

KENTUCKY BOARD OF PHARMACY
Sullivan College of Pharmacy
Louisville KY

May 29, 2019
9:00 AM
Agenda

I. CALL TO ORDER

II. MINUTES

- A. *March 27, 2019

III. INTERAGENCY

IV. BOARD REPORTS

A. Executive Director

- 1. *eMars – March and April 2019
- 2. FARB – October 3-6, 2019 in Saint Louis, MO
- 3. Board Opinions

B. Anthony Gray

- 1. *CBD Oil
- 2. *ISMP Med Errors
- 3. *Benjamin Clark – Reinstatement of license after 2 year suspension per Agreed Order

V. CURRENT/PENDING CASES

- A. *Case Update and Fines Report
- B. *Pharmacy Technician Summary

VI. CORRESPONDENCE

- A. *Molly Pate - CE Extension Request
- B. *Baptist Health Lagrange – Dual PIC Request
- C. *Burton Foster – Dual PIC Request [Nature Technologies and Plaza Drug Specialty Care]
- D. *Robert’s Pharmacy – Offsite Storage Request
- E. *Norton Pharmacies – Offsite Storage Request
- F. *Highands Regional, Vylinda Howard – USP 797 Waiver Request
- G.*The Christ Hospital – Remote Order Verification
- H.*Walgreens, Lorri Walmsley – Offsite Storage Request
- I. *UK Healthcare SDV Waiver
- J. *Heartland Family Pharmacy, P07649 – Offsite Storage Request

VII. LEGISLATION/REGULATION

- A. *Proposed Personal Care regulation CHFS

VIII. CONTINUING EDUCATION

- A. *CE Programs – 19-25 through 19-38

IX. OLD BUSINESS

- A. *Comments on USP 800

X. NEW BUSINESS

- A. *UTI Protocol Revision
- B. *Board Approved Protocol Training question
- C. *Protocol for Pharmacist Dispensing of Epinephrine – Revised May 29 2019
- D. *Pharmacy technicians performing point of care testing per Board approved protocols

*Information enclosed with this agenda.

MINUTES

KENTUCKY BOARD OF PHARMACY

125 Holmes Street

Frankfort KY 40601

BOARD MEETING

May 29, 2019

CALL TO ORDER A regularly scheduled meeting was held at Sullivan College of Pharmacy in Louisville, Kentucky. President Martin called the meeting to order on May 29, 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 Linda Fox recorded the meeting.

Guests: Chris Killmeier, Walgreens; Mark Glasper, KPhA; Trish Freeman, UK College of Pharmacy; Cathy Hanna, APSC; Ralph Bouvette, APSC; Lauren Adams, Walgreens; Cindy Stowe, Sullivan College of Pharmacy; Josh Elder, KSHP; Brenda Shafer, Quarles & Brady; Wes Goodloe, Kindred; Chris Frasure, Commons Corner Apothecary; Brittany Tyler, Shirin Bigdeli and Ryan Babb, University of Kentucky College of Pharmacy students; Lorri Walmsley; Lisa Poole; Matt Martin; Philip Schwieterman, UK; Vylinda Howard, Highlands Regional Hospital; La Vanya Peters, Park Duvalle; Chris Harlow, KPhA and the students at Sullivan College of Pharmacy.

MINUTES On motion by Ron Poole, seconded by Jody Forgy and passed unanimously, the minutes of the March 27, 2019 Board Meeting were approved.

INTERAGENCY Chris Harlow, KPhA, presented to the Board a financial report of the first Opioid Summit held on March 30, 2019. The summit was attended by 134 attendees and 10 exhibitors. The event generated \$5,895 in revenue at a cost of \$12,657.46. The Planning Committee plans to survey attendees and other pharmacists before deciding on future plans.

Josh Elder, KSHP, informed the Board of that the Spring Meeting held on May 10, 2019 was attended by 200 attendees.

BOARD REPORTS Larry Hadley presented the eMars reports for March 2019 and April 2019 to the Board.

Mr. Hadley requested approval for Anthony Gray, General Counsel to attend the upcoming FARB Regulatory Law Seminar in St. Louis, MO on October 3-6, 2019. Ron Poole moved to approve this travel. Jody Forgy seconded, and the motion passed unanimously.

