

KENTUCKY BOARD OF PHARMACY
125 Holmes Street
Frankfort, KY
November 13, 2019, 9:00 AM
Agenda

I. CALL TO ORDER

II. MINUTES

- A. *September 25, 2019

III. APPEARANCES

- A. *Ned Milenkovich – USP <795> Nonsterile Compounding and Flavoring
- B. *Alexander Anderson – Reconsideration of licensure requirements
- C. *Amy Wildermuth - Reinstatement
- D. *Kentucky Medical Equipment Suppliers Association – Teresa Aldridge
- E. *Neal Watson, NABP – Eligibility Services

IV. INTERAGENCY

V. BOARD REPORTS

- A. Executive Director
 - 1. *eMars – September and October 2019
 - 2. *2020 Board Calendar

- B. Board Counsel
 - 1. *Scott Brierton – Reciprocal Application
 - 2. *Expungement Issues – 201 KAR 2:270
 - 3. Modification of Case Review Procedure
 - 4. NABP Amicus Brief on 503B Outsourcing
 - 5. CBD letters:
 - a) *KY CBD pharmacy response
 - b) *Pharm CBD LLC response

VI. CASES

- A. *Case Update and Fines Report
- B. *Final Orders
- C. *Disciplinary Action Guidelines

VII. CORRESPONDENCE

- A. * Kentucky Hospital Association – 18 month delay to comply with USP <800>
- B. *Barbourville ARH Specialty Pharmacy – Equipment Waiver Request
- C. *Continuecare Hospital Pharmacy – Offsite Storage Request
- D. *Jewish Hospital Shelbyville – Assessment of Risk for handling of hazardous medication
- E. *Lee Steele – Dual PIC Request

VIII. LEGISLATION/REGULATION

- A. *201 KAR 2:310
 - 1. *Written Comments summary
 - 2. *Written Comments
 - 3. Craft regulation

IX. CONTINUING EDUCATION

- A. *CE Programs – 19-48 through 19-52
- B. *Guidelines for Executive Director approval of continuing education courses.

X. OLD BUSINESS

- A. * CE Policy for Consideration of granting CE Extension requests.
- B. * Kentucky Board of Pharmacy Policy and Procedures
- C. * FDA Revised Draft MOU
- D. Case 19-0006 A and B – Revised Order from Settlement Conference

XI. NEW BUSINESS

- A. Advisory Council Appointment – one opening
 - 1. *Anthony Tagavi
 - 2. *Brian Hancock
 - 3. *Brian Yarde
 - 4. *Chad Thompson
 - 5. *Christina Hatfield
 - 6. *Geoffrey Groenke
 - 7. *Hayden Pehl
 - 8. *Martika Martin
 - 9. *Paul Mahan
 - 10. *Ross Goetz
 - 11. *Thomas Kaye
 - 12. *Troy Huddleston
 - 13. *Wesley Rowe

B. Pharmacy Recovery Network Committee Appointments – three openings

1. *Amber Cann
2. *Courtney Eatman
3. *Hannah Johnson
4. *Leo Parrino
5. *Lynn Lamkin
6. *Mike Lusk
7. *Olivia Simpson
8. *Rusty Cromer
9. *Son Vo
10. *Spencer Bolton
11. *Virginia Hammon

*Information included in Board Packet

MINUTES

KENTUCKY BOARD OF PHARMACY

held at

125 Holmes Street

Frankfort KY 40601

BOARD MEETING

November 13, 2019

CALL TO ORDER A regularly scheduled meeting was held at the Kentucky Board of Pharmacy, Frankfort, Kentucky. President Martin called the meeting to order on November 13, 2019 at 9:01 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; 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 Jolinda Todd recorded the meeting.

Guests: Chris Killmeier, Walgreens; Mark Glasper, KPhA; Cathy Hanna, APSC; Brian Fingerson, KYPRN Committee; Carolyn Basford, KMESA; Mike Downing, RSVP; Michael Burleson; Steve Hart; Amy Wildermuth; Mike Wildermuth; Emily Caporal, KYPRN; Eric Lindahl, student; Brian Good; Alex Anderson; Lorri Walmsley, Walgreens; Justin Lewis, student; John Carver, Baptist Health; Devin Wallace, VCA; Ned Milenkovich, Much Shelist; and Michelle Shane, KBVE.

