense a legitimate 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.**

17-0497B

Pharmacist allegedly engaged in unprofessional or unethical conduct by failing to dispense a legitimate prescription. Alleged Violation 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.**

17-0498A

Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 148 tablets of clonazepam 2 mg, and 395 tablets of alprazolam 1 mg, over a period of 498 days due to employee pilferage. 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.**

17-0498B

Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 148 tablets of clonazepam 2 mg, and 395 tablets of alprazolam 1 mg, over a period of 498 days due to employee pilferage. Alleged Violation 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.**

17-0498C

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 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.

17-0499

Registered Pharmacist allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering drugs for which prescription drug orders are required, without first receiving prescription drug orders for the drugs. 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. Standard terms and one year suspension, maintain continued sobriety.**

17-0500A

Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by allowing the unauthorized release of confidential patient information. 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.**

17-0500B

Pharmacy technician allegedly engaged in unprofessional or unethical conduct by divulging confidential patient information to an unauthorized person. Alleged Violation of Law: KRS 315.121 (2)(b), (d). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

17-0501A

Pharmacy permit holder allegedly sold a misbranded drug due to a medication error. Patient was allegedly dispensed a prescription for oxycodone/apap 10/325mg tablets that contained acetaminophen 500mg 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.**

17-0501B

Pharmacist allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Patient was allegedly dispensed a prescription for oxycodone/apap 10/325mg tablets that contained acetaminophen 500mg 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.

17-0509A

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 dispensing a counterfeit medication. Patient was allegedly dispensed a counterfeit medication instead of morphine sulfate ER 15mg. 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.

17-0509B

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 dispensing a counterfeit medication. Patient was allegedly dispensed a counterfeit medication instead of morphine sulfate ER 15mg. 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.

17-0510A

Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 2213 tramadol tablets due to employee pilferage. 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.**

17-0510B

Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 2213 tramadol tablets due to employee pilferage. Alleged Violation 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.**

17-0510C

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 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.**

17-0513A

Pharmacy permit holder allegedly engaged in unprofessional or unethical manner by failing to provide pharmacy services to a patient and delaying patient care. 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.**

17-0513B

Pharmacist allegedly engaged in unprofessional or unethical manner by failing to provide pharmacy services to a patient and delaying patient care. 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.**

17-0514A

Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct, with or without established proof of actual injury, by refusing to dispense prescriptions for a patient. 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.**

17-0514B

Pharmacist-in-charge allegedly engaged in unprofessional or unethical conduct, with or without established proof of actual injury, by refusing to dispense prescriptions for a patient. 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.**

17-0515A

Pharmacy permit holder allegedly sold a misbranded drug on two occasions. Patient was allegedly dispensed 125 tablets of hydrocodone/APAP 10/325 instead of the labeled 130 tablets on June 4, 2017 and on September 6, 2017 was allegedly dispensed 113 tablets instead of the labeled 120 tablets of hydrocodone/APAP 10/325. 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.**

17-0515B

Pharmacist in charge 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 dispensed 113 hydrocodone/APAP 10/325 tablets instead of the labeled 120 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.**

17-0515C

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 dispensed 125 hydrocodone/APAP 10/325 tablets instead of the labeled 130 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.**

17-0516

Permit holder allegedly failed to provide written notification to the Kentucky Board of Pharmacy 15 days prior to permanent closure. Alleged Violation of Law: 201 KAR 2:106 Sec. 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.**

17-0517A

Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 36 tablets of alprazolam 0.25 mg, 55 tablets of alprazolam 0.5 mg, 485 tablets of alprazolam 1 mg, 27 tablets of alprazolam 2 mg, 151 tablets of clonazepam 1 mg, 479 tablets of diazepam 10 mg, 53 tablets of diazepam 2 mg, 118 tablets of hydrocodone-acetaminophen 10 mg -325 mg, 213 tablets of lorazepam 1 mg, 26 tablets of lorazepam 2 mg, 110 tablets of modafinil 200 mg, 80 capsules of phentermine 15 mg, 220 capsules of phentermine 37.5 mg, 1427 tablets of phentermine 37.5 mg, and 748 tablets of tramadol 50 mg due to employee pilferage. 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. Standard terms and \$1000 administrative fine.**

17-0517B

Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 36 tablets of alprazolam 0.25 mg, 55 tablets of alprazolam 0.5 mg, 485 tablets of alprazolam 1 mg, 27 tablets of alprazolam 2 mg, 151 tablets of clonazepam 1 mg, 479 tablets of diazepam 10 mg, 53 tablets of diazepam 2 mg, 118 tablets of hydrocodone-acetaminophen 10 mg -325 mg, 213 tablets of lorazepam 1 mg, 26 tablets of lorazepam 2 mg, 110 tablets of modafinil 200 mg, 80 capsules of phentermine 15 mg, 220 capsules of phentermine 37.5 mg, 1427 tablets of phentermine 37.5 mg, and 748 tablets of tramadol 50 mg due to employee pilferage. Alleged Violation 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.**

17-0517C

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 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.**

17-0518A

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 not ordering a necessary medication to fill a patient's prescription. Pharmacy permit holder allegedly did not order mycophenolic acid to fill a patient's prescription, thus delaying treatment and endangering his transplant. 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.**

17-0518B

Pharmacist allegedly engaged in unprofessional or unethical conduct, with or without established proof of actual injury, by demonstrating a willful or careless disregard for the health, welfare, or safety of a patient by not ordering a necessary medication to fill a patient's prescription. Pharmacist allegedly did not order mycophenolic acid to fill a patient's prescription, thus delaying treatment and endangering his transplant. 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.**

17-0519A

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. Pharmacy permit holder allegedly dispensed eight more tablets of hydrocodone than what was prescribed. Pharmacy permit holder allegedly failed to provide adequate security and control of pharmacy. Pharmacy permit holder allegedly allowed employees within pharmacy when a pharmacist was not present. Alleged Violation of Law: KRS 315.121(1)(a) and 201 KAR 2:100(1). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

17-0519B

Pharmacist-in-charge allegedly failed to provide adequate security and control of pharmacy. Pharmacist-in-charge allegedly allowed employees within pharmacy when a pharmacist was not present. Alleged Violation of Law: 201 KAR 2:100 (1) and 315.121 (2)(d). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

17-0520A

Pharmacy permit holder allegedly sold a misbranded medication, a compounded preparation not labeled with the active ingredients. Alleged Violation of Law: A. KRS 217.065 (5)(b).

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

17-0520B

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 dispensed a compounded preparation not labeled with the active ingredients. 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. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on pharmacy law.

17-0521A

Pharmacy permit holder allegedly sold a misbranded medication, prescription was labeled with directions for intramuscular use when written for subcutaneous use. Alleged Violation of Law: KRS 217.062(6)(a). **CRC Recommendation: There is insufficient evidence of a violation to**

warrant disciplinary action and the case is closed without prejudice.

17-0521B

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 dispensed a medication labeled for intramuscular use that was prescribed for subcutaneous use. 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. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention.

17-0521C

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 dispensed a medication labeled for intramuscular use that was prescribed for subcutaneous use. 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. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention.

17-0537A

Pharmacy permit holder allegedly sold a misbranded drug due to dispensing a quantity greater than prescribed of oxycodone oral solution. Physician prescribed a 25 day supply and pharmacy dispensed a 30 day supply on six occasions. 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.**

17-0537B

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 medical error. Physician prescribed a 25 day supply and pharmacist dispensed a 30 day supply on five occasions. 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. Standard terms and \$2,500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention.**

17-0537C

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 medical error. Physician prescribed a 25 day supply and pharmacist dispensed a 30 day supply on one occasion. 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. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention.**

Ms. Brewer seconded, and the motion passed unanimously.

FINAL ORDER Dr. Martin moved to accept the Agreed Order in Case 15-0334B; Ms. Brewer seconded, and the motion passed unanimously. Hearing Officer recommended orders and Final Orders for Cases 17-0407, 17-0439B, 14-0462B and 17-0468B were approved upon motion of Dr. Martin, seconded by Ms. Brewer, and passed unanimously.

RECIPROCITY/RELICENSURE/INTERNSHIP/PHARMACY TECHNICIANS

Apex Pharmacy – Non-Resident Pharmacy Permit Mr. Poole moved to deny this application. Dr. Martin seconded, and the motion passed unanimously.

Ipharm Inc – Wholesale Distributor License Mr. Poole moved to deny this application. Ms. Brewer seconded, and the motion passed unanimously.

Orenthal James Carter – Reciprocal Request Dr. Martin moved to table this request until the Board receives a response from the applicant. Dr. Hanna seconded, and the motion passed unanimously.

CORRESPONDENCE/COMMUNICATION

Kevin Enzweiler – Dual PIC Request Dr. Hanna moved to deny this request. Dr. Martin seconded, and the motion passed unanimously.

Zach Roberts – Non-Resident Permit Exemption Dr. Hanna moved to deny this request. Mr. Poole seconded, and the motion passed unanimously.

Dominic Pileggi – Agreed Order Exemption Request Ms. Brewer moved to table this request until more information is obtained. Dr. Hanna seconded, and the motion passed unanimously.

