

**KENTUCKY BOARD OF PHARMACY**

via Zoom

<https://us02web.zoom.us/j/85753602986?pwd=V1B1UDAwdlM5SmgzTU56aHBRdEsydz09>

**Meeting ID: 857 5360 2986 Passcode: 1L2t4v**

**Dial by your location**

**+1 312 626 6799 US (Chicago) +1 646 558 8656 US (New York)**

**Meeting ID: 857 5360 2986 Passcode: 560816**

**March 30, 2021**

**9:00 a.m.**

**AGENDA**

- I. CALL TO ORDER**
- II. MINUTES**
  - A. February 23, 2021
- III. APPEARANCES**
  - A. Richard Schultz – Initial Application for Licensure
  - B. Chris Clifton, GoGoMeds – PV2 Bypass-Extension of Automation
- IV. INTERAGENCY**
- V. BOARD REPORTS**
  - A. Executive Director
    - 1. eMars – February 2021
  - B. General Counsel
    - 1. Uradu v. KBML, Kentucky Court of Appeals Case
    - 2. Past examples of Board of Pharmacy Discipline
    - 3. Open Case Update
- VI. COMMITTEE REPORTS**
  - A. Kentucky Professional Recovery Committee, Brian Fingerson
  - B. Advisory Council, Matt Martin
  - C. Regulation Committee, Ralph Bouvette
    - 1. 201 KAR 2:061 Proposed Amendments
  - D. Pharmacy Technician Committee, Sarah Lawrence
  - E. Diversity and Inclusion Task Force, Shannon Borden and Crystal Isaacs
  - F. Case Review Panel, Jill Rhodes
- VII. CASES**
  - A. Case Review Panel Recommendations

**VIII. LEGISLATION/REGULATION**

- A. General Assembly Update
  - 1. HB 219
  - 2. Regulation Status Spreadsheet
- B. 201 KAR 2:380 – comments

**IX. APPLICATIONS**

- A. ProHealth Pharmacy Services, - Non-resident Pharmacy
- B. Wecare Medical, MG1022 – Initial application
- C. WP Pharma – Non-resident Pharmacy

**X. OLD BUSINESS**

- A. FDA Compounding MOU
- B. Emergency Preparedness – Charge to the Advisory Council
- C. Naloxone Regulation
- D. USP 795, Exclude flavorings language
- E. USP 825, Nuclear Pharmacy
- F. KY PRN Participation Review
- G. Continuing Education to Professional Development

**XI. INSPECTION STAFF**

- A. Inspection Software Upgrade
- B. RX Crossroads – Alternative PV2 Processes Inspection Report

**XII. CORRESPONDENCE**

- A. Baptist Health Louisville Outpatient Pharmacy, P07823 – Offsite Storage Request
- B. Michael Lin, P01226 and TBD – Dual PIC Request

**X. NEW BUSINESS**

- A. 2020 Continuing Education Case Review
- B. Regulation Committee Appointments to replace staff – two positions
- C. Pharmacy Technician Committee Appointments to replace staff – one position

*ATTENTION: A portion of the meeting may be held in closed/executive session for the purpose of (1) deliberating as a judicial or quasi-judicial body regarding the final adjudication of the Board's pending cases; (2) discussing and deliberating upon open investigations, which are preliminary matters that may result in litigation being filed on behalf of the Board and include the review of information required to be conducted in privacy according to federal and state law; and (3) 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. The specific statutory sections providing exemptions are: KRS 61.810(1)(c) KRS 61.878(1)(a) KRS 61.810(1)(j) KRS 61.878(1)(h) KRS 61.810(1)(f) KRS 61.810(1)(k). Following discussion and deliberation, any and all action will be taken in open/public session.*

## MINUTES

### KENTUCKY BOARD OF PHARMACY

held at

125 Holmes Street

Frankfort KY 40601

via teleconference

### BOARD MEETING

March 30, 2021

**CALL TO ORDER** A regularly scheduled meeting was held via teleconference from the Kentucky Board of Pharmacy, Frankfort, Kentucky. President Rhodes called the meeting to order on March 30, 2021 at 9:02 a.m.

Members present: Jill Rhodes, Peter Cohron, John Fuller, Jody Forgy and Chris Harlow. Jonathan Van Lahr was absent.

Staff: Larry Hadley, Executive Director; Eden Davis, General Counsel; John Romines, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector, Rhonda Hamilton, Pharmacy and Drug Inspector; Katie Busroe, Pharmacy Inspections and Investigations Supervisor and Darla Sayre, Executive Staff Advisor.

Guests: Lily Kamvar, Home Infusion Pharmacy; Lauren Adams, Walgreens and Ben Mudd, KPhA.

**MINUTES** Peter Cohron moved to accept the minutes from the February 23, 2021. Chris Harlow seconded, and the motion passed unanimously.

### APPEARANCE

**Richard Schultz** John Fuller moved to go into closed session pursuant to KRS 61.810(1)(c) and (j) to discuss proposed or pending litigation for Richard Schultz, permission to sit for exams to include the Board, Richard Schultz, Larry Hadley, Eden Davis and Darla Sayre. Peter Cohron seconded, and the motion passed unanimously. John Fuller moved to come out of closed session after a discussion for Richard Schultz, permission to sit for exams. Peter Cohron seconded, and the motion passed unanimously.