MINUTES On motion by Peter Cohron, seconded by Ron Poole and passed unanimously, the minutes of the September 25, 2019 Board Meeting were approved.

APPEARANCES

Ned Milenkovich – Mr. Milenkovich appeared before the Board requesting the Board to implement a regulation amendment excluding flavoring from the definition of compounding. After much discussion, Ron Poole moved to direct Anthony Gray to draft amended language to exclude flavorings from non-sterile compounding. Flavorings must be nonallergenic and inert, not to exceed five [5] percent of the drug product's total volume. Peter Cohron seconded, and the motion passed unanimously.

Alexander Anderson – Mr. Anderson appeared before the Board accompanied by his legal representation, Brian Good requesting to reduce his previously approved probation of 2 years to 1 year. Mr. Anderson intends to leave the state within one year. Mr. Good stated that the additional year of probation would be detrimental to his licensure/employment outside of Kentucky. Jill Rhodes moved to retain the original Agreed Order stipulating a two year probation with the original terms. Ron Poole seconded, and the motion passed unanimously.

Amy Wildermuth - Amy Wildermuth was sworn in by the court reporter, Jolinda Todd. Amy Wildermuth appeared before the Board to request reinstatement of her Kentucky pharmacist

license. Amy Wildermuth gave a brief overview of the events leading to the surrender of her license. Her Ohio pharmacist license was suspended on November 1, 2017. Amy Wildermuth surrendered her Kentucky pharmacist license in 2018. Amy Wildermuth signed a monitoring contract with OHPRO on December 22, 2017. She signed an Agreed Order of Surrender with the Kentucky Board of Pharmacy stipulating twelve months of continuous sobriety and scrupulous compliance with the directives of the KYPRN Monitoring Agreement on May 29, 2018. Her sobriety date is October 31, 2017. Brian Fingerson, chairman of the Kentucky Pharmacy Recovery Network, informed the Board that the committee voted 7-0 in favor of reinstatement with one abstention.

Ron Poole moved to allow Amy Wildermuth reinstatement of her pharmacist license. The terms will mirror the Ohio terms and stipulations. Amy Wildermuth shall not seek to amend or modify her Agreed Order. Above information shall be reported to NABP and is subject to disclosure under the Kentucky Open Records Act. President Martin cautioned Amy Wildermuth that the Board requires strict compliance with all stipulations. John Fuller seconded, and the motion passed unanimously.

Caroline Basford, KMESA – Ms. Basford appeared before the Board requesting a special limited pharmacy permit – medical gas be expanded to include the ability to purchase and dispense sterile water and sterile saline. Dr. Martin stated that this would require a regulation change. The Board directed Mr. Hadley to work with KMESA to draft amended regulation language.

Neal Watson, NABP – Mr. Watson appeared before the Board to present an option available through NABP allowing them to verify licensure eligibility. The goal of NABP is to decrease the processing time at the Board level and protect the integrity of the exams. Mr. Hadley stated that this implementation would be a continuation of the Board’s philosophy to streamline the process. Ron Poole moved to direct Board staff to work with NABP to implement this change. Jody Forgy seconded, and the motion passed with one nay vote by Jill Rhodes.

INTERAGENCY

Mark Glasper, KPhA – Mark Glasper informed the Board that plans are underway for the 2020 Opioid Summit in September. Preliminary plans include a morning session available at satellite locations. Each satellite location will have an afternoon session tailored for their region.

Mr. Glasper presented the KPha Telepharmacy Position Statement to the Board.

Telepharmacy Position Statement Kentucky Pharmacists Association November 2, 2019

KPhA supports the use of telepharmacy technology to provide patient access to the services of a pharmacist when the use of such technology benefits the patient and community. KPhA supports the use of

telepharmacy technology when limited to suitable functions of pharmacy operations and patient care that improve patient outcomes, expand access to healthcare, and enhance patient safety when direct on-site pharmacist oversight is unachievable.

Regarding remote dispensing as a specific activity accomplished through the use of telepharmacy technology, KPhA supports the following limitations when the act of dispensing is completed by a certified pharmacy technician under remote supervision of a pharmacist, and not under immediate supervision as defined in KRS 315.010.

Geographical restrictions: A remote dispensing site shall not be authorized if a community retail pharmacy is located within 20 miles of the proposed remote dispensing site.

Supply and Demand: Prior to authorizing the license of a remote dispensing site, the Board of Pharmacy shall consider the availability of pharmacists, the population of the community and the community's need for the service. A remote dispensing pharmacy may fill a maximum of 125 prescriptions per day over one year average.

Supervision limitations: A pharmacist performing remote supervision shall not supervise more than one (1) remote dispensing site and a "home pharmacy" or affiliated parent company shall not own more than one (1) remote site.

BOARD REPORTS Larry Hadley presented the eMars reports for September and October 2019 to the Board. Mr. Hadley presented a proposed draft of the 2020 Board Calendar. On motion by Peter Cohron and seconded by Ron Poole, the 2020 Board calendar was approved.

- January 29, 2020
- March 25, 2020
- May 27, 2020 to be held at Sullivan College of Pharmacy
- July 29, 2020
- September 30, 2020
- November 5, 2020 to be held at University of Kentucky College of Pharmacy

Mr. Hadley proposed an ACE award be approved for Darla Sayre. This will be an increase of 10% of the midpoint. Ron Poole moved to approve. Jill Rhodes seconded, and the motion passed unanimously.

Anthony Gray presented a reciprocal application to be considered by the Board. The applicant has a suspended license in Colorado resulting from drug diversion and federal charges. Mr. Gray stated the applicant is licensed in three additional states. The Board requested the opinion of

Brian Fingerson, Chairperson of the KYPRN Committee. Mr. Fingerson indicated that he had no issues with the application due to the length of time elapsed since the occurrence. The Board tabled this item until the December meeting requesting verification of applicant's pharmacist licenses.

Anthony Gray requested the Board revisit the recent amended regulation, 201 KAR 2:270, Expungement. The regulation as amended prevents the expungement of pharmacy technicians working with an expired registration greater than 7 days. John Fuller moved to direct the Regulation Committee to draft an amendment allowing for expungement of disciplinary actions resulting from the unregistered practice of pharmacy technicians for up to 30 days. Ron Poole seconded, and the motion passed unanimously with one nay vote by Peter Cohron.

Anthony Gray informed the Board that he received two letters in response to the cease and desist letters to entities using 'farmacy' to promote their business. After much discussion, the Board directed Mr. Gray to proceed with the letters.

Anthony Gray requested a change in the case review panel process to allow all inspectors be present during the closed sessions. Voting members of the panel would consist of the Board President, Executive Director and the inspector. The remaining inspectors would be present only for the case discussion with no vote on the recommendation. The presence of all inspectors will allow for greater input and continuity of disciplinary actions. Katie Busroe stated that this will provide consistency. Each case recommendation will be individual for that case but similar cases will have a more consistent outcome. Dr. Martin agreed that this inclusion will be beneficial in the decision process. Peter Cohron moved to allow investigative staff to be present during the closed session for case review panel discussions. Ron Poole seconded, and the motion passed unanimously.

Anthony Gray informed the Board that NABP has requested Kentucky to sign an Amicus brief on 503B Outsourcing. After much discussion, the Board tabled this item until the December meeting. The Board requested the brief or an outline be provided at that time.

CURRENT/PENDING CASES Peter Cohron moved to accept the Case Review Panel recommendations for:

Case 19-0055 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by employing a pharmacist who allegedly failed to perform a prospective drug utilization review. A patient was allegedly instructed to split an extended release tablet to attain the prescribed dose of medication. 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 19-0055 B. Pharmacist allegedly failed to perform a prospective drug utilization review

and engaged in unprofessional or unethical conduct likely to harm the public, with or without established proof of actual injury. A patient was allegedly instructed to split an extended release tablet to attain the prescribed dose of medication. Alleged Violations of Law: KRS 315.121 (2)(d) and 201 KAR 2:210 Section 4. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0055 C. Pharmacist allegedly failed to perform a prospective drug utilization review and engaged in unprofessional or unethical conduct likely to harm the public, with or without established proof of actual injury. A patient was allegedly instructed to split an extended release tablet to attain the prescribed dose of medication. Alleged Violations of Law: KRS 315.121 (2)(d) and 201 KAR 2:210 Section 4. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0055 D. Pharmacist allegedly failed to perform a prospective drug utilization review and engaged in unprofessional or unethical conduct likely to harm the public, with or without established proof of actual injury. A patient was allegedly instructed to split an extended release tablet to attain the prescribed dose of medication. Alleged Violations of Law: KRS 315.121 (2)(d) and 201 KAR 2:210 Section 4. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0105 B REVISIT. 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 additional 6 hours of continuing education on compounding. Motion passed with one abstention.**

Case 19-0105 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 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 \$1,000 administrative fine, additional 6 hours of continuing education on compounding. Motion passed with one abstention.**

Case 19-0105 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 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 \$500 administrative fine, additional 6 hours of continuing education on compounding. 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 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. 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 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. Motion passed with one abstention.**

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 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 \$1,500 administrative fine. PIC to conduct monthly compounding record review for accuracy and completeness. Monthly reviews must be submitted to the Board for a period of one year. 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 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 \$1,500 administrative fine, additional 6 hours of continuing education on compounding. 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 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. 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 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 additional 6 hours of continuing education on compounding. Motion passed with one abstention.**

Case 19-0270 A REVISIT. 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 Violations 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 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 \$10,000 administrative fine. If pharmacy or pharmacy owner resumes compounding, pharmacy must notify the Board and provide monthly compounding records submitted to the Board for reconciliation on accurateness for one year and corrective action plan to prevent future occurrences. Pic must be involved in the corrective action plan. Motion passed with one abstention.**

Case 19-0270 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 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 Violations 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 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 additional 6 hours of continuing education on compounding. Motion passed with one abstention.**

Case 19-0270 C REVISIT. 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 Violations 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 \$1,000 administrative fine, additional 6 hours of continuing education on compounding. Motion passed with one abstention.**

Case 19-0270 D REVISIT. 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 Violations 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 additional 6 hours of continuing education on compounding. Motion passed with one abstention.**

Case 19-0277 A REVISIT. 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 Violations of Law: KRS 217.065 (1); KRS 217.055 (1)(a), (2), 4(a); 201 KAR 2:076 Section 2 (2); and KRS 315.121 (1)(g). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$50,000 administrative fine, five year probation. Quarterly inspections for 2 years then semi-annually for remainder of probation. PIC to conduct monthly reconciliation for one year, must follow USP 797. Must specify unit packaging information for each lot in compounding records. Must maintain complete compounding records [to include total number of units compounded, the contents/volume of each unit, and the number of units of each package size] and have available upon inspection. Vote was unanimous.**

Case 19-0277 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. Pharmacist verified 3 lots of sterile preparations with an assigned beyond use date past the expiration of a component. Alleged Violations 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 administrative fine of \$2,500, additional 6 hours of continuing education on sterile compounding. Vote was unanimous.**

Case 19-0280 A REVISIT. 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 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 administrative fine of \$2,500, monthly compounding records submitted to the Board for reconciliation on accurateness for one year and corrective action plan to prevent future occurrences. PIC must be involved in the corrective action plan. Motion passed with one abstention.

Case 19-0284 A. Pharmacy allegedly sold misbranded prescriptions, 244 prescriptions were dispensed labeled with a non-resident pharmacy's address. Alleged Violations of Law: KRS 217.065 (11)(b) and (12)(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 \$25,000 administrative fine, approved corrective action plan to prevent future occurrences. PIC must be involved in corrective action plan. Motion passed with one abstention.

Case 19-0284 B. Pharmacist in charge allegedly failed to implement an effective quality assurance program to identify system problems. Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(a). **CRC Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on quality assurance. Motion passed with one abstention.

Case 19-0284 C. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 40 misbranded prescriptions labeled with a non-resident pharmacy's address. 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 \$750 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.

Case 19-0284 D. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 34 misbranded prescriptions labeled with a non-resident pharmacy's address. 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 \$750 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.

Case 19-0284 E. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 21 misbranded prescriptions labeled with a non-resident pharmacy's address. 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 \$750 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 F. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 20 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 G. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 17 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 H. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 13 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 I. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 13 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 J. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 13 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 K. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 12 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 L. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 11 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 M. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 11 misbranded prescriptions labeled with a non-resident pharmacy's address. Alleged Violation of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is**

sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.

Case 19-0284 N. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 9 misbranded prescriptions labeled with a non-resident pharmacy's address. 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 \$250 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 O. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 7 misbranded prescriptions labeled with a non-resident pharmacy's address. 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 \$250 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 P. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 6 misbranded prescriptions labeled with a non-resident pharmacy's address. 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 \$250 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 Q. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 6 misbranded prescriptions labeled with a non-resident pharmacy's address. 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 \$250 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.

Case 19-0284 R. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 3 misbranded prescriptions labeled with a non-resident pharmacy's address. 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 \$250 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 S. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 3 misbranded prescriptions labeled with a non-resident pharmacy's address. 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 \$250 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 T. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 2 misbranded prescriptions labeled with a non-resident pharmacy's address. 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 \$250 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 U. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 2 misbranded prescriptions labeled with a non-resident pharmacy's address. 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 \$250 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0284 V. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof of actual injury by dispensing 1 misbranded prescription labeled with a non-resident pharmacy's address. 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 \$250 administrative fine, additional 6 hours of continuing education on pharmacy law. Motion passed with one abstention.**

Case 19-0289 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 1023 tramadol tablets in a 15-month period for unknown reasons. 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 \$500 administrative fine. Baseline counts on all strengths of tramadol, alprazolam, clonazepam, lorazepam, diazepam and phentermine with a correction to hydrocodone/APAP tablets. An audit to be performed 6 months from date of signed Agreed Order. Counts must be submitted to the Board office. Motion passed with one abstention.**

Case 19-0289 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 1023 tramadol tablets in a 15-month period for unknown reasons. Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on quality assurance or drug diversion. Motion passed with one abstention.**

Case 19-0294 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to request prescription refills from the correct prescriber. 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 19-0294 B. Pharmacist in charge allegedly failed in the provision of pharmacy services. The incorrect prescriber was contacted to request refills. 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 19-0295 B. Pharmacist in charge allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury. Pharmacist in charge allegedly dispensed adulterated drugs, compounded preparations purported to be sterile were filtered through non-pharmaceutical grade filter in worse than ISO 5 air and no integrity testing was performed on the sterilizing filters. Compounded stock solution was further manipulated after sterilization in non-depyrogenated glassware. Pharmacist in charge allegedly dispensed misbranded drugs, repackaged syringes and compounded preparations were assigned beyond use dates outside FDA and USP guidance without supporting stability data. Pharmacist in charge allegedly engaged in unprofessional or unethical conduct by engaging in deceptive behavior related to the practice of pharmacy. Samples from compounded preparation batch sent for sterility testing allegedly underwent an additional sterilizing filtration step. Pharmacist in charge allegedly engaged in unprofessional or unethical conduct by not sending samples for sterility testing in a timely manner, samples from stock solution not tested for up to 36 days after compounding. Pharmacist in charge allegedly failed to compound sterile preparations per USP Chapter <797> and allegedly failed to maintain compounding records for all compounded preparations. Alleged Violations of Law: KRS 315.121 (1)(a)(h), (2)(a)(d); and 201 KAR 2:076 Section 2(2), Section 3 and Section 4 (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 \$5,000 administrative fine, 5 year probation, additional 5 hours of continuing education on compounding each year of probation. Cannot be PIC unless proof of attendance at the Critical Point Boot Camp has been submitted to the Board. Motion passed with one abstention.**

Ron Poole seconded, and the motion passed unanimously.

John Fuller recused. Ron Poole moved to accept the Case Review Panel recommendations for: **Case 19-0264 A.** Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. The pharmacy reported a loss of 100 acetaminophen/codeine 300mg/60mg tablets, 16 alprazolam ER 3mg tablets, 196 clobazam 10mg tablets, 140 clonazepam 2mg tablets, 30 lorazepam 0.5mg tablets, 118 lorazepam 2mg tablets, 45 phentermine 37.5mg tablets, and 30 Horizant ER 600mg tablets, for a total of 675 tablets. Alleged Violation of Law: 201 KAR 2:100 Section 1. **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed with one abstention.**

Case 19-0264 B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. The pharmacy reported a loss of 100 acetaminophen/codeine 300mg/60mg tablets, 16 alprazolam ER 3mg tablets, 196 clobazam 10mg tablets, 140 clonazepam 2mg tablets, 30 lorazepam 0.5mg tablets, 118 lorazepam 2mg tablets, 45 phentermine 37.5mg tablets, and 30

Horizant ER 600mg tablets, for a total of 675 tablets. Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Motion passed with one abstention**

Case 19-0264 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 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.**

Peter Cohron seconded, and the motion passed unanimously. John Fuller returned to the meeting.

Jill Rhodes requested clarifications on: 19-0105A, 19-0113A, 19-0118C, 19-0277B, 19-0277C, 19-0280B, 19-0295A and 19-0295C. After much discussion, Mr. Hadley proposed a comparison chart for cases, 19-0105A, 19-0113A and 19-0118C to be provided at the December meeting for further clarity.

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

Case 19-0277 B REVISIT. 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 Violations of Law: KRS 315.121 (2)(d); 201 KAR 2:076 Section 3 (2); and KRS 315.121 (1)(g). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and five year probation, additional 5 hours of continuing education on compounding for each year on probation. Vote was unanimous.**

Case 19-0277 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. Pharmacist verified 3 lots of sterile preparations with an assigned beyond use date past the expiration of a component. Alleged Violations 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 administrative fine of \$2,500, additional 6 hours of continuing education on sterile compounding. Vote was unanimous.

Case 19-0280 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 additional 6 hours of continuing education on compounding. Motion passed with one abstention.**

Case 19-0295 A. Pharmacy permit holder allegedly sold adulterated drugs, compounded preparations purported to be sterile were filtered through non-pharmaceutical grade filter in worse than ISO 5 air and no integrity testing was performed on the sterilizing filters. Compounded stock solution was further manipulated after sterilization in non-depyrogenated glassware. Pharmacy permit holder allegedly sold misbranded drugs, repackaged syringes and compounded preparations were assigned beyond use dates outside Food and Drug Administration (FDA) and United States Pharmacopeia (USP) guidance without supporting stability data. Pharmacy permit holder allegedly failed to follow the provisions of USP Chapter <797> when preparing sterile compounded preparations. Permit holder allegedly failed to maintain compounding records for all compounded preparations. Alleged Violations of Law: KRS 217.055 (1)(b); KRS 217.065 (1); KRS 315.121 (1)(h); and 201 KAR 2:076 Section 2(2), Section 4 (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 \$100,000 administrative fine, five year probation. Motion passed with one abstention.**

Case 19-0295 C. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury. Pharmacist allegedly dispensed adulterated drugs, compounded preparations purported to be sterile were filtered through non-pharmaceutical grade filter in worse than ISO 5 air and no integrity testing was performed on the sterilizing filters. Compounded stock solution was further manipulated after sterilization

in non-depyrogenated glassware. Pharmacist allegedly dispensed misbranded drugs, repackaged syringes and compounded preparations were assigned beyond use dates outside FDA and USP guidance without supporting stability data. Alleged Violations of Law: KRS 315.121 (1)(h) and (2)(a) and (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 \$5,000 administrative fine, five year probation and additional 5 hours of continuing education on compounding. Cannot be PIC unless proof of attendance at the Critical Point Boot Camp has been submitted to the Board. Motion passed with one abstention.**

Peter Cohron seconded, and the motion passed unanimously.

President Martin called for a lunch recess.

President Martin called the meeting to order at 1:03 p.m. Jody Forgy did not return to the meeting.

LEGISLATION/REGULATION

201 KAR 2:310 The Board considered the public comments received for the proposed amendment to the regulation. Working with several representatives of the veterinary profession, the Board discussed and developed agreeable amended language as outlined below:

- Amend title to ‘Compounding for veterinary use’
- Amend Necessity, Function, and Conformity to ‘...This administrative regulation addresses compounding for veterinary use.’
- Amend Section 1 to ‘...veterinarian’s administration with beyond use dates as assigned in accordance to United States Pharmacopeia (USP) 795, Revision Bulletin, Official January 1, 2014.’
- Amend Section 2 to ‘...drug that contains a controlled substance shall only be compounded for patient specific dispensation directly from the pharmacy to the ultimate user.’
- Section 4 (a)(9) – Strike ‘Only-Do Not Dispense’
- Amend Section 5 to read: ‘The compounded drug shall be administered or dispensed by the veterinarian or veterinarian technician for emergency take home use for up to a 14 day supply in accordance with veterinarian labeling requirements.’

Ron Poole moved to accept this amendment. Peter Cohron seconded, and the motion passed unanimously.

FINAL ORDERS Ron Poole moved to accept the Final Orders for:

CASE 18-0392 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.**

CASE 18-0037 Pharmacy technician assisted in the practice of pharmacy without a pharmacy technician registration from 11/13/2017 through 12/2/2017. Alleged Violation of Law: 315.138[g]. **Standard Parameters: 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 administrative fine.**

Peter Cohron seconded, and the motion passed unanimously.

President Martin requested all Board members to review the information regarding case disciplinary guidelines for discussion at the December meeting.

CORRESPONDENCE

Barbourville ARH Specialty Pharmacy, Equipment Waiver Request – Ron Poole moved to approve this request. Peter Cohron seconded. Katie Busroe informed the Board that this request was not needed due to the recent regulation amendment effective August 2019. Mr. Poole withdrew his motion.

Continuecare Hospital Pharmacy, Offsite Storage Request – Ron Poole moved to approve this request. Peter Cohron seconded, and the motion passed unanimously.

Jewish Hospital Shelbyville, Request for waiver from full compliance with regulations regarding sterile compounding of hazardous medications – Upon the request of the Board at the September 2019 meeting, Jewish Hospital Shelbyville submitted an assessment of risk for handling of hazardous medication. Peter Cohron moved to approve this assessment and the waiver request. John Fuller seconded, and the motion passed unanimously.

Lee Steele, Dual PIC Request – Ron Poole moved to approve this request. Peter Cohron seconded, and the motion passed unanimously.

CONTINUING EDUCATION

Ron Poole moved to approve 19-48 thru 19-52. Peter Cohron seconded, and the motion passed unanimously.

Larry Hadley presented guidelines for Executive Director review of continuing education programs. President Martin suggestion the addition of commercial bias to the list. Ron Poole moved to approve these guidelines:

Upon receipt in the Board office, the Executive Director will review the approval forms for:

1. Completeness
2. Pharmaceutical content – verifying that the information is beneficial for the practice of pharmacy.
3. Verify that the presenters are qualified to present the material.
4. Verify that the hours requested meet the presentation hours.
5. Verify there is no commercial bias on the part of the sponsor or presenters.

Forms not meeting the above criteria will be denied and the sponsors notified. Forms meeting the above criteria will be presented to the Board at the next scheduled Board meeting for approval.

John Fuller seconded, and the motion passed unanimously.

OLD BUSINESS

CE Policy for Consideration of granting CE Extension Requests – After much discussion, John Fuller moved to accept the following policy for future continuing education extension requests:

Pharmacists who are licensed in multiple states are solely responsible for maintaining and completing CE requirements for each state regardless of the differences of requirements for each state. A pharmacist who has confusion between states CE requirements will not be granted extra time to complete CE.

The KYBOP encourages all pharmacists to obtain CE suitable to your practice, as early and often in the beginning of the calendar year to prevent any unintended incidents from interfering with obtaining the required CE hours for any given calendar year.

Peter Cohron seconded, and the motion passed unanimously. Jill Rhodes requested this policy be added to the Policy and Procedure Manual. Anthony Gray advised that a regulation change regarding continuing education may be needed in the future.

Kentucky Board of Pharmacy Policy and Procedures – Larry Hadley presented for the Board’s review a revised edition of the Policy and Procedures Manual. This item was tabled until the December meeting. Jill Rhodes requested a revision date of each section.

NEW BUSINESS

Advisory Council Appointment [one opening] – The Board voted by ballot from the applicants for one position on the Advisory Council. Larry Hadley and Anthony Gray tabulated the votes. President Martin cast the tie-breaking vote. Anthony Tagavi was selected for a four year term to the Advisory Council to begin January 1, 2020.

Pharmacy Recovery Network Committee [three openings] – The Board voted by ballot from the applicants for three positions on the PRN Committee. Larry Hadley and Anthony Gray tabulated the votes. Amber Cann, Hannah Johnson and Lynn Lamkin were selected for four year terms to the committee to begin January 1, 2020.

Ron Poole recused.

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

Peter Cohron moved to approve the revised terms and conditions for cases 19-0006A and 19-0006B. Jill Rhodes seconded, and the motion passed unanimously.

Ron Poole returned to the meeting.

ADJOURNMENT On motion by Jill Rhodes, seconded by Ron Poole and passed unanimously, President Martin adjourned the meeting at 3:38 p.m. The next regularly scheduled meeting begins at 9:00 am on December 11, 2019 at the Kentucky Board of Pharmacy in Frankfort, KY.

Larry A. Hadley
Executive Director