

KENTUCKY BOARD OF PHARMACY

via Zoom

<https://us02web.zoom.us/j/81895900357?pwd=RnAzQlVTSzBwcDNYK2FKK2NqV2xzdz09>

Meeting ID: 818 9590 0357

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+1 312 626 6799 US (Chicago)

Meeting ID: 818 9590 0357

Passcode: 999572

May 25, 2021

9:00 a.m.

AGENDA

- I. CALL TO ORDER**
- II. MINUTES**
 - A. March 30, 2021
- III. PUBLIC HEARING [if requested]**
 - A. 201 KAR 2:171, Computerized recordkeeping
 - B. 201 KAR 2:205, Pharmacist-in-charge
 - C. 201 KAR 2:390, Requirements for third-party logistics provider
 - D. 201 KAR 2:040, Pharmacist Interns
- IV. APPEARANCES**
- V. INTERAGENCY**
- VI. BOARD REPORTS**
 - A. Executive Director
 - 1. eMars – March 2021 and April 2021
 - 2. 201 KAR 2:050, Fee Amendments
 - B. General Counsel
 - 1. Proposal to draft emergency suspension/restrictions regulation.
 - C. Board Members
 - 1. NABP Annual Meeting – Jill Rhodes
 - 2. APRN Council Meeting – Chris Harlow
- VII. COMMITTEE REPORTS**
 - A. Kentucky Professional Recovery Committee, Brian Fingerson
 - B. Advisory Council, Matt Martin
 - C. Regulation Committee, Ralph Bouvette
 - D. Pharmacy Technician Committee, Sarah Lawrence
 - E. Diversity and Inclusion Task Force, Shannon Borden and Crystal Isaacs

- F. Medication Safety Committee, TBD
- G. Case Review Panel, Jill Rhodes

VIII. CASES

- A. Fine Report
- B. Case Review Panel Recommendations

IX. LEGISLATION/REGULATION

- A. 201 KAR 2:360, Naloxone dispensing
- B. 201 KAR 2:061, Procedures followed by the Kentucky Board of Pharmacy in the investigation and hearing of complaints.
- C. 201 KAR 2:380, Board Authorized Protocols
- D. 201 KAR 2:410E, Ordering and administering vaccinations.
 - 1. Draft Vaccination Ordinary Regulation
- E. 201 KAR 2:270, Expungement

X. APPLICATIONS

- A. Prohealth Pharmacy Solutions – Non-resident Pharmacy
- B. Medvantx/MiniMed Shared Services Proposal
- C. WP Pharma – Non-resident Pharmacy
- D. HDM Pharmacy – change of ownership application
- E. WeCare Pharmacy – Medical Gas permit application

XI. OLD BUSINESS

- A. Naloxone Regulation – Declaratory Opinion
- B. USP 795, Exclude flavorings language
- C. USP 825, Nuclear Pharmacy
- D. Prescription storage requirements during transit – Charge to Advisory Council
- E. Kentucky Board of Pharmacy PRN participation

XII. INSPECTION STAFF

- A. Inspection Software Upgrade

XIII. CORRESPONDENCE

- A. U of L Health, Peace Hospital P08082 and P08108 – Dual PIC Request
- B. Nephron Pharmacy – Non-resident Pharmacy Waiver
- C. Owensboro Family Pharmacy, P08149 – Offsite Storage Request

XIV. NEW BUSINESS

- A. Board Authorized Protocols – revision to remove COVID testing requirement
 - 1. Acute Group A Streptococcal Pharyngitis Infection Protocol
 - 2. Acute Influenza Infection Antiviral Therapy Protocol
- B. NaloxBox

C. Regulation Committee – two vacancies

1. Aaron Gilbert
2. Ben Mudd
3. Chad Thompson
4. Chris Killmeier
5. Cole Wendeln
6. Deborah Larison
7. Erik Mayes
8. Gary Davis
9. J. Tyler Stevens
10. Jacob Dotson
11. Jeremy Campbell
12. John Tran
13. Joseph Todd Carter
14. Kalista Pirkle
15. Kimberly Croley
16. Kyle Bryan
17. Lauren Adams
18. Lewis Wilkerson
19. Martika Martin
20. Olivia Simpson
21. Ross Goetz
22. Ryan Naseman
23. Spencer Hirschi
24. Stacey Emmons
25. Steve Hart
26. Tiffany Vicars
27. Zachary Cenfetelli
28. Zain Razvi

XV. CLOSED SESSION

A. Settlement Conferences

1. 19-0326B
2. 19-0320B
3. 19-0358 A and B
4. 19-0302 B and C
5. 20-0202 A, B and C
6. 19-0323 B

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

May 25, 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 May 25, 2021 at 9:01 a.m.

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

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; Amanda Harding, Pharmacy and Drug Inspector; Paul Daniels, Pharmacy and Drug Inspector; Katie Busroe, Pharmacy Inspections and Investigations Supervisor and Darla Sayre, Executive Staff Advisor.

Guests: Joan Haltom and Sam Silek.

MINUTES Chris Harlow moved to accept the minutes from the March 30, 2021. John Fuller seconded, and the motion passed unanimously.

PUBLIC HEARING President Rhodes advised the Board that no requests to appear regarding 201 KAR 2:171; 201 KAR 2:205; 201 KAR 2:390 and 201 KAR 2:040 were received. The public hearing for these amended regulations is canceled. Written comments will be accepted until May 31, 2021.

INTERAGENCY

Kentucky Pharmacist Association Ben Mudd, Executive Director, advised the Board that the results from their Safety and Satisfaction Survey are being calculated. The results will be distributed later. The KPhA 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 March and April 2021 to the Board. Mr. Hadley informed the Board of a potential increase of fees. The fee increase is needed due to the impact of the recalculation of retirement funding by the State. Under advisement of the Board's Budget Analyst, Mr. Hadley will continue to research this and bring it back to the Board at the July meeting.

Eden Davis, General Counsel Ms. Davis proposed drafting a regulation for emergency suspensions and/or restrictions as required under KRS 218A.205. Chris Harlow moved to direct Ms. Davis to draft a regulation for presentation at the next meeting. Jonathon Van Lahr seconded, and the motion passed unanimously.

APRN Council Chris Harlow provided a summary of the May 21, 2021 APRN Council meeting. Items discussed included multiple state license sharing and upcoming buprenorphine updates.

NABP Annual Meeting President Rhodes provided a summary of the NABP Annual Meeting held on May 13, 2021. Topics discussed:

- Point of care/vaccinations during the pandemic – the Model Act will be updated to allow this practice.
- Work group created to determine if regulatory waivers during the pandemic should be extended beyond the state of emergency.
- Reviewing international supply chains to reduce patient costs.
- Task force created to evaluate patient safety and pharmacy practice metrics.
- Task force created to evaluate medication errors.

COMMITTEE REPORTS

Kentucky Professionals Recovery Network Committee Brian Fingerson reported 33 clients, 31 clients under Agreed Orders and 2 voluntary clients.

Advisory Council Matt Martin presented the recommendations of the Advisory Council for HB 219:

- Definition of general supervision includes supervision by electronic means.
- Remote order entry requires general supervision.
- Definitions in KRS 315.010 be reviewed and updated to reflect modern practice and technology.
- The current body of law does not prohibit remote order entry or verification; therefore, House Bill 219 has no implication on current practices.

Matt Martin inquired about the charge to the Council for prescription storage requirements during transit tabled at the last meeting. Concerns raised by Board members include physical conditions during transit and at what point is the consumer responsible for the product's environment. John Fuller moved to direct the Advisory Council to study the issue of shipped medications for temperature excursions/integrity during transit until received by the ultimate consumer. Peter Cohron seconded, and the motion passed unanimously. The Board would like a recommendation from the Council no later than June 2022.

There were no reports from the Regulation Committee, Pharmacy Technician Committee, Diversity and Inclusion Task Force [next meeting June 17, 2021] and the Medication Safety Committee [initial meeting June 9, 2021].

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

19-0365 Revisit

CASE PRESENTED: MAY 19, 2020

CASE REVISIT: JANUARY, 2021

VIOLATION OF LAW: KRS 315.121(1)(l)-violation of any order issued by the Board to comply with any applicable law or administrative regulation.

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

19-0122 Revisit

CASE PRESENTED: July, 2019

VIOLATION OF LAW: KRS 315.121(1)(i): (i) Violation of any order issued by the board to comply with any applicable law or administrative regulation;

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 three-year probation backdated to July 2019 when the Board voted for the original recommendation. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

19-0346E Revisit

CASE PRESENTED: March, 2020

VIOLATION OF LAW: KRS 315.020(3) –no person shall engage in the practice of pharmacy unless licensed to practice under the provisions of KRS Chapter 315, except as provided in subsection 4.

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

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 one-year probation. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

20-0112F Revisit

CASE PRESENTED: October 22, 2020

VIOLATION OF LAW: KRS 315.121 (2)(f) - unprofessional or unethical conduct to dispense drug for which a prescription drug order is required without having first received a prescription drug order for the drug; and

KRS 315.121 (2)(j) – unprofessional or unethical conduct for failing to exercise appropriate professional judgment 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 describing the importance of knowing the law and understanding the legal requirements prior to initiating an order and as it relates to a CCA. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

CASE 21-0012 A, B, and C.

SUMMARY:

- Pharmacy permit holder identified improper purchase of merchandise by technician. Continual investigation and review of video surveillance led to discovery of diversion of controlled substance and non-controlled substance medications.
- Permit holder reported a loss of 477 controlled substance doses.
- Technician admitted to medication diversion in interview with permit holder personnel. Technician worked a few days (3-4) in the pharmacy.
- Pharmacist in charge conducted additional audits in months after technician termination and did not identify further loss.

Case 21-0012 A. Pharmacy permit holder allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of 477 controlled substance doses including 225 benzodiazepine, 125 oxycodone/APAP, and 46 phentermine doses and loss of non-controlled substances due to employee pilferage.

Alleged Violation of Law:

- 201 KAR 2:100 Section 1 – security and control requirement

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 21-0012 B. Pharmacist in charge allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of 477 controlled substance doses including 225 benzodiazepine, 125 oxycodone/APAP, and 46 phentermine doses and loss of non-controlled substances due to employee pilferage.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – security of drugs requirement

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 21-0012 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) – 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.

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 to Attorney General. Change registration status to 'Do Not Renew'. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

CASE 21-0033 A and B.

SUMMARY:

- Consumer complaint that pharmacist behaved unprofessionally when counseling pregnant patient receiving COVID-19 vaccine.
- Pharmacist says that he used clinical and professional judgement in determining appropriateness of COVID-19 vaccine for pregnant patient.

Case 21-0033 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by employing a pharmacist who engaged in unprofessional or unethical conduct when counseling a pregnant patient receiving the COVID-19 vaccine.

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 21-0033 B. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct when counseling a pregnant patient receiving the COVID-19 vaccine.

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. Issuance of Letter of Concern regarding

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

CASE 21-0045 A and B.

SUMMARY:

- Consumer complaint that pharmacist and technicians not properly wearing masks in the pharmacy.
- Governor executive order requiring facial coverings in pharmacies.
- Inspector observed PIC not wearing a mask when at the pharmacist workstation.
- PIC said that employees maintained 6 feet distancing while in the pharmacy and wore masks when approaching customers.
- Permit holder policy that all employees wear face masks while on duty.

Case 21-0045 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by failing to ensure employees properly wear facial coverings in pharmacy during state of emergency due to the coronavirus (COVID-19) pandemic.

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 21-0045 B. Pharmacist in charge (PIC) allegedly:

- Engaged in unprofessional or unethical conduct by failing to properly wear a facial covering in the pharmacy during state of emergency due to the coronavirus (COVID-19) pandemic.

Alleged Violations of Law:

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

CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand specifying their actions showed a disregard for patient safety and wellness. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

CASE 21-0054 A and B.

SUMMARY:

- Consumer complaint that pharmacy sold narcotic prescription to an unauthorized individual in October 2020.
- Pharmacy policy allows for someone other than patient to pick up prescriptions if able to answer identifying questions.
- Replacement prescription sent to the pharmacy and dispensed.

- Notation added to patient profile to limit who is authorized to pick up prescriptions.

Case 21-0054 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by selling a prescription to an unauthorized individual.
- 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 21-0054 B. Pharmacist in charge (PIC) allegedly:

- Failed in the provision of pharmacy services by selling a prescription to an unauthorized individual.
- Alleged Violation of Law:
- 201 KAR 2:205 Section 2 (3)(b) – PIC responsibility 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 21-0070 A and B.

SUMMARY:

- Consumer complaint that pharmacy staff does not maintain patient confidentiality. Drug names are said at pick up in the pharmacy and drive thru in hearing range of other customers.
- Consumer complaint that notification that prescription is ready sent to patients prior to the prescription being ready.
- Pharmacy has policy and procedure to not state drug names unless asked to by patient and only after confirming patient's information.
- Pharmacy has a notification system that alerts patients to when prescription are ready to be refilled, delayed in filling, ready for pick up or if refill requests are denied by prescriber.

Case 21-0070 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by allowing confidential patient information to be released. Consumer alleged that pharmacy staff on different occasions said the name of medications within hearing of other customers.

Alleged Violations of Law:

- KRS 315.121 (1)(a) – general unprofessional or unethical conduct; and
- 201 KAR 2:210 Section 3 – Confidentiality of patient record, communicated only to the patient, as the patient directs or as prudent, professional discretion dictates

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 21-0070 B. Pharmacist in charge allegedly:

- Engaged in unprofessional or unethical conduct by allowing confidential patient information to be released. Consumer alleged that pharmacy staff on different occasions said the name of medications within hearing of other customers.

Alleged Violations of Law:

- KRS 315.121 (2)(b) – unprofessional or unethical conduct to divulge or reveal patient information to unauthorized persons without the patient’s express consent;
- 201 KAR 2:205 Section 2 (3)(b) – pharmacist in charge 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 21-0072 A and B.

SUMMARY:

- Consumer complaint that an electronically prescribed controlled substance prescription was deleted from the pharmacy system instead of being placed on the patient’s file for later fill.
- Pharmacy’s information technology team was able to locate the electronic prescription and determined it was deleted from the pharmacy’s system.
- Pharmacist in charge providing continual training on proper procedures for placing prescription on hold.

Case 21-0072 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by allowing a received electronic controlled substance prescription to be improperly deleted from the pharmacy system.
- Failed to maintain accurate records of all electronic controlled substance prescriptions received.

Alleged Violations of Law:

- KRS 315.121 (1)(a) – general unprofessional or unethical conduct;
- 21 CFR 1311.205 (b)(1)(i) – pharmacy application receiving electronic controlled substances must have logical access controls to limit access to deletion of prescription information; and
- 21 CFR 1311.305 – pharmacy to maintain an electronic record of all electronic controlled substance prescriptions received

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 21-0072 B. Pharmacist in charge (PIC) allegedly:

- Failed in the provision of pharmacy services. A received electronic controlled substance prescription was improperly deleted from the pharmacy system.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – PIC 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 21-0127 A and B.

SUMMARY:

- Consumer complaint because received an epinephrine 0.3 mg auto-injector when prescription and label were for epinephrine 0.15 mg auto-injector.
- Workflow in pharmacy system shows that prescription was dispensed without any pharmacist involvement. No data entry verification, drug use review or labeled product verification by pharmacist.
- Point of sale system alerts employee if prescription not verified by pharmacist but does not stop sale.
- Pharmacy owner has contacted software vendor to update point of sale to include a hard stop instead of an alert.

Case 21-0127 A. Pharmacy permit holder allegedly:

- Sold a misbranded prescription. Prescription and label were for epinephrine 0.15 mg auto-injector and patient was sold epinephrine 0.3 mg auto-injector.
- Allowed a non-pharmacist to practice pharmacy. Prescription was dispensed without pharmacist performing prospective drug use review or labeled product verification.
- Engaged in unprofessional or unethical conduct by allowing a prescription to be sold without pharmacist prospective drug use review or labeled product verification.
- Alleged Violations of Law:
 - KRS 217.065 (1) – drug misbranded if labeling false or misleading in any particular;
- KRS 315.020 (1) – pharmacist to be in charge of and supervise dispensing of prescription drugs; and
- KRS 315.121 (1)(a) – general unprofessional or unethical conduct

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, approved corrective action plan that addresses these system problems of not placing hard stop prior to point of sell if not verified by a pharmacist implemented within 3 months of the Agreed Order being signed. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

Case 21-0127 B. Pharmacist in charge allegedly:

- Engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury. Prescription and label were for epinephrine 0.15 mg auto-injector and patient was sold epinephrine 0.3 mg auto-injector.
- Failed to perform a prospective drug use review prior to dispensing of a prescription. Prescription was dispensed without pharmacist performing drug use review or labeled product verification.

Alleged Violations of Law:

- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury; and
- 201 KAR 2:210 Section 4 (1) – prospective drug use review to be conducted by a pharmacist prior to dispensing

CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention. Must provide oversight in the creation and implementation of the corrective action plan. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

CASE 21-0044 A, B, and C.

SUMMARY:

- Consumer requested a refill on his ezopiclone, a schedule IV controlled substance medication.
- Pharmacist reviewed consumer's request and determined refill was five days too soon.
- When consumer claimed their prescription was missing pills, the pharmacist verified ezopiclone inventory count.
- Pharmacist contacted the consumer's physician to authorize an early refill. The physician office denied the request.

Case 21-0044 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by employing a pharmacist who refused to dispense a prescription.

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 21-0044 B. Pharmacist in charge (PIC) allegedly:

- Failed in the provision of pharmacy services.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – PIC requirements 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 21-0044 C. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful.

Alleged Violations of Law:

- KRS 315.121 (2)(j) - failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful.

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 21-0064 A, B, and C.

SUMMARY:

- Pharmacy staff received consumer complaints of missing tablets from schedule II prescriptions.
- PIC reviewed prescription processing and asset protection staff reviewed security videos.
- Asset protection conducted an interview with a pharmacy technician.
- Pharmacy technician admitted to taking 15-20 tablets of schedule II controlled substances.

Case 21-0064 A. Pharmacy permit holder allegedly:

- Failed to provide adequate security and control of drugs. The pharmacy reported a loss of 449 dosage units of schedule II controlled substances over 185 days due to employee pilferage.

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 21-0064 B. Pharmacist in charge allegedly:

- Failed to provide adequate security and control of drugs. The pharmacy reported a loss of 449 dosage units of schedule II controlled substances over 185 days due to employee pilferage.

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 21-0064 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) – 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 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 with the investigator abstaining from the vote to limit their role to that of a factfinder.

CASE 21-0078 A and B.

SUMMARY:

- Consumer allegedly found a tablet of a different strength in her ropinirole 0.5 mg prescription vial filled in March of 2021.
- Consumer previously received 0.25 mg tablets of ropinirole in February of 2021.
- Consumer contacted the pharmacy and a pharmacy technician attempted to explain the physician wrote for a higher strength on her March prescription.
- PIC reviewed pharmacy operations and determine no other ropinirole prescriptions filled on the same day as the consumer prescription.
- PIC inspected all opened stock to ensure pharmacy staff did not combine the two different ropinirole strengths into one bottle.

Case 21-0078 A. Pharmacy permit holder allegedly:

- Sold a misbranded drug due to a medication error. Patient allegedly found a tablet of a different strength in her prescription vial.

Alleged Violation of Law:

- KRS 217.065 (1) – a drug is deemed to be misbranded if its labeling is false in any manner

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 21-0078 B. Pharmacist in Charge allegedly:

- Engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Patient allegedly found a tablet of a different strength in her prescription vial.

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 21-0119 A and B.

SUMMARY:

- Consumer alleged the pharmacy dispensed a prescription containing one tablet of a different medication.
- PIC conducted investigation and determined the pharmacy staff counted the other medication before the consumer's prescription.
- PIC educated pharmacy staff to confirm the counting trays are cleared prior to counting a next prescription.

Case 21-00119 A. Pharmacy permit holder allegedly:

- Sold a misbranded drug by dispensing a prescription containing one tablet of a different medication.

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 21-0119 B. Pharmacist in charge (PIC) allegedly:

- Failed in the proper disposition of drugs and the provision of pharmacy services;
- 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. Consumer dispensed a prescription containing one tablet of a different medication.

Alleged Violations of Law:

- 201 KAR 2:205 Section 2 (3)(b)- The procurement, storage, security, and disposition of drugs and the provision of pharmacy services; and
- 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 specifying violations and recommend continued adherence to the corrective action plan already in place. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

CASE 20-0091 A and B.

SUMMARY:

- Patient was prescribed Adderall XR capsules.
- Prescriber did not indicate no generic substitution of prescription.
- On two separate occasions, pharmacy initially processed prescription through Patient's primary insurance for generic equivalent and claim was rejected because brand name preferred by plan.
- Pharmacy reprocessed prescription for brand name.
- Patient questioned price when picking up prescription and discovered it was filled with brand name.
- Patient asked pharmacy to reprocess prescription for generic.
- Pharmacy filled prescription for generic and applied discount card instead of using insurance in order to lower price for Patient.
- Patient said pharmacy staff did not provide clear explanation as to why prescription was filled for brand name since it was not requested.

Case 20-0091 A. Pharmacy permit holder allegedly:

- Engaged in unethical or unprofessional conduct by filling a prescription with a brand name drug instead of a lower-priced therapeutically equivalent drug.

Alleged Violation of Law:

- KRS 315.121 (1)(a) – unprofessional and 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 20-0091 B. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct likely to deceive, defraud, or harm the public, with or without established proof of actual injury, by filling a prescription with a brand name drug instead of a lower-priced therapeutically equivalent drug.

Alleged Violations of Law:

- 315.121 (2)(d) - engaging in conduct likely to deceive, defraud, or harm the public, with or without established proof of actual injury;
- KRS 217.822 (1) – requires pharmacist filling a prescription written for a brand name drug to substitute a lower-priced therapeutically equivalent drug for which the pharmacist has in stock, unless otherwise instructed by the patient at the point of purchase or by the patient's practitioner

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 21-0002 A, B, and C.

SUMMARY:

- Patient was prescribed methylphenidate 5mg tablets.
- The vial dispensed to Patient was labeled as methadone 5mg tablets.
- Patient read the patient information sheet and contacted pharmacy after reading that the medication is used to treat pain.
- PIC confirmed the order entry error and dispensed replacement prescription for the correct medication when Patient returned to pharmacy.
- The verifying pharmacist was notified of the error and contacted Patient's prescriber.
- PIC determined that order entry technician only entered the first 4 letters of the drug and selected the wrong medication from the dropdown list.
- Technician was re-trained on entering a minimum of 5 letters of drug name and order entry verification steps were reinforced.
- Patient did not take any doses of the incorrect medication.

Case 21-0002 A. Pharmacy permit holder allegedly:

- Sold a misbranded drug due to a medication error. Patient was prescribed methylphenidate 5mg tablets but allegedly received methadone 5mg tablets.

Alleged Violation of Law:

- KRS 217.065 (1) – misbranding of drug

CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand recommending implementation of a corrective action plan to prevent future occurrences. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

Case 21-0002 B. Pharmacist-in-charge (PIC) allegedly:

- Failed in the provision of pharmacy services. Patient was prescribed

methylphenidate 5mg tablets but allegedly received methadone 5mg 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 sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand recommending a complete review of prescription prior to dispensing. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

Case 21-0002 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. Patient was prescribed methylphenidate 5mg tablets but allegedly received methadone 5mg 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 to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

CASE 21-0073 A and B.

SUMMARY:

- Kentucky Labor Cabinet (KLC) inspected pharmacy for reported violations of workplace requirements associated with COVID-19.
- KLC findings and deficiencies referred to Board as a result of pharmacy employees not wearing facial coverings inside the pharmacy.
- Governor executive order requiring facial coverings in pharmacies.
- Board inspector observed PIC and technicians working within 6 feet of one another and not wearing facial coverings inside the pharmacy during inspection of facility.
- PIC said he would review the most recent orders from the governor and information from Kentucky Department for Public Health, CDC, and OSHA and implement necessary changes.

Case 21-0073 A and B. Pharmacy permit holder allegedly:

- Engaged in unethical or unprofessional conduct by failing to ensure employees wear facial coverings in pharmacy during state of emergency due to the coronavirus (COVID-19) pandemic.

Alleged Violations of Law:

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

Pharmacist-in-charge (PIC) allegedly:

- Engaged in unprofessional or unethical conduct by failing to wear a facial covering in the pharmacy during state of emergency due to the coronavirus (COVID-19) pandemic.

Alleged Violations of Law:

- KRS 315.121 (2)(d) - engaging in conduct likely to harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, and 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 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, split evenly between the cases. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

CASE 19-0296 A and B Revisit.

SUMMARY:

- Asset Protection Solutions Manager received notification on July 16, 2019 that there were shortages of oxycodone/acetaminophen 10mg/325mg, promethazine with codeine, and tramadol. After conducting an investigation and completing daily counts of these medications, the unexplained shortages seemed to stop. However, small, unexplained shortages were discovered on two strengths of hydrocodone/acetaminophen.
- A second investigation was conducted, including daily counts, security videos being reviewed, and interviews being conducted. Asset Protection Solutions Manager noticed suspicious behavior on video of Pharmacy Technician when counting hydrocodone/acetaminophen prescriptions. The case was eventually closed after determining the video was not definitive and Pharmacy Technician had denied diverting any medications during her interview.
- On September 30, 2019, Asset Protection Solutions Manager noticed unexplained shortages on three strengths of hydrocodone/acetaminophen while reviewing pharmacy inventory adjustments. His investigation led him to again review security

video of prescriptions being filled for hydrocodone/acetaminophen. He again noticed suspicious behavior on Pharmacy Technician's part.

- He interviewed Pharmacy Technician again on October 7, 2019. She denied diverting any medication from the pharmacy, but could not explain her actions on the video. Pharmacy Technician's employment was terminated and Police Department was notified.
- A completed DEA 106 form was sent to me on or about December 4, 2019. Six hundred seventy-one tablets of hydrocodone/acetaminophen 10mg/325mg were listed as missing.
- All loss was attributed to employee pilferage.
- Case was originally brought forward in March 2020. The decision was made to revoke the technician's registration.
- Asset Protection Solutions Manager continued to notice additional small shortages of hydrocodone/acetaminophen.
- A second DEA 106 form was received by the Board office on October 26, 2020. It showed a loss of 123 hydrocodone/acetaminophen 7.5mg/325mg and 3 tablets of oxycodone/acetaminophen 5mg/325mg.
- After conducting an investigation, Asset Protection Solutions Manager determined causes of additional losses were not due to theft but recordkeeping (a prescription was deleted twice) and inappropriate counting (using scales instead of counting by hand).

Case 19-0296 A Revisit. Pharmacy permit holder allegedly:

- Failed to provide adequate security and control of drugs.
- The pharmacy initially reported a loss of two hydrocodone/acetaminophen 10mg/325mg, which was updated to 671 tablets.
- The pharmacy reported additional losses of 123 hydrocodone/acetaminophen 7.5mg/325mg and 3 tablets of oxycodone/acetaminophen 5mg/325mg.
- Alleged Violation of Law:
201 KAR 2:100 Section 1 – a pharmacy shall provide adequate security and control 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 19-0296 B Revisit. Pharmacist-in-charge allegedly:

- Failed to provide adequate security and control of drugs.
- The pharmacy initially reported a loss of two hydrocodone/acetaminophen 10mg/325mg, which was updated to 671 tablets.
- The pharmacy reported additional losses of 123 hydrocodone/acetaminophen 7.5mg/325mg and 3 tablets of oxycodone/acetaminophen 5mg/325mg.

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 sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand recommending implementation of a corrective action plan for inventory control management for all controlled substances. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

CASE 21-0057 A and B.

SUMMARY:

- Consumer complaint was received via voicemail at the Board office.
- Consumer stated a pharmacy refused to allow her to come in to get a vaccination after being on the waitlist for a few weeks.
- Consumer stated if they had told her that originally, she could have gone elsewhere and already gotten at least one dose of the vaccine.

Case 21-0057 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by refusing to allow a patient to get a vaccination after placing her on a waitlist, thus delaying care.

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 21-0057 B. Pharmacist in charge allegedly:

- Engaged in unprofessional or unethical conduct by refusing to allow a patient to get a vaccination after placing her on a waitlist, thus delaying care.

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 or pharmacy intern, 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 21-0111 A, B, and C.

SUMMARY:

- Consumer complaint was received stating that a pharmacy gave him the wrong strength of his medication.
- Investigation showed an old prescription for a lower strength was refilled. His current prescription for the correct strength was out of refills.

- Pharmacy records indicate the prescription was requested either by phone or mobile application during a time when the pharmacy was closed.

Case 21-0111 A. Pharmacy permit holder allegedly:

- Engaged in unethical or unprofessional conduct by selling an inappropriate prescription.
- Sold an old refill for Trintellix 10mg after patient had been on Trintellix 20mg for six months.