John Fuller moved to go into closed session pursuant to KRS 61.810(1)(c) and (j) to discuss proposed or pending litigation for Richard Schultz, permission to sit for exams to include the Board, Brian Fingerson, Joel Thornbury, Larry Hadley, Eden Davis and Darla Sayre. Peter Cohron seconded, and the motion passed unanimously. John Fuller moved to come out of closed session after a discussion for Richard Schultz, permission to sit for exams. Peter Cohron seconded, and the motion passed unanimously.

John Fuller moved to allow Richard Schultz to sit for the exams [NAPLEX and MPJE] upon completion of one year under the standard Kentucky Board of Pharmacy PRN agreement and voluntary surrender of his intern registration. Peter Cohron seconded, and the motion passed unanimously.

Peter Cohron moved to file a complaint against Richard Schultz for behavioral violations related to drugs and alcohol. The complaint will be investigated and presented to the Case Review Panel. John Fuller seconded, and the motion passed with one nay vote by Chris Harlow.

Peter Cohron recused.

**Chris Clifton, GoGoMeds** Chris Clifton requested a waiver to bypass the PV2 verification. This verification is completed prior to automation. John Fuller moved to approve this waiver with a revisit by the inspector in six months. Chris Harlow seconded, and the motion passed unanimously.

Peter Cohron returned to the meeting.

## **INTERAGENCY**

**Kentucky Pharmacist Association** Ben Mudd, Executive Director, requested clarification from the Board on the effects of HJR 77 to the pharmaceutical profession. Larry Hadley advised that discussion would be later in the agenda. Dr. Mudd informed the Board that the association has requested applications for Board member appointments have been requested and the Annual Meeting will be held in downtown Louisville, June 3-6, 2021.

## **BOARD REPORTS**

**Larry Hadley, Executive Director** Mr. Hadley presented the eMars reports for February 2021 to the Board.

**Eden Davis, General Counsel** Ms. Davis gave an overview of *Urada v KMBL*. Due to the findings of this case, the permissive language in 201 KAR 2:061 requires each disciplinary case be reviewed independently. The resolution of the case cannot be based on historical actions of the Board. Case resolution cannot be standardized. Ms. Davis presented two spreadsheets to the Board informing them of the status of all cases from 2017 thru 2020 with the outcomes and the status of current open cases.

## **COMMITTEE REPORTS**

**Professional Recovery Committee** Brian Fingerson reported 37 clients, 30 clients under Agreed Orders, 6 clients unknown to the Board and 1 client classified as a student.

**Advisory Council** Matt Martin reported that the Council has not met due to no charges from the Board.

**Regulation Committee** Ralph Bouvette presented to the Board the recommended amended 201 KAR 2:061. Eden Davis reviewed the amendments for the Board. Chris Harlow moved to approve the amended regulation and file with LRC with the following changes:

- Section 2. (2) replace 'executive director's designee' with 'General Counsel'.
- Section 4. (4) replace 'may' with 'shall'.

Peter Cohron seconded, and the motion passed unanimously. Ralph Bouvette stated that the following charges to the committee were still under review;

- Decentralized Pharmacies
- RFID Language
- Repository regulation
- Non-resident pharmacy permits.

**CASE REVIEW RECOMMENDATIONS** Chris Harlow moved to accept the recommendations from the Case Review Panel.

CASE 19-0326 B REVISIT New information received by General Counsel from Brian Good and Yogesh Salvi.  
CASE PRESENTED: MARCH 3, 2020 VIOLATION OF LAW: KRS 315.121(1)(H) AND (2)(D), KRS 217.065(11)(B)-MISBRANDING; DISCIPLINE: 6 CE HOURS (3 ON PHARMACY LAW AND 3 ON MEDICATION ERRORS

**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. No change in previously recommendation of standard terms and additional 3 hours of continuing education on medication errors and their prevention, additional 3 hours of continuing education on pharmacy law. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

Case 20-0116 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by failing to deliver insulin to patient in a timely manner. Pharmacy staff promised delivery on a specific date on three different occasions and the insulin was not delivered on those dates.
- Engaged in unprofessional or unethical conduct by failing to have a functioning auto-refill scheduling program. Patient enrolled in auto-refill and was not contacted to schedule delivery of insulin prior to running out of the medication.
- Engaged in unprofessional or unethical conduct by not responding to patient calls in a timely manner. Consumer waited on hold for several hours prior to being able to speak with pharmacy staff.

Alleged Violation of Law:

- KRS 315.121 (1)(a) – general unprofessional or unethical conduct.

**CRP Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

- **Information about company policy on training of technicians on how to handle inbound calls to technicians and escalation to pharmacists based on acuity.**
- **Policy on handling problematic prescriptions/exceptions to queue.**

**Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0116 B. Pharmacist in charge (PIC) allegedly:

- Failed in the provision of pharmacy services. Pharmacy staff promised delivery on a specific date on three different occasions and the insulin was not delivered on those dates.
- Failed in the provision of pharmacy services. Patient enrolled in auto-refill and was not contacted to schedule delivery of insulin prior to running out of the medication.
- Failed in the provision of pharmacy services. Consumer waited on hold for several hours prior to being able to speak with pharmacy staff.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – PIC responsible for the provision of pharmacy services.

