

KENTUCKY BOARD OF PHARMACY
125 Holmes Street
Frankfort, KY
December 11, 2019, 9:00 AM
Agenda

I. CALL TO ORDER

II. MINUTES

- A. *November 13, 2019

III. INTERAGENCY

- A. *KASPER Reporting

IV. BOARD REPORTS

A. Executive Director

- 1. *eMars – November 2019
- 2. Travel Requests:
 - a) 2020 FARB Forum, January 23-26, Colorado Springs CO – Anthony Gray
 - b) APhA, March 20-23, Gaylord National
 - c) Rx Drug Abuse and Heroin Summit, April 13-16, Nashville TN
 - d) 116th NABP Annual Meeting, May 13-16, Baltimore MD
- 3. Upcoming Bills
 - a) *Bill Request 7
 - b) *Bill Request 8
 - c) *Bill Request 9
 - d) *Bill Request 50
 - e) *Bill Request 105
 - f) *Bill Request 221
 - g) *Bill Request 257
 - h) *Bill Request 278
 - i) *Bill Request 366
 - j) *Bill Request 409

B. Board Counsel

- 1. *Scott Brierton – Reciprocal Application

V. CASES

- A. *Case Update and Fines Report
- B. 17-0511 A Settlement Conference
- C. *Comparison Chart for Cases 19-0105, 19-0113 and 19-0118
 - 1. Comparison Chart for Compounding Cases
- D. Disciplinary Action Guidelines
 - 1. *Kentucky Board of Pharmacy Case Discipline
 - 1. *Disciplinary Guideline Sample
 - 2. *Summary of states responses to out of dates and compounding violations

3. *Arizona Board of Pharmacy Guidelines for Complaint Resolution
4. *Utah Reference

VI. PENDING APPLICATIONS

- A. *Samantha Sullivan – Pharmacy Technician reinstatement
- B. *Health and Wellness Pharmacy Inc – Non-resident pharmacy application

VII. CORRESPONDENCE

- A. *Faith Pharmacy – Equipment Waiver Request

VIII. LEGISLATION/REGULATION

- A. 201 KAR 2:310
- B. *201 KAR 2:280, Prescription dispensing for formulary compliance.

IX. CONTINUING EDUCATION

- A. *CE Programs – 19-53 through 19-58

X. OLD BUSINESS

- A. *Policy and Procedures

XI. NEW BUSINESS

- A. Election of New Officers
- B. Protocols
 1. *Acute Uncomplicated Urinary Tract Infection Treatment Protocol
 2. *Anaphylaxis Treatment Protocol for Emergency Epinephrine Injection Devices
 3. *Self-Care Conditions Protocol Over-the-Counter Probiotics
 4. *Acute Influenza Infection Antiviral Therapy Protocol
 5. *Opioid Use Disorder Protocol
 6. *Acute Influenza Infection Chemoprophylaxis Protocol
 7. *Protocol for Pharmacist Dispensing of Allergic Rhinitis Therapies
 8. *Self-Care Conditions Protocol Diabetes Testing Supplies
 9. *Acute Group A Streptococcal Pharyngitis Infection Protocol
 10. *Tuberculin Skin Testing Two Step Protocol
 11. *Travel Health Therapies Protocol
 12. *Tuberculin Skin Testing One-Step Protocol
 13. *Tobacco Cessation Protocol

*Information included in Board Packet

MINUTES

KENTUCKY BOARD OF PHARMACY

held at

125 Holmes Street

Frankfort KY 40601

BOARD MEETING

December 11, 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 December 11, 2019 at 9:05 a.m. President Martin congratulated Chris Killmeier on his recent retirement from Walgreens. President Martin recognized Misty Stutz as the new dean of Sullivan University College of Pharmacy.

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; Amanda Harding, Pharmacy and Drug Inspector; Katie Busroe, Pharmacy Inspections and Investigations Supervisor and Darla Sayre, Executive Staff Advisor. Court Reporter Terri Pelosi recorded the meeting.

Guests: Chris Killmeier; Mark Glasper, KPhA; Cathy Hanna, APSC; Brian Fingerson, KYPRN Committee; Steve Hart; Justin Lewis, student; Paula York, KY OIG; Shannon Stiglitz, Kentucky Retail Federation; Brenda Shafer, Quarles and Brady, LLP and Misty Stutz, Sullivan University College of Pharmacy.

MINUTES On motion by Jill Rhodes, seconded by Ron Poole and passed unanimously, the minutes of the November 13, 2019 Board Meeting were approved.

INTERAGENCY

Mark Glasper, KPhA – Mark Glasper informed the Board that dates for the 2020 Opioid Summit have not been finalized. Preliminary plans include a morning session available at satellite locations. Each satellite location will have an afternoon session tailored for their region.

Paula York, KY OIG – Ms. York presented the Board with changes for KASPER reporting by pharmacies. These changes are to be implemented in September 2020. The Office of Inspector General requested feedback from the Board regarding the proposed changes.

BOARD REPORTS Larry Hadley presented the eMars reports for November 2019 to the Board. Mr. Hadley requested the following out of state travel:

- 2020 FARB Forum, January 23-26, Colorado Springs CO – Board Counsel
- APhA, March 20-23, Gaylord National – Executive Director, Board President, John Fuller

- Rx Drug Abuse and Heroin Summit, April 13-16, Nashville TN – Executive Director, Board President, Board Counsel
- 116th NABP Annual Meeting, May 13-16, Baltimore MD - Executive Director, Board President, Board Counsel

On motion by Ron Poole, seconded by Peter Cohron and passed unanimously, the above travel requests were approved.

Mr. Hadley presented to the Board proposed bills for the upcoming Legislative Session. He requested the Board provide a position statement on bills regarding the practice of pharmacy. Position statement will be drafted at the next scheduled meeting.

Anthony Gray presented a reciprocal application to be considered by the Board. Ron Poole moved to allow the applicant to proceed with the reciprocal process. Jill Rhodes seconded, and the motion passed unanimously.

Katie Busroe informed the Board that she and Amanda Harding were recently notified that they had passed the Board of Pharmacy Specialties (BPS) in Compounded Sterile Preparations examination and are now Board Certified Sterile Compounding Pharmacists (BCSCP). BPS is the gold standard for determining which pharmacists are qualified to contribute at advanced practice levels. Through the rigorous BPS standards, the BPS board certified pharmacist stands out as the most qualified to take on today's expanding expectations. By definition, the BPS board certified pharmacist brings an extra measure of quality . . . with demonstrated initiative and a commitment to professional excellence. There were 434 pharmacists worldwide that obtained the BCSCP certification, 423 of these in the United States and 8 were in Kentucky. President Martin recognized Amanda Harding and Katie Busroe for recently receiving BPS Board Certification in Compounded Sterile Preparations.

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

Case 18-0137 A Revisit. Pharmacy permit holder allegedly engaged in unprofessional or unethical by employing a pharmacist that dispensed a drug for which a prescription drug order is required, without having first received a prescription drug order for the drug and engaging in conduct likely to deceive, defraud or harm the public, demonstrating a willful 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. Alleged Violation of Law: KRS 315.121(1)(a). **CRP**

Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Vote was unanimous.

Case 18-0137 B. Revisit. Kentucky licensed pharmacist-in-charge allegedly engaged in unprofessional or unethical by dispensing a drug for which a prescription drug order is required,

without having first received a prescription drug order for the drug and engaging in conduct likely to deceive, defraud or harm the public, demonstrating a willful 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. Alleged Violations of Law: KRS 315.121(2)(f) and (d). **CRP Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Vote was unanimous.**

Case 18-0149 A. Pharmacy permit holder allegedly engaged in unethical or unprofessional conduct by failing to transfer requested prescriptions, maintaining false information in a patient record system, allowing unauthorized access, use, and release of patient information, failing to release patient records as directed by the patient, and obstructing patient access to pharmacy records. Alleged Violation of Law: KRS 315.121(1)(a). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Motion passed with one abstention.**