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 21-0111 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 21-0111 C. Pharmacist allegedly:

- Failed to conduct a prospective drug use review prior to dispensing.
- Dispensed an old refill for Trintellix 10mg after patient had been on Trintellix 20mg for six months.

Alleged Violation of Law:

- 201 KAR 2:210 Section 4 (1) and (2)—a prospective drug use review shall be conducted by the pharmacist prior to dispensing, including an assessment of the patient’s drug therapy

CRP Recommendation: There is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand recommending a review of medication history prior to pharmacist prescription approval. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

CASE 21-0005 A and B.

SUMMARY:

- On January 12, 2021, citizen contacted Board of Pharmacy stating the Pharmacy did not transfer spouse’s prescriptions to another Pharmacy on December 29, 2020.

- Transferring Pharmacy Owner/PIC provided documentation that patient's prescriptions were transferred to Receiving Pharmacy on January 11, 2021, three days before the prescriptions were due to be filled.
- Receiving Pharmacy received one transferred prescription on January 11, 2021. Receiving Pharmacy had already obtained new prescriptions for patient from prescribers before January 11, 2021. Patient was never without medication.
- Neither the patient nor the patient's spouse requested Receiving Pharmacy obtain transfers from the Original Pharmacy, but did request the Original Pharmacy transfer prescriptions to the Receiving Pharmacy.

Case 21-0005 A. Pharmacy permit holder allegedly:

- Failed to transfer patient's prescriptions upon request of patient.

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 21-0005 B. Pharmacist in Charge (PIC) allegedly:

- Failed to transfer patient's prescriptions upon request of patient.
- Failed to provide name of transferring Pharmacist.

Alleged Violations of Law:

- KRS 315.121 (1)(a) – Unprofessional or unethical conduct;
- KRS 315.121 (2)(d) – Engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist or pharmacy intern, with or without established proof of actual injury; and
- 201 KAR 2:165 Section 1(2)(c) – The name of the pharmacist transferring the 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 21-0010 A and B.

SUMMARY:

- Former employee submitted complaint Pharmacy disposed of Protected Health Information (PHI) improperly exposing patient's personal information, violating HIPAA (Health Insurance Portability and Accountability Act), and the Pharmacy was not collecting copays for Medicare and Medicaid patients.
- Owner and Pharmacist in Charge both state that the owner takes sealed boxes of PHI to owner's residence for destruction by burning.
- Owner and Pharmacist in Charge both state that customers who are unable to pay copays are allowed to charge copays. Pharmacy makes attempts to collect amounts

charged but had never denied patient medication based on inability to pay and the Pharmacy has never turned delinquent accounts over to collections.

Case 21-0010 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct

Alleged Violation of Law:

- KRS 315.121 (1)(a) – Pharmacy engaged in unprofessional or unethical conduct. Pharmacy dispensed medication without a valid prescription

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Letter of Concern recommending a written policy and procedure to include documentation of destruction of PHI. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

CRP Recommendation: Refer complaint regarding collection of co-pays to CHFS Office of Inspector General. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

Case 21-0010 B. Pharmacist in Charge allegedly:

- Engaged in unprofessional or unethical conduct by failing to protect patient information from unlawful disclosure. Pharmacist disclosed patient information without proper authorization or authority.

Alleged Violation of Law:

- KRS 315.121 (2)(b) – Pharmacist divulged or revealed to unauthorized persons patient information or the nature of professional services rendered without the patient's express consent or without order or direction of a court

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 21-0052 A and B.

SUMMARY:

- On February 12, 2021, prescriber contacted Board of Pharmacy stating the Pharmacy provided control substance to a patient without a legal prescription.
- Pharmacist admitted that patient received incorrect medication due to original prescription on hold at the pharmacy being entered the pharmacy's computer system for the incorrect medication.
- Pharmacy has implemented new procedures and retrained staff to prevent a possible reoccurrence of the same error.

Case 21-0052 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct. Pharmacy dispensed medication without a valid prescription.

Alleged Violation of Law:

- KRS 315.121 (1)(a) – Pharmacy engaged in unprofessional or unethical conduct. Pharmacy dispensed medication without a valid prescription

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 21-0052 B. Pharmacist in Charge allegedly:

- Engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful. Pharmacist dispensed medication without a valid prescription.

Alleged Violation of Law:

- KRS 315.121 (2)(j) – Pharmacist failed to exercise appropriate professional judgment in determining whether a prescription drug order is lawful

CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

CASE 21-0114 A and B.

SUMMARY:

- On March 4, 2021, Board of Pharmacy received complaint that patient received Gabapentin instead of Ibuprofen in a prescription filled February 10, 2021.
- Pharmacist stated although possible it is highly unlikely based on inventory and circumstances that patient received incorrect medication.

Case 21-0114 A. Pharmacy permit holder allegedly:

- Sold a misbranded drug due to medication error. Patient allegedly was dispensed a prescription for Ibuprofen that contained Gabapentin.

Alleged Violation of Law:

- KRS 217.065 (1) - If its labeling is false or misleading in any particular

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 21-0114 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 Ibuprofen that contained Gabapentin.

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 or pharmacy intern, 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 21-0116 A and B.

SUMMARY:

- On March 15, 2021, owner contacted Kentucky Board of Pharmacy via email stating that on March 12, 2021, the Pharmacy permanently closed and the records were transferred to another Pharmacy in the same town.
- The owner notified Pharmacist in Charge less than 24 hours before the permanent closure occurred.
- Owner stated that Board Staff informed him that the purchaser was responsible to submit change of ownership paperwork.

Case 21-0116 A. Pharmacy permit holder allegedly:

- Failure to notify the Board of Pharmacy of by written notice fifteen (15) days prior to the anticipated closure. Pharmacy permanently closed and records transferred to another Pharmacy on March 12, 2021. Board of Pharmacy notified of closure by email on March 15, 2021.