**CRP Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

- **Information about company policy on training of technicians on how to handle inbound calls to technicians and escalation to pharmacists based on acuity.**
- **Policy on handling problematic prescriptions/exceptions to queue.**

**Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 A. Pharmacy permit holder allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported the loss of 2 acetaminophen-codeine (apap-cod) #3 tabs, 2 dextroamphetamine-amphetamine 30mg tabs, 59 carisoprodol 350mg tabs, 5 lorazepam 1mg tabs, 41 lorazepam 2mg tabs, 5 oxycodone 15mg tabs, 6 oxycodone 20mg tabs, 30 oxycodone 30mg tabs, 6 oxycodone 5mg tabs, 4 phentermine 37.5mg caps, and 3 phentermine 37.5mg tabs due to suspected employee pilferage over the course of approximately 2.5 months.

Alleged Violation of Law:

- 201 KAR 2:100 Section 1 – requirement of pharmacy to provide adequate security and control of its controlled substances and prescription legend drugs.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 B. Pharmacist-in-charge (PIC) allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported the loss of 2 acetaminophen-codeine (apap-cod) #3 tabs, 2 dextroamphetamine-amphetamine 30mg tabs, 59 carisoprodol 350mg tabs, 5 lorazepam 1mg tabs, 41 lorazepam 2mg tabs, 5 oxycodone 15mg tabs, 6 oxycodone 20mg tabs, 30 oxycodone 30mg tabs, 6 oxycodone 5mg tabs, 4 phentermine 37.5mg caps, and 3 phentermine 37.5mg tabs due to suspected employee pilferage over the course of approximately 2.5 months.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – Pharmacist-in-charge is responsible for the procurement, storage, security, and disposition of drugs.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 C. Pharmacy permit holder allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported the loss of 12 carisoprodol 350mg tabs, 38 oxycodone 15mg tabs, 18 oxycodone 30mg tabs, 10 oxycodone 10mg tabs due to suspected employee pilferage over the course of approximately 2.5 months.

Alleged Violation of Law:

- 201 KAR 2:100 Section 1 – requirement of pharmacy to provide adequate security and control of its controlled substances and prescription legend drugs.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 D. PIC allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported the loss of 12 carisoprodol 350mg tabs, 38 oxycodone 15mg tabs, 18 oxycodone 30mg tabs, 10 oxycodone 10mg tabs due to suspected employee pilferage over the course of approximately 2.5 months.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – Pharmacist-in-charge is responsible for the procurement, storage, security, and disposition of drugs.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 E. Pharmacy permit holder allegedly:

- Failed to provide adequate security of drugs. Pharmacy reported the loss of 77 lorazepam 1mg tabs, 9 oxycodone 10mg tabs, 26 oxycodone 30mg tabs, 10 oxycodone 20mg tabs, and 31 oxycodone-acetaminophen (oxy-apap) 10-325mg tabs due to suspected employee pilferage over the course of approximately 2.5 months.

Alleged Violation of Law:

- 201 KAR 2:100 Section 1 – requirement of pharmacy to provide adequate security and control of its controlled substances and prescription legend drugs.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 F. PIC allegedly:

- Failed to provide adequate security of drugs. Pharmacy reported the loss of 77 lorazepam 1mg tabs, 9 oxycodone 10mg tabs, 26 oxycodone 30mg tabs, 10 oxycodone 20mg tabs, and 31 oxycodone-acetaminophen (oxy-apap) 10-325mg tabs due to suspected employee pilferage over the course of approximately 2.5 months.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – Pharmacist-in-charge is responsible for the procurement, storage, security, and disposition of drugs.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 G. Pharmacy permit holder allegedly:

- Failed to provide adequate security of drugs. Pharmacy reported the loss of 14 oxycodone 20mg tabs due to suspected employee pilferage over the course of approximately 2.5 months.

Alleged Violation of Law:

- 201 KAR 2:100 Section 1 – requirement of pharmacy to provide adequate security and control of its controlled substances and prescription legend drugs.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 H. PIC allegedly:

- Failed to provide adequate security of drugs. Pharmacy reported the loss of 14 oxycodone 20mg tabs due to suspected employee pilferage over the course of approximately 2.5 months.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – Pharmacist-in-charge is responsible for the procurement, storage, security, and disposition of drugs.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 I. Pharmacy permit holder allegedly:

- Failed to provide adequate security of drugs. Pharmacy reported the loss of 6 oxy-apap 10-325mg tabs, 8 apap-cod #3 tabs, 21 lorazepam 2mg tabs, 15 oxycodone 20mg tabs, 15 oxycodone 5mg tabs, 20 oxycodone 10mg tabs, 1 oxycodone 15mg tabs, 10 oxycodone 30mg tabs, 1 phentermine 37.5mg caps, and 2 phentermine 37.5mg tabs due to suspected employee pilferage over the course of approximately 2.5 months.

Alleged Violation of Law:

- 201 KAR 2:100 Section 1 – requirement of pharmacy to provide adequate security and control of its controlled substances and prescription legend drugs.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 J. PIC allegedly:

- Failed to provide adequate security of drugs. Pharmacy reported the loss of 6 oxy-apap 10-325mg tabs, 8 apap-cod #3 tabs, 21 lorazepam 2mg tabs, 15 oxycodone 20mg tabs, 15 oxycodone 5mg tabs, 20 oxycodone 10mg tabs, 1 oxycodone 15mg tabs, 10 oxycodone 30mg tabs, 1 phentermine 37.5mg caps, and 2 phentermine 37.5mg tabs due to suspected employee pilferage over the course of approximately 2.5 months.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – Pharmacist-in-charge is responsible for the procurement, storage, security, and disposition of drugs.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 K. Pharmacy permit holder allegedly:

- Failed to provide adequate security of drugs. Pharmacy reported the loss of 10 oxy-apap 10-325mg tabs, 1 apap-cod #3 tabs, 1 lorazepam 2mg tabs, 1 oxycodone 5mg tabs, 16 oxycodone 15mg tabs, 15 oxycodone 20mg tabs, 20 oxycodone 30mg tabs, and 1 phentermine 37.5mg caps due to suspected employee pilferage over the course of approximately 2.5 months.