Case 18-0149 B. Pharmacist-in-charge (PIC) allegedly engaged in conduct likely to deceive, defraud, or harm the public, demonstrated a willful or careless disregard for the health, welfare, or safety of a patient, and engaged in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist, with or without established proof of actual injury. PIC allegedly failed to provide adequate pharmacy services, failed to transfer prescriptions to the pharmacy, retained false information in a patient record, allowed unauthorized access/use of the patient record system, and failed to communicate/release patient records as directed by the patient. Alleged Violations of Law: KRS 315.121 (2)(d); 201 KAR 2:205 Section 2 (3)(a) and (b); and 201 KAR 2:210 Section 3 (2)(a) and (b). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Motion passed with one abstention.**

Case 18-0149 C. Pharmacist allegedly engaged in conduct likely to deceive, defraud, or harm the public, demonstrated a willful or careless disregard for the health, welfare, or safety of a patient, and engaged 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 released confidential patient information without consent from patient, inappropriately accessed patient information in the pharmacy system, entered false information into a patient record, failed to transfer prescriptions to the pharmacy, and failed to communicate/release patient records as directed by the patient. Alleged Violations of Law: KRS 315.121 (2)(b), (d) and (i) and 201 KAR 2:210 Section 3 (2)(a) and (b). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Motion passed with one abstention.**

Case 18-0149 D. Pharmacist allegedly engaged in conduct likely to deceive, defraud, or harm the public, demonstrated a willful or careless disregard for the health, welfare, or safety of a patient, and engaged 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 allowed release of patient information to an unauthorized person at the pharmacy counter, failed to release patient records as directed by the patient, and obstructed patient access to pharmacy records. Alleged Violations of Law: KRS 315.121 (2)(b) and (d); and 201 KAR 2:210 Section 3 (2)(a) and (b). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Motion passed with one abstention.**

Case 18-0364 Revisit. Out of state wholesale distributor entered into a Settlement Agreement with the Drug Enforcement Administration (DEA) to pay \$22 million in civil penalties for failure to report suspicious orders of hydrocodone and oxycodone. Alleged Violation of Law: KRS 315.121(1)(c)2. **CRP Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Vote was unanimous.**

Case 18-0386 A Revisit. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to dispense a medication in a timely manner. Pharmacy permit holder allegedly engaged in the practice of pharmacy and allowed individuals to assist in the practice of pharmacy in an unlicensed out of state location. Alleged Violations of Law: KRS 315.121(1)(a) and KRS 315.0351 (1). **CRP Recommendation: No revisions to Agreed Order previously recommended and approved [January 2019]. *There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$5000 administrative fine [unlicensed location], \$1000 administration fine [failing to dispense in a timely manner].* Vote was unanimous.**

Case 18-0386 B Revisit. Pharmacist in charge allegedly failed in the provision of pharmacy services. Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b). **CRP Recommendation: No revisions to Agreed Order previously recommended and approved [January 2019]. *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 19-0082 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct. Pharmacy provided improperly labeled non-patient specific compounded samples. Pharmacy provided misbranded compounded medications to prescribers. Alleged Violations of Law: KRS 217.065 (2)(a), KRS 315.121 (1)(a), 21 CFR 203.38, 21 USC 353a Section 503a. **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the**

issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$2500 administrative fine, one year probation with monthly reconciliation of compounding records to include prescription and patient names be sent to the Board by the PIC. Vote was unanimous.

