

KENTUCKY BOARD OF PHARMACY

125 Holmes Street

Frankfort KY 40601

July 31, 2019

9:00 AM

Agenda

I. CALL TO ORDER

II. MINUTES

A. *May 29, 2019

III. ETHICS – Kathryn Gabhart, Executive Director of the Executive Branch Ethics Commission

IV. APPEARANCES

A. *Ashish Parehk – Pharmacy Technician Application

B. *Margaret Sawyers – Pharmacy Technician Application

C. *Alexander Anderson – Permission to sit for exams

D. *Alexander Rababeh – Initial Pharmacist Application

E. *Rich Palombo – Express Scripts

F. *Cubex LLC

1. *201 KAR 3:370 Pharmacy services in long-term care facility(LTCF).

V. INTERAGENCY

VI. BOARD REPORTS

A. Executive Director

1. *eMars – May and June 2019

2. 2019 ASPL Fall Meeting – November 7-10, 2019

3. NABP District III, Chattanooga, TN – August 11-13, 2019

4. MALTAGON, Biloxi, MS – October 27-30, 2019

B. Anthony Gray

1. *Modification of Application for Pharmacist Licensure

2. Medication Error case review panel recommendations

a. *Summary of administrative fines for med error cases

VII. CURRENT/PENDING CASES

A. *Case Update and Fines Report

B. *Pharmacy Technician Summary

C. *Sarah Wallace - Reciprocal

VIII. CORRESPONDENCE

A. *Brett Vickey, 'Farmacy' concern

B. *Chewy Pharmacy, Compounding Equipment Waiver

C. *Genoa Healthcare – Offsite Storage Requests

- D. *St. Matthews Community Pharmacy and Specialty Pharmacy – Offsite Storage Requests
- E. *St. Claire Healthcare – Compounding Waiver
- F. *Meijer – Compounding Equipment Waiver
- G. *Lou Rego – CE Extension Request
- H. *Mark Rueth – CE Extension Request
- I. *Minh-Hai Pelkey – CE Extension Request
- J. *Douglas Mack – CE Extension Request
- K. *David Kazarian – CE Extension Request
- L. *Julie Harting – CE Extension Request
- M. *Peter Van Ess – CE Extension Request

IX. LEGISLATION/REGULATION

- A. *201 KAR 2:310 Compounding for Veterinarian’s Office
 - 1. *Summary of Written Comments
 - 2. *Written Comments
 - 3. *NABP Modeling Act – Compounding Section
- B. *201 KAR 2:095 Pharmacist Interns
- C. 201 KAR 2:175 Emergency 72 hour refills
 - 1. *Current version
 - 2. *HB 64
 - 3. *Proposed amended version due to HB 64
- D. *201 KAR 2:165 Transfer of prescription information.
 - 1. *Written Comments

X. CONTINUING EDUCATION

- A. *CE Programs – 19-39 through 19-42

XI. OLD BUSINESS

- A. *Comments on USP 800
 - 1. *Safe Handling of Hazardous Drugs: ASCO Standards
 - 2. *USP Chapter 800 Hazardous Drugs – Handling in Healthcare Settings, 2017 ACPE Fall Conference
 - 3. USP 795
 - 4. USP 797
 - 5. USP 825

XII. NEW BUSINESS

- A. *Iron Mountain Storage – Offsite Storage Blanket Waiver
- B. *LegitScript

*Information enclosed with this agenda.

MINUTES

KENTUCKY BOARD OF PHARMACY

125 Holmes Street
Frankfort KY 40601

BOARD MEETING

July 31, 2019

CALL TO ORDER A regularly scheduled meeting was held at the Kentucky Board of Pharmacy in Frankfort, Kentucky. President Martin called the meeting to order on July 31, 2019 at 9:00 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 and Darla Sayre, Executive Staff Advisor. Court Reporter Terri Pelosi recorded the meeting.

Guests: Chris Killmeier, Walgreens; Mark Glasper, KPhA; Cathy Hanna, APSC; Ralph Bouvette, APSC; Josh Elder, KSHP; Brenda Shafer, Quarles & Brady; John Long, CVS Health; Brian Yarberry, Norton Children's Hospital; Matthew Casper, Norton Healthcare; Matt Blum, Norton Healthcare; Mary Cambron, Norton Healthcare; David Fulkerson, Norton Healthcare; Brian Fingerson, KYPRN Committee; Mike Wyant, Cardinal Health; Chrissy Hatfield, Baptist Health; Jennifer Baker, West Knox Pharmacy; Margaret Sawyers, West Knox Pharmacy; Stephanie Justice, St. Claire Healthcare; Martika Martin, Danhauer Drug Company; Rich Palumbo, Express Scripts, Alex Anderson, Joel Tjeerdsma, Cubex; Ashish Parekh; Kyle Bryon, APSC; Seth Depasquale, BET Pharm; Karen Nishi, Cubex; Jeff Scott, Kroger; Katelyn Brubaker; Michelle Shane, KBVE; Dr. Steven Wills, KBVE; and Dr. Doug Peterson, KVMA.

MINUTES On motion by Jill Rhodes, seconded by Ron Poole and passed unanimously, the minutes of the May 29, 2019 Board Meeting were approved.

ETHICS TRAINING Kathryn Gabhart, Executive Director of the Executive Branch Ethics Commission presented a training program for the Board members.

APPEARANCES

Ashish Parekh – Ashish Parekh was sworn in by Terri Pelosi, Court Reporter. Mr. Parekh appeared before the Board seeking registration as a pharmacy technician. Mr. Parekh was previously registered as a pharmacist intern effective 3/4/2011. This registration was permanently revoked pursuant to 15-0299. Mr. Parekh gave a brief summary of the circumstances instigating the case and what has transpired since. Anthony Gray reiterated to him that pursuant to 15-0299 he was unable to seek registration as a pharmacist intern. Peter

Cohron moved to grant this registration. Ron Poole seconded, and the motion passed with one nay vote.

Margaret Sawyers – Margaret Sawyers was sworn in by Terri Pelosi, Court Reporter. Ms. Sawyers appeared before the Board requesting a review of her pharmacy technician registration application. Her application was denied at the May 29, 2019 board meeting. Ms. Sawyers gave a brief summary of the circumstances resulting in the denial. Jennifer Baker, West Knox Pharmacy gave testimony of Ms. Sawyers employment and character. Peter Cohron moved to grant this registration. Ron Poole seconded, and the motion passed unanimously.

Alexander Anderson – Alexander Anderson was sworn in by Terri Pelosi, Court Reporter. Mr. Anderson appeared before the Board seeking permission to sit for pharmacist licensure exams. Pursuant to 19-0001, Mr. Anderson was required to seek Board approval to sit for the exams. This case resulted from a violation of his KYPRN agreement. Brian Fingerson, KYPRN Committee stated that the committee had no issue with this request. Peter Cohron moved to grant this request under the stipulation of two additional years participation with the KYPRN. Ron Poole seconded, and the motion passed unanimously.

Rich Palumbo, Express Scripts – Mr. Palumbo appeared before the Board requesting consideration for regulations regarding RX Adaptation. These regulations would allow pharmacists to use their professional judgement to adapt prescriptions while still meeting the intent of the physician. Ron Poole moved to direct the Advisory Council to consider this issue. Jody Forgy seconded, and the motion passed unanimously.

Cubex LLC – Joel Tjeerdsma and Karen Nishi were sworn in by Terri Pelosi, Court Reporter. They requested clarification on 201 KAR 2:370 regarding eKits and the requirement of bar coded systems being loaded by pharmacy personnel. After much discussion, President Martin stated that the wording on 201 KAR 2:370 was specific and did not allow a waiver process for any different practices.

INTERAGENCY Mark Glasper, KPhA, requested clarification on the directive of the Board at the May meeting regarding a medical safety course. President Martin stated that KPhA was suggested as a possible provider for the course not directed by the Board to provide one. Mark Glasper informed the Board that the results from the participants of the March Opioid meeting would soon be available. All participants were in favor of an annual meeting on this topic.

Josh Elder, KSHP, informed the Board of that the Fall Meeting to be held on November 14-15, 2019 in Lexington, Kentucky.

BOARD REPORTS Larry Hadley presented the eMars reports for May and June 2019 to the Board.

Mr. Hadley requested approval for himself Anthony Gray, General Counsel to attend the NABP District III meeting on August 11-14, 2019 in Chattanooga, TN.

Mr. Hadley requested approval for Anthony Gray, General Counsel and Board inspection staff to attend the MALTAGON meeting on October 27-30, 2019 in Biloxi, MS.

Mr. Hadley requested approval to attend the NABP Executive Officers meeting on October 1-2, 2019 in Mount Prospect, IL.

Ron Poole moved to approve these travel request. John Fuller seconded, and the motion passed unanimously.

Anthony Gray presented a request to the Board to modify the initial application for pharmacist licensure and amend 201 KAR 2:020. He requested the removal of Item 11 due to Item 12 identifying the intent of convictions and/or violation. Ron Poole moved to approve this request. Peter Cohron seconded. Jill Rhodes moved to amend the motion to include additional changes to make the application duplicate the Items listed on the application for registration as a pharmacist intern; specifically the addition of Items A – E on the application be inserted into the pharmacist application. Jody Forgy seconded, and the motion passed unanimously.

Jill Rhodes moved to modify the application for registration as a pharmacist intern and amend 201 KAR 2:040 with the corrected of FPGEC to read Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification. Ron Poole seconded, and the motion passed unanimously.

Anthony Gray presented to the Board a breakdown of medication errors and fines received requested by the Board at the May meeting.

Peter Cohron recused himself and left the meeting.

CURRENT/PENDING CASES Anthony Gray informed the Board that a summary of allegations was included in the Case Review Summary to comply with the request made by Jill Rhodes at the May meeting for additional information. This is only a summary of allegations not the facts of the case. Ron Poole questioned why in some cases the recommendation is dismissal for the permit holders. President Martin stated that if the error occurred due to a pharmacy system issue the permit holder is held accountable. If the error occurred due to non-compliance with the pharmacy system, the permit holder's case is dismissed. Ron Poole requested a summary of the criteria used to make this determination.

Ron Poole moved to withdraw the recommendations for Cases 19-0105A, 19-0113A and 19-0118A from Case Review and be returned to the case review panel for:

- a considerable or even massive reduction in fines that is commensurate of patient harm as the result of the violation (not the potential, but the proven patient harm)
- fines that aren't punitive in nature for those who truly wish to continue compounding without fear of being placed in a financial crisis due to the excessive fines.
- within 90 days, the permit holders, PIC's, and compounding staff will submit to the inspector of record and/or the KYBOP, a detailed plan of the changes in Standard Operating Procedures that will occur at their compounding pharmacies that will allow

for compliance with USP 795 and/or USP 797 if applicable, along with any other changes identified by the inspector.

- Depending on what the CRP decides, a follow-up inspection may be in order at 6 months following the prior inspection at a cost of \$250 to \$500 paid for by the permit holder
- The CRP and inspection staff will identify CE or programs that will allow the Compounding Pharmacy permit holder and Staff to obtain the education necessary to attain compounding compliance.

John Fuller seconded, and the motion passed unanimously.

Ron Poole moved to accept the Case Review Panel recommendations for:

Case 17-0511 A Revisit. 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 developed and the investigator is directed to conduct further investigation. Vote was 2-1 abstention.**

Case 17-0511 B 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 sufficient evidence developed and the investigator is directed to conduct further investigation. Vote was 2-1 abstention.**

Case 17-0511 C Revisit. 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 sufficient evidence developed and the investigator is directed to conduct further investigation. Vote was 2-1 abstention.**

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 requirement for compounding sterile preparations. Alleged Violations of Law: KRS 315.121(1)(h) and (2)(d) and 201 KAR 2:076 Section 2(2). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 18-0381 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. Patient allegedly was dispensed a prescription for 30 Vyvanse 30 mg capsules that also contained one hydrocodone/acetaminophen 10mg/325mg tablet. 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. Vote was unanimous.**

Case 19-0007 A Revisit. Pharmacy permit holder allegedly sold a misbranded drug due to a medication error. Patient allegedly received Trazodone 100 mg tablets instead of Trazodone 50 mg tablets. 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 submitted prescriptive

drug order. Alleged Violations of Law: KRS 217.065(1) and 201 KAR 2:210 Section 1 (d)(3). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$1500 administrative fine, approved corrective action plan to prevent future occurrences. Vote was 2-1 abstention.**

Case 19-0007 B Revisit. 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 was allegedly dispensed Trazodone 100 mg tablets instead of Trazodone 50 mg tablets. Alleged Violation of Law: KRS 315.121(2)(d). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention. Vote was 2-1 abstention.**

Case 19-0007 C Revisit. Pharmacist allegedly failed to perform a proper prospective drug use review 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. Vote was 2-1 abstention.**

Case 19-0007 D Revisit. Pharmacist allegedly failed to perform a proper prospective drug use review prior to dispensing a prescription. Alleged Violation of Law: 201 KAR 2:210 Section 4 (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, additional 6 hours of continuing education on medication errors and their prevention. Vote was 2-1 abstention.**

Case 19-0010 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 1920 milliliters (ml) of Promethazine with Codeine Cough Syrup over a period of 7 months from June 28, 2018 to January 28, 2019 due to employee pilferage using forged prescriptions. 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. Vote was unanimous.**

Case 19-0010 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 1920 ml of Promethazine with Codeine Cough Syrup over a period of 7 months from June 28, 2018 to January 28, 2019 due to employee pilferage using forged prescriptions. 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. Vote was unanimous.**

Case 19-0010 C. Pharmacist allegedly failed to verify that a prescription for a controlled substance was valid and allegedly failed to reduce verbally authorized controlled substance prescriptions to writing. Verbal prescription was received by Pharmacy Technician that was later determined to be forged.

Alleged Violations of Law: KRS 315.121 (2)(j) and (1)(h) and KRS 218A.180(6). **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, additional 6 hours of continuing education on pharmacy law. Vote was unanimous.**

Case 19-0010 D. Pharmacist allegedly failed to verify that a prescription for a controlled substance was valid and allegedly failed to reduce verbally authorized controlled substance prescriptions to writing. Verbal prescription was received by Pharmacy Technician that was later determined to be forged. Alleged Violations of Law: KRS 315.121 (2)(j) and (1)(h) and KRS 218A.180(6). **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, additional 6 hours of continuing education on pharmacy law. Vote was unanimous.**

Case 19-0010 E. 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 Violations 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. Vote was unanimous.**

Case 19-0012 A Revisit. Pharmacy permit holder allegedly showed unprofessional or unethical conduct by violating patient confidentiality by allegedly dispensing Lantus insulin to patient with incorrect patient name on the label. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to dispense a medication in a timely manner. Alleged Violations of Law: KRS 315.121(2)(b)(d) and 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 \$500 administrative fine, approved corrective action plan to prevent future occurrences. Vote was unanimous.**

Case 19-0012 B Revisit. Pharmacist allegedly divulged unauthorized persons patient information without the patient's express consent by dispensing Lantus insulin to patient with incorrect patient name on the label. Pharmacist in charge allegedly failed in the provision of pharmacy services. Alleged Violations of Law: KRS 315.121(2)(b)(d) and 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. Vote was unanimous.**

Case 19-0073 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 967 Oxycodone tablets, 632 Hydrocodone/APAP tablets, 90 Buprenorphine tablets, and 528 Gabapentin tablets over a period of 10 weeks from December 31, 2018 to March 12, 2019 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. Vote was unanimous.**

Case 19-0073 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 967 Oxycodone tablets, 632 Hydrocodone/APAP tablets, 90 Buprenorphine tablets, and 528 Gabapentin tablets over a period of 10 weeks from December 31, 2018 to March 12, 2019 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. Vote was unanimous.**

Case 19-0073 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. Vote was unanimous.**

Case 19-0087 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by breaching patient confidentiality. Permit holder allegedly failed to maintain an accurate patient record. A patient's prescription was mailed to the wrong address. Alleged Violations of Law: KRS 315.121 (1)(a) and 201 KAR 2:210 Section 1 (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 \$1000 administrative fine, approved corrective action plan to prevent future occurrences regarding shipping address issues. Vote was 2-1 abstention.**

Case 19-0087 B. Pharmacist in charge allegedly failed to maintain an accurate patient record. Alleged Violation of Law: 201 KAR 2:205 Section (2)(3)(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, additional 6 hours of continuing education on quality assurance programs for pharmacy services. Vote was 2-1 abstention.**

Case 19-0087 C. Pharmacist allegedly engaged in unprofessional or unethical conduct by divulging or revealing to unauthorized persons patient information or the nature of professional services rendered without the patient's express consent. A patient's prescription was mailed to the wrong address. 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. Vote was 2-1 abstention.**

Case 19-0087 D. Pharmacist allegedly engaged in unprofessional or unethical conduct by divulging or revealing to unauthorized persons patient information or the nature of professional services rendered without the patient's express consent. A patient's prescription was mailed to the wrong address. 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. Vote was 2-1 abstention.**

Case 19-0087 E. Pharmacy permit holder allegedly failed to maintain an accurate patient record. An incorrect address was recorded in the patient record. Alleged Violation of Law: 201 KAR 2:210 Section 1 (1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was 2-1 abstention.**

Case 19-0087 F. Pharmacist in charge allegedly failed to establish a procedure for obtaining, recording, and maintaining information required for a patient record. The pharmacist's designee entered an incorrect address into the patient record. Alleged Violation of Law: 201 KAR 2:210 Section 1 (1)(b) and (c). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was 2-1 abstention.**

Case 19-0089 A Revisit. Permit holder allegedly sold misbranded drugs due to medication errors. One pharmacist dispensed a prescription labeled for generic Adderall 5 mg tablets that contained generic Adderall 5 mg XR capsules. Another pharmacist dispensed a prescription labeled oxcarbazepine that contained quetiapine. 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 \$1000 administrative fine, approved corrective action plan to prevent future occurrences, schedule a Board inspection within six months of CAP completion. Vote was unanimous.**

Case 19-0089 B Revisit. Pharmacist in charge allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Pharmacist in charge allegedly dispensed a prescription labeled for oxcarbazepine 300 mg that contained quetiapine 300 mg. 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. Vote was unanimous.**

Case 19-0089 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 committing a medication error. Pharmacist allegedly dispensed a prescription labeled for generic Adderall 5 mg tablets that contained generic Adderall 5mg XR capsules. 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. Vote was unanimous.

Case 19-0093 A. Pharmacy permit holder allegedly sold a misbranded drug due to a medication error. A patient was prescribed fluoxetine 20mg capsules and allegedly received fluoxetine 40mg capsules. 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. Vote was unanimous.**

Case 19-0093 B. Pharmacist allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by committing a medication error. A patient was prescribed fluoxetine 20mg capsules and allegedly received fluoxetine 40mg capsules. 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. Vote was unanimous.**

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 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 \$6000 administrative fine, PIC to conduct monthly compounding record review for accuracy and completeness for one year providing documentation of these reviews to the Board. Vote was 2-1 abstention.**

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 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 compounding. Vote was 2-1 abstention.**

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 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 \$3500 administrative fine [based on 7 scripts], additional 6 hours of continuing education on compounding. Vote was 2-1 abstention.

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 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 \$2000 administrative fine, additional 6 hours of continuing education on compounding. Vote was 2-1 abstention.**

Case 19-0113 A. 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 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, PIC to conduct monthly compounding record review for accuracy and completeness for one year providing documentation of these reviews to the Board. Vote was 2-1 abstention.**

Case 19-0113 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 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 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, additional 6 hours of continuing education on compounding. Vote was 2-1 abstention.**

Case 19-0113 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 two compounded preparations containing expired ingredients. Alleged Violation of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a**

Formal Complaint and Notice of Hearing. Standard terms and \$2000 administrative fine, additional 6 hours of continuing education on compounding. Vote was 2-1 abstention.

Case 19-0115 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 2996 benzodiazepine tablets, 179 gabapentin capsules, and 30 Lyrica capsules 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 \$2000 administrative fine, approved corrective action plan addressing drug diversion reported to the Board within 30 days of order. Vote was 2-1 abstention.**

Case 19-0115 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 2996 benzodiazepine tablets, 179 gabapentin capsules, and 30 Lyrica capsules 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. Vote was 2-1 abstention.**

Case 19-0115 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. Vote was 2-1 abstention.**

Case 19-0116 A. Medical gas permit holder allegedly operated from an unlicensed location from 4/15/19 to 5/13/19. The medical gas permit holder allegedly did not have separate license that is required for each facility due to moving without notification to the Board. Alleged Violation of Law: KRS 315.035 (5). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine. Vote was unanimous.**

Case 19-0116 B. Licensee served as pharmacist-in-charge (PIC) of a medical gas permit holder that allegedly operated from an unlicensed location from 4/15/19 to 5/13/19. The medical gas permit holder allegedly did not have separate license that is required for each facility due to moving without notification to the Board. Alleged Violations of Law: 201 KAR 2:205 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. Vote was unanimous.**

Case 19-0116 C. Manufacturer allegedly delivered prescription drugs to a medical gas facility operating at an unlicensed location. Alleged Violation of Law: 201 KAR 2:320 Section 2 (3)(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. Vote was unanimous.

Case 19-0118 A. 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 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 \$5500 administrative fine, PIC to conduct monthly compounding record review for accuracy and completeness for one year providing documentation of these reviews to the Board. Vote was 2-1 abstention.**

Case 19-0118 B. 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 Violation of Law: KRS 315.121 (2)(d) and 201 KAR 2:076 Section 3 (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 \$1000 administrative fine, additional 6 hours of continuing education on compounding. Vote was 2-1 abstention.**

Case 19-0118 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. 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 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, additional 6 hours of continuing education on compounding. Vote was 2-1 abstention.**

Case 19-0118 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. 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 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, additional 6 hours of continuing education on compounding. Vote was 2-1 abstention.

Case 19-0118 E. 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 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 compounding. Vote was 2-1 abstention.**

Case 19-0120 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by employing a pharmacist who allegedly dispensed a Schedule II medication without a valid prescription. Alleged Violation of Law: KRS 315.121 (1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0120 B. Pharmacist in charge 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. Pharmacist allegedly dispensed a Schedule II medication without a valid prescription. 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 \$1000 administrative fine, additional 6 hours of continuing education on pharmacy law. Vote was unanimous.**

Case 19-0121 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by delaying the dispensing of a patient's hydrocodone/APAP prescription by 10 days. 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. Vote was 2-1 abstention.**

Case 19-0121 B. Pharmacist in charge (PIC) allegedly failed in the timely 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. Vote was 2-1 abstention.**

Case 19-0122. Pharmacist allegedly engaged in unprofessional or unethical conduct by violating the terms of an Agreed Order. 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 of 5 years and 1 day. Vote was 2-1 abstention.**

Case 19-0128. Pharmacist allegedly has a mental or physical incapacity that prevents licensee from engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public.

Alleged Violation of Law: KRS 315.121 (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 temporary suspension for 60 days. Respondent must complete a mental and physical evaluation within those 60 days. Vote was unanimous.**

Case 19-0129 A. Pharmacy permit holder allegedly sold a misbranded prescription due to a medication error. Patient allegedly received hydrocodone/APAP instead of the labeled oxycodone/APAP. 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. Vote was 2-1 abstention.**

Case 19-0129 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 received hydrocodone/APAP instead of the labeled oxycodone/APAP. 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. Vote was 2-1 abstention.**

Case 19-0255. Pharmacy permit holder failed to renew permit in a timely manner and allegedly continued to operate without an active permit for the period of July 1, 2019. Alleged Violation of Law: KRS 315.035(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. Vote was 2-1 abstention.**

Case 19-0256. Pharmacy permit holder failed to renew permit in a timely manner and allegedly continued to operate without an active permit for the period of July 1, 2019. Alleged Violation of Law: KRS 315.035(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. Vote was 2-1 abstention.**

Case 19-0257. Special limited pharmacy permit holder failed to renew permit in a timely manner and allegedly continued to operate without an active permit for the period of July 1, 2019. Alleged Violations of Law: KRS 315.035(4) and 201 KAR 2:225 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. Vote was 2-1 abstention.**

Case 19-0258. Special limited pharmacy permit holder failed to renew permit in a timely manner and allegedly continued to operate without an active permit for the period of July 1, 2019 through July 9, 2019. Alleged Violations of Law: KRS 315.035(4) and 201 KAR 2:225 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. Vote was 2-1 abstention.

Case 19-0259. Pharmacy permit holder failed to renew permit in a timely manner and allegedly continued to operate without an active permit. Alleged Violation of Law: KRS 315.035(4). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Vote was 2-1 abstention.**

Case 19-0260. Special limited pharmacy permit – medical gas allegedly failed to notify the Kentucky Board of Pharmacy in writing 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. Vote was 2-1 abstention.**

Case 19-0261 A. Out of state pharmacy permit was indicted by the United States Government on 11 counts involving defrauding government health insurers by inflating drug costs and providing kickbacks and bribes to a Kentucky physician for sending patients to this pharmacy. 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. Vote was 2-1 abstention.**

Case 19-0261 B. Pharmacist-in-charge (PIC) of out of state pharmacy permit was indicted by the United States Government on 11 counts involving defrauding government health insurers by inflating drug costs and providing kickbacks and bribes to a Kentucky physician for sending patients to the pharmacy where PIC is employed. 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. Vote was 2-1 abstention.**

Case 19-0262 A. 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 developed and the investigator is directed to conduct further investigation. Vote was 2-1 abstention.**

Case 19-0262 B. 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 developed and the investigator is directed to conduct further investigation. Vote was 2-1 abstention.**

Case 19-0262 C. 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 developed and the investigator is directed to conduct further investigation. Vote was 2-1 abstention.**

Case 19-0262 D. 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 developed and the investigator is directed to conduct further investigation. Vote was 2-1 abstention.**

Jill Rhodes questioned the recommendation for Case 19-0262 A, B, C and D. Anthony Gray stated that this was a federal case. Historically the Board continues their investigation until the federal case has been settled. Peter Cohron seconded, and the motion passed unanimously.

Ron Poole recused himself from the meeting.

Peter Cohron moved to accept the Case Review Panel recommendation for:

Case 19-0006 A. Revisit. Pharmacy permit holder allegedly sold adulterated drugs; compounded preparations 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); 201 KAR 2:076 Section 2 (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 \$20,000 administrative fine, submission of VPP or Compounding Consult of permit holder's choice report within nine [9] months of order. Vote was 2-1 abstention.**

Case 19-0006 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 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 of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$5,000 administrative fine, additional 12 hours of continuing education on non-sterile compounding if respondent remains PIC or if not, additional 6 hours of continuing education on medication errors and their prevention, additional 6 hours of continuing education on pharmacy law. Vote was 2-1 abstention.**

Jody Forgy seconded, and the motion passed with one abstention [Jill Rhodes].

Ron Poole returned to the meeting.

PHARMACY TECHNICIAN SUMMARY

Jill Rhodes moved to take no action for Case 19-0271. Peter Cohron seconded, and the motion passed unanimously.

Reciprocal Application – Sarah Wallace John Fuller moved to accept this application under the stipulation that Ms. Wallace participate in KYPRN until June 30, 2023. Ron Poole seconded, and the motion passed unanimously.

CORRESPONDENCE

'Farmacy' – Brett Vickey Brett Vickey presented his concern over the usage of farmacy, pharmacist, farmassist and farmacology. With the sale of CBD oil and talk of medical marijuana, this terminology is being used raising a concern for misinterpretation. Jill Rhodes moved to direct Anthony Gray to send letters to these businesses requesting them to cease and desist citing violation of KRS 315.030. John Fuller seconded, and the motion passed unanimously.

Chewy Pharmacy, Compounding Equipment Waiver Ron Poole moved to approve this request. Peter Cohron seconded, and the motion passed unanimously.

Genoa Healthcare - Offsite Storage Requests Ron Poole moved to approve this request. Jill Rhodes seconded, and the motion passed unanimously.

Jill Rhodes recused herself from the meeting.

St. Matthews Community Pharmacy and Specialty Pharmacy – Offsite Storage Request Ron Poole moved to approve this request. Peter Cohron seconded, and the motion passed unanimously.

Jill Rhodes returned to the meeting.

St. Claire Healthcare – Compounding Waiver Ron Poole moved to approve this request. Peter Cohron seconded, and the motion passed unanimously.

Meijer – Compounding Equipment Waiver Ron Poole moved to accept this request. Jody Forgy seconded, and the motion passed unanimously.

Lou Rego – CE Extension Request Ron Poole moved to approve this request. Jody Forgy seconded, and the motion passed unanimously.

Mark Rueth – CE Extension Request Ron Poole moved to deny this request. Peter Cohron seconded, and the motion passed unanimously.

Minh-Hai Pelkey – CE Extension Request Peter Cohron moved to approve this request. Ron Poole seconded, and the motion passed unanimously.

Douglas Mack – CE Extension Request Ron Poole moved to deny this request. Jill Rhodes seconded, and the motion passed unanimously.

David Kazarian – CE Extension Request Jill Rhodes moved to approve this request. John Fuller seconded, and the motion passed with one nay vote (Peter Cohron).

Julie Harting – CE Extension Request Ron Poole moved to approve this request. Jody Forgy seconded, and the motion passed unanimously.

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

LEGISLATION/REGULATION

201 KAR 2:310 Representatives from KBVE and KVMA, Michelle Shane, Dr. Steven Wills and Dr. Doug Peterson spoke regarding the current amendment of 201 KAR 2:310. The changes will directly impact the ability of veterinarians to provide care and medications to their patients. President Martin agreed that these concerns need to be addressed. Ron Poole moved to defer this regulation with LRC until these concerns can be addressed. Jill Rhodes seconded, and the motion passed unanimously.

201 KAR 2:095 Ron Poole moved to return this regulation draft to the Regulation Committee to review the compiler's questions. Jill Rhodes seconded, and the motion passes unanimously.

201 KAR 2:175 Proposed amended language for 201 KAR 2:175 was submitted to the Board. This was the result of the recent passage of House Bill 64 regarding emergency 72 hour refills. Ron Poole moved to accept this amendment. Peter Cohron seconded, and the motion passed unanimously.

201 KAR 2:165 Larry Hadley informed the Board that comments were received requesting expanded pharmacy technician duties to include the transfer of prescriptions. Ron Poole stated that he did believe with the expansion of pharmacist duties the need for expanded pharmacy technician duties will be needed in the future. Ron Poole moved to take no action on these comments at this time, allowing the amended draft of 201 KAR 2:165 continue the legislative process. Jill Rhodes seconded, and the motion passed unanimously.

CONTINUING EDUCATION

Ron Poole moved to approve 19-39, 19-40, and 19-41 thru 19-42. Peter Cohron seconded, and the motion passed unanimously.

OLD BUSINESS

Comments on USP 800

Ron Poole informed the Board that he was only concern with 5% of USP 800. He is concerned over the impact of implementation of USP 800 on pharmacies and hospitals. He is not in favor of a waiver process. If an event of contamination does happen at a facility practicing under a Board approved waiver, would the Board be held accountable?

Jill Rhodes stated that USP 800 was proposed to prevent contamination. The most current versions of USP 795 and 797 address these concerns. She is not in favor of the waiver process raising a concern that this would allow too much facility interpretation. She is in favor of a plan prior to implementation to advise pharmacies on exactly what is expected, when and the consequences of non-compliance.

Josh Elder, KSHP, spoke in favor of Option #2 allowing for a waiver process. He informed the Board that those pharmacies requiring approval by the Joint Commission would be required to comply with USP 800. They would need a waiver to meet these requirements instead of complying with USP 795, January 2014 and 797, June 2008.

Barb Jolly, Sullivan College of Pharmacy, spoke in favor of Option #2 allowing for a waiver process if there was no risk to employees or patients.

Shannon Stiglitz, Kentucky Retail Federation, raised concerns regarding the language in the compounding regulation suggesting clearer language regarding infractions, violation and discipline from non-compliance. She requested language that would establish a minimum requirement allowing for pharmacies to go above that requirement without seeking a waiver.

President Martin informed the audience that the charge to the Board is to protect the safety of the public. There is a balance between that safety and providing a service to the public. He is not in favor of broad implementation of USP 800.

John Fuller suggested a deferral of implementation of USP 800. Jill Rhodes stated that there were still several medical professionals that were evaluating the material included in USP 800.

Barb Jolly stated that action would need to be taken on the implementation of USP 800 due to the fact that the current version of USP 797 does not address hazardous drugs.

Jill Rhodes moved to not adopt USP 800. Ron Poole seconded, and the motion passed with one abstention [Peter Cohron].

USP 795, 797 and 825

Katie Busroe requested clarification from the Board; will the Board amend 201 KAR 2:076 which references USP 795, January 2014 and USP 797, June 2008 to the most recent versions? After much discussion, no action was taken by the Board for this request.

Katie Busroe requested the Board consider adding USP 825 to 201 KAR 2:076. This chapter is specific to nuclear pharmacies removing them from USP 795 and 797. The implementation of this chapter is December 1, 2019. This item was tabled until the September Board meeting.

NEW BUSINESS

Iron Mountain Storage – Larry Hadley proposed the staff to approve offsite storage requests to Iron Mountain Storage. After much discussion, Ron Poole moved to deny this request. The Board will continue to review individual requests. Jill Rhodes seconded, and the motion passed unanimously.

Peter Cohron recused himself from the meeting.

LegitScript – Larry Hadley presented to the Board a request to approve LegitScript as a substantially similar program as referenced in KRS 315.0351(1)(i). After much discussion, the item was tabled until the September meeting. The Board requested an opinion from NABP regarding this request.

Peter Cohron returned to the meeting.

Jill Rhodes requested the Board to consider allowing the Executive Director to evaluate and determine the outcome of CE Extension and CE approval requests. This item was tabled until the September meeting. The Board requested specific criteria be proposed for this determination.

Jill Rhodes requested the Kentucky Board of Pharmacy Policy and Procedures be updated. This item was tabled until the November meeting. President Martin and Larry Hadley will provide the update version.

ADJOURNMENT On motion by Peter Cohron, seconded by Jody Forgy and passed unanimously, President Martin adjourned the meeting at 2:40 p.m. The next regularly scheduled meeting begins at 9:00 am on September 25, 2019 at the University Of Kentucky College Of Pharmacy in Lexington, KY.

Larry A. Hadley

Executive Director