Alleged Violation of Law:

- 201 KAR 2:100 Section 1 – requirement of pharmacy to provide adequate security and control of its controlled substances and prescription legend drugs.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 L. PIC allegedly:

- Failed to provide adequate security of drugs. Pharmacy reported the loss of 10 oxy-apap 10-325mg tabs, 1 apap-cod #3 tabs, 1 lorazepam 2mg tabs, 1 oxycodone 5mg tabs, 16 oxycodone 15mg tabs, 15 oxycodone 20mg tabs, 20 oxycodone 30mg tabs, and 1 phentermine 37.5mg caps due to suspected employee pilferage over the course of approximately 2.5 months.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – Pharmacist-in-charge is responsible for the procurement, storage, security, and disposition of drugs.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 M. Pharmacy permit holder allegedly:

- Failed to provide adequate security of drugs. Pharmacy reported the loss of 13 oxy-apap 10-325mg tabs, 655 apap-cod #3 tabs, 7 dextroamphetamine-amphetamine 30mg tabs, 106 carisoprodol 350mg tabs, 58 lorazepam 2mg tabs, 29 oxycodone 15mg tabs, 16 oxycodone 20mg tabs, 24 phentermine 37.5mg caps, 55 expired oxycodone 30mg tabs, 9 expired oxycodone 10mg tabs, 3 expired OxyContin 30mg tabs, and 14 expired OxyContin 40mg tabs due to suspected employee pilferage over the course of approximately 2.5 months.

Alleged Violation of Law:

- 201 KAR 2:100 Section 1 – requirement of pharmacy to provide adequate security and control of its controlled substances and prescription legend drugs.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 N. PIC allegedly:

- Failed to provide adequate security of drugs. Pharmacy reported the loss of 13 oxy-apap 10-325mg tabs, 655 apap-cod #3 tabs, 7 dextroamphetamine-amphetamine 30mg tabs, 106 carisoprodol 350mg tabs, 58 lorazepam 2mg tabs, 29 oxycodone 15mg tabs, 16 oxycodone 20mg tabs, 24 phentermine 37.5mg caps, 55 expired oxycodone 30mg tabs, 9 expired oxycodone 10mg tabs, 3 expired OxyContin 30mg tabs, and 14 expired OxyContin 40mg tabs due to suspected employee pilferage over the course of approximately 2.5 months.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – Pharmacist-in-charge is responsible for the procurement, storage, security, and disposition of drugs.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0120 O. Pharmacist allegedly:

- Has a mental or physical incapacity that prevents the licensee from engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public.

- Engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without having first received a prescription drug order for the drug.

**Alleged Violations of Law:**

- KRS 315.121 (1)(b) - mental or physical incapacity that prevents the licensee from engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public.
- KRS 315.121(2)(f) - selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without having first received a prescription drug order for the drug.

**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. Temporary suspension of license per KRS 315.131(6) and to send complaint to Attorney General's office to set for hearing with resolution of revocation for five years and a day. If licensee is willing to enter into settlement of an agreed order of suspension for impaired pharmacist which includes signed KYPRN agreement, six months of documented sobriety/90 days of NA/AA, and standard terms for reinstatement. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

**Case 20-0198 A. Pharmacy permit holder allegedly:**

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of controlled substances due to employee pilferage. The pharmacy reported a loss of 949 dosage units of alprazolam tablets and 7,443 dosage units of various schedule II controlled substances due to employee pilferage.

**Alleged Violations of Law:**

- 201 KAR 2:100 Section 1 – a pharmacy shall provide adequate security of its controlled substances and prescription legend drugs.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

**Case 20-0205 E Revisit. Non-resident PIC on a pending non-resident pharmacy permit application, allegedly:**

- Engaged in unprofessional or unethical conduct by engaging in the wholesale distribution of prescription drugs.
- PIC of pharmacy permit holder applicant allegedly sold prescription drugs to a wholesale distributor located in Kentucky 10 times in 2020.

**Alleged Violations of Law:**

- KRS 315.121(1)(a) – unprofessional or unethical conduct by engaging in the wholesale distribution of drugs as a pharmacy
- 201 KAR 2:205 Section 2(3)(b) – the pharmacist-in-charge (PIC) is responsible for the procurement, storage, security, and disposition of drugs.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0209 A. Pharmacy permit holder allegedly:

- Sold a misbranded drug due to a medication error. Patient allegedly received 90 oxycodone tablets instead of the labeled quantity of 120 tablets.

Alleged Violation of Law:

- KRS 217.065 (1) – a drug is deemed misbranded when its labeling is false or misleading.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0209 B. Pharmacist-in-charge (PIC) allegedly:

- Failed in the provision of pharmacy services. Patient allegedly received 90 oxycodone tablets instead of the labeled quantity of 120 tablets.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – PIC shall be responsible for the provision of pharmacy services.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0209 C. 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. Pharmacist allegedly dispensed a prescription vial containing 90 oxycodone tablets instead of the labeled quantity of 120 tablets.