Case 19-0082 B. Pharmacist in Charge allegedly engaged in unprofessional or unethical conduct. Pharmacist in Charge provided improperly labeled non-patient specific compounded samples. Pharmacist in Charge provided misbranded compounded medications to prescribers. Alleged Violations of law: KRS 217.065 (2)(a), KRS 315.121 (1)(a), 21 CFR 203.38, and 21 USC 353a Section 503a. **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$5000 administrative fine, additional 6 hours of continuing education on compounding. Vote was unanimous.**

Case 19-0087 A Revisit. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by breaching patient confidentiality. Permit holder allegedly failed to maintain an accurate patient record. A patient's prescription was mailed to the wrong address. Alleged Violations of Law: KRS 315.121 (1)(a) and 201 KAR 2:210 Section 1 (1)(a). **CRP Recommendation: No revisions to Agreed Order previously recommended and approved [July 2019]. There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$1000 administrative fine, approved corrective action plan to prevent future occurrences regarding shipping address issues. Vote was unanimous.**

Case 19-0087 B Revisit. Pharmacist in charge allegedly failed to maintain an accurate patient record. Alleged Violation of Law: 201 KAR 2:210 Section 1 (1)(c) and 201 KAR 2:205. **CRP Recommendation: No revisions to Agreed Order previously recommended and approved [July 2019]. There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on quality assurance programs for pharmacy services. Vote was unanimous.**

Case: 19-0097. Out of state pharmacy permit surrendered Kentucky pharmacy permit based on an emergency suspension of pharmacy permit in home state. Home state Board of Pharmacy

permanently revoked pharmacy permit after an Administrative Conference four months after the emergency suspension. Alleged Violation of Law: KRS 315.121(1)(c). **CRP**

Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and revocation. Motion passed with one abstention.

Case 19-0109 A. Pharmacy permit holder allegedly sold misbranded drugs. Medication was allegedly dispensed in error on six separate occasions and without first receiving a prescription on one occasion. Patient was prescribed hydralazine 10mg tablets and allegedly received hydroxyzine 10mg tablets. Alleged Violations of Law: KRS 217.065 (1); KRS 315.121 (a), (h); 201 KAR 2:170. **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$1000 administrative fine. Vote was unanimous.**

Case 19-0109 B. Pharmacist-in-charge (PIC) allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by committing a medication error on six separate occasions and dispensing a drug for which a prescription drug order is required, without having first received a prescription order for the drug on one occasion. Patient was prescribed hydralazine 10mg tablets and allegedly received hydroxyzine 10mg tablets. Alleged Violations of Law: KRS 315.121 (2)(d) and (f) and 201 KAR 2:170. **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$1500 administrative fine, additional 6 hours of continuing education on pharmacy law and additional 6 hours of continuing education on medication errors and their prevention. Vote was unanimous.**

Case 19-0123 A. Pharmacy permit holder allegedly sold a misbranded drug due to a medication error. Patient was allegedly dispensed a prescription for tamoxifen 20mg tablets that contained atenolol/chlorthalidone 100/25mg tablets. Alleged Violation of Law: KRS 217.065(1). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0123 B. Pharmacist allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Patient was allegedly dispensed a prescription for tamoxifen 20mg tablets that contained atenolol/chlorthalidone 100/25mg tablets. Alleged Violation of Law: KRS 315.1212(2)(d). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention. Vote was unanimous.**

Case 19-0264 A Revisit. 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. **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0264 B Revisit. 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). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0290. Pharmacy technician allegedly has a mental or physical incapacity that prevents licensee from engaging in assisting in the practice of pharmacy with reasonable skill, competence, and safety to the public. Alleged Violation of Law: KRS 315.121 (1)(b). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and revocation. Motion passed with one abstention.**

Case 19-0297 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 9,943 Hydrocodone/APAP tablets, 3,446 Buprenorphine tablets, 465 Alprazolam tablets, and 199 Phentermine tablets over a period of 20 Months from January 3, 2016 to August 21, 2017 due to employee pilferage. Alleged Violation of Law: 201 KAR 2:100 Section 1. **CRP Recommendation: There is insufficient**

evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.

Case 19-0297 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 9,943 Hydrocodone/APAP tablets, 3,446 Buprenorphine tablets, 465 Alprazolam tablets, and 199 Phentermine tablets over a period of 20 Months from January 3, 2016 to August 21, 2017 due to employee pilferage. Alleged Violation of Law: 201 KAR 2:205 Section 2(3)(b). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0297 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). **CRP 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 19-0300 A. Pharmacy permit holder allegedly sold a misbranded drug due to medication error. Pharmacy permit holder allegedly filled a prescription for cefdinir 125mg/5mL suspension with incorrect directions. Alleged Violation of Law: KRS 217.065 (1). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.**

Case 19-0300 B. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Pharmacist allegedly filled a prescription for cefdinir 125mg/5mL suspension with incorrect directions. Alleged Violation of Law: KRS 315.121 (2)(d). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention. Vote was unanimous.**

Case 19-0301. Wholesale distributor permit holder allegedly engaged in unprofessional or unethical conduct by misrepresenting the storage conditions of distributed drugs. Wholesale distributor allegedly failed to provide adequate storage conditions by not storing a drug per the label requirements. Alleged Violation of Law: KRS 315.121 (1)(a) and 201 KAR 2:105 Section 2(4)(a). **CRP 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, three year probation with quarterly reports to include list of drugs distributed and their storage requirements, annual inspection during probation to be paid by the respondent. Motion passed with one abstention.

Case 19-0339 A. Owner of out of state Special Limited Pharmacy Permit – Medical Gas was issued a temporary restraining order from the United States Government based on a civil complaint for owning two pharmacies that allegedly dispensed controlled substance prescriptions outside the usual course of professional practice and in violation of the pharmacists’ corresponding responsibility to ensure the controlled substance prescriptions were written for a legitimate medical purpose. The pharmacies billed Medicaid for the allegedly questionable prescriptions. Alleged Violation of Law: KRS 315.121(1)(c). **CRP Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Vote was unanimous.**

Case 19-0339 B. Pharmacist was indicted by the United States Government on 21 counts of dispensing Schedule II and Schedule IV controlled substances, outside the usual course of professional practice and without a legitimate medical purpose, between April 27, 2017 and December 6, 2017. Pharmacist was practicing pharmacy outside of Kentucky. Alleged Violation of Law: KRS 315.121(1)(c). **CRP Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Vote was unanimous.**

Case 19-0340 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by selling a prescription dispensed from an unlawful prescription drug order. Alleged Violation of Law: KRS 315.121 (1)(a). **CRP 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 19-0340 B. Pharmacist allegedly engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful. Alleged Violations of Law: KRS 315.121 (1)(h), 2(j); KRS 218A.180(1) and 902 KAR 55:095 Section 2 (1)(a). **CRP 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 19-0343 A. Wholly owned wholesale distributor subsidiary of a wholesale distributor, paid a \$22.05 million fine to the United States Government for allegedly establishing false and

inflated Average Wholesale Prices for active pharmaceutical ingredients used in compounded prescriptions. Alleged Violation of Law: KRS 315.121(1)(c). **CRP Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Vote was unanimous.**

Case 19-0343 B. Wholly owned wholesale distributor subsidiary of a wholesale distributor, paid a \$22.05 million fine to the United States Government for allegedly establishing false and inflated Average Wholesale Prices for active pharmaceutical ingredients used in compounded prescriptions. Alleged Violation of Law: KRS 315.121(1)(c). **CRP Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Vote was unanimous.**

Case 19-0343 C. Wholly owned pharmacy subsidiary of a wholesale distributor paid a \$22.05 million fine to the United States Government for allegedly knowingly submitting fraudulent compounded prescription claims to Federal healthcare programs, using sham insurance programs to manipulate pricing, paying kickbacks to physicians for bogus consulting agreements and illegally waiving copays. Alleged Violation of Law: KRS 315.121(1)(c). **CRP Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Vote was unanimous.**

Case 19-0345. Corporation agreed to pay the United States Government \$5.25 million to resolve allegations that it violated the False Claims Act by submitting false or fraudulent claims that misrepresented the ingredients used in certain compounded prescription pain creams. Alleged Violation of Law: KRS 315.121(1)(c). **CRP 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, owner prohibited from ownership of a facility permitted or licensed by the Board. Motion passed with one abstention.**

Ron Poole seconded, and the motion passed unanimously.

Anthony Gray presented to the Board the current process for case review panel recommendations and the process from other states. After much discussion, Ron Poole moved to have an afternoon work session after a Board meeting to hold a mock case review panel and discuss a standardized disciplinary action guidelines for more consistent penalties and fines. Peter Cohron seconded, and the motion passed unanimously.

PENDING APPLICATIONS

Health and Wellness Pharmacy Inc., Non-resident pharmacy application - The Board directed Anthony Gray to provide the corrective actions taken in resolution of their Tennessee action at the next scheduled meeting.

CORRESPONDENCE

Faith Pharmacy, Equipment Waiver Request – John Fuller moved to approve this request. Jill Rhodes seconded, and the motion passed unanimously.

LEGISLATION/REGULATION

201 KAR 2:280, Prescription dispensing for formulary compliance - The Board considered the proposed amendments received from the Regulation Committee. Ron Poole moved to accept this amendment and directed Anthony Gray to proceed with LRC. Peter Cohron seconded, and the motion passed unanimously.

CONTINUING EDUCATION

Ron Poole moved to approve 19-53, 19-54, 19-55, 19-56 and 19-58. Peter Cohron seconded, and the motion passed unanimously.

Jill Rhodes recused herself from the meeting.

Peter Cohron moved to approve 19-57. Ron Poole seconded, and the motion passed unanimously.

Jill Rhodes returned to the meeting.

OLD BUSINESS

Kentucky Board of Pharmacy Policy and Procedures – Larry Hadley presented for the Board's review a revised edition of the Policy and Procedures Manual. Jill Rhodes requested specific names be removed from the manual and add a section with committee information. Ron Poole recommended adding the revision date of review/approval to the P & Ps and require annual board review and approval of the P & P Manual. Ron Poole moved to accept this version with the proposed changes. Jody Forgy seconded, and the motion passed unanimously.

NEW BUSINESS

Protocols – Ron Poole moved to approve the modifications to the protocols listed below:

- Acute Uncomplicated Urinary Tract Infection Treatment Protocol – removed numbering from antibiotic list [no order preference per guidelines], clarified inclusion criteria statement and change physician/practitioner to prescriber.

- Anaphylaxis Treatment Protocol for Emergency Epinephrine Injection Devices – Add wording to incorporate KRS 311.646 and change physician/practitioner to prescriber.
- Self-Care Conditions Protocol Over-the-Counter Probiotics - Change physician/practitioner to prescriber.
- Acute Influenza Infection Antiviral Therapy Protocol - Change physician/practitioner to prescriber.
- Opioid Use Disorder Protocol – Clarified informed content wording for inclusion criteria and change physician/practitioner to prescriber.
- Acute Influenza Infection Chemoprophylaxis Protocol - Change physician/practitioner to prescriber.
- Protocol for Pharmacist Dispensing of Allergic Rhinitis Therapies - Change physician/practitioner to prescriber.
- Self-Care Conditions Protocol Diabetes Testing Supplies - Change physician/practitioner to prescriber.
- Acute Group A Streptococcal Pharyngitis Infection Protocol - Change physician/practitioner to prescriber.
- Tuberculin Skin Testing Two Step Protocol – Updated Appendix C with current KY DHP Forms and change physician/practitioner to prescriber.
- Travel Health Therapies Protocol - Change physician/practitioner to prescriber.
- Tuberculin Skin Testing One-Step Protocol - Updated Appendix C with current KY DHP Forms and change physician/practitioner to prescriber.
- Tobacco Cessation Protocol - Change physician/practitioner to prescriber.

Peter Cohron seconded, and the motion passed unanimously.

Election of New Officers – Jill Rhodes moved to nominate Ron Poole as Board President for 2020. Peter Cohron seconded, and the vote was unanimous. Ron Poole moved to nominate Jill Rhodes as Vice President for 2020. John Fuller seconded, and the vote was unanimous.

Ron Poole and Peter Cohron recused themselves from the meeting.

Jill Rhodes moved to accept the Case Review Panel recommendations for:

Case 19-0110 A. Pharmacy permit holder allegedly engaged in unethical or unprofessional conduct by selling misbranded drugs. Two prescription medications were discontinued and one new medication was dispensed to the patient without authorization from prescriber. Alleged Violations of Law: KRS 315.121 (1)(a), (h); 201 KAR 2:170. **CRP 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 19-0110 B. Pharmacist-in-charge (PIC) allegedly engaged in unethical or unprofessional conduct by dispensing drugs for which a prescription order is required, without having first received a prescription order for the drug. Alleged Violations of Law: KRS 315.121 (2)(d) and (f). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$1000 administrative fine, additional 6 hours of continuing education on pharmacy law. Vote was unanimous.**

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

Jill Rhodes moved to accept the Case Review Panel recommendations for:

Case 19-0105 A REVISIT. Pharmacy permit holder allegedly sold misbranded drugs – four compounded preparations dispensed with an assigned beyond use date past the expiration of a component and two preparations dispensed with an assigned beyond use date past the stability dating of the preparation. Permit holder allegedly failed to compound non-sterile compounded preparations pursuant to United States Pharmacopeia (USP) Chapter 795. Permit holder allegedly failed to maintain complete compounding records for all compounded preparations. Alleged Violations of Law: KRS 217.065 (1) and 201 KAR 2:076 Section 2 (1). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$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 19-0113 A REVISIT. Pharmacy permit holder allegedly sold adulterated drugs; four preparations compounded with expired components were dispensed. Permit holder allegedly failed to compound non-sterile preparations pursuant to United States Pharmacopeia (USP) 795. Permit holder allegedly failed to maintain complete records as required by USP 795. Alleged Violations of Law: KRS 217.055 (1)(a), (2), (4)(a) and 201 KAR 2:076 Section 2 (1). **CRC Recommendation: There is sufficient evidence 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. 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.**

Ron Poole seconded, and the motion passed unanimously.

Samantha Sullivan, Pharmacy Technician Reinstatement – Peter Cohron moved to deny this reinstatement. Ron Poole seconded, and the motion passed unanimously.

RECOGNITION

Larry Hadley presented Craig Martin a plaque and lapel pin for his year of service as Board President. Mr. Hadley thanked Dr. Martin for his dedication to the practice of pharmacy and the Kentucky Board of Pharmacy.

17-0511 A Settlement Conference – Jill Rhodes moved to go into closed session pursuant to KRS 61.810(1)(c) to discuss proposed or pending litigation. Peter Cohron seconded, and the motion passed unanimously. Ron Poole moved to come out of closed session. Peter Cohron seconded, and the motion passed unanimously.

Peter Cohron moved to approve the recommended dismissal and letter of concern for 17-0511 A. Ron Poole seconded, and the motion passed unanimously.

2020 CALENDAR – After discussion, the Board decided to continue to hold Case Review Panel and the KY PRN Committee meetings on the Tuesday one week prior to the Board meeting. The next scheduled CRP and KY PRN Committee meetings will be held January 21st. The Board cancelled the January 29, 2020 Board meeting and President Martin called for a Special Called Board meeting on February 5, 2020.

Peter Cohron moved to go into closed session pursuant to KRS 61.810 (1)(f) for discussions or hearings which might lead to the appointment, discipline, or dismissal of an individual employee, member, or student without restricting that employee's, member's, or student's right to a public hearing if requested. This exception shall not be interpreted to permit discussion of general personnel matters in secret. Ron Poole seconded, and the motion passed unanimously. Peter Cohron moved to come out of closed session. Ron Poole seconded, and the motion passed unanimously.

Peter Cohron moved to take no action on the item discussed in closed session. Ron Poole seconded, and the motion passed unanimously.

ADJOURNMENT On motion by Ron Poole, seconded by Jody Forgy and passed unanimously, President Martin adjourned the meeting at 12:06 p.m. The next special called meeting begins at 9:00 am on February 5, 2019 at the Kentucky Board of Pharmacy in Frankfort, KY.

Larry A. Hadley
Executive Director