

KENTUCKY BOARD OF PHARMACY

125 Holmes Street

Frankfort KY 40601

December 12, 2018

9:00 AM

Agenda

I. CALL TO ORDER

II. MINUTES

- A. *October 17, 2018
- B. *November 8, 2018 Special Called
- C. *December 6, 2018 Special Called

III. APPEARANCES

- A. *Joseph Fawns, Public Protection Cabinet
- B. NABP Interactive Conference – Ron Poole
 - Average make-up of boards
 - Opioid Lawsuits
 - Document retention policy
 - Louisiana Board sued over choosing marijuana dispensaries
 - Develop broader expungement policy
 - NABP APP store CPE Plus
 - Competency based CE
 - Max # of NAPLEX attempts
 - Remote processing
 - Abuse of PMP access

IV. INTERAGENCY

V. BOARD REPORTS

- A. Executive Director
 - 1. *eMars – October and November 2018
 - 2. *Board Calendar 2019

VI. CURRENT/PENDING CASES

- A. *Case Update and Fines Report

VII. CORRESPONDENCE

- A. *GoGoMeds Request
- B. *Louisville Pharmacy – Off Site Storage Request
- C. *Board Approved Protocols – Gary Hatfield

VIII. LEGISLATION/REGULATION

- A. 201 KAR 2:370 Update

IX. CONTINUING EDUCATION

- A. *CE Programs – 18-50 through 18-56

X. OLD BUSINESS

- A. *Approval of Advisory Council Appointments
- B. Election of Board Officers

XI. NEW BUSINESS

- A. *Board Authorized Protocol for Epinephrine Concerns
- B. *Influenza Protocol Revised 11/8/2018
- C. *Opioid Use Disorder Naltrexone Therapy Protocol Revised 12/12/2018
- D. *VIPPS/NABP .Pharmacy Top-Level Domain
- E. *Pharmacists Practicing Pharmacy Outside a Permitted Facility

XII. FYI

- A. Expungement
 - 1. 15-0007
 - 2. 15-0226
 - 3. 15-0136
- B. Awards and Recognitions

*Information enclosed with this agenda.

MINUTES

KENTUCKY BOARD OF PHARMACY

125 Holmes Street
Frankfort KY 40601

BOARD MEETING

December 12, 2018

CALL TO ORDER A regularly scheduled meeting was held at the Kentucky Board of Pharmacy in Frankfort, Kentucky. President Hanna called the meeting to order on December 12, 2018 at 9:03 a.m.

Members present: Cathy Hanna, Ron Poole, Peter P. Cohron, Jill Rhodes, Jody Forgy and Craig Martin.

Staff: Larry Hadley, Executive Director; Katie Busroe, Pharmacy Inspections and Investigations Coordinator; Amanda Harding, Pharmacy and Drug Inspector; Rhonda Hamilton, Pharmacy and Drug Inspector; John Romines, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector and Darla Sayre, Executive Staff Advisor. Court Reporter Terri Pelosi recorded the meeting. Shan Dutta, Assistant Attorney General providing Board Counsel.

Guests: Cindy Stowe, Sullivan College of Pharmacy; Chris Killmeier, Walgreens; Mark Glasper, KPhA; Chris Palutis, KPhA; Scott Dilley, PharMerica; Chris Clifton, GoGoMeds; Mike Wyant, Cardinal Health; Lauren Adams, Walgreens; Tammy Schlensker, PCA Pharmacy; Paula York, OIG; Trish Freeman, UK College of Pharmacy; Joel Thornbury, Nova Pharmacy; Josh Elder, KSHP; Amanda Bresnske, University of Louisville; Shannon Stiglitz; John Carver, Baptist Health; students from Sullivan College of Pharmacy [Fong Her, Bris Patel, Simoni Marfatia, Rachael Morris, Dian Huynh, Zorana Prajdic and Aksa Alex].

APPEARANCE Joseph Fawns, Legislative Liaison from the Public Protection Cabinet, appeared before the Board to give an update on HB 465 The Professional Licensing Modernization Act regarding reorganization of boards and commissions. Mr. Poole thanked Mr. Fawns for listening to the concerns and presenting a bill that addressed many of them.

MINUTES Ms. Busroe addressed the Board regarding the October 17, 2018 meeting. She read a section of 18-OMD-162 to verify that the Board was aware of the decision.

On motion by Mr. Forgy, seconded by Dr. Martin and passed unanimously, the minutes of the October 17, 2018 Board Meeting were approved.

On motion by Mr. Poole, seconded by Dr. Cohron and passed with one abstention by Dr. Rhodes, the minutes of the November 8, 2018 Board Meeting were approved.

On motion by Mr. Poole, seconded by Dr. Rhodes and passed unanimously, the minutes of the December 6, 2018 Board Meeting were approved.

APPEARANCE Mr. Poole gave an update of his recent attendance at the NABP Interactive Member Conference. Topics discussed at the conference included:

- Average make-up of boards
- Opioid Lawsuits
- Document retention policy
- Louisiana Board sued over choosing marijuana dispensaries
- Develop broader expungement policy
- NABP APP store CPE Plus
- Competency based CE
- Max # of NAPLEX attempts
- Remote processing
- Abuse of PMP access

INTERAGENCY Mark Glasper, KPhA, updated the Board on the Joint Drug Educational grant. The date of March 30, 2019 has been selected for the first Opioid Summit.

Paula York, OIG addressed the Board regarding Mr. Poole's presentation. She assured the Board that statutes are in place to prevent abuse of PMP access [KASPER]. Criminal charges may be filed for improper use of the KASPER program.

Josh Elder, KSHP, informed the Board that they are distributing information requesting comments on the proposed language from the Hazardous Drug Committee for the March 31, 2019 deadline.

BOARD REPORTS Mr. Hadley presented the eMars reports for October 2018 and November 2018 to the Board.

Mr. Hadley proposed the following dates for the 2019 Board Calendar:

- January 30, 2019
- March 27, 2019
- May 29, 2019 at Sullivan College of Pharmacy
- July 31, 2019
- September 25, 2019 at UK College of Pharmacy
- November 13, 2019
- December 11, 2019

Dr. Martin moved to approve this calendar. Dr. Rhodes seconded, and the motion passed unanimously.

Mr. Hadley presented the Board with additional information regarding unused permits. Unused facility permits and licenses may be a source of fraudulent activity. He informed the Board of the North Carolina Board of Pharmacy model. Ms. Busroe suggested obtaining additional state

policies. Dr. Martin indicated that this was a concern of the Board and would require a regulation. Dr. Hanna directed Mr. Hadley and Ms. Busroe to obtain additional information from other states for the next meeting.

Mr. Hadley presented the Board with information regarding hydration centers. These centers provide IV fluids to individuals. He found that some states require a physician to be on-site while others require a registered nurse.

Mr. Hadley presented the Board with information regarding pharmacy inspectors inspecting physician's offices that compound pharmaceuticals. He contacted the KMA and KBML with plans to follow-up with them at a later date.

CURRENT/PENDING CASES Dr. Hanna informed the Board of the new process for the Case Review Panel established at the October 2018 meeting. Each panel consisting of the Board President, Executive Director, Board Inspector meet to discuss and vote on pending cases accompanied by the Board Counsel [non-voting]. Ms. Busroe inquired if the Board would like to know the vote totals pertaining to each case. Ms. Hanna suggested that knowing the makeup of the vote may create bias. Dr. Martin and Dr. Rhodes stated that it was not necessary. Dr. Cohron stated that he would like to know the vote totals. Dr. Cohron moved to have the vote totals provided in the Case Review Panel Summary. The motion failed for lack of a second.

Mr. Poole moved to accept the Case Review Panel Recommendations except of Case 18-0255 A & B for:

Case 17-0416 A Revisit. 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 medications to a patient that had been discontinued by the treating physician. Pharmacy permit holder allegedly dispensed baclofen and olanzapine to a patient after they were discontinued at the hospital, causing the patient to fall and seek medical treatment. Alleged Violations 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 17-0416 B Revisit. Pharmacist-in-charge allegedly engaged in unprofessional or unethical conduct by demonstrating a willful or careless disregard for the health, welfare, or safety of a patient with or without established proof of actual injury by dispensing medications to a patient that had been discontinued by the treating physician. Pharmacist-in-charge allegedly dispensed baclofen and olanzapine to a patient after they were discontinued at the hospital, causing the patient to fall and seek medical treatment. Pharmacist allegedly failed to perform a proper prospective drug use review prior to dispensing a prescription. 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 17-0416 C. Revisit. Pharmacist allegedly engaged in unprofessional or unethical conduct by demonstrating a willful or careless disregard for the health, welfare, or safety of a patient with or without established proof of actual injury by dispensing medications to a patient that had been discontinued by the treating physician. Pharmacist allegedly dispensed baclofen and olanzapine to a patient after they were discontinued at the hospital, causing the patient to fall and seek medical treatment. Pharmacist allegedly failed to perform a proper prospective drug use review prior to dispensing a prescription. 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 17-0512. Pharmacist allegedly engaged in unethical or unprofessional conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without having first received a prescription drug order for the drug. Pharmacist allegedly stole numerous medications, both in stock bottles and prescription vials, from his employer(s). Alleged Violations of Law: KAR 315.121 (2) (f). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

Case 17-0538A Revisit. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to dispense a medication in a timely manner. 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. Standard terms and \$1500 administrative fine.**

Case 17-0538B Revisit. Pharmacist-in-charge allegedly failed in the provision of pharmacy services. 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.**

Case 17-0549A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 957 Oxycodone tablets, 592 Oxycodone/Acetaminophen tablets, and 573 Hydrocodone/Acetaminophen tablets over a period of 6 Months from April 2017 to October 2017 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 \$2500 administrative fine, approved corrective action plan to prevent future occurrences [PIC involved in CAP] and pyxis reconciliation deviation in controlled substance audits.

Case 17-0549B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 957 Oxycodone tablets, 592 Oxycodone/Acetaminophen tablets, and 573 Hydrocodone/Acetaminophen tablets over a period of 6 Months from April 2017 to October 2017 due to employee pilferage. Alleged Violation of Law: 201 KAR 2:205 Section 2 (3) (b). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/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, drug diversion, quality assurance or opioid abuse.**

Case 17-0549C. 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.**

Case 17-0558 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy permit holder reported a suspected loss of 210 hydrocodone/apap 5/235mg tablets. Alleged Violations 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 17-0558 B. Pharmacist allegedly engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist. Pharmacist allegedly billed approximately 150 fraudulent immunizations. Pharmacist allegedly replaced tablets of medications he took from the pharmacy shelves with his own previously dispensed prescriptions. Alleged Violations of Law: KAR 315.121 (2)(d) and KRS 217.055(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.**

Case 18-0279. Pharmacist allegedly violated an Agreed Order of Reinstatement by testing positive for and admitting to the consumption of alcohol. Alleged Violation of Law: KRS

315.121(1)(i). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/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 for five years and one day.**

Case 18-0283 A. Pharmacy permit holder allegedly sold a misbranded drug due to medication error. Patient allegedly was dispensed a prescription for zolpidem 10mg that contained 25 tablets instead of the labeled 30 tablets. Patient allegedly was dispensed a prescription for hydrocodone/APAP 7.5/325 that contained 80 tablets instead of the labeled 90 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 18-0283 B. 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 allegedly was dispensed a prescription for zolpidem 10mg that only contained 25 tablets instead of the labeled 30 tablets and a prescription for hydrocodone/APAP 7.5/325 that contained 80 tablets instead of the labeled 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 18-0285 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by dispensing a prescription with an inappropriate dose to a pediatric patient. Pharmacy permit holder allegedly dispensed a prescription for Bromfed DM with a dose that was too high for a patient under 2 years of age. Alleged Violations 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 18-0285 B. Pharmacist allegedly did not perform an appropriate drug utilization review, resulting in dispensing a prescription with an inappropriate dose to a pediatric patient. Pharmacist allegedly did not perform a manual drug utilization review, resulting in dispensing a prescription for Bromfed DM with a dose that was too high for a patient under 2 years of age. Alleged Violations of Law: 201 KAR 2:210 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. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention or drug utilization review.**

Case 18-0330 A. Pharmacy permit holder allegedly failed to maintain an accurate record of the quantity of medication that was dispensed originally and upon each refill. Permit holder allegedly failed to maintain an accurate record of the refills authorized. Pharmacy electronically accessed the same prescription record and allegedly failed to accurately record the refill

authorization remaining. Alleged Violations of Law: 201 KAR 2: 170 Section 1 (1)(e) (g) and (2); and 201 KAR 2:165 Section 1 (3)(c) and (e), (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. Standard terms and \$5000 administrative fine [consolidate with 18-0331 A].**

Case 18-0330 B. Pharmacist in charge allegedly failed to maintain a complete and accurate prescription record. Pharmacist allegedly failed to obtain and provide required information during a transfer of a prescription. Alleged Violations of Law: 201 KAR 2:170 Section 1(2); and 201 KAR 2:165 Section 1 (3)(c) and (e), (5). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0331 A. Pharmacy permit holder allegedly failed to maintain an accurate record of the quantity of medication that was dispensed originally and upon each refill. Permit holder allegedly failed to maintain an accurate record of the refills authorized. Pharmacy electronically accessed the same prescription record and allegedly failed to accurately record the refill authorization remaining. Alleged Violations of Law: 201 KAR 2: 170 Section 1 (1)(e) (g) and (2); and 201 KAR 2:165 Section 1 (3)(c) and (e), (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. Standard terms and \$5000 administrative fine [consolidate with 18-0330 A].**

Case 18-0331 B. Pharmacist in charge allegedly failed to maintain a complete and accurate prescription record. Pharmacist allegedly failed to provide required information during a transfer of a prescription. Alleged Violations of Law: 201 KAR 2:170 Section 1(2); and 201 KAR 2:165 Section 1 (3)(c) and (e), (5). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0331 C. Pharmacist allegedly failed to maintain a complete and accurate prescription record. Pharmacist allegedly failed to obtain required information during a transfer of a prescription. Alleged Violations of Law: 201 KAR 2:170 Section 1(2); and 201 KAR 2:165 Section 1 (3)(c) and (e), (5). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0335A. Pharmacy permit holder allegedly sold a misbranded drug and released confidential patient information due to a medication error. Patient's prescription bag allegedly given to unauthorized person. *Alleged Violation of Law:* KRS 217.065 (1); 201 KAR 2:210 Section 3; KRS 315.121 (1)(h). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0335B. Pharmacist in Charge 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 and allowing the unauthorized release of confidential patient information. Patient's prescription bag allegedly given to unauthorized person. *Alleged Violation of Law:* KRS 315.121 (2)(b),(d); 201 KAR 2:210 Section 3; KRS 315.121 (1)(h). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0335C. Pharmacy Technician 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 and allowing the unauthorized release of confidential patient information. Patient's prescription bag allegedly given to unauthorized person. *Alleged Violation of Law:* KRS 315.121 (2)(b),(d); 201 KAR 2:210 Section 3; KRS 315.121 (1)(h). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0340 A. Pharmacy permit holder allegedly engaged in unethical or unprofessional conduct by withholding patient records when requested by the patient. Pharmacy permit holder allegedly did not give the patient all the documentation she requested and withheld certain notes. *Alleged Violations 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 18-0340 B. Pharmacist allegedly engaged in unethical or unprofessional conduct by engaging in conduct likely to deceive, defraud, or harm the public by withholding patient records when requested by the patient. Pharmacist allegedly did not give the patient all the documentation she requested and withheld certain notes. Pharmacist allegedly never offered to counsel patient on her prescriptions. Pharmacist allegedly never told patient that taking hormones could potentially cause cancer. *Alleged Violations of Law:* KRS 315.121 (2)(d) and 201 KAR 2:210 Section 2. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0350 A Revisit. Out of state pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to maintain appropriate temperature of a shipped medication. *Alleged Violations 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 18-0350 B Revisit. Pharmacist-in-charge engaged in unprofessional or unethical conduct by failing to maintain appropriate temperature of a shipped medication. *Alleged Violations of Law:* KRS 315.121(1)(a) and 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 18-0352 A. Pharmacy permit holder allegedly sold a misbranded drug due to medication error. Patient allegedly was dispensed a prescription for zolpidem 10mg that contained diphenhydramine 25mg. Patient allegedly was dispensed a prescription for hydrocodone/APAP 7.5/325 that contained acetaminophen 500mg. 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 18-0352 B. 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. Patient allegedly was dispensed a prescription for zolpidem 10mg that contained diphenhydramine 25mg. 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 18-0352 C. 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 allegedly was dispensed a prescription for hydrocodone/APAP 7.5/325 that contained acetaminophen 500mg. 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 18-0355 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 36 oxycodone 5 mg tablets due to employee pilferage. Permit holder allegedly failed to dispense controlled substance to end user. Alleged Violations of Law: 201 KAR 2:100 Section 1 and KRS 315.121 (1)(h). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0355 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 36 oxycodone 5 mg tablets 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.**

Case 18-0356 A. Pharmacy permit holder allegedly compounded sterile products in an environment not compliant with USP 797. Pharmacy permit holder allegedly compounded sterile products in an isolator that had been out of compliance for twelve months. Alleged Violations of Law: 201 KAR 2:076 Section 2 (2). **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 \$3000 administrative fine [consolidate with 18-0356 B].**

Case 18-0356 B. Pharmacist allegedly compounded sterile products in an environment not compliant with USP 797. Pharmacist allegedly compounded sterile products in an isolator that had been out of compliance for twelve months. Alleged Violations of Law: 201 KAR 2:076 Section 2 (2). **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 \$3000 administrative fine [consolidate with 18-0356 A].**

Case 18-0361 A Revisit. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to comply with applicable requirements for compounding sterile preparations and failing to maintain complete and accurate records of drugs compounded by the pharmacy, and violating terms of Agreed Order. Alleged Violations of Law: 201 KAR 2:076 Section 2 (2); 201 KAR 2:170; KRS 315.121 (1)(i); KRS 315.121 (1)(h). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0361 B Revisit. Pharmacist-in-charge allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by failing to comply with applicable requirements to ensure quality of sterile preparations compounded by the pharmacy. Alleged Violations of Law: KRS 315.121 (2)(d); 201 KAR 2:076 Section 2 (2); 201 KAR 2:076 Section 3 (2); KRS 315.121 (1)(h). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0361 C Revisit. Pharmacist allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by failing to comply with applicable requirements for compounding sterile preparations. Alleged Violations of Law: KRS 315.121 (2)(d); 201 KAR 2:076 Section 2 (2); 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. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on pharmacy law or compounding.**

Case 18-0369. Special pharmacy permit holder for medical gases allegedly failed to notify the Kentucky Board of Pharmacy 15 days prior to a permanent closure. 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. Standard terms and \$500 administrative fine.**

Case 18-0370 A. Pharmacy permit holder allegedly failed to maintain a patient record that enabled the pharmacist to determine the impact of previously dispensed drugs and known disease conditions upon the newly submitted prescriptive drug order. Alleged Violation of Law: 201 KAR 2:210 Section 1 (1) (d)(3). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0370 B. Pharmacist allegedly failed to perform a proper prospective drug use review evaluating known allergies prior to dispensing a prescription. Alleged Violation of Law: 201 KAR 2:210 Section 4 (1). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0371 A. Pharmacy permit holder allegedly sold a misbranded drug due to medication error. Prescription was written for triazolam 0.125 mg a quantity of 3 tablets and patient was dispensed triazolam 0.25 mg a quantity of 2 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 18-0371 B. 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. Prescription was written for triazolam 0.125 mg a quantity of 3 tablets and patient was dispensed triazolam 0.25 mg a quantity of 2 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.**

Case 18-0379 A. 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 oxycodone 15mg. Alleged Violations 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 18-0379 B. 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 dispensing a counterfeit medication. Patient was allegedly dispensed a counterfeit medication instead of oxycodone 15mg. Alleged Violations 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 18-0382 A. Pharmacy permit holder allegedly sold a misbranded drug. Patient allegedly was dispensed a prescription containing 58 oxycodone/APAP 7.5/325 tablets instead of the labeled 90 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 18-0382 B. 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 allegedly was dispensed a prescription containing 58 oxycodone/APAP 7.5/325 tablets instead of the labeled 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 18-0383A. Pharmacy permit holder allegedly sold a misbranded drug due to medication error. Patient allegedly was dispensed a prescription for Ibuprofen that contained Gabapentin. 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 18-0383B. 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 allegedly was dispensed a prescription for Ibuprofen that contained Gabapentin. 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.**