Alleged Violation of Law:

- KRS 315.121 (2)(d) – engaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist, with or without established proof of actual injury.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0210 A. Pharmacy permit holder allegedly:

- Sold a misbranded drug due to a medication error. Patient allegedly received 30 alprazolam 2mg tablets instead of the labeled quantity of 60 tablets.

Alleged Violation of Law:

- KRS 217.065 (1) – a drug is deemed misbranded when its labeling is false or misleading.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0210 B. Pharmacist-in-charge (PIC) allegedly:

- Failed in the provision of pharmacy services. Patient allegedly received 30 alprazolam 2mg tablets instead of the labeled quantity of 60 tablets.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – PIC shall be responsible for the provision of pharmacy services.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0210 C. 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. Pharmacist allegedly dispensed a prescription vial containing 30 alprazolam 2mg tablets instead of the labeled quantity of 60 tablets.

Alleged Violation of Law:

- KRS 315.121 (2)(d) – engaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist, with or without established proof of actual injury.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0220 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by not contacting a patient's prescriber for refill requests as stated in the automated telephone refill request system.
- Engaged in unprofessional or unethical conduct by not providing a patient with an emergency refill of insulin therapy.

Alleged Violation of Law:

- KRS 315.121 (1)(a) – general unprofessional or unethical conduct

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0220 B. Pharmacist in charge allegedly:

- Failed in the proper provision of pharmacy services. Patient's prescriber was allegedly not contacted for a refill request in a timely manner after patient requested refill in the pharmacy's automated telephone system.
- Failed in the proper provision of pharmacy services. Patient was not dispensed an emergency refill of insulin therapy.
- Engaged in unprofessional or unethical conduct by engaging in conduct that substantially departs from accepted standards of pharmacy practice with or without established proof of actual injury. Patient was not dispensed an emergency supply of insulin.

Alleged Violations of Law:

- KRS 315.121 (1)(a) – general unprofessional or unethical conduct; and
- 201 KAR 2:205 Section 2 (3)(b) – pharmacist in charge responsible for provision of pharmacy services.

**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. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0222 A. Pharmacy permit holder allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of controlled substances due to possible employee pilferage. Pharmacy reported a loss of 274 ml of promethazine-codeine cough syrup and 31 tablets of alprazolam 2 mg.

Alleged Violation of Law:

- 201 KAR 2:100 Section 1 – a pharmacy shall provide adequate security of its controlled substances and prescription legend drugs.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0222 B. Pharmacist in charge allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of controlled substances due to possible employee pilferage. Pharmacy reported a loss of 274 ml of Promethazine with Codeine cough syrup and 31 tablets of alprazolam 2 mg.

Alleged Violation of Law:

- 201 KAR 2:205. Section 2(3)(b) – the pharmacist-in-charge shall be responsible for the procurement, storage, security, and disposition of drugs.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0222 C. Unregistered 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) – Except as provided in KRS 315.500, selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without having first received a prescription drug order for the drug.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. A letter of warning to be issued with dismissal letter. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0224 A. Pharmacy permit holder employed a pharmacist that allegedly:

- Engaged in unprofessional or unethical conduct by violating patient confidentiality.

Alleged Violation of Law:

- KRS 315.121 (1) (a) – unprofessional or unethical conduct

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0224 B. Pharmacy-in-charge (PIC) allegedly:

- Engaged in unprofessional or unethical conduct by violating patient confidentiality.

Alleged Violation of Law:

- KRS 315.121 (2) (b) – revealing to unauthorized persons patient information.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0228 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by failing to sell prescriptions as a 30-day supply as requested by patient and for failing to sell prescriptions with a non-child safety cap as requested by the patient.

Alleged Violation of Law:

- KRS 315.121 (1)(a) – general unprofessional or unethical conduct.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0228 B. Pharmacist in charge (PIC) allegedly:

- Failed in the proper provision of pharmacy services. Patient was dispensed 90-day supplies of prescriptions when 30-day supplies were requested. Patient was dispensed prescriptions in child safety caps when non-child safety caps were requested.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – PIC responsible for provision of pharmacy services.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0228 C. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public, or engaging in conduct which substantially departs from accepted standards of pharmacy practice with or without established proof of actual injury. Pharmacist dispensed 90-day supplies of prescriptions in child safety caps when patient requested 30-day supplies and non-child safety caps.

- Failed to perform a proper prospective drug use review.

Alleged Violations of Law:

- KRS 315.121 (2)(d) - unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public, or engaging in conduct which substantially departs from accepted standards of pharmacy practice with or without established proof of actual injury; and
- 201 KAR 2:210 Section 4 – Requirement for a prospective drug use review.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0229 A. Pharmacy permit holder allegedly:

- Sold a misbranded drug due to a medication error.
- Sold a prescription for tramadol with the label reflecting no refills when the prescriber had authorized three refills.
- Sold a prescription for acetaminophen with codeine 300mg/30mg with the label reflecting no refills when the prescriber had authorized three refills.

Alleged Violation of Law:

- KRS 217.065 (1)—drug misbranded if labeling is false or misleading.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0229 B. Pharmacist in charge allegedly:

- Failed in the provision of pharmacy services.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b)— the pharmacist in charge shall be responsible for provision of pharmacy services.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0229 C. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by committing a medication error.
- Dispensed a prescription for acetaminophen with codeine 300mg/30mg with the label reflecting no refills when the prescriber had authorized three refills.
- Transferred both prescriptions incorrectly.

Alleged Violation of Law:

- KRS 315.121 (2)(d)—unprofessional or unethical conduct by engaging in conduct likely to harm public with or without established proof of actual injury.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0229 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.

- Dispensed a prescription for tramadol with the label reflecting no refills when the prescriber had authorized three refills.

Alleged Violation of Law:

- KRS 315.121 (2)(d)—unprofessional or unethical conduct by engaging in conduct likely to harm public with or without established proof of actual injury.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0230 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by selling a prescription to unauthorized person.
- Delivered a controlled substance prescription to the wrong motel room.

Alleged Violation of Law:

- KRS 315.121(1)(a)—unprofessional or unethical conduct.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 20-0230 B. Pharmacist allegedly:

- Failed in the appropriate provision of pharmacy services by selling a prescription to unauthorized person.
- Had a controlled substance prescription delivered to the wrong motel room.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b)—the pharmacist in charge shall be responsible for provision of pharmacy services.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 21-0003 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by failing to maintain sanitary conditions for the storage and dispensing of drugs.

Alleged Violation of Law:

- KRS 315.121 (1)(a) – general unprofessional or unethical conduct.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 21-0003 B. Pharmacist in charge (PIC) allegedly:

- Failed in the responsibility for the proper provision of pharmacy services.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(d) – PIC responsible for provision of pharmacy services

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 21-0003 C. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public or engaging in conduct, which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist, with or without established proof of actual injury. Pharmacist allegedly poured the complainant's prescription medication into bare hand as part of verification process.

Alleged Violation of Law:

- KRS 315.121 (2)(d) - Unprofessional or unethical conduct for conduct likely to harm public or substantially departs from standard practice with or without established proof of actual injury.

**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.**

Case 21-0007 A. Pharmacy permit holder allegedly:

- Aided and abetted an individual to engage in the practice of pharmacy without a license.
- Allowed pharmacy technician to change the label and contents of the prescription vial dispensed to patient without it being verified by a pharmacist.

Alleged Violations of Law:

- KRS 315.121(1)(a) – unprofessional or unethical conduct.
- KRS 315.121(1)(g) – aiding and abetting an individual to engage in the practice of pharmacy without a license.

**CRP Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

- **Gather policy and procedures as they relate to 201 KAR 2:100 for maintaining appropriate security and access controls and any changes that have been made.**

**Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 21-0007 B. Pharmacist-in-charge (PIC) allegedly:

- Aided and abetted an individual to engage in the practice of pharmacy without a license.
- Allowed pharmacy technician to change the label and contents of the prescription vial dispensed to patient without it being verified by a pharmacist.

Alleged Violations of Law:

- KRS 315.121(1)(a) – unprofessional or unethical conduct.
- 201 KAR 2:205 Section 2 (3)(a) - PIC shall be responsible for quality assurance programs for pharmacy services.

**CRP Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

- **Gather policy and procedures as they relate to 201 KAR 2:100 for maintaining appropriate security and access controls and any changes that have been made.**

**Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 21-0007 C. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by failing to appropriately supervise pharmacy technician.

Alleged Violation of Law:

- KRS 315.121(2)(d) – engaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist, with or without established proof of actual injury.

**CRP Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

- **Gather policy and procedures as they relate to 201 KAR 2:100 for maintaining appropriate security and access controls and any changes that have been made.**

**Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 21-0007 D. Pharmacy technician allegedly:

- Engaged in the practice of pharmacy without a license.
- Changed the label and contents of the prescription vial dispensed to patient without it being verified by a pharmacist.

Alleged Violation of Law:

- KRS 315.121(1)(g) – engaging in the practice of pharmacy without a license.

**CRP Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

- **Gather policy and procedures as they relate to 201 KAR 2:100 for maintaining appropriate security and access controls and any changes that have been made.**

**Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 21-0013 A. Pharmacy permit holder allegedly:

- Failed to have proper recordkeeping of prescriptions dropped off by a patient. Pharmacy allegedly had no record of a hydroxychloroquine prescription dropped off in November 2020 and requested to be put on hold.

Alleged Violations of Law:

- KRS 315.121 (1)(a) – general unprofessional or unethical conduct; and
- 201 KAR 2:210 Section 1 – Requirement for patient record system.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 21-0013 B. Pharmacist in charge (PIC) allegedly:

- Failed to maintain proper records. Pharmacy allegedly had no record of a hydroxychloroquine prescription dropped off in November 2020 and requested to be put on hold.

Alleged Violation of Law:

- 201 KAR 2:210 Section 1 (1)(b) – pharmacist responsibility to establish procedure for obtaining, recording, and maintaining information required for a patient record.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 21-0014 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by not selling filled prescriptions to the patient.
- Alleged Violation of Law:
- KRS 315.121 (1)(a) – general unprofessional or unethical conduct.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 21-0014 B. Pharmacist in charge allegedly:

- Engaged in unprofessional or unethical conduct by refusing to sell prescriptions to the patient.
- Alleged Violations of Law:
- KRS 315.121 (1)(a) – general unprofessional or unethical conduct; and
  - KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public with or without established proof of actual injury.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 21-0053 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by telling a patient that a prescription had not been received from a prescriber’s office when it had.
  - Sold a prescription with a “do not fill until” date earlier than the prescriber allowed.
- Alleged Violation of Law:
- KRS 315.121 (1)(a)—unprofessional or unethical conduct.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 21-0053 B. Pharmacist in charge allegedly:

- Failed in the provision of pharmacy services.
- Alleged Violation of Law:
- 201 KAR 2:205 Section 2 (3)(b)—the pharmacist in charge shall be responsible for provision of pharmacy services.

**CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 21-0053 C. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by telling a patient that a prescription had not been received from a prescriber's office when it had.
- Dispensed a prescription with a "do not fill until" date earlier than the prescriber allowed.

Alleged Violations of Law:

- 21 CFR 1306.14 (e)—where a prescription that has been prepared in accordance with section [1306.12](#) (b) contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date.
- KRS 315.121 (2)(d)—engaging in conduct likely to deceive, defraud, or harm the public and engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily practiced by pharmacists, with or without established proof of actual injury.
- KRS 315.121 (2)(j)—failing to exercise appropriate professional judgement in determining whether a prescription drug order is lawful.

**CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

Case 21-0076. Non-resident wholesale distributor:

- Entered into a Settlement Agreement of \$325,000 and a Memorandum of Agreement with the Drug Enforcement Administration (DEA) for failure to adequately maintain controlled substance records.

Alleged Violation of Law:

- KRS 315.121(1)(c)2 – being convicted of a violation of drug laws of the federal government.

**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 probation while under MOU and settlement agreement with DEA for period of three years unless DEA agrees in writing to terminate the agreement earlier. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.**

**GENERAL ASSEMBLY LEGISLATIVE UPDATE** Larry Hadley provided an update on the legislative session. House Bill 219 was recently signed into law, effective 90 days from the end of the legislative session. This legislation will eliminate the syringe/needle log for OTC sales of syringes and needles. Chris Harlow moved to charge the Advisory Council to amend current regulations or draft a new regulation for clarification of recordkeeping/remote order entry due to House Bill 219. Jody Forgy seconded, and the motion passed unanimously.

Eden Davis advised that 201 KAR 2:030 is the remaining regulation due to sunset in 2021.

House Joint Resolution 77 limits the Executive Orders under the State of Emergency to 90 days from the effective date. The passing of this legislation will impact multiple emergency orders issued during the pandemic. Chris Harlow moved to direct General Counsel to file an emergency regulation allowing for COVID testing and immunization mirroring the language used in the previous emergency regulations and orders. Trish Freeman requested a review of point of care Covid testing. Peter Cohron seconded, and the motion passed unanimously.

Jody Forgy left the meeting.

**201 KAR 2:380** The Board reviewed comments received from the Kentucky Medical Association on filed amendment of 201 KAR 2:380. After review, Chris Harlow moved to address the comments with the following changes; limit the treatment of alcohol abuse disorder to Naltrexone based therapy only and include the previous language ‘pursuant to recommendations by the Centers for Disease Control and Prevention (CDC)’. Peter Cohron seconded, and the motion passed unanimously.

## **APPLICATIONS**

**ProHealth Pharmacy Services** Katie Busroe presented the Board with a non-resident pharmacy application for ProHealth Pharmacy Services. This pharmacy is requesting special consideration to provide services for a hospital located in Kentucky. Peter Cohron moved to approve this application and issue the non-resident pharmacy permit. John Fuller moved to revisit this pharmacy practice at the May meeting and requested additional input from the General Counsel. Chris Harlow seconded, and the motion passed with Peter Cohron abstaining.

**Wecare Medical** The Board reviewed the initial application for a Special Limited Medical Gas permit. Chris Harlow moved to deny the application. The motion died for lack of a second. Chris Harlow moved to table this until the May meeting requesting inspector concerns over lack of pharmacist supervision of the oxygen tank storage. Peter Cohron seconded, and the motion passed unanimously.

**WP PHARMA** Katie Busroe presented the Board with a non-resident pharmacy application for WP Pharma. John Fuller moved to deny the application. Peter Cohron seconded. After discussion, John Fuller withdrew his motion to deny. John Fuller moved to table this item requesting the applicant appear at the May meeting to answer questions. Chris Harlow seconded, and the motion passed unanimously.

## **OLD BUSINESS**

**FDA Compounding MOU** Chris Harlow moved to begin the process to enter into the FDA Compounding MOU directing the General Counsel to amend 201 KAR 2:061 to meet the requirements. Peter Cohron seconded, and the motion passed unanimously.

The Board returned to Committee Reports.

**Pharmacy Technician Committee** Sarah Lawrence advised the Board the committee continued to work through the responses of the survey on enhanced pharmacy technician role in pharmacy. The committee recommended the Board allow a test program with selected pharmacies allowing:

1. Kentucky registered technicians to perform interpretation of Clia waived or Point of Care testing with appropriate training as determined by supervising pharmacist.
2. Kentucky registered technicians holding an active national certification with appropriate training as determined by the pharmacist-in-charge to:
  - Receive verbal orders of new non-controlled prescriptions and clarifications of non-controlled prescriptions from provider; and
  - Transfer non-controlled prescriptions.