Mr. Hadley reported his findings regarding Board opinions. Both the Kentucky Board of Nursing and the Kentucky Board of Medical Licensure stated that their Board opinions were only an interpretation of that Board. They have no force of law or regulation.

CBD OIL Anthony Gray presented a position statement from the Board on CBD oil. After much discussion, the Board decided not to provide a position statement on CBD oil. The Board directed Mr. Gray to use this information for a newsletter article. The article should include law citations and testing information. The newsletter article will not be considered a position statement of the Kentucky Board of Pharmacy. This topic may be used for a future work session.

ISMP Med Errors Anthony Gray presented to the Board a proposed option of handling cases involving medication errors. Currently the standard disciplinary action for a medication error is a \$500 fine and 6 hours of continuing education on Medication Errors and Their Prevention. This has been the standard discipline for at least 20 years. The new option adopts the tools and resources from the Institute for Safe Medication Practices in place of the continuing education requirement. After much discussion, this item was tabled until the July meeting. President Martin, Larry Hadley, Anthony Gray and inspection staff will look at the possibility of eliminating the administrative fine and adding other options for self-assessment. Upon the request of Ron Poole, all medication error cases in Current/Pending Cases were removed for consideration at this meeting. These cases will be presented at the July meeting with the standard recommendation until the Board has made a decision to implement any changes.

Peter Cohron recused himself and left the meeting.

Benjamin Clark Anthony Gray presented a request from Benjamin Clark for reinstatement of his pharmacist license. Ron Poole moved to approve the reinstatement without stipulations. Jody Forgy seconded, and the motion passed unanimously.

Peter Cohron returned to the meeting.

CURRENT/PENDING CASES Ron Poole moved to accept the Case Review Panel recommendations for:

Case 17-0445 A and B Revisit. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 53,154 dosage units over a period of 323 days due to employee pilferage. Alleged Violation of Law: 201 KAR 2:100 Section 1. **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and probation of five years, two audits per year at the cost of the permit holder [not to exceed \$3,000], implementation of Board directed policies to prevent drug diversion. Vote was unanimous.**

Case 17-0445 B Revisit. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 53,154 dosage units over a period of 323 days. Alleged Violation of Law: 201 KAR 2:205 Section 2(3)(b). **Merged with 17-0445 A.**

Case 17-0512 Revisit. Pharmacist allegedly engaged in unethical or unprofessional conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without having first received a prescription drug order for the drug. Pharmacist allegedly stole numerous medications, both in stock bottles and prescription vials, from his employer(s). Alleged Violation of Law: KAR 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 of five years and one day. Vote was unanimous.**

Case 18-0380 A. Pharmacy permit holder allegedly engaged in unethical or unprofessional conduct by allowing confidential patient information to be revealed to unauthorized persons. 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 18-0380 B. Pharmacist allegedly engaged in unethical or unprofessional conduct by revealing confidential patient information and the nature of professional services rendered to unauthorized persons and allegedly engaged in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist. Alleged Violations of Law: KRS 315.121 (2)(b) and (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 18-0384 A. Out of state pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by mailing a prescription to the incorrect address. Alleged Violations of Law: KRS 315.121(1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 18-0384 B. Pharmacist-in-charge of an out of state pharmacy permit allegedly engaged in unprofessional or unethical conduct by mailing a prescription to the incorrect address. Alleged Violations of Law: KRS 315.121(1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 18-0402 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to transfer prescription information to a different pharmacy for the purpose of refill dispensing. 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 18-0402 B. Pharmacist allegedly engaged in unethical or unprofessional conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist, with or without established proof of actual injury, by failing to transfer prescription information to a different pharmacy for the purpose of refill dispensing. 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 unanimous.**

Case 18-0404 A. Pharmacy permit holder allegedly engaged in unethical or unprofessional conduct by allowing confidential patient information to be revealed to unauthorized persons. 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 18-0404 B. Pharmacist-in-charge (PIC) allegedly engaged in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist by allowing confidential patient information to be revealed to unauthorized persons. 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 unanimous.**

Case 18-0404 C. Pharmacy technician allegedly engaged in unethical or unprofessional conduct by revealing confidential patient information to unauthorized persons in the pharmacy waiting area. 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 unanimous.**

Case 19-0005 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Pharmacy permit holder allegedly filled the patient's prescriptions for clonazepam 0.5mg with clonazepam 1mg repeatedly for the last two years. 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 19-0005 B. Pharmacist in charge allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Pharmacist in charge allegedly filled the patient's prescriptions for clonazepam 0.5mg with clonazepam 1mg repeatedly for the last two years. 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 unanimous.**

Case 19-0005 C. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Pharmacist allegedly filled the patient's prescriptions for clonazepam 0.5mg with clonazepam 1mg repeatedly for the last two years. 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 unanimous.**

Case 19-0005 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 committing a medication error. Pharmacist allegedly filled the patient's prescriptions for clonazepam 0.5mg with clonazepam 1mg repeatedly for the last two years. 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 unanimous.**

Case 19-0057 A. Pharmacy permit holder allegedly engaged in unprofessional conduct by failing to dispense the full quantity of medication prescribed to a patient. Pharmacy permit holder allegedly dispensed 25 hydrocodone/apap 7.5mg/325mg tablets instead of the labeled 30 tablets. 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 19-0057 B. Pharmacist allegedly engaged in unethical or unprofessional conduct likely to deceive, defraud, or harm the public, with or without established proof of actual injury by failing to dispense the full quantity of medication prescribed to a patient. Pharmacist allegedly dispensed 25 hydrocodone/apap 7.5mg/325mg tablets instead of the labeled 30 tablets. Alleged Violation of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0069. Pharmacy permit holder allegedly failed to maintain controlled room temperature for drug storage. Alleged Violations of Law: 201 KAR 2:180 Section 5 and 201 KAR 2:076 Section 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, submission of quarterly temp reports to Board office for two years . Vote was unanimous.**

Case 19-0070 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. The pharmacy reported a loss of one bottle of butorphanol 10mg/mL spray due to employee pilferage. Alleged Violations of Law: 201 KAR 2:100 Section 1. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0070 B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. The pharmacy reported a loss of one bottle of butorphanol 10mg/mL spray due to employee pilferage. Alleged Violations 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 19-0070 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 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 19-0071 A. Pharmacy permit holder allegedly engaged in unprofessional conduct by failing to dispense the full quantity of medication prescribed to a patient. Pharmacy permit holder allegedly dispensed 143 hydrocodone/apap 10mg/325mg tablets instead of the labeled 150 tablets. 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 18-0071 B. Pharmacist-in-charge allegedly engaged in unethical or unprofessional conduct likely to deceive, defraud, or harm the public, with or without established proof of actual injury by failing to dispense the full quantity of medication prescribed to a patient. Pharmacist-in-charge allegedly dispensed 143 hydrocodone/apap 10mg/325mg tablets instead of the labeled 150 tablets. Alleged Violation of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0072 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 1,433 dosage units of controlled substances. 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, review of controlled substance handling within six months of Order. Vote was unanimous.**

Case 19-0072 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 1,433 dosage units of controlled substances. 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 19-0072 C. Pharmacy technician allegedly has a mental or physical incapacity that prevents the licensee from assisting 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 revocation. Vote was unanimous.**

Case 19-0079 A. Pharmacy permit holder allegedly failed to provide adequate security and control of pharmacy. Employees were permitted within pharmacy when a pharmacist was not present. Alleged Violation of Law: 201 KAR 2:100(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. Vote was unanimous.**

Case 19-0079 B. Pharmacist-in-charge (PIC) allegedly engaged in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist. Employees were permitted within pharmacy when a pharmacist was not present. Alleged Violations of Law: 201 KAR 2:100 (1) and 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. Vote was unanimous.**

Case 19-0080 A. A home health coordination company located outside of Kentucky allegedly engaged in unprofessional or unethical conduct by creating a prescription that was not authorized by a 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. Vote was unanimous.**

Case 19-0080 B. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by dispensing a prescription medication without have a prescription and dispensed the incorrect dose. Alleged Violation of Law: KRS 315.121(1)(j). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0083 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 60 hydrocodone/APAP 10/325 tablets. 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 19-0083 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 60 hydrocodone/APAP 10/325 tablets. 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 19-0083 C. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported an unspecified amount of amphetamine salts 10 mg tablets and oxycodone/APAP 10/325 tablets missing from filled prescriptions in the waiting bin. 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 19-0083 D. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported an unspecified amount of amphetamine salts 10 mg tablets and oxycodone/APAP 10/325 tablets missing from filled prescriptions in the waiting bin. 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 19-0083 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 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 19-0084. Pharmacy permit holder allegedly failed to provide written notice to the Board of Pharmacy fifteen (15) days prior to anticipated 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 unanimous.**

Case 19-0085. Pharmacy permit holder allegedly transferred ownership of a pharmacy without the buyer applying for a pharmacy permit. Permit holder allegedly failed to place a pharmacist in charge of the pharmacy between February 8, 2019 and March 7, 2019 and between April 9, 2019 and May 2, 2019. Permit holder allegedly closed the pharmacy involuntarily for more than five days without notification to the Board of Pharmacy. Permit holder allegedly failed to maintain security and control of pharmacy. Permit holder allegedly failed to maintain complete dispensing records. Permit holder allegedly allowed access to a common database for the

purposes of dispensing medication without all involved pharmacies being permitted in Kentucky. Permit holder allegedly failed to maintain functional telephone for use in patient counseling at a closed door, mail order pharmacy. Permit holder accepted pre-printed prescriptions for a controlled substance medication. Alleged Violations of Law: KRS 315.035 (5); KRS 351.020 (1); KRS 315.121 (1)(h); 201 KAR 2:106 Section 2 (3)(a)1.; 201 KAR 2:100 Section 1; 201 KAR 2:170 Section 1 (5); 201 KAR 2:300 Section 2 (2); 201 KAR 2:210 Section 2 (2)(b)3., (3)(b); and 902 KAR 55:105 Section 3 (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 revocation. Vote was unanimous.**

Case 19-0088 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by repeatedly soliciting a prescription from a prescriber including after denial of prescription request. Alleged Violations of Law: KRS 315.121 (1)(a). **CRC Recommendation: Case is dismissed with prejudice. Vote was unanimous.**

Case 19-0088 B. Pharmacist in charge allegedly failed in the provision of pharmacy services. The pharmacy allegedly repeatedly solicited a prescription from a prescriber including after denial of prescription request. Alleged Violations of Law: 201 KAR 2:205 Section 2 (3)(b). **CRC Recommendation: Case is dismissed with prejudice. Vote was unanimous.**

Case 19-0088 C. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by repeatedly soliciting a prescription from a prescriber including after denial of prescription request. Alleged Violations of Law: KRS 315.121 (1)(a). **CRC Recommendation: Case is dismissed with prejudice. Vote was unanimous.**

Case 19-0088 D. Pharmacist in charge allegedly failed in the provision of pharmacy services. The pharmacy allegedly repeatedly solicited a prescription from a prescriber including after denial of prescription request. Alleged Violations of Law: 201 KAR 2:205 Section 2 (3)(b). **CRC Recommendation: Case is dismissed with prejudice. Vote was unanimous.**

Case 19-0092 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. The pharmacy reported 10 hydrocodone/apap 10mg/325mg tablets were taken from a patient's bag hanging in the will call area. 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 19-0092 B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. The pharmacy reported 10 hydrocodone/apap 10mg/325mg tablets were taken from a patient's bag hanging in the will call area. 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 19-0092 C. Pharmacy cashier 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 permanent prevention of registration as a pharmacy technician. Vote was unanimous.**

Case 19-0094 A. Out of state pharmacy permit holder allegedly failed to have a pharmacist available for patients. Alleged Violation of Law: KRS 315.0351(6). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0094 B. Pharmacist-in-charge allegedly failed to maintain required compliance by the out of state pharmacy by not having a pharmacist available for patients. Alleged Violation of Law: KRS 315.0351(7). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0096 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by selling a misbranded prescription. Patient allegedly received less than the labeled quantity of four different medications on various dates. Alleged Violations 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 19-0096 B. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by dispensing a misbranded prescription. Patient allegedly received less than the labeled quantity of four different medications on various dates. 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 19-0102 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. The pharmacy reported 22 hydrocodone/apap 10mg/325mg tablets and 7 hydrocodone/apap 7.5mg/325mg were taken from patients' bags hanging in the will call area. 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 19-0102 B. Pharmacist-in-charge allegedly failed to provide adequate security and control of drugs. The pharmacy reported 22 hydrocodone/apap 10mg/325mg tablets and 7 hydrocodone/apap 7.5mg/325mg were taken from patients' bags hanging in the will call area. 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 19-0102 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. Vote was unanimous.**

Case 19-0103. Pharmacist allegedly engaged in unprofessional or unethical conduct by violating an Agreed Order of Reinstatement. Pharmacist relapsed. Alleged Violations of Law: KRS 315.121(1)(b) and (i). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and surrender of license for five years and one day. Vote was unanimous.**

Case 19-0106 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to dispense a legitimate prescription. Alleged Violation of Law: KRS 315.121 (1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0106 B. Pharmacist allegedly engaged in unprofessional or unethical conduct by failing to dispense a legitimate prescription. Alleged Violation of Law: KRS 315.121 (2)(j). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0112. Pharmacy intern allegedly violation a Kentucky Pharmacist Recovery Network (KYPRN) Agreement. Alleged Violations of Law: KRS 315.121 (1)(h) and (i) and 201 KAR 2:250 Section 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 19-0117 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by repeatedly soliciting a prescription from a prescriber including after denial of prescription request. Alleged Violations of Law: KRS 315.121 (1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0117 B. Pharmacist in charge allegedly failed in the provision of pharmacy services. The pharmacy allegedly repeatedly solicited a prescription from a prescriber including after denial of prescription request. Alleged Violations 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 19-0117 C. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by repeatedly soliciting a prescription from a prescriber including after denial of prescription request. Alleged Violations of Law: KRS 315.121 (1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0117 D. Pharmacist in charge allegedly failed in the provision of pharmacy services. The pharmacy allegedly repeatedly solicited a prescription from a prescriber including after denial of prescription request. Alleged Violations 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.**

Peter Cohron seconded, and the motion passed unanimously. Case 19-0007, Case 19-0012 and Case 19-0089 were tabled until the July meeting. Jill Rhodes commented on Case 19-0086 requesting additional information due to the higher administrative fine. Amanda Harding stated this was due to multiple prescriptions being involved. Jill Rhodes moved that the Case Review Recommendations include more detailed information for those recommendations equal to or greater than \$2,500. Ron Poole seconded, and the motion passed unanimously.

Jill Rhodes moved to accept the recommendation:

Case 19-0086 A. Pharmacy permit holder allegedly sold misbranded drugs – compounded preparation dispensed with an assigned beyond use date past the expiration of a component. Permit holder allegedly failed to compound non-sterile compounded preparations pursuant to United States Pharmacopeia (USP) 795. Permit holder allegedly failed to maintain 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 \$2,500 administrative fine, monthly reconciliation of compounding records for one year. Vote was unanimous.**

Case 19-0086 B. Pharmacist in charge allegedly failed to compound non-sterile compounded preparations pursuant to United States Pharmacopeia (USP) 795. Permit holder allegedly failed to maintain 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 an additional 6 hours of continuing education on compounding. Vote was unanimous.**

Case 19-0086 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 compounding record for all compounded preparations. Compounded preparation 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 \$2,500 administrative fine, additional 6 hours of continuing education on compounding. Vote was unanimous.**

Peter Cohron seconded, and the motion passed unanimously.

PHARMACY TECHNICIAN SUMMARY

Peter Cohron moved to deny the application, Case 19-0098. Ron Poole seconded, and the motion passed unanimously.

Jill Rhodes moved to deny the application, Case 19-0099. Ron Poole seconded, and the motion passed unanimously.

Peter Cohron moved to approve the application, Case 19-0101. Ron Poole seconded, and the motion passed unanimously.

Ron Poole moved to deny the application, Case 19-0100. Jody Forgy seconded, and the motion passed unanimously.

Ron Poole moved to deny the application, Case 19-0104. Peter Cohron seconded, and the motion passed unanimously.

CORRESPONDENCE

Molly Pate – CE Extension Request Ron Poole moved to approve an extension allowing the completion of the 2018 CE requirement of 15 hours through 2019. These hours may not be used to fulfill the 2019 CE requirement of 15 hours. John Fuller seconded, and the motion passed unanimously.

Ron Poole recused himself and left the meeting.

Baptist Health Lagrange – Dual PIC Request Jill Rhodes moved to approve this request. Peter Cohron seconded, and the motion passed unanimously.

Ron Poole returned to the meeting.

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

Robert’s Pharmacy – Offsite Storage Request John Fuller moved to deny this request. Ron Poole seconded, and the motion passed unanimously.

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

Highlands Regional, Vylinda Howard – USP 797 Waiver Request Jill Rhodes moved to approve this request. Ron Poole seconded, and the motion passed unanimously.

The Christ Hospital – Remote DUR of Physician Dispensing Ron Poole moved to deny this request. The Kentucky Board of Pharmacy has no jurisdiction to regulate this practice. Peter Cohron seconded, and the motion passed unanimously.

Walgreens – Offsite Storage Request Ron Poole moved to approve this request. John Fuller seconded, and the motion passed unanimously.

President Martin recused himself and left the meeting. Vice President Ron Poole assumed the running of the meeting.

UK Healthcare – SDV Waiver Request Peter Cohron moved to approve this request. Jill Rhodes seconded, and the motion passed unanimously.

President Martin returned to the meeting.

Heartland Family Pharmacy – Offsite Storage Request Ron Poole moved to approve this request. Jill Rhodes seconded, and the motion passed unanimously.

LEGISLATION/REGULATION Mr. Hadley presented to the Board the Cabinet for Health and Family Services proposed amendments for 902 KAR 20:036 filed with LRC on April 15, 2019. Mr. Hadley requested the Board’s opinion of this amendment. The deadline for comments is May 31, 2019. After much discussion, the Board instructed Mr. Hadley to draft a comment to include; language from 201 KAR 2:370 that is not in line with the amendment, the minutes from the January Board meeting with CHFS agreeing to the new language in 201 KAR 2:370 and a request for medication errors to be reported to the provider and the patient of the error, not merely documented in the chart.

CONTINUING EDUCATION

Ron Poole moved to approve 19-25 for a total of 8 hours. Peter Cohron seconded, and the motion passed unanimously.

Ron Poole moved to approve 19-28 for a total of 11 hours. Peter Cohron seconded, and the motion passed unanimously.

Ron Poole moved to approve 19-26, 19-27, 19-29 thru 19-38. Peter Cohron seconded, and the motion passed unanimously.

OLD BUSINESS The Board has currently received 5 comments on the proposed options for USP 800. The item was tabled until the July meeting. The Board directed staff to provide additional information for Board's review and an impact statement of enforcement and regulation of USP 795 and USP 797 from the inspection staff including pros and cons.

NEW BUSINESS

Acute Uncomplicated Urinary Tract Infection Treatment Protocol Revision – The Kentucky Board of Nursing requested a change in the language of this protocol. After much discussion, Peter Cohron moved to change the language from physician to provider. Ron Poole seconded, and the motion passed unanimously.

Board Approved Protocol Training – The Board received a question regarding the expiration of protocol training and if annual training is required. After much discussion, Jill Rhodes stated the protocol training did not have an expiration date and there was no need for annual training. Peter Cohron seconded, and the motion passed unanimously.

Protocol for Pharmacist Dispensing of Epinephrine Revision – Anthony Gray presented a revised protocol with additional language specifying certification has been completed. After much discussion, Ron Poole moved to approve this revision. Jody Forgy seconded, and the motion passed unanimously.

Pharmacy Technicians performing protocol testing – Ron Poole moved to allow properly trained and authorized pharmacy technicians to perform protocol testing under the supervision of a pharmacist. The technician may perform the testing only; not interpret or act upon the results of the test. Peter Cohron seconded, and the motion passed unanimously.

ADJOURNMENT On motion by Ron Poole, seconded by Jill Rhodes and passed unanimously, President Martin adjourned the meeting at 12:10 p.m. The next regularly scheduled meeting begins at 9:00 am on July 31, 2019 at the Kentucky Board of Pharmacy in Frankfort, KY.

Larry A. Hadley

Executive Director

