KENTUCKY BOARD OF PHARMACY

125 Holmes Street Frankfort KY 40601

9:00 AM

Agenda

I. CALL TO ORDER

II. MINUTES

A. *January 30, 2019

III. APPEARANCES

- A. *Abby Stone
- B. *Michael Gillium
- C. Jessica Adams Cardinal Health

IV. INTERAGENCY

V. BOARD REPORTS

- A. Executive Director
- 1. *eMars January and February 2019
- 2. 2019 National Drug Abuse & Heroin Summit April 22-25, 2019
- 3. 2019 NABP Annual Meeting May 16-18, 2019
- 4. *NABP Inspection Report
- 5. Advisory Council Recommendation Unused Permits

VI. CURRENT/PENDING CASES

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

VII. CORRESPONDENCE

- A. *Michelle Primavera CE Extension Request
- B. *Erica Bartolowits CE Extension Request
- C. *Mary Burns CE Extension Request
- D. *Molly Pate CE Extension Request
- E. *Paul Mahan PETNET Waiver Request
- F. *Jeremy Edmonds Kingdom Health Pharmacy Equipment Waiver
- G. *Justin Bell Offsite Storage Request
- H. *UK Healthcare SDV Waiver
- I. *KPHA Equipment Waiver Request
- J. *Leslie Bidwell POCT Testing

VIII. LEGISLATION/REGULATION

A. 201 KAR 2:370 Update

IX. CONTINUING EDUCATION

A. *CE Programs – 19-02 through 19-24

X. OLD BUSINESS

A. USP 800 comment period

XI. NEW BUSINESS

- A. CBD Oil
- B. *Acute Uncomplicated Urinary Tract Infection Treatment Protocol
- C. *Self-Care Conditions Protocol: Over-the-Counter Probiotics
- D. *Anaphylaxis Treatment Protocol for Epinephrine Autoinjectors Revision

XII. REGULATION COMMITTEE

- A. Recommendations
 - 1. *201 KAR 2:010
 - 2. *201 KAR 2:090
 - 3. *201 KAR 2:095
 - 3. *201 KAR 2:100
 - 4. *201 KAR 2:116
 - 5. *201 KAR 2:165
 - 6. *201 KAR 2:225
 - 7. *201 KAR 2:230
 - 8. *201 KAR 2:240
 - 9. *201 KAR 2:270
 - 10. *201 KAR 2:310
 - 11. *201 KAR 2:340

^{*}Information enclosed with this agenda.

MINUTES

125 Holmes Street Frankfort KY 40601

BOARD MEETING

March 27, 2019

CALL TO ORDER A regularly scheduled meeting was held at the Kentucky Board of Pharmacy in Frankfort, Kentucky. President Martin called the meeting to order on March 27, 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; Katie Busroe, Pharmacy Inspections and Investigations Coordinator; Jessica Williams, Pharmacy and Drug Inspector; John Romines, Pharmacy and Drug Inspector and Darla Sayre, Executive Staff Advisor. Court Reporter Terri Pelosi recorded the meeting.

Guests: Chris Killmeier, Walgreens; Mark Glasper, KPhA; Chris Palutis, KPhA; Tammy Schlensker, PCA Pharmacy; Trish Freeman, UK College of Pharmacy; John Long, CVS Health; Brian Fingerson, PRNC; Cathy Hanna, APSC; Ralph Bouvette, APSC; Alex Fisher; Abby Stone; Lauren Adams, Walgeens; Cindy Stowe; D. Malcon; Josh Elder, KSHP; Brenda Shafer, Quarles & Brady; Jessica Adams, Cardinal Health; Lavanya Peter, Park Duvalle and Paul Mahan, PETNET Solutions.

MINUTES On motion by Jill Rhodes, seconded by Jody Forgy and passed unanimously, the minutes of the January 30, 2019 Board Meeting were approved.

APPEARANCE

ABBY STONE Abby Stone was sworn in by the court reporter, Terri Pelosi. Abby Stone appeared before the Board to request reinstatement of her Kentucky pharmacist license. Alex Fisher representing Abby Stone gave a brief overview of the events leading to the surrender of her license. Abby Stone surrendered her Kentucky pharmacist license May 29, 2014. Abby Stone signed a KYPRN agreement on July 8, 2014. She signed an Agreed Order of Surrender with the Kentucky Board of Pharmacy stipulating one year of continuous sobriety and scrupulous compliance with the directives of the KYPRN Monitoring Agreement on December 26, 2014. Her sobriety date is June 8, 2014. Brian Fingerson, chairman of the Kentucky Pharmacy Recovery Network, informed the Board that the committee voted 7-0 in favor of reinstatement.

Jill Rhodes moved to reinstate Abby Stone's pharmacist's license with stipulations as follows: five years of probation [beginning from date of the President's signature on the Agreed Order of Reinstatement]; perpetual inventory at all places of employment for Schedule II drugs;

electronic tracking of Schedule III-V drugs and expired controlled substances; perpetual inventory available; audits; 12 monthly AA/NA meetings; inspections; maximum work hours with no overtime; copy of Agreed Order to all employers and pharmacists-in-charge; KYPRN; signed release of medical records; monthly report of AA/NA meetings; observed urine, other body fluid, or hair samples for drug/alcohol screens; prohibited from accepting position as pharmacist-in-charge, power of attorney, or preceptor; attendance within 1 year of entry of her Agreed Order at Utah School or CAPTASA; monthly written self-performance evaluations. The specifics of her agreement will be detailed for Abby Stone later by Mr. Fingerson. Abby Stone stated she understood that any violation of the Agreed Order of Reinstatement shall cause her to automatically lose her license to practice pharmacy for not less than five years and one day and shall require her to petition the Board for reinstatement only after she has taken and successfully passed the entire Kentucky Board of Pharmacy licensure examination. Abby Stone 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 Abby Stone that the Board requires strict compliance with all stipulations. Ron Poole seconded, and the motion passed unanimously.

MICHAEL GILLIAM Michael Gilliam appeared before the Board requesting to amend his Agreed Order of Restrictions 18-0309, with the stipulation of working a maximum of fifty hours in any seven consecutive days. Mr. Gilliam requests an amendment to allow accepting a job closer to home working seven days on/seven days off. Peter P. Cohron moved to approve this Agreed Order amendment of working seven days on/seven days off. Ron Poole seconded, and the motion passed unanimously.

JESSICA ADAMS, Cardinal Health Jessica Adams, Telepharmacy Manager of regulatory Affairs for Cardinal Health, appeared before the Board to provide an overview of the current timeline for Kentucky's telepharmacy regulation. She stated that the Advisory Council appeared to be making little to no progress in drafting a regulation. She requested the Board consider Cardinal's proposed regulation draft in order to move telepharmacy forward. Matt Martin, Chair of the Advisory Council addressed those concerns. He advised that the council was currently taking each issue involved with this regulation, reviewing regulations from other states and determining if there is an actual need for this regulation other than the technology is available. President Martin advised that this regulation would be a fundamental change to the practice of pharmacy; being both important and impactful. President Martin requested an estimated time frame for completion. Matt Martin advised that the council is now meeting monthly and he expected to have a resolution in 6 months. President Martin stated that the Council appeared to be moving forward appropriately. President Martin charged the Advisory Council to continue their work to draft a telepharmacy regulation if it may be done effectively, appropriately and with minimum impact to the practice of pharmacy.

INTERAGENCY Mark Glasper, KPhA, informed the Board of the first Opioid Summit being held on March 30, 2019. Josh Elder, KSHP, informed the Board of the Spring Meeting being held on May 10, 2019.

BOARD REPORTS Larry Hadley presented the eMars reports for January 2019 and February 2019 to the Board.

Mr. Hadley informed the Board of the upcoming 2019 National Drug Abuse Summit, April 22-25, 2019. The Board previously approved the Board President and Executive Director to attend. President Martin stated that he was unavailable to attend. Ron Poole moved to allow another Board member to attend in President Martin's absence. Peter Cohron seconded, and the motion passed unanimously.

Mr. Hadley informed the Board of the upcoming NABP Annual Meeting. The Board previously approved the Board members, Executive Director and inspection staff to attend. Mr. Hadley requested those interested to contact the Board office.

NAPLEX/MPJE EXAMS Matt Martin, Chair of the Advisory Council advised the Board of the decision of the Council to table this issue for one year to monitor the situation.

UNUSED PERMITS/LICENSES Matt Martin, Chair of the Advisory Council reported the recommendation of the Council regarding unused permits or licenses to amend all regulations/statutes requiring all licensees and permit holders to notify the Board upon the date they begin actively engaged in business. If no notification is received within one year of issuance, the license/permit is suspended. Ron Poole moved to direct Anthony Gray, General Counsel to draft language for these amendments to be presented at the next Board meeting. Peter Cohron seconded, and the motion passed unanimously.