The test program will include a graduated assumption of duties to include observation, direct supervision and then general supervision. Policies and procedures must be in place for pharmacies to include training parameters for the technicians. Eden Davis advised that the law is silent on these roles and the Board can proceed with a test program. Chris Harlow moved to direct the committee to implement the test program with the removal of the interpretation of Clia waived or Point of Care testing. John Fuller seconded, and the motion passed unanimously.

The Board returned to Old Business.

**ADVISORY COUNCIL CHARGE** Chris Harlow moved to approve the charge to the Advisory Council:

1. Related to Pandemics, Epidemics, Natural Disasters, Terroristic Disasters and Biologic Disasters:
  - (a) CHARGE: Evaluate pharmacy practice changes due to COVID-19 – short-term additions with long-term plans or implications, that include but are not limited to remote order entry
  - (b) CHARGE: Review current law in KY to determine if they are sufficient to allow potential response and change in work practice to meet patient care needs immediately; evaluate other state laws to determine if other changes should be adopted to ensure pharmacists may practice legally
  - (c) CHARGE: Evaluate and recommend permanent practice changes that are temporarily being done at this time to meet the demands of the pandemic
  - (d) CHARGE: Evaluate the opioid epidemic and make recommendations to the board for any necessary regulatory changes that would improve the health of the Commonwealth / and reduce opioid OD and addiction
  - (e) CHARGE: Simulate a recovery exercise for each type of emergency and outline the legal restraints and allowances that impact operations – provide a list of these and whether other changes should be invoked in an emergency pharmacy powers regulation
  - (f) CHARGE: Determine the role that the KY Board of Pharmacy Executive Director, staff and inspection staff can serve in emergency/disaster response. Determine if the KY Board of Pharmacy office and staff could/should serve as a command center or coordination center.
  - (g) CHARGE: Seek input and coordination with KPhA and KSHP
2. NABP Passport Program / Development of a State Pharmacist Database for response
  - (a) CHARGE: Create a readily usable and UTD robust pharmacy / pharmacist database to recognize the pharmacists who can be called upon to assist based on their capacity, i.e. certifications, job expertise and work location
  - (b) CHARGE: Create a process to allow no-practicing retirees of the pharmacy practice to re-enter work to meet the patient care demands of various types of emergencies

Peter Cohron seconded, and the motion passed unanimously.

**Naloxone Regulation** John Fuller moved to direct General Council draft a Declaratory Opinion to allow the dispensing of naloxone to an agency until the regulation is amended. Chris Harlow seconded, and the motion passed unanimously. Chris Harlow moved to direct General Counsel to proceed with drafting the amendment of 201 KAR 2:360 to allow for this practice. Peter Cohron seconded, and the motion passed unanimously.

**USP 795 and USP 825** These items were tabled until the May meeting.

#### **INSPECTION STAFF**

**Inspection software upgrade** Katie Busroe presented the price quote for the upgrade of the inspection software. Larry Hadley requested this be tabled until the May meeting to allow additional information from another software vendor.

**RX Crossroads – Six month inspection of alternative PV2 process** Inspection staff reported no issues with the alternative process in the six months from Board approval.

**CORRESPONDENCE** Peter Cohron moved to approve the off-site storage request submitted by Baptist Health Louisville Outpatient Pharmacy, P07823. Chris Harlow seconded, and the motion passed unanimously. John Fuller moved to approve the dual PIC request submitted by Michael Lin, P01226 and P08158. Chris Harlow seconded, and the motion passed unanimously.

## **NEW BUSINESS**

**2020 Continuing Education Case Review** President Rhodes requested a review of the 2020 continuing education credits due to the pandemic. Chris Harlow moved to extend the deadline of fifteen hours of continuing education during the calendar year of 2020 to December 31, 2021. Pharmacists must complete thirty hours of continuing education by the end of the year. The motion also included a reversal of all previously executed Agreed Orders due to insufficient continuing education hours in 2020. John Fuller seconded, and the motion passed unanimously.

**Regulation Committee Appointments** Chris Harlow requested this be tabled until the May meeting to allow for the acceptance of additional applications.

**Pharmacy Technician Committee Appointment** Sarah Lawrence recommended the appointment of Melissa Burgess to replace Katie Busroe on the committee. Peter Cohron moved to accept the recommendation. Chris Harlow seconded, and the motion passed unanimously.

**Medication Safety Committee** Ben Mudd, Executive Director of KPha recommended Dreama Johnson for the pharmacy technician appointment on the committee. Chris Harlow moved to accept the recommendation. Peter Cohron seconded, and the motion passed unanimously.

**Continuing Education to Professional Development** This item was tabled until the May meeting. Board staff to provide information from other states.

**Kentucky Board of Pharmacy PRN Participation** President Rhodes presented the following concerns of participation in the KY Board of Pharmacy Professional Recovery Network:

- Students that are unknown to the Board due to participation at the request of the school
- Participation of individuals after a one time DUI
- Participation of individuals without acknowledgement of substance use disorder

Chris Harlow proposed a review by the Professional Recovery Network Committee for;

- an interpretation of current practices and concerns that have been raised; and
- an evaluation of 201 2:250 for amendments to address these concerns.

John Fuller suggested an assessment of the individual prior to participation to verify a substance use disorder. President Rhodes stated that this may be cost prohibitive.

President Rhodes advised the next meeting will be May 25, 2021 beginning at 9:00 a.m.

**ADJOURNMENT** John Fuller moved to adjourn. Peter Cohron seconded and the motion passed unanimously. President Rhodes adjourned the meeting at 2:57 p.m.