Alleged Violation of Law:

- 201 KAR 2:106 Section 2 (1) (a) – Failure to notify the Board of Pharmacy of by written notice fifteen (15) days prior to the anticipated closure

CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

Case 21-0116 B. Pharmacist in Charge allegedly:

- Failed to immediate notify the Board of Pharmacy of a deviation of business hours of 5 consecutive business days or greater.

Alleged Violations of Law:

- 201 KAR 2:205 Section 2 (3) (d) – Pharmacist in Charge is required to report to the Board of Pharmacy within 14 calendar days any change in the operating hours of the Pharmacy

- 201 KAR 2:205 Section 2 (3) (e) – Pharmacist in Charge is required to make or file any reports required by state or federal laws and regulations

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 21-0121 A, B, and C.

SUMMARY:

- On March 19, 2021, citizen contacted Board of Pharmacy stating the pharmacy only filled part of their prescription per their corporate policy denying them pain relief. Citizen filed complaint the same day.
- On April 12, 2021, Inspector visited pharmacy to obtain documents and interview staff.
- On April 13, 2021, Inspector requested policies and all pertinent records from corporate office.
- On April 28, 2021, corporate office provided the requested policies and records. Based on the policies and records provided the pharmacist who filled the prescription was following the corporate policy.
- On April 29, 2021, received pharmacist in charge’s statement.

Case 21-0121 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct. Pharmacy had a policy preventing patient from receiving full amount of their prescription.

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 21-0121 B. Pharmacist in Charge allegedly:

- Engaged in unprofessional or unethical conduct by failing to provide pharmacy services.

Alleged Violation of Law:

- 201 KAR 2:205 Section (3)(b) –The procurement, storage, security, and disposition of drugs and 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 21-0121 C. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful.

Alleged Violation of Law:

- KRS 315.121 (2) (j) – Failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful

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.

John Fuller seconded, and the motion passed with Peter Cohron voting nay on Case 21-0002C.

LEGISLATION/REGULATION

201 KAR 2:360, Naloxone dispensing Eden Davis presented an amended draft that removed the education requirement for certification. Jonathan Van Lahr moved to approve the draft as presented and directed Ms. Davis to file with LRC. Chris Harlow seconded, and the motion passed unanimously.

President Rhodes advised the Board that 201 KAR 2:061 and 201 KAR 2:380 were progressing through the legislative process.

201 KAR 2:410E, Ordering and administering vaccinations Eden Davis advised the Board that this regulation will expire August 20, 2021. Jonathan Van Lahr moved to renew this emergency regulation with a small change and inform pharmacists of the need to obtain 20 hours of training in advance of the state of emergency ending. Jody Forgy seconded, and the motion passed unanimously.

Ms. Davis presented a draft vaccination regulation. Jonathan Van Lahr moved to approve as presented and directed Ms. Davis to file with LRC. Peter Cohron seconded, and the motion passed unanimously.

201 KAR 2:270, Expungement Eden Davis presented an amended draft that allows the Board's discretion on what is expungable. Her research found that the majority of state's do not allow expungement. Some states use a 'Revision of Report' in conjunction with their discipline report. Florida uses an 'Order to Vacate' to expunge disciplinary actions. Chris Harlow moved to table this item until the next meeting. The motion died for lack of a second. Peter Cohron moved to approve the draft as presented and directed Ms. Davis to file with LRC. Jonathan Van Lahr seconded, and the motion passed with Chris Harlow abstaining.

Peter Cohron recused himself and was placed in the waiting room.

APPLICATIONS

Prohealth Pharmacy Solutions, Non-resident pharmacy application Mark Mikhael informed the Board that Prohealth Pharmacy Solutions would like to amend their application for a non-resident pharmacy permit to a central fill pharmacy permit. He requested the Board consider a waiver of the common database requirement for central fill pharmacies. Their pharmacy practice model identifies the dispensing pharmacy as the back-end pharmacy. After discussion, Chris Harlow moved to deny the waiver request. The motion died for lack of a second. Joan Haltom provided additional information on the pharmacy practice. John Fuller moved to

approve the waiver and direct the Regulation Committee to evaluate the Central Fill regulation for possible amendment. After further discussion, John Fuller rescinded his motion. John Fuller moved to allow this pharmacy to practice as a non-resident pharmacy and direct the Regulation Committee to evaluate the Central Fill regulation to broaden the scope of practice allowing dispensing from the front-end pharmacy or the back-end pharmacy. The motion died for lack of a second. Jonathan Van Lahr moved to direct the Regulation Committee to evaluate 201 KAR 2:230 for a broader scope of practice allowing for modern business models. Chris Harlow seconded, and the motion passed unanimously.

Medvantx/MiniMed Shared Services Nick Meza requested a waiver allowing shipment directly to the patient. After discussion, the Board determined this request was similar to the previous request from Prohealth Pharmacy Solutions. Jonathan Van Lahr moved to direct the Regulation Committee to evaluate 201 KAR 2:230 for a broader scope of practice allowing for modern business models. Chris Harlow seconded, and the motion passed unanimously.

WP Pharma, Non-resident pharmacy application Jason McLaren provided additional details on this permit application. The pharmacy has proposed shipping of pharmaceuticals that are pending FDA approval. Chris Harlow moved to approve the pending application with restrictions. Compounds shipped to Kentucky must fall under 503A. No products not having FDA approval may be shipped to Kentucky. Peter Cohron seconded, and the motion passed unanimously.

WeCare Pharmacy, Medical Gas pharmacy application Chris Harlow moved to approve this permit application. Peter Cohron seconded, and the motion passed unanimously.

OLD BUSINESS

Naloxone Regulation Eden Davis informed the Board that the Declaratory Opinion requested at the March meeting was drafted, approved and posted on the Board's website.

USP 795/USP 825 This item was tabled until the July meeting to allow Board members sufficient time to educate themselves on this topic.