NABP Mr. Hart informed the Board that Cheryl Lalonde and Amanda Harding will be attending the 2017 NABP Interactive Compliance Officer and Legal Counsel Forum, November 28-30, 2017. There is no cost to the Board.

LEGISLATION/REGULATION

- 1. 201 KAR 2:400** The Board received comments on this regulation from Healthcare Distribution Alliance (HDA). Ms. Lalonde reported that the comments received for this regulation only pertained to the emergency regulation and not the ordinary administrative regulation. Dr. Hanna moved not to amend after comments. Mr. Poole seconded, and the motion passed unanimously.
- 2. 201 KAR 2:390** The Board received comments on this regulation from HDA. The Board considered an amendment that would allow the Board to inspect 3PL records pertaining to prescription drugs, if such records are maintained. In a phone call with Board Counsel, Mr. Lowe with HDA agreed to the amended language. Dr. Martin moved to amend the regulation as presented in draft. Dr. Dewire seconded, and the motion passed unanimously.

CONTINUING EDUCATION Dr. Hanna left the room and recused herself comment or voting in cases 17-57 through 17-60 because the presenter was her intern. Dr. Martin moved to approve continuing education programs 17-57, 17-58, 17-59, and 17-60. Mr. Poole seconded, and the motion passed unanimously. Dr. Hanna rejoined the meeting. Mr. Poole moved to approve continuing education programs 17-48, 17-49, 17-50, 17-51, 17-52, 17-53, 17-54, 17-55, 17-56, 17-61, 17-62, 17-63 and 17-64. Dr. Martin seconded, and the motion passed unanimously. Mr. Poole moved to approve continuing education program 17-65 for 3 hours. Dr. Martin seconded, and the motion passed unanimously.

OLD BUSINESS

USP 800 Task Force Mr. Hart requested that the Board reduce the amount of members of the task force if the task force will draft its own version of USP 800. Dr. Hanna moved to direct Mr. Poole to submit a list of names at the December meeting. Dr. Dewire requested that at least one member of this task force by a Pharmacy and Drug Inspector at the Board. Dr. Martin seconded, and the motion passed unanimously.

President Greenwell recessed the meeting at 10:50 a.m. for a break. President Greenwell resumed the meeting at 11:02 a.m.

NEW BUSINESS The Board voted to fill the vacancy on the Advisory Council by ballot. Paul Daniels, Pharmacy and Drug Inspector and Paula York, OIG counted the ballots. The applicant appointed for a four-year term was Matthew Martin. His term will begin January 1, 2018.

President Greenwell recessed the meeting for lunch at 11:07 a.m. President Greenwell resumed the meeting 12:15 p.m. Dr. Dewire left the meeting at 1:50 p.m.

WORK SESSION Automation in Long Term Care

1. **201 KAR 2:370** Mr. Hart presented two versions of proposed amendments to the regulation. The Board directed staff to prepare a draft with discussed changes for consideration at the December meeting.
2. **201 KAR 2:074** The Board directed staff to prepare a draft with discussed changes for consideration at the December meeting.

President Greenwell requested that all Board members and interested parties attend the Hearing on 201 KAR 2:0380 Board Authorized Protocols, which will be held on November 13, 2017 at 10:00 a.m. in Room 149 at the Capital Annex.

President Greenwell recognized Mr. Hart for his years of service to the Board.

President Greenwell recessed the meeting at 2:42 p.m. for a break. President Greenwell resumed the meeting at 2:55 p.m. Ms. Lalonde was absent for the remainder of the meeting.

President Greenwell recognized Ms. Lalonde for her dedication to the Board since her employment in 2015. The case management process has improved dramatically. The process is

much more streamlined and efficient. The backlog of unresolved cases has decreased under her expertise. Ms. Lalonde has not received an increase in pay since her employment began. The Board directed Mr. Hart to conduct a performance evaluation of Ms. Lalonde. Mr. Poole moved to increase Ms. Lalonde's salary by 7%. Ms. Brewer seconded, and the motion passed unanimously.

President Greenwell requested Mr. Hart to reconsider his retirement date until the appointment of Larry Hadley as Executive Director, which is under review at the Governor's office. Mr. Hart agreed to postpone his retirement date until a replacement for his position is appointed and trained or until January 31, 2018.

ADJOURNMENT On motion by Dr. Martin, seconded by Mr. Poole, and passed unanimously, President Greenwell adjourned the meeting at 3:14 p.m. The next regularly scheduled meeting begins at 9 a.m. on December 20, 2017 in Frankfort, Kentucky.

B. Steven Hart
Executive Director
Kentucky Board of Pharmacy