Case 18-0389A. Pharmacy permit holder allegedly sold a misbranded drug and released confidential patient information due to a medication error. Patient's prescription bag allegedly given to unauthorized person. *Alleged Violation of Law:* KRS 217.065 (1); 201 KAR 2:210 Section 3; 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. Standard terms and \$1000 administrative fine.**

Case 18-0389B. Pharmacist in Charge 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 and allowing the unauthorized release of confidential patient information. Patient's prescription bag allegedly given to unauthorized person.

Alleged Violation of Law: KRS 315.121 (2)(b),(d); 201 KAR 2:210 Section 3; KRS 315.121 (1)(h). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0390 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to maintain an accurate prescription record. Patient was allegedly dispensed more refills than were prescribed. 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 18-0390 B. Pharmacist allegedly failed to enter accurate information into the prescription dispensing system. Patient was allegedly dispensed more refills than were prescribed. Alleged Violations of Law: 201 KAR 2:170 Section 1 (1)(e) and (2). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Case 18-0393A. Out of state pharmacy permit holder allegedly shipped 148 prescription medications into Kentucky prior to obtaining an out of state Kentucky pharmacy permit. Alleged Violation of Law: KRS 315.0351(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 \$7400 administrative fine.**

Case 18-0393B. Pharmacist-in-charge of an out of state pharmacy permit allegedly shipped 175 prescription medications into Kentucky prior to the pharmacy obtaining an out of state Kentucky pharmacy permit. Alleged Violation of Law: 201 KAR 2:205 Section 1. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Dr. Cohron seconded, and the motion passed unanimously.

Mr. Poole recused himself and left the meeting.

Dr. Martin moved to approve the Case Review Panel Recommendations for:

Case 18-0255 A Revisit. Pharmacy permit holder allegedly sold a misbranded drug due to medication error. Pharmacy permit holder allegedly dispensed oxycodone IR 15mg instead of the prescribed oxycodone ER 15mg. In correcting the prescription, the directions and quantity dispensed were incorrect. In correcting the prescription, the partial dispensing recordkeeping was inadequate. Pharmacy allegedly failed to keep adequate computer records. Returned

medication was allegedly placed back in stock to redispense. Alleged Violations of Law: (A)KRS 217.065 (1), 902 MR 55:095 Section 4 (4), 201 KAR 2:190, and 201 KAR 2: 170. **CRC**

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

Case 18-0255 B Revisit. 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 oxycodone IR 15mg instead of the prescribed oxycodone ER 15mg. 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 delaying appropriate treatment. Pharmacist allegedly did not dispense the corrected oxycodone prescription until more than seven hours had passed since the medication error was discovered. Pharmacist allegedly contacted the prescriber's office to have the prescription changed from oxycodone ER to oxycodone IR, which had already been dispensed, after learning from the patient that the oxycodone IR made him too drowsy and did not control his pain. In correcting the prescription, the directions and quantity dispensed were incorrect. Returned medication was allegedly placed back in stock to redispense. Alleged Violations of Law: KRS 315.121 (1)(a)(h), 201 KAR 2:170 (1)(g), and 201 KAR 2:190. **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 \$1500 administrative fine, additional 3 hours of continuing education on medication errors and their prevention, additional 3 hours of continuing education on pharmacy law.**

Mr. Forgy seconded, and the motion passed unanimously.

Mr. Poole returned to the meeting.

CORRESPONDENCE

Chris Clifton, GoGoMeds, appeared before the Board requesting additional pharmacy space located in the basement of the pharmacy without a shared door. After much discussion, Dr. Rhodes moved to approve this request. Mr. Forgy seconded, and the motion passed unanimously. Dr. Martin moved to direct the staff to appear at the January 2019 Board meeting regarding the pharmacy practice at this location. Previous discussion suggested common ownership/central refill issues. Mr. Poole seconded, and the motion passed unanimously.

Louisville Pharmacy requested off-site storage for pharmacy records. Mr. Poole moved to approve this request. Dr. Martin seconded, and the motion passed unanimously.

Gary Hatfield requested clarification on Board approved protocols specifically if pharmacists named on the protocol were limited to their pharmacy location. After much discussion, Dr.

Martin requested this be tabled until the January 2019 Board Meeting requesting more information or Dr. Hatfield's appearance at the meeting.

LEGISLATION/REGULATIONS Dr. Hanna presented an updated version of 201 KAR 2:370 after edits from LRC. This discussion will resume later in the meeting.

CONTINUING EDUCATION Dr. Martin moved to approve 18-50, 18-51, 18-52, 18-53, 18-54, 18-55 and 18-56. Dr. Cohron seconded, and the motion passed unanimously.

OLD BUSINESS On motion by Dr. Cohron, seconded by Mr. Poole the appointments voted on at the October 17th Board Meeting were approved.

Dr. Hanna called for a short recess. Dr. Hanna called the meeting to order at 10:56 a.m.

LEGISLATION/REGULATIONS After much discussion, Dr. Martin moved to accept 201 KAR 2:370 as amended. Mr. Forgy seconded, and the motion passed unanimously.

OLD BUSINESS Mr. Poole moved to elect Dr. Craig Martin as Board President beginning January 1, 2019. Dr. Cohron seconded, and the motion passed unanimously. Dr. Martin moved to elect Mr. Ron Poole as Vice President of the Board. Dr. Cohron seconded, and the motion passed unanimously.

NEW BUSINESS

Dr. Harding requested clarification on the epinephrine protocol. Does the pharmacist named in the protocol have to obtain verification that the certified individuals have completed training required by the Cabinet for Health and Family Services? After much discussion, Dr. Martin directed Mr. Hadley to ask this specific question in writing to the Cabinet for Health and Family Services for a response.

Trish Freeman, UK College of Pharmacy presented a revised Influenza Protocol for the inclusion of baloxavir. Mr. Poole moved to approve this protocol. Dr. Martin seconded, and the motion passed unanimously.

Dr. Freeman presented a revised Opioid Use Disorder Naltrexone Therapy Protocol. These changes were made from issues after implementation. Dr. Martin questioned the requirement for testing of HIV and Hepatitis. He believes this is outside the original intent of the protocol. Dr. Rhodes agreed. Dr. Martin moved to approve the revised protocol with the exception of HIV/Hepatitis testing. Dr. Cohron seconded, and the motion passed unanimously.

Dr. Harding questioned if revised protocols invalidated existing protocols. Dr. Freeman stated that in training pharmacists are directed to the Board to obtain the most recent version of protocols. The Board determined that a pharmacist may continue under an older version of a protocol unless that protocol has been invalidated by the Board. Only the most recent versions of protocols will be posted on the Board's website.

Ms. Busroe informed the Board of the NABP's decision to discontinue the Vet-VIPPS program. This certification is required per KRS 315.0351[9]. She requests the Board to accept .pharmacy verification from NABP in its place. Dr. Martin moved to approve this request. Mr. Poole seconded, and the motion passed unanimously.

Dr. Hanna thanked Ms. Busroe and the inspectors for the information regarding pharmacy practice outside a permitted facility. Dr. Hanna suggested this topic be discussed at a work session in 2019 to allow all parties time to study this information.

Mr. Hadley recognized Chris Kilmeier on his 8 years of service on the Advisory Council. Mr. Hadley recognized Dr. Hanna on her 8 years of service on the Kentucky Board of Pharmacy and serving as Board President in 2018.

Mr. Hadley also recognized the following for their years of service:

Joseph Bickett, 6 years on the Advisory Council

Lisa Hart, 4 years on the Advisory Council

Taryn Harris, 4 years on the Advisory Council

Cheryl Lalonde, 1996-2018, General Counsel

ADJOURNMENT On motion by Dr. Cohron, seconded by Mr. Forgy and passed unanimously, President Hanna adjourned the meeting at 12:08 p.m. The next regularly scheduled meeting begins at 9:00 a.m. on January 30, 2019 at the Board Office in Frankfort, Kentucky.

Larry A. Hadley

Executive Director