Kentucky Board of Pharmacy PRN Participation President Rhodes presented the Board with information from Brian Fingerson and Emily Corporal regarding participation in the program for those individuals without a substance abuse disorder. This is used by the colleges of pharmacy as a cautionary means for students. Mr. Fingerson stated that there has been an increase of students testing positive for THC. The committee needs guidance on how to proceed. Chris Harlow requested the committee review both situations and present their recommendations to the Board at the July meeting. John Fuller requested that both University of Kentucky College of Pharmacy and Sullivan University College of Pharmacy be included in this review.

INSPECTION STAFF The Board reviewed the upgrade proposal received for inspection software from Outlier Technologies. Chris Harlow moved to approve the software upgrade at a cost of \$52,500. This will be paid for from the US Marshall Drug Interdict Fund. Jonathan Van Lahr seconded, and the motion passed unanimously.

CORRESPONDENCE

U of L Health, Peace Hospital, Dual PIC Request Peter Cohron moved to approve this request until October 30, 2021. Jonathan Van Lahr seconded, and the motion passed unanimously.

Nephron Pharmacy, Non-resident pharmacy waiver Chris Harlow moved to deny this request. John Fuller seconded, and the motion passed unanimously.

Owensboro Family pharmacy, Off-site Storage Request Peter Cohron moved to direct inspector Rhonda Hamilton to obtain additional information on the requested storage facility. Jonathan Van Lahr seconded, and the motion passed unanimously.

NEW BUSINESS

Board Authorized Protocols The Board reviewed amended drafts of the Acute Group A Streptococcal Pharyngitis Infection Protocol and the Acute Influenza Infection Antiviral Therapy Protocol. The draft language removes the requirement to test for COVID. Based on the current CDC recommendations, Chris Harlow moved to deny these drafts. Peter Cohron seconded, and the motion passed unanimously.

NaloxBox Dr. Trish Freeman presented information on NaloxBox, wall-mounted boxes used to improve the capacity of bystander rescuers to save the lives of victims of opioid overdose by increasing access to publicly available overdose response resources in settings most in need of quickly accessible, public use naloxone. After much discussion, Peter Cohron moved to support the use of NaloxBox in Kentucky. Information on NaloxBox will be posted on the Board of Pharmacy website and published in the Board's newsletter. Chris Harlow seconded, and the motion passed unanimously.

Regulation Committee Appointments President Rhodes requested Board members submit their votes for the appointment of two members to the Regulation Committee by using the Chat feature in Zoom. Votes received [majority indicated with an asterisk] with Jody Forgy abstaining:

- Chris Killmeier - 3
- Kimberly Croley - 3
- Ben Mudd - 1
- Jacob Dotson - 1
- Joseph Carter - 2

Peter Cohron moved to appoint Chris Killmeier and Kimberly Croley to the Regulation Committee. Jonathan Van Lahr seconded, and the motion passed unanimously.

CLOSED SESSION Peter Cohron moved to go into closed session pursuant to KRS 61.810(1)(c) and (j) to discuss proposed or pending litigation on 19-0326 B, 19-0320 B, 19-0358 A and B, 19-0302 A, B and C, 19-0323 B and the HDM Pharmacy application to include the Board, Larry Hadley, Eden Davis and Darla Sayre. Jonathan Van Lahr seconded, and the motion passed unanimously. Peter Cohron moved to come out of closed session after a discussion of 19-0326

B, 19-0320 B, 19-0358 A and B, 19-0302 A, B and C, 19-0323 B and the HDM Pharmacy application and a small break. Chris Harlow seconded, and the motion passed unanimously.

HDM Pharmacy permit application Peter Cohron moved to approve this permit with a signed Agreed Order with the following restrictions:

- Probation of three years,
- Quarterly inspections for one year, every six months thereafter [at the cost of the pharmacy not to exceed \$1,000 per inspection], and
- Non-compliance or failure to follow corrective action plan to be brought to the Board for review.

Chris Harlow, seconded and the motion passed unanimously.

19-0326 B Jonathan Van Lahr moved to issue a letter of reprimand. Chris Harlow seconded, and the motion passed with Peter Cohron opposing.

19-0320 B Chris Harlow moved to issue a letter of reprimand. Jonathan Van Lahr seconded, and the motion passed with Peter Cohron opposing.

19-0358 A Chris Harlow moved to issue a letter of reprimand. John Fuller seconded, and the motion passed with Peter Cohron opposing.

19-0358 B Chris Harlow moved to dismiss this case. The case is closed without prejudice. Jonathan Van Lahr seconded, and the motion passed unanimously.

19-0302 A Chris Harlow moved to issue a letter of reprimand. John Fuller seconded, and the motion passed with Peter Cohron opposing.

19-0302 B Chris Harlow moved to issue a letter of reprimand. John Fuller seconded, and the motion passed with Peter Cohron opposing.

19-0302 C Chris Harlow moved to issue a letter of reprimand. John Fuller seconded, and the motion passed with Peter Cohron opposing.

190323 B Chris Harlow moved to issue a letter of reprimand. John Fuller seconded, and the motion passed with Peter Cohron opposing.

20-0202 A Peter Cohron moved to dismiss this case. The case is closed without prejudice. Chris Harlow seconded, and the motion passed unanimously.

20-0202 B Peter Cohron moved to dismiss this case. The case is closed without prejudice. Chris Harlow seconded, and the motion passed unanimously.

20-0202 C Peter Cohron moved to dismiss this case. The case is closed without prejudice. Chris Harlow seconded, and the motion passed unanimously.

Jonathan Van Lahr praised the inspection staff for their hard work on cases brought before the Board.

Chris Harlow requested the Board review the issues with KASPER reporting and correction at the July meeting. John Fuller requested an invitation be extended to OIG and KASPER staff.

Eden Davis stated the June 22, 2021 Board meeting is a Special Called meeting for a Public Hearing, 201 KAR 2:061. President Rhodes advised the next regularly scheduled meeting will be July 27, 2021 beginning at 9:00 a.m.

ADJOURNMENT Peter Cohron moved to adjourn. Chris Harlow seconded and the motion passed unanimously. President Rhodes adjourned the meeting at 5:57 p.m.