APhA Meeting President Martin presented to the Board his experience from his attendance at the APhA meeting in Seattle, WA. The primary focus during event was Legislative/Regulatory programming.

Notable Topics Discussed During Sessions

- Opening session
 - Focus was on the pharmacist's role in suicidality awareness and suicide prevention
 - Delivered by retired California Highway Patrol officer assigned to Golden Gate
 Bridge
 - There are nearly 3x more suicides than homicides in the United States
 - Pharmacists are accessible to patients and should be aware of the warning signs
 - Stockpiling or discontinuing medications
 - Excessive worry over medication expense
 - Change in appearance
 - Having no plans for the future

- Pharmacists need to practice effective conversational techniques if suicidality is suspected
 - Active listening
 - Validation/normalization/gratitude
 - Follow-up

Regulatory updates

- Drug prices are an ongoing focus at the federal level
- o Prices are down 0.6% for 2018, but increases are expected
- HHS has proposed eliminating the safe harbor protection for drug rebates and discounts to insurance companies unless they are shared with patients at the point of sale
- Significant discussion around DSCSA, a.k.a "Track and Trace"
 - Phase II of the implementation plan is now in effect, which pertains to product identification at the manufacturer and wholesaler level
 - By 2020, pharmacies are required to accept only verifiable products
 - There were 5 draft and 1 final guidance document(s) in 2018
 - Significant guidance to continue
 - FDA has a Track and Trace webinar posted on their site, which seems to be a high value for pharmacists
 - Compounding billing practices are under FDA scrutiny
 - Product diversion is still being discovered

Hazardous Waste Disposal

- Facilities can now accumulate up to 365 days of waste, providing enhanced flexibility for pharmacies
- OTC nicotine products have been removed from hazardous drug lists
- Sewering in any form has been banned

FDA Update

- There were a record number of drug approvals in 2018 (59 novel drugs; 39 of which were granted orphan status)
- o 19 drugs were first-in-class
- There are now 17 biosimilars approved (7 approved in 2018)
- Drug shortages
 - Continuing to increase
 - A new task force has been developed, with several agencies involved
- Drug recalls
 - Approximately 1200 in 2018
 - There were a large number of dietary supplement recalls due to presence of active ingredients
 - Compounding product recalls are down
 - ARB recalls due to nitrosamine contaminants continue to evolve

Medical marijuana

- o Town hall discussion on status/risks/benefits of medical marijuana
- Pharmacist role differs across states
- Limited efficacy evidence in several areas

- Obviously, no consensus on how to address these issues
- Expect national pharmacy organizations to develop policies
- USP 800
 - High-level overview of requirements
 - o Focus on identification of responsible party and risk assessment
 - o Cleaning, spill containment, disposal were covered
 - Tools referenced
 - Gap analysis
 - Certification

President Martin stated that the topic of medical marijuana was one that the Board should be addressing. Mark Glasper provided the KPhA Position Statement on Medical Marijuana: "KPhA neither endorses nor opposes legislation in the Kentucky General Assembly related to the use of marijuana for medical purposes. Rather, KPhA has adopted the following policy position. KPhA supports regulatory changes to facilitate clinical research related to the clinical efficacy and safety associated with the use of cannabis and its various components. Also, KPhA will support pharmacist participation in furnishing cannabis and its various components for medical purposes, to include reviewing a patient's complete medication regimen, pursuant to an order from a state approved qualified and licensed provider if and when, federal, state, or territory laws or regulations permit them to do so. KPhA supports oversight of dispensaries by the Kentucky Board of Pharmacy and advocates cannabis furnishing activities transpire within a licensed dispensary, not a licensed pharmacy. KPhA would support Pharmacist owned dispensaries. KPhA opposes pharmacist involvement in furnishing cannabis and its various components for recreational use." Mr. Hadley informed the Board that this issue will be addressed in a work session at an upcoming Board meeting.

CORRESPONDENCE

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

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

Mary Burns – CE Extension Request Ron Poole moved to approve this request allowing an extension until May 30th. John Fuller seconded, and the motion passed unanimously.

Molly Pate – CE Extension Request This item was tabled for further information.

Paul Mahan – PETNET Waiver Request Ron Poole moved to approve PETNET's request for a waiver for two USP Chapter 797 requirements: disinfecting the radiopharmaceutical vial before being introduced into the ISO Class 5 PEC due to radiation exposure to employees, and opening of dose syringes outside of the ISO Class 5 PEC due to the dexterity limitation of the remote manipulation system. Jill Rhodes seconded, and the motion passed unanimously.

Jeremy Edmonds – Kingdom Health Pharmacy Jill Rhodes moved to approve the equipment waiver request. Peter Cohron seconded, and the motion passed unanimously. The barrier exception request was tabled for inspector input.

Justin Bell – Offsite Storage Request Jill Rhodes moved to approve this request for Family Drug in Manchester to store records at Georgetown Pharmacy. Ron Poole 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 Jessica Williams stated that UK requested this waiver be tabled until the May meeting to allow for their attendance.

President Martin returned to the meeting.

KPHA – Waiver Request Ron Poole moved to approve the equipment waiver request and the request for Jody Jaggers to be dual PIC for RX Therapy Management and Kentucky Mobile Harm Reduction Pharmacy but deny the exemption of reference materials. Peter Cohron seconded, and the motion passed unanimously.

Leslie Bidwell – POCT Testing The current Board approved protocol, Acute Influenza Infection Antiviral Therapy Protocol, does not allow for the dispensing of antivirals to family members of those individuals testing positive. Ron Poole moved not to allow the protocol to be modified. Jody Forgy seconded, and the motion passed unanimously. Trish Freeman advised that the Board approved Acute Influenza Infection Chemoprophylaxis Protocol does allow for this treatment in limited circumstances.

OLD BUSINESS The Board has currently received 5 comments on the proposed options for USP 800. The deadline for submission is March 31, 2019. The Board will review these comments at the May meeting.

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

Case 18-0126 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct. Pharmacist owner was indicted on 37 Federal charges, including 35 charges of knowingly and intentionally distributing and dispensing, outside the scope of professional practice and not for a legitimate medical purpose, a Schedule II controlled substance; one charge of knowingly and intentionally opening and maintaining and managing and controlling a place for the purpose of distributing controlled substances outside the scope of professional practice and not for a legitimate medical purpose; and one charge of knowingly and willfully

executing, and attempting to execute, a scheme and artifice to defraud health care benefit programs by causing claims for payment to be submitted for prescription drugs that were never dispensed. Pharmacist was found guilty on seven of the charges of knowingly and intentionally distributing and dispensing outside the scope of professional practice and not for a legitimate medical purpose, a Schedule II controlled substance. Pharmacy allegedly failed to provide adequate security and control of controlled substances. Alleged Violations of Law: KRS 315.121(1)(a), (c), (f) and (h) and 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 five years & one day suspension. Vote was unanimous.

Case 18-0126 B. Pharmacist owner and pharmacist-in-charge allegedly engaged in unprofessional or unethical conduct. Pharmacist owner was indicted on 37 Federal charges, including 35 charges of knowingly and intentionally distributing and dispensing, outside the scope of professional practice and not for a legitimate medical purpose, a Schedule II controlled substance; one charge of knowingly and intentionally opening and maintaining and managing and controlling a place for the purpose of distributing controlled substances outside the scope of professional practice and not for a legitimate medical purpose; and one charge of knowingly and willfully executing, and attempting to execute, a scheme and artifice to defraud health care benefit programs by causing claims for payment to be submitted for prescription drugs that were never dispensed. Pharmacist was found guilty on seven of the charges of knowingly and intentionally distributing and dispensing outside the scope of professional practice and not for a legitimate medical purpose, a Schedule II controlled substance. Pharmacist-in-charge allegedly failed to provide adequate security and control of controlled substances; allegedly obtained Kentucky All Schedule Prescription Electronic Reporting (KASPER) data not related to a bona fide current or prospective patient; and allegedly violated patient confidentiality by discarding patient prescription labels in the trash. Alleged Violations of Law: KRS 315.121(1)(a), (c), (f), (h) and (2) (b), (c), (d), (e), (f), (g), (h) and (j); 201 KAR 2:205 Section 2(3)(b); and KRS 218A.202(7)(e) and (13). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.

Case 18-0277. Pharmacist was found guilty of one count of a violation of 18 United States Code (USC) § 670(a)(l) and (b)(l), theft of pre-retail medical products. Pharmacist allegedly diverted phentermine and hydrocodone combination products from a pharmacy. Alleged Violations of Law: KRS 315.121(1)(c)2, KRS 315.121(1)(b) and 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, five years & one day suspension with documented sobriety and KYPRN monitoring agreement. Vote was unanimous.

Case 18-0278. Pharmacist plead guilty to one count of a violation of 18 United States Code (USC) § 371, conspiracy to introduce misbranded drugs in interstate commerce. Alleged Violation of Law: KRS 315.121(1)(c)2. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and revocation of five years and one day. Vote was unanimous.

Case 18-0318 A. Pharmacy permit holder allegedly engaged in unprofessional conduct by failing to dispense the full quantity of medication prescribed to a patient. 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 18-0318 B. Pharmacist-in-charge (PIC) 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 exercise appropriate professional judgment in determining whether a prescription drug order is lawful and by failing to dispense the full quantity of medication prescribed to a patient. Alleged Violations of Law: KRS 315.121 (2)(d) and (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 18-0318 C. 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 exercise appropriate professional judgment in determining whether a prescription drug order is lawful and by failing to dispense the full quantity of medication prescribed to a patient. Alleged Violations of Law: KRS 315.121 (2)(d) and (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 18-0319 A. Pharmacy permit holder allegedly sold a misbranded drug due to a medication error. A patient was allegedly dispensed 100 OxyContin 80mg tablets instead of the prescribed quantity of 60 tablets. Alleged Violations of Law: KRS 217.065 (1). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, approved corrective action plan to prevent future occurrences. Vote was unanimous.

Case 18-0319 B. Pharmacist allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by committing a medication error. A patient was allegedly dispensed 100 OxyContin 80mg tablets instead of the prescribed quantity of 60 tablets. 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 \$1000 administrative fine, additional 12 hours of continuing education on medication errors and their prevention. Vote was unanimous.

Case: 18-0333 A. Pharmacy permit holder allegedly knew or had reason to know that a pharmacist was incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public and failed to report any relevant information to the board. Alleged Violation of Law: KRS 315.121(1)(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 18-0333 B. Pharmacist in charge allegedly knew or had reason to know that a pharmacist was incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public and failed to report any relevant information to the board. Alleged Violation of Law: KRS 315.121(1)(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 18-0333 C. Pharmacist allegedly had a mental or physical incapacity that prevented him from engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public. Pharmacist allegedly engaged in conduct likely to deceive, defraud, or harm the public, with or without established proof of actual injury. Alleged Violations of Law: KRS 315.121(1)(b) 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 five year probation with quarterly inspections [two years] and KYPRN monitoring agreement. Vote was unanimous.

Case 18-0381 A. Pharmacy permit holder allegedly sold a misbranded drug due to a medication error. Patient allegedly was dispensed a prescription for 30 Vyvanse 30 mg capsules that also contained one hydrocodone/acetaminophen 10mg/325mg tablet. Alleged Violations of Law: KRS 217.065 (1). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and

\$500 administrative fine, approved corrective action plan to prevent future occurrences. Vote was unanimous.

Case 18-0381 B. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Patient allegedly was dispensed a prescription for 30 Vyvanse 30 mg capsules that also contained one hydrocodone/acetaminophen 10mg/325mg tablet. Alleged Violations of Law: KRS 315.121 (2)(d). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education. Vote was unanimous.

Case 18-0395 A. Pharmacy permit holder allegedly engaged in unprofessional conduct by canceling a patient's prescriptions, which led to the patient going a week and a half without her medications. 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 18-0395 B. Pharmacist allegedly engaged in unethical or unprofessional conduct likely to deceive, defraud, or harm the public and demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, with or without established proof of actual injury, by canceling a patient's prescriptions, which led to the patient going a week and a half without her medications and allegedly committed a medication error by dispensing a prescription for gabapentin with the wrong directions. 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 18-0399. Pharmacist allegedly engaged in unprofessional or unethical conduct by accessing or attempting to access confidential patient information for persons other than those with whom a pharmacist has a current pharmacist-patient relationship and where such information is necessary to the pharmacist to provide pharmacy care by accessing a patient's Kentucky All Schedule Prescription Electronic Reporting (KASPER) report prior to receiving a prescription for the patient. Alleged Violation of Law: KRS 315.121 (2)(i). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.

Case 18-0400 A. Pharmacy permit holder allegedly engaged in unethical or unprofessional conduct by allowing confidential patient information to be revealed to unauthorized persons in the pharmacy waiting area. 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 18-0400 B. Pharmacist allegedly engaged in unethical or unprofessional conduct by revealing confidential patient information to unauthorized persons in the pharmacy waiting area. Alleged Violations of Law: KRS 315.121 (2)(b), (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 18-0401 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. The pharmacy reported the loss of 6 azithromycin 250mg tablets 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 18-0401 B. Pharmacist-in-charge (PIC) allegedly failed to provide adequate security and control of drugs. The pharmacy reported the loss of 6 azithromycin 250mg tablets 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 18-0401 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 18-0406 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 524 dosage units of three controlled substances over a period of four months 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 18-0406 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 524 dosage units of three controlled substances over a period of four months due to employee pilferage. Alleged Violations 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 cannot serve as pharmacist in charge for six months. Vote was unanimous.

Case 18-0406 C. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 248 dosage units of three controlled substances over a period of nine months 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 18-0406 D. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 248 dosage units of three controlled substances over a period of nine months 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 18-0406 E. Registered Pharmacy Technician allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without first receiving a prescription drug order for the drug. Alleged Violations of Law: KRS 315.121 (2) (f). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and revocation. Vote was unanimous.

Case: 19-0003 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. Patient was allegedly prescribed Humalog Kwikpen to inject 10 units three times a day before meals and received a prescription stating to inject 2 units three times a day before meals. 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 19-0003 B. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Patient was allegedly prescribed Humalog Kwikpen to inject 10 units three times a day before meals and received a prescription stating to inject 2 units three times a day before meals. 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 19-0003 C. 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 transferred a prescription for Humalog Kwikpen with incorrect directions. 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 19-0003 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 transferred a prescription for Humalog Kwikpen with incorrect directions. 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: 19-0004 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by divulging or revealing patient information to an unauthorized person. The patient's father was given someone else's prescription at the point of sale instead of the one belonging to the patient. Alleged Violation of Law: KRS 315.121(1)(a). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, approved corrective action plan to prevent future occurrences. Vote was unanimous.

Case 19-0004 B. Pharmacist allegedly engaged in unprofessional or unethical conduct by divulging or revealing patient information to an unauthorized person. The patient's father was given someone else's prescription at the point of sale instead of the one belonging to the patient. Alleged Violation of Law: KRS 315.121(2)(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 pharmacy law. Vote was unanimous.

Case 19-0004 C. Pharmacy technician allegedly engaged in unprofessional or unethical conduct by divulging or revealing patient information to an unauthorized person. The patient's father was given someone else's prescription at the point of sale instead of the one belonging to the patient. 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 19-0004 D. Pharmacy technician allegedly engaged in unprofessional or unethical conduct by divulging or revealing patient information to an unauthorized person. The patient's father was given someone else's prescription at the point of sale instead of the one belonging to the patient. 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 19-0008. Pharmacy permit holder allegedly failed to provide written notification to the Kentucky Board of Pharmacy 15 days prior to permanent closure. Alleged Violation of Law: 201 KAR 2:106 Sec. 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 19-0009 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by filling prescriptions that were not requested by the patient, her son, or the 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 19-0009 B. Pharmacist allegedly engaged in unprofessional or unethical conduct by demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, with or without established proof of actual injury, by filling prescriptions that were not requested by the patient, her son, or the prescriber. 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 19-0011 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 166 Alprazolam tablets, 639 Hydrocodone/APAP tablets, 363 Buprenorphine/Naloxone tablets, and 511 Tramadol tablets over a period of 2 weeks from December 14, 2018 to January 2, 2019 due to employee pilferage. Alleged Violation of Law: 201 KAR 2:100 Section 1. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.

Case 19-0011 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 166 Alprazolam tablets, 639 Hydrocodone/APAP tablets, 363 Buprenorphine/Naloxone tablets, and 511 Tramadol tablets over a period of 2 weeks from December 14, 2018 to January 2, 2019 due to employee pilferage. Alleged Violation of Law: 201 KAR 2:205 Section 2 (3) (b). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous.

Case 19-0011 C. Registered Pharmacy Technician allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without first receiving a prescription drug order for the drug. Alleged Violation of Law: KRS 315.121 (2) (f). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed

with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and revocation. Vote was unanimous.

Case 19-0014. Out of state pharmacy permit holder entered into a Consent Judgment with the United States District Court for the Northern District of Ohio, Eastern Division. From April 2013 through August 2014, pharmacy allegedly permitted controlled substances to be dispensed and/or administered from its controlled contingency stock (emergency stock) without a valid prescription at eight correctional facilities in Ohio. Alleged Violation of Law: KRS 315.121(1)(c)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 19-0015. Out of state pharmacy permit holder agreed to pay \$17 million to settle allegations that the permit holder submitted false claims to Medicare and other federal government healthcare programs from 2007 to 2018. Alleged Violation of Law: KRS 315.121(1)(c)2. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and probation while under CIA [Corporate Integrity Agreement]. Vote was unanimous.

Case 19-0016. Registered pharmacy technician allegedly engaged in unprofessional or unethical conduct. He has been charged with 1 count of distribution and 20 counts of possession of matter portraying a sexual performance by a minor. Alleged Violation of Law: KRS 315.121(1)(a). CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation. Vote was unanimous.

Case 19-0054. Registered Kentucky pharmacist was disciplined by another state board of pharmacy due to alleged medication errors and alleged failure to keep and maintain complete and accurate records of purchases and disposals of 25,013 hydrocodone/acetaminophen 10mg/325mg tablets. Alleged Violation of Law: KRS 315.121(1)(c)2. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and probation to mirror Texas, cannot serve as pharmacist in charge or have POA to order controlled substances. Vote was unanimous.

Peter Cohron seconded, and the motion passed unanimously.

Ron Poole recused himself and left the meeting.

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

Case 19-0006 A. Pharmacy permit holder allegedly sold adulterated drugs; compounded preparations with expired components were dispensed. Permit holder allegedly failed to compound non-sterile preparations pursuant to United States Pharmacopeia (USP) 795. Permit holder allegedly failed to maintain complete records as required by USP 795. Alleged Violations of Law: KRS 217.055 (1)(a), (2), (4)(a); 201 KAR 2:076 Section 2 (1). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$20,000 administrative fine and VPP inspection showing compounding compliance OR standard terms and \$20,000 administrative fine and notification to the Board within 9 months of agreed order indicating cessation of all compounding. Vote was unanimous.

Case 19-0006 B. Pharmacist in charge (PIC) allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public, with or without established proof of harm by dispensing compounded preparations containing expired ingredients. PIC was allegedly not knowledgeable in the specialized functions of preparing and dispensing compounded non-sterile preparations and allegedly failed to properly compound non-sterile preparations. PIC allegedly failed to implement a quality assurance program and in the provision of pharmacy services. Alleged Violations of Law: KRS 315.121 (2)(d); 201 KAR 2:076 Section 3 (1) and (2); 201 KAR 2:205 Section 2 (3)(a) and (b). CRC Recommendation: There is sufficient evidence 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 and proof of completion of non-sterile compounding course OR standard terms and \$5,000 administrative fine and notification to the Board of stepping down as pharmacist in charge of compounding pharmacy, additional 6 hours of continuing education on medication errors and their prevention, additional 6 hours of continuing education on pharmacy law. Vote was unanimous.

Jody Forgy seconded, and the motion passed unanimously with Jill Rhodes abstaining.

Ron Poole returned to the meeting.

PHARMACY TECHNICIAN SUMMARY Peter Cohron moved to deny this application, Case 19-0077. Jill Rhodes seconded, and the motion passed unanimously.

LEGISLATION/REGULATION Mr. Hadley provided an update on the current legislative session. 201 KAR 2:379 passed. HB 64, HB 197, HB218, HB342 and HB470 passed and have been signed into law.

CONTINUING EDUCATION Jill Rhodes moved to approve 19-02 through 19-24. Peter Cohron seconded, and the motion passed unanimously.

NEW BUSINESS Anthony Gray, General Counsel provided a presentation on CBD oil. The presentation included how other states have treated the recent legalization and selling of CBD oil. Data was compiled from 48 states and several state boards of pharmacy. Katie Busroe pointed out that in Kentucky, CBD oil is regulated by the Department of Agriculture. According to Ms. Busroe, in 2017, the Kentucky General Assembly passed HB 333 which amended KRS 218A.010 to allow for CBD products. In December 2018 the FDA said that since drugs approved by FDA that contain CBD and/or THC, therefore, it is illegal to introduce CBD containing products into the market as food supplements. How or if the FDA is going to enforce this is a question. It could be that the FDA treats this the same as DEA treats recreational and medical marijuana - the state law prevails. She indicated that the inspection staff does get this question about pharmacies selling CBD oil OTC. Our answer has been it is legal in Kentucky if it is manufactured in Kentucky and is equal to or less than 0.3%. The Board of Pharmacy has never regulated OTC products before. After much discussion, President Martin requested Board members to review this material for an in-depth discussion at the May meeting to provide a Board statement regarding the selling of CBD oil.

PROTOCOLS

Acute Uncomplicated Urinary Tract Infection Treatment Protocol – After much discussion, Ron Poole moved to approve this protocol. Jody Forgy seconded, and the motion passed unanimously.

Self-Care conditions Protocol: Over-the-Counter Probiotics – After much discussion, Ron Poole moved to approve this protocol. Jody Forgy seconded, and the motion passed unanimously.

Anaphylaxis Treatment Protocol for Epinephrine Autoinjectors Revision – After much discussion, Jill Rhodes moved to approve this revision. Ron Poole seconded, and the motion passed unanimously. Katie Busroe inquired on a previous request to obtain a statement from CHFS regarding certification for non-family members to administer epinephrine. Mr. Hadley stated that he will continue working to obtain that statement.

REGULATION COMMITTEE RECOMMENDATIONS

Trish Freeman, Chair of the Regulation Committee, provided a summary of the recommendations and requested the Board view each amended regulation separately.

201 KAR 2:010 Jill Rhodes moved to approve the amended regulation as presented by the Regulation Committee. Peter Cohron seconded, and the motion passed unanimously.

201 KAR 2:090 Jody Forgy moved to approve the amended regulation as presented by the Regulation Committee. John fuller seconded, and the motion passed unanimously.

201 KAR 2:095 Jill Rhodes moved to approve the amended regulation as presented by the Regulation Committee. Peter Cohron seconded, and the motion passed unanimously.

201 KAR 2:100 Peter Cohron moved to approve the amended regulation as presented by the Regulation Committee. Jody Forgy seconded, and the motion passed unanimously.

201 KAR 2:116 Jill Rhodes moved to approve the amended regulation as presented by the Regulation Committee. Peter Cohron seconded, and the motion passed unanimously.

201 KAR 2:165 Peter Cohron moved to approve the amended regulation as presented by the Regulation Committee with the addition of 'or pharmacist interns' in Section 1 (1)(a), line 14. Jill Rhodes seconded, and the motion passed with a vote of 3-2. Ron Poole and John Fuller cast nay votes.

201 KAR 2:225 Jill Rhodes moved to approve the amended regulation as presented by the Regulation Committee. Peter Cohron seconded, and the motion passed unanimously.

201 KAR 2:230 Jill Rhodes moved to approve the amended regulation as presented by the Regulation Committee. Peter Cohron seconded, and the motion passed unanimously.

201 KAR 2:240 John Fuller moved to approve the amended regulation as presented by the Regulation Committee. Jody Forgy seconded, and the motion passed unanimously.

201 KAR 2:270 John Fuller moved to approve the amended regulation as presented by the Regulation Committee. Jody Forgy seconded, and the motion passed with a 4-1 vote. Jill Rhodes cast a nay vote.

201 KAR 2:310 Peter Cohron moved to approve the amended regulation as presented by the Regulation Committee. Jill Rhodes seconded, and the motion passed unanimously.

201 KAR 2:340 Peter Cohron moved to approve the amended regulation as presented by the Regulation Committee. Jill Rhodes seconded, and the motion passed unanimously.

Jody Forgy moved to approve the following recommendations from the Regulation Committee:

201 KAR 2:070 - KEEP AS IS

201 KAR 2:080 – EXPIRE

201 KAR 2:105 – KEEP BUT AMEND [UNDER REVIEW]

201 KAR 2:106 - KEEP BUT AMEND [UNDER REVIEW]

201 KAR 2:115 - EXPIRE

201 KAR 2:160 - KEEP AS IS

201 KAR 2:170 - KEEP BUT AMEND [UNDER REVIEW]

201 KAR 2:175 - KEEP BUT AMEND [UNDER REVIEW]

```
201 KAR 2:180 – KEEP AS IS
201 KAR 2:185 – KEEP AS IS
201 KAR 2:190 – KEEP AS IS
201 KAR 2:210 – KEEP AS IS
201 KAR 2:215 – KEEP AS IS
201 KAR 2:250 – KEEP AS IS
201 KAR 2:260 – KEEP AS IS
201 KAR 2:280 – KEEP AS IS
201 KAR 2:300 – KEEP AS IS
201 KAR 2:300 – KEEP BUT AMEND [UNDER REVIEW]
201 KAR 2:330 – KEEP BUT AMEND [UNDER REVIEW]
```

Jill Rhodes seconded, and the motion passed unanimously.

ADJOURNMENT On motion by Jill Rhodes, seconded by Jody Forgy and passed unanimously, President Martin adjourned the meeting at 1:09 p.m. The next regularly scheduled meeting begins at 9:00 am on May 29, 2019 at the Sullivan College of Pharmacy in Louisville, KY.

Larry A. Hadley

Executive Director