

KENTUCKY BOARD OF PHARMACY
via Zoom teleconference

<https://us02web.zoom.us/j/88935395233?pwd=dVJmNEtELzJtaHlyTkI5U0JvVWhZUT09>

Meeting ID: 889 3539 5233 Passcode: 8WRy8u

Dial by your location

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Meeting ID: 889 3539 5233

Passcode: 572467

If a closed session is needed, attendees will be placed in the waiting room for the duration of the closed session.

February 23, 2021

9:00 a.m.

Board Meeting and Board Retreat
Agenda

- I. CALL TO ORDER**
- II. MINUTES**
- III. CASES**
 - A. Case Review
 - B. Fine Report
 - C. 20-0198 A
 - D. 20-0205 D, E, I and G
- IV. CORRESPONDENCE**
 - A. Med Care Pharmacy, P07782 – Offsite Storage Request
 - B. Adam Crone, P08082 and P08108 – Dual PIC Request
 - C. Lisa Patton, P05150 and P08168 – Dual PIC Request
- V. LEGISLATION/REGULATION**
 - A. 201 KAR 2:061
 - B. Letter of Reprimand Board Counsel Opinion
 - C. Emergency Regulation Filing
 - D. General Assembly legislative update
- VI. OLD BUSINESS**
 - A. Advisory Council Consumer Member (1)
 - B. Policy and Procedures Manual Annual Review
 - C. FDA Compounding MOU
 - D. Self-Care Conditions Protocol Diabetes Testing and Injection Supplies revised

VII. BOARD RETREAT

- A. Law Review Basics, Eden Davis
- B. Mock PRN Meeting, Brian Fingerson
- C. Mock Case Review Panel, Katie Busroe
- D. Budget
 - 1. Requests for FY 22-24 Budget
 - 2. eMars
- E. Review of Board office staff and duties
- F. Review of committees and their responsibilities/Board Liaisons
- G. Hot Topics
 - 1. Charge to Advisory Council regarding Emergency Preparedness and Response
 - (a) Pandemic, Epidemic, Natural Disaster, Terroristic Disaster, Biologic Disasters
 - (b) Practice changes due to COVID-19 – short-term additions with long-term plans or implications
 - (c) NABP Passport Program / Development of a State Pharmacist Database for response
 - 2. Disciplinary Standardization Document
 - 3. NABP Meeting Report
- H. Interest or Concerns
 - 1. Board Members
 - 2. Inspection Staff
 - 3. Office Staff
 - 4. Related agencies:
 - (a) Advancing Pharmacy Practice in Kentucky Coalition
 - (b) American Pharmacy Services Corporation
 - (c) Kentucky Society of Health Systems Pharmacists
 - (d) Kentucky Pharmacists Association
 - (e) Kentucky Independent Pharmacist Alliance
 - (f) University of Kentucky College of Pharmacy
 - (g) Sullivan University College of Pharmacy

MINUTES

KENTUCKY BOARD OF PHARMACY

held at

125 Holmes Street
Frankfort KY 40601
via teleconference

BOARD MEETING

February 23, 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 February 23, 2021 at 9:00 a.m.

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

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

MINUTES Jonathan Van Lahr moved to accept the minutes from the January 28, 2021 Board meeting with the addition of the Declaratory Ruling. Peter Cohron seconded, and the motion passed unanimously. Jonathan Van Lahr moved to accept the minutes from the February 8, 2021 Special Called meeting. Peter Cohron seconded, and the motion passed unanimously.

CASE REVIEW RECOMMENDATIONS Jill Rhodes recused from 19-0365 and was placed in the Waiting Room. Vice President Cohron presided over the meeting in her absence.

John Fuller moved to accept the recommendation of 19-0365. Chris Harlow seconded, and the motion passed unanimously.

Case 19-0365 Revisit. Pharmacist allegedly:

- Violated his Kentucky Pharmacist Recovery Network (KYPRN) Agreement and his Kentucky Board of Pharmacy Agreed Order by testing positive for diphenhydramine.

Alleged Violation of Law:

- KRS 315.121(1)(i) – Violation of any order issued by the board to comply with any applicable law or administrative regulation.

Finding: Mental and physical evaluation to determine if there is a root cause to his positive screens within 60 days. Extension can be granted by the Board. Once evaluation will reconvene in case review to determine if alleged violation did occur. Investigator abstained from the vote to limit their role to that of a factfinder. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

President Rhodes returned to the meeting.

John Fuller moved to accept the recommendation of the remaining cases. Chris Harlow seconded, and the motion passed with Peter Cohron voting nay on cases 20-0223 B and 21-0001 B.

Case 17-0496 A. Permit holder allegedly:

- Failed to maintain an accurate computerized recordkeeping system. The system does not have an identifying designation of the dispensing pharmacist.
- Dispensed misbranded prescriptions.
- Failed to report all required information to the Kentucky All-Schedule Prescription Electronic Reporting System (KASPER).
- Failed to dispense a drug within the same therapeutic class as the prescribed drug when dispensing for formulary compliance.
- Engaged in unprofessional or unethical conduct by mailing prescriptions into states in which the pharmacy did not hold licensure.
- Engaged in unprofessional or unethical conduct by dispensing compounded preparations when a commercially available product is available.

Alleged Violations of Law:

- KRS 315.121 (1)(a) – general unethical or unprofessional conduct;
- KRS 315.121 (1)(h) - violation of KRS 315, KRS 218A, KRS 217 and associated regulations;
- KRS 217.065(1) – misbranding;
- 201 KAR 2:170 Section 1 (1)(h) – computerized recordkeeping requirement, identifying dispensing pharmacist;
- 201 KAR 2:280 Section 1 (1)(c) – dispensing for formulary compliance requirement; and
- 902 KAR 55:110 Section 2(2)(a) – KASPER submission requirements.

CRP Recommendation [original permit holder]: 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. Combine 17-0496 A with 17-0496 B. Standard terms and \$10,000 [total] administrative fine, surrender of closed permit with the agreement from permit holder to not apply for a pharmacy permit in Kentucky for five years and a day. Conditions of 17-0496 B [other than fine] remain. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

CRP Recommendation [current permit holder]: 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 20-0003 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct. Patient's record was allegedly not updated appropriately following a change in dose and Patient subsequently received prescriptions for 2 different tablet strengths of Viibryd on the same day.

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 20-0003 B. Pharmacist-in-charge (PIC) allegedly:

- Failed to perform an appropriate drug utilization review prior to dispensing and failed to update the patient record pursuant to instructions noted on prescription.

Alleged Violation of Law:

- 201 KAR 2:210 Section 4 – pharmacist shall conduct a drug use review and assess the patient's drug therapy, including proper dose, prior to dispensing a prescription.

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 20-0003 C. Pharmacist allegedly:

- Failed to perform an appropriate drug utilization review prior to refilling 2 prescriptions for 2 different tablet strengths of Viibryd on the same day.

Alleged Violation of Law:

- 201 KAR 2:210 Section 4 – pharmacist shall conduct a drug use review and assess the patient’s drug therapy, including proper dose, prior to dispensing a prescription.

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 20-0003 D. Pharmacist allegedly:

- Failed to perform an appropriate drug utilization review prior to dispensing. Pharmacist completed product verification of the 2 Viibryd prescriptions refilled on the same day.

Alleged Violation of Law:

- 201 KAR 2:210 Section 4 – pharmacist shall conduct a drug use review and assess the patient’s drug therapy, including proper dose, prior to dispensing a prescription.

CRP Recommendation: There is sufficient evidence of a violation, however, the disposition shall be the issuance of a Letter of Reprimand with a recommendation of an 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 20-0018 A. Pharmacy permit holder allegedly:

- Sold a misbranded drug due to medication error.
- Filled a prescription for enoxaparin 300mg/3mL multi-dose vials with enoxaparin 30mg/0.3mL syringes.
- Filled a prescription for one box (five patches) of fentanyl 25mcg/hr patches with two boxes (ten patches).
- Has inaccurate recordkeeping due to what was actually dispensed is not documented.

Alleged Violations of Law:

- KRS 217.065 (1)— a drug or device shall be deemed to be misbranded if its labeling is false or misleading
- 201 KAR 2:170 Section 1 (1) (g)—the name, strength, dosage form, and quantity of the drug dispensed originally and upon each refill shall be entered into the pharmacy’s 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 20-0018 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.
- Filled a prescription for enoxaparin 300mg/3mL multi-dose vials with enoxaparin 30mg/0.3mL syringes.
- Filled a prescription for one box (five patches) of fentanyl 25mcg/hr patches with two boxes (ten patches).
- Worked while being sick, resulting in two medication errors.

Alleged Violations of Law:

- KRS 315.121 (2)(d)—unprofessional or unethical conduct includes engaging in conduct likely to harm the public with or without established proof of actual injury
- KRS 315.121 (1)(b)—the board may refuse to issue or renew a license, may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee for mental or physical incapacity that prevents the licensee from engaging or assisting in the practice of pharmacy with reasonable skill, competence, and safety to the public

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 20-0119 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct.
- Divulged or revealed patient information to unauthorized persons when a pharmacist spoke too loudly about a patