

KENTUCKY BOARD OF PHARMACY
University of Kentucky College of Pharmacy
Lexington KY
September 25, 2019
9:00 AM
Agenda

- I. CALL TO ORDER**
- II. EMPLOYEE PERFORMANCE REVIEW**
- III. MINUTES**
 - A. *July 31, 2019
- IV. APPEARANCES**
 - A. *Kentucky Medical Equipment Suppliers Association – Teresa Aldridge
 - B. *Nick Howard
 - C. Paul Mahan – USP 825
 - D. Joel Williams – Initial pharmacist application
- V. INTERAGENCY**
- VI. BOARD REPORTS**
 - A. Executive Director
 - 1. *eMars – July and August 2019
 - B. Anthony Gray
- VII. CURRENT/PENDING CASES**
 - A. *Case Update and Fines Report
- VIII. CORRESPONDENCE**
 - A. *Jewish Hospital Shelbyville – Request for waiver from full compliance with regulations regarding sterile compounding of hazardous medications.
 - B. *Tabithia Fischbeck – Dual PIC Request
 - C. *Ken Streder – CE Extension Request
 - D. *Susan Smith - CE Extension Request
- IX. LEGISLATION/REGULATION**
 - A. *201 KAR 2:280
- X. CONTINUING EDUCATION**
 - A. *CE Programs – 19-43 through 19-47
 - B. *Guidelines for Executive Director approval of continuing education courses.
- XI. OLD BUSINESS**
 - A. USP 795
 - 1. *PowerPoint
 - B. USP 797
 - 1. *PowerPoint

*Information enclosed with this agenda.

MINUTES
KENTUCKY BOARD OF PHARMACY
held at
UNIVERSITY OF KENTUCKY COLLEGE OF PHARMACY
LEXINGTON KY
BOARD MEETING
September 25, 2019

CALL TO ORDER A regularly scheduled meeting was held at the University Of Kentucky College Of Pharmacy, Lexington, Kentucky. President Martin called the meeting to order on September 25, 2019 at 9:02 a.m.

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

Staff: Larry Hadley, Executive Director; Anthony Gray, General Counsel; Amanda Harding, Pharmacy and Drug Inspector; John Romines, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector, Katie Busroe, Pharmacy Inspections and Investigations Supervisor and Darla Sayre, Executive Staff Advisor. Court Reporter Susan Elsensohn recorded the meeting.

Guests: Chris Killmeier, Walgreens; Mark Glasper, KPhA; Cathy Hanna, APSC; Ralph Bouvette, APSC; Josh Elder, KSHP; Brian Fingerson, KYPRN Committee; Misty M. Stutz, Sullivan College of Pharmacy; Brad Pfister, RX Crossroads by McKesson; Jack McGuire, Theracom; Paul Mahan, PETNET Solutions; Paula York, OIG; Kelli Myers, University of Kentucky College of Pharmacy student on rotation with the Board; Anne Policastri, ASHP; Lindsay Villalobos, KSHP; Kourtney Shewmaker, Ephraim McDowell Health; Daniel L. Deem, RX Crossroad by McKesson; Don Kupper, New Vitalis/KPHA and the students at the University of Kentucky College of Pharmacy.

President Martin welcomed the students and thanked the University of Kentucky College of Pharmacy for hosting the meeting. He gave a brief overview of the purpose of the Board of Pharmacy and the agenda for the meeting. Introductions were made for Board members, Board staff, committee members and those affiliated with pharmacy organizations.

MINUTES On motion by Peter Cohron, seconded by Ron Poole and passed unanimously, the minutes of the July 31, 2019 Board Meeting were approved.

APPEARANCES

Nick Howard - Nick Howard was sworn in by the court reporter, Susan Elsensohn. Nick Howard appeared before the Board to request reinstatement of his Kentucky pharmacist license. Nick Howard gave a brief overview of the events leading to the surrender of his license. Nick Howard surrendered his Kentucky pharmacist license in 2014. Nick Howard signed a KYPRN agreement on December 5, 2014. He signed an Agreed Order of Surrender with the Kentucky Board of

Pharmacy stipulating six months of continuous sobriety and scrupulous compliance with the directives of the KYPRN Monitoring Agreement on April 4, 2014. His sobriety date is November 12, 2013. Brian Fingerson, chairman of the Kentucky Pharmacy Recovery Network, informed the Board that the committee voted 8-0 in favor of reinstatement.

Ron Poole moved to allow Nick Howard to sit for the NAPLEX and MPJE for reinstatement his pharmacist's license with stipulations as follows: three years of probation [beginning from date of the President's signature on the Agreed Order of Reinstatement]; pharmacy of employment shall not contain controlled substances; scrupulous compliance with the directives of the KYPRN Monitoring Agreement for the duration of probation; inspections; maximum work hours with no overtime; copy of Agreed Order to all employers and pharmacists-in-charge; signed release of medical records; monthly report of AA/NA meetings; observed urine, other body fluid, or hair samples for drug/alcohol screens; prohibited from accepting position as pharmacist-in-charge, power of attorney, or preceptor; attendance within 1 year of entry of his Agreed Order at Utah School or CAPTASA; monthly written self-performance evaluations. The specifics of his agreement will be detailed for Nick Howard later by Mr. Fingerson. Nick Howard stated he understood that any violation of the Agreed Order of Reinstatement shall cause him to automatically lose his license to practice pharmacy for not less than five years and one day and shall require him to petition the Board for reinstatement only after he has taken and successfully passed the entire Kentucky Board of Pharmacy licensure examination. Nick Howard shall not seek to amend or modify his Agreed Order. Mr. Howard must successfully pass the exams within two years of Agreed Order of Reinstatement. If unable to do so, he must petition the Board requesting permission at that time. Above information shall be reported to NABP and is subject to disclosure under the Kentucky Open Records Act. President Martin cautioned Nick Howard that the Board requires strict compliance with all stipulations. Peter Cohron seconded, and the motion passed unanimously.

Paul Mahan, PETNET Solutions – Dr. Martin informed the Board that the effective date of the new versions of USP Chapter <795>, <797> and <825> have been delayed due to appeals. Dr. Martin introduced Paul Mahan to give a brief summary of USP Chapter <825>, Radiopharmaceuticals – Preparation, Compounding, Dispensing and Repackaging. USP Chapter <825> was created to better address the practice of nuclear pharmacy.

Joel Williams – Joel Williams was sworn in by the court reporter, Susan Elsensohn. Joel Williams and his attorney, Brad Clark appeared before the Board requesting permission to sit for the NAPLEX and MPJE. An outstanding warrant for harassment was discovered during his background check. Mr. Williams stated that he was unaware of the warrant and has been working with authorities to resolve the issue.

Ron Poole moved to go into closed session pursuant to KRS 61.810(1)(c) to discuss proposed or pending litigation. Peter Cohron seconded, and the motion passed unanimously. Ron Poole moved to come out of closed session. Peter Cohron seconded, and the motion passed unanimously.

Peter Cohron moved to defer this request until documented proof of the resolution of the case is received. Mr. Williams may then repetition the Board for permission to sit for the exams. Ron Poole seconded, and the motion passed unanimously.

INTERAGENCY

Josh Elder, KSHP – Josh Elder notified the Board of the upcoming annual meeting to be held in Lexington, KY on November 14th and 15th. Brooke Herndon and Josh Elder have been appointed to the Joint Drug Education Grant Planning Committee. Mr. Elder presented the results of the survey of KSHP members on the implementation of USP Chapters <795> and <797>. Of the participating pharmacies, the responses were:

- Will work to comply with the newest versions 93%
- Prefer a blanket waiver for those complying with new versions 85%
- Individual waivers would be burdensome 82%
- Will comply with USP 800 regardless of BOP decision 91%

Mark Glasper, KPhA – Mark Glasper indicated that a poll of the participants at the Opioid Summit were in favor of a 2020 Opioid Summit with the addition of other relevant topics. Mr. Glasper notified the Board of the upcoming Legislative Summit to be held in Lexington, KY on November 1st and 2nd.

Trish Freeman – Dr. Freeman informed that Board that new protocols were forthcoming. She stated that several programs have been held for training on strep and flu testing.

Ralph Bouvette, ASPC – Ralph Bouvette informed the Board that legislation will be introduced in the 2020 Legislative Session to enable pharmacists to be reimbursed for services provided outside the scope of pharmacy practice.

BOARD REPORTS Larry Hadley presented the eMars reports for July and August 2019 to the Board. Anthony Gray notified the Board that 201 KAR 2:095 has been sent to LRC as directed at the last board meeting. He informed the Board that as directed he sent two cease and desist letters to entities using ‘farmacy’ to promote their business.

CURRENT/PENDING CASES John Fuller moved to accept the Case Review Panel recommendations for:

Revisit Case 17-0511 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by dispensing the incorrect medication. Patient was expecting cyclosporine but was dispensed Colcrys (colchicine). Pharmacy permit holder engaged in unprofessional or unethical conduct by failing to have a system in place for patient counseling. Pharmacy permit holder allegedly did not maintain a patient record including significant individual medical

history. Alleged Violations of Law: KRS 315.121 (1)(a) and 201 KAR 2:210 Section 1 (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 \$1000 administrative fine, approved corrective action plan on procedure to route calls to pharmacist and the criteria to transfer calls to pharmacist. Motion passed with one abstention.**

Revisit Case 17-0511 B. Pharmacist allegedly engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful. Alleged Violation 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. Motion passed with one abstention.**

Revisit Case 17-0511 C. Pharmacist allegedly failed to perform a complete prospective drug use review prior to dispensing a prescription. Alleged Violation of Law: 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. Motion passed with one abstention.**

Case 18-0131 C Revisit. Pharmacist allegedly engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful. Alleged Violation 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. Motion passed unanimously.**

Case 18-0131 D Revisit. Pharmacist allegedly engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful. Alleged Violation 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. Motion passed unanimously.**

Revisit Case 19-0105 A. Pharmacy permit holder allegedly sold misbranded drugs – four compounded preparations dispensed with an assigned beyond use date past the expiration of a component and two preparations dispensed with an assigned beyond use date past the stability dating of the preparation. Permit holder allegedly failed to compound non-sterile compounded preparations pursuant to United States Pharmacopeia (USP) Chapter 795. Permit holder allegedly failed to maintain complete compounding records for all compounded preparations. Alleged Violations of Law: KRS 217.065 (1) and 201 KAR 2:076 Section 2 (1). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed with one abstention.**

Revisit Case 19-0105 B. Pharmacist in charge allegedly failed to compound non-sterile compounded preparations pursuant to United States Pharmacopeia (USP) Chapter 795. Permit holder allegedly failed to maintain complete compounding records for all compounded preparations. Alleged Violation of Law: 201 KAR 2:076 Section 3 (2). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed with one abstention.**

Revisit Case 19-0105 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 dispensing a misbranded prescription and failure to create a complete compounding record for all compounded preparations. Three compounded preparations dispensed with an assigned beyond use date past the expiration of a component. 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. Motion passed with one abstention.**

Revisit Case 19-0105 D. 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 misbranded prescription and failure to create a complete compounding record for all compounded preparations. One compounded preparation dispensed with an assigned beyond use date past the expiration of a component. Two compounded preparations dispensed with an assigned beyond use date past the stability dating of the preparation. 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. Motion passed with one abstention.**

Case 19-0111 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported three prescriptions for controlled substances were signed out to deliver to patients before discharge from the hospital, but the patients did not receive them. 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. Motion passed with one abstention.**

Case 19-0111 B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported three prescriptions for controlled substances were signed out to deliver to patients before discharge from the hospital, but the patients did not receive them. 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. Motion passed with one abstention.**

Case 19-0111 C. 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 insufficient evidence of a**

violation to warrant disciplinary action and the case is closed without prejudice. Motion passed with one abstention.

Case 19-0113 A Revisit. Pharmacy permit holder allegedly sold adulterated drugs; four preparations compounded with expired components were dispensed. Permit holder allegedly failed to compound non-sterile preparations pursuant to United States Pharmacopeia (USP) 795. Permit holder allegedly failed to maintain complete records as required by USP 795. Alleged Violations of Law: KRS 217.055 (1)(a), (2), (4)(a) and 201 KAR 2:076 Section 2 (1). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed with one abstention.**

Case 19-0113 B Revisit. Pharmacist in charge (PIC) allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public, with or without established proof of harm by dispensing two compounded preparations containing expired ingredients. PIC allegedly failed to compound non-sterile compounded preparations pursuant to United States Pharmacopeia (USP) Chapter 795. PIC allegedly failed to maintain complete compounding records for all compounded preparations. Alleged Violations of Law: KRS 315.121 (2)(d) and 201 KAR 2:076 Section 3 (2). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed with one abstention.**

Case 19-0113 C 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 dispensing two compounded preparations containing expired ingredients. 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. Motion passed with one abstention.**

Case 19-0114 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 3,403 dosage units of controlled substances over a period of 325 days due to suspected 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. Motion passed with one abstention.**

Case 19-0114 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 3,403 dosage units over a period of 325 days due to suspected 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. Motion passed with one abstention.**

Case 19-0118 A Revisit. Pharmacy permit holder allegedly sold misbranded drugs – ten compounded preparations dispensed with an assigned beyond use date past the expiration of a

component. Permit holder allegedly sold an adulterated drug – one compounded preparation made with an expired ingredient. Permit holder allegedly failed to compound non-sterile compounded preparations pursuant to United States Pharmacopeia (USP) Chapter 795. Permit holder allegedly failed to maintain complete compounding records for all compounded preparations. Alleged Violations of Law: KRS 217.065 (1), KRS 217.055 (1)(a), (2), 4(a), and 201 KAR 2:076 Section 2 (1). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed with one abstention.**

Case 19-0118 B Revisit. Pharmacist in charge (PIC) 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 misbranded prescriptions. Two compounded preparations dispensed with an assigned beyond use date past the expiration of a component. PIC allegedly failed to compound non-sterile compounded preparations pursuant to United States Pharmacopeia (USP) Chapter 795. Alleged Violations of Law: KRS 315.121 (2)(d) and 201 KAR 2:076 Section 3 (2). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed with one abstention.**

Case 19-0118 C 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 dispensing misbranded prescriptions. Six compounded preparations dispensed with an assigned beyond use date past the expiration of a component. 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. Motion passed with one abstention.**

Case 19-0118 D 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 dispensing misbranded prescriptions. Two compounded preparations dispensed with an assigned beyond use date past the expiration of a component. 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. Motion passed with one abstention.**

Case 19-0118 E 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 dispensing an adulterated preparation. Compounded preparation dispensed compounded after the expiration of a component. 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. Motion passed with one abstention.**

Case 19-0124 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 126 dosage units of controlled substances over a period of 5 days due to employee pilferage. Pharmacy employed a delivery driver that allegedly diverted controlled substances. 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. Motion passed unanimously.

Case 19-0124 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 126 dosage units over a period of 5 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. Motion passed unanimously.**

Case 19-0262 A Revisit. Outsourcer facility entered into a Consent Decree of Permanent Injunction with the Department of Justice on behalf of the United States Food and Drug Administration (FDA). Alleged Violation of Law: KRS 315.121(1)(c)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 \$25,000 administrative fine and respondent must notify the Board upon reopening. Motion passed with one abstention.**

Case 19-0262 B Revisit. Outsourcer facility entered into a Consent Decree of Permanent Injunction with the Department of Justice on behalf of the United States Food and Drug Administration (FDA). Alleged Violation of Law: KRS 315.121(1)(c)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, administrative fine included in Case 19-0262 A and probation during the Consent Decree of Permanent Injunction with the Department of Justice on behalf of the United States Food and Drug Administration (FDA). Motion passed with one abstention.**

Case 19-0262 C Revisit. Outsourcer facility entered into a Consent Decree of Permanent Injunction with the Department of Justice on behalf of the United States Food and Drug Administration (FDA). Alleged Violation of Law: KRS 315.121(1)(c)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, administrative fine included in Case 19-0262 A and probation during the Consent Decree of Permanent Injunction with the Department of Justice on behalf of the United States Food and Drug Administration (FDA). Motion passed with one abstention.**

Case 19-0262 D Revisit. Outsourcer facility entered into a Consent Decree of Permanent Injunction with the Department of Justice on behalf of the United States Food and Drug

Administration (FDA). Alleged Violation of Law: KRS 315.121(1)(c)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, administrative fine included in Case 19-0262 A and probation during the Consent Decree of Permanent Injunction with the Department of Justice on behalf of the United States Food and Drug Administration (FDA). Motion passed with one abstention.**

Case 19-0265 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 97 tablets of oxycodone/acetaminophen 10/325mg; 11 tablets of hydrocodone/acetaminophen 10/325mg; 114 tablets of hydrocodone/acetaminophen 7.5/325mg; 4 tablets of amphetamine aspartate/amphetamine sulfate/dextroamphetamine 10mg; 156 tablets of alprazolam 1mg; and 73 tablets of alprazolam 0.5mg. 226 tablets of Schedule II drugs and 229 tablets of Schedule IV drugs, for a total of 455 dosage units of controlled substances were diverted over approximately 3 weeks. 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. Motion passed with one abstention.**

Case 19-0265 B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 97 tablets of oxycodone/acetaminophen 10/325mg; 11 tablets of hydrocodone/acetaminophen 10/325mg; 114 tablets of hydrocodone/acetaminophen 7.5/325mg; 4 tablets of amphetamine aspartate/amphetamine sulfate/dextroamphetamine 10mg; 156 tablets of alprazolam 1mg; and 73 tablets of alprazolam 0.5mg. 226 tablets of Schedule II drugs and 229 tablets of Schedule IV drugs, for a total of 455 dosage units of controlled substances were diverted over approximately 3 weeks. 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. Motion passed with one abstention.**

Case 19-0265 C. 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. Technician allegedly diverted 97 tablets of oxycodone/acetaminophen 10/325mg; 11 tablets of hydrocodone/acetaminophen 10/325mg; 114 tablets of hydrocodone/acetaminophen 7.5/325mg; 4 tablets of amphetamine aspartate/amphetamine sulfate/dextroamphetamine 10mg; 156 tablets of alprazolam 1mg; and 73 tablets of alprazolam 0.5mg. 226 tablets of Schedule II drugs and 229 tablets of Schedule IV drugs, for a total of 455 dosage units of controlled substances were diverted over approximately 3 weeks. 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. Motion passed with one abstention.

Case 19-0270 A. Pharmacy permit holder allegedly sold adulterated drugs by dispensing preparations compounded with expired components. Pharmacy permit holder allegedly sold misbranded drugs by dispensing compounded preparations with an assigned beyond use date (BUD) past the expiration of a component. Permit holder allegedly failed to compound non-sterile preparations pursuant to United States Pharmacopeia (USP) 795. Permit holder allegedly failed to maintain complete records as required by USP 795. Permit holder allegedly compounded a sterile compounded preparation ophthalmic suspension in a non-sterile compounding environment. Alleged Violation of Law: KRS 217.055 (1)(a), (2), (4)(a); KRS 217.065 (1), and 201 KAR 2:076 Section 2 (1) and (2). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed with one abstention.**

Case 19-0270 B. Pharmacist in charge (PIC) allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public, with or without established proof of harm by verifying 74 compounded preparations with expired components and 10 compounded preparations that the BUD exceeded that of the components. PIC allegedly failed to implement a quality assurance program in the provision of pharmacy services. PIC allegedly compounded a sterile compounded preparation ophthalmic suspension in a non-sterile compounding environment. Alleged Violation of Law: KRS 315.121 (2)(d); 201 KAR 2:076 Section 3 (1) and (2) and Section 2 (1) and (2); 201 KAR 2:205 Section 2 (3)(a) and (b). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed with one abstention.**

Case 19-0270 C. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public, with or without established proof of harm by verifying 17 compounded preparations with expired components, and 1 compounded preparation that the BUD exceeded that of the components' expiration. 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. Motion passed with one abstention.**

Case 19-0270 D. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public, with or without established proof of harm by verifying 1 compounded preparation with expired components. 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. Motion passed with one abstention.**

Case 19-0272 A. Pharmacy permit holder allegedly sold a misbranded drug due to a medication error. Patient was allegedly dispensed a prescription for heparin syringes that contained sodium chloride syringes. Alleged Violation of Law: KRS 217.065 (1). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/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, approved corrective action plan to address lookalike medication errors. Motion passed with one abstention.**

Case 19-0272 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 was allegedly dispensed a prescription for heparin syringes that contained sodium chloride syringes. 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. Motion passed with one abstention.**

Case 19-0274 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by employing a pharmacist that refused to dispense a prescription due to religious discrimination. 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. Motion passed with one abstention.**

Case 19-0274 B. Pharmacist allegedly engaged in unprofessional or unethical conduct by refusing to dispense a prescription due to religious discrimination. 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. Motion passed with one abstention.**

Case 19-0276 A. Pharmacy permit holder allegedly sold a misbranded drug due to a medication error. Patient allegedly was dispensed oxycodone/acetaminophen 5mg/325mg tablets for a prescription written for hydrocodone/acetaminophen 5mg/325mg 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. Motion passed unanimously.**

Case 19-0276 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 oxycodone/acetaminophen

5mg/325mg tablets for a prescription written for hydrocodone/acetaminophen 5mg/325mg 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. Motion passed unanimously.**

Case 19-0277 A. Pharmacy permit holder allegedly sold misbranded and adulterated drugs. Sterile preparations from 15 separate lots were dispensed with an assigned beyond use date past the expiration of a component. One lot was compounded with an expired ingredient. Permit holder allegedly failed to compound sterile preparations pursuant to United States Pharmacopeia (USP) Chapter 797. Permit holder allegedly engaged in unethical or unprofessional conduct by aiding and abetting an individual with a revoked license to engage in the practice of pharmacy. Alleged Violation of Law: KRS 217.065 (1); KRS 217.055 (1)(a), (2), 4(a); 201 KAR 2:076 Section 2 (2); KRS 315.121 (1)(g). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed unanimously.**

Case 19-0277 B. Pharmacist in charge (PIC) allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by dispensing misbranded and adulterated prescriptions. PIC verified 8 lots of sterile preparations with an assigned beyond use date past the expiration of a component. PIC verified 1 lot of sterile preparations made with an expired ingredient. PIC allegedly failed to compound sterile preparations pursuant to United States Pharmacopeia (USP) Chapter 797. PIC allegedly engaged in unethical or unprofessional conduct by aiding and abetting an individual with a revoked license to engage in the practice of pharmacy. Alleged Violation of Law: KRS 315.121 (2)(d); 201 KAR 2:076 Section 3 (2); KRS 315.121 (1)(g). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed unanimously.**

Case 19-0277 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 dispensing misbranded prescriptions. Pharmacist verified 3 lots of sterile preparations with an assigned beyond use date past the expiration of a component. 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. Motion passed unanimously.**

Case 19-0277 D. 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 misbranded prescriptions. Pharmacist verified 3 lots of sterile preparations with an assigned beyond use date past the expiration of a component. 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. Motion passed unanimously.**

Case 19-0277 E. Individual allegedly violated an Agreed Order of Revocation by engaging in the practice of pharmacy without a license. Alleged Violation of Law: KRS 315.121 (1)(g) and (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, \$5000 administrative fine and revocation of five years and one day during which no presence in a pharmacy except for personal use. Motion passed unanimously.**

Case 19-0278 A. Out of state pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by employing a pharmacist who dispensed a prescription without authorization. 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. Motion passed with one abstention.**

Case 19-0278 B. Pharmacist-in-charge of an out of state pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by 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: KRS 315.121(2)(f). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Motion passed with one abstention.**

Case 19-0279 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 5,525 dosage units of schedule IV and V controlled substances over a period of 77 days 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, additional 6 hours of continuing education on medication errors and their prevention. Motion passed with one abstention.**

Case 19-0279 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 5,525 dosage units of schedule IV and V controlled substances over a period of 77 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. Motion passed with one abstention.

Case 19-0279 C. 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. Motion passed with one abstention.**

Case 19-0280 A. Pharmacy permit holder allegedly sold adulterated drug. Allegedly sold misbranded drugs; compounded preparations with a beyond use date past the expiration date of components expired components that were dispensed. Permit holder allegedly failed to compound non-sterile preparations pursuant to United States Pharmacopeia (USP) 795. Permit holder allegedly failed to maintain complete records as required by USP 795. Alleged Violations of Law: KRS 217.055 (1)(a), (2), (4)(a); 201 KAR 2:076 Section 2 (1); KRS 217.0651. **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed with one abstention.**

Case 19-0280 B. Pharmacist in charge (PIC) allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public, with or without established proof of harm by dispensing compounded preparations containing expired ingredients. PIC was allegedly not knowledgeable in the specialized functions of preparing and dispensing compounded non-sterile preparations and allegedly failed to properly compound non-sterile preparations. PIC allegedly failed to implement a quality assurance program and in the provision of pharmacy services. Alleged Violations of Law: KRS 315.121 (2)(d); 201 KAR 2:076 Section 3 (1) and (2); 201 KAR 2:205 Section 2 (3)(a) and (b). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed with one abstention.**

Case 19-0281 A. Pharmacy permit holder employed a pharmacist that allegedly showed unprofessional or unethical conduct by violating patient confidentiality. 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. Motion passed unanimously.**

Case 19-0281 B. Pharmacist-in-charge allegedly showed unprofessional or unethical conduct by violating patient confidentiality. Alleged Violation of Law: KRS 315.121 (2) (b). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Motion passed unanimously.**

Case 19-0282 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 1,630 dosage units of schedule II and IV controlled substances over a period of 510 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. Motion passed with one abstention.**

Case 19-0282 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 1,630 dosage units of schedule II and IV controlled substances over a period of 510 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. Motion passed with one abstention.**

Case 19-0282 C. 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. Motion passed with one abstention.**

Case 19-0285 Pharmacy permit holder allegedly failed to place a pharmacist in charge of the pharmacy from July 29, 2019 to August 20, 2019. Alleged Violation of Law: KRS 315.020 (1). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine. Motion passed with one abstention.**

Case 19-0286. A wholesale distributor, its former President and Compliance Officer have been indicted by a federal grand jury, charged with conspiring to illegally distribute controlled substances. Alleged Violation of Law: KRS 315.121(1)(c). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed with one abstention.**

Case 19-0287. Pharmacist has been indicted by a federal grand jury, charged with conspiring to illegally distribute controlled substances. Alleged Violation of Law: KRS 315.121(1)(c). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed with one abstention.**

Case 19-0288. Pharmacy technician allegedly engaged in unprofessional or unethical conduct by impersonating a nurse. 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 revocation. Motion passed with one abstention.**

Case 19-0291 Pharmacy technician allegedly engaged in unprofessional or unethical conduct by entering into pre-trial diversion program for an attempt to practice medicine without a license. Alleged Violation of Law: KRS 315.121 (1)(c) 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 status of 'Do Not Renew'. Motion passed with one abstention.**

Case 19-0292. 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 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. Motion passed unanimously.**

Ron Poole seconded, and the motion passed unanimously.

CORRESPONDENCE

Jewish Hospital Shelbyville, Request for waiver from full compliance with regulations regarding sterile compounding of hazardous medications – Ron Poole moved to approve this request upon receipt of a Board approved risk assessment. Peter Cohron seconded, and the motion passed unanimously.

Tabithia Fischbeck, Dual PIC Request – Ron Poole moved to approve this request. Jill Rhodes seconded, and the motion passed unanimously.

Ken Streder, CE Extension Request – Ron Poole moved to deny this request. John Fuller seconded, and the motion passed unanimously.

Susan Smith, CE Extension Request – Ron Poole moved to deny this request. John Fuller seconded, and the motion passed unanimously.

LEGISLATION/REGULATION

201 KAR 2:280 The Regulation Committee recommended amendments to 201 KAR 2:280. This administrative regulation establishes procedural and substantive requirements for dispensing an equivalent drug product pursuant to a practitioner declaration of formulary compliance approval. Ron Poole moved to accept this amendment. Peter Cohron seconded, and the motion passed unanimously.

CONTINUING EDUCATION

Ron Poole moved to approve 19-43 thru 19-47. Peter Cohron seconded, and the motion passed unanimously.

OLD BUSINESS The inspection staff led by Katie Busroe, presented the handouts from their presentations, Broad Comparison of USP 795 and Broad Comparison of USP 797. These presentations address the differences between the recent versions of 795/797 and the USP 795 2014 version and the USP 797 2008 version. Ron Poole thanked the inspection staff on these presentations. He found them to be the most detailed and informative presentations available. The Board directed office staff to post these presentations to the Board's website.

NEW BUSINESS

Ron Poole informed the Board of the results of the ARNP committee meeting.

- Report was given on CBD oil: APRN's encouraged to use judgement founded on evidence-based medicine.
- Voted to not allow CRNA's to manage and write for prescriptions for dermatological specialty practices such as medi-spas.
- Had long discussion on if APRN's should be allowed to write prescriptions for family members: tabled until next time.

Ron Poole requested clarification on the charges made to the various committees and councils of the Board. Dr. Martin stated that moving forward the Board would be more explicit in their charges to include precisely what the Board expects. Charges to the various committees and councils would not be uniform but would be tailored to meet the intent of the Board.

Ron Poole presented to the Board a guideline for the Executive Director's review and approval of continuing education extension requests. This issue was tabled until the November meeting.

Dr. Martin called for a recess at 12:00 p.m. Dr. Martin reconvened the meeting at 12:12 p.m. John Fuller moved to go into closed session pursuant to KRS 61.810(1)(f) to discuss employee performance. Jody Forgy seconded, and the motion passed unanimously. John Fuller moved to come out of closed session. Peter Cohron seconded, and the motion passed unanimously.

Peter Cohron moved to approve a 5% pay increase for Anthony Gray. The Board acknowledges and appreciates the hard work and efforts of Mr. Gray in the six months of his employment as General Counsel. Ron Poole seconded, and the motion passed unanimously.

ADJOURNMENT On motion by Ron Poole, seconded by Jill Rhodes and passed unanimously, President Martin adjourned the meeting at 12:42 p.m. The next regularly scheduled meeting begins at 9:00 am on November 13, 2019 at the Kentucky Board of Pharmacy in Frankfort, KY.

Larry A. Hadley
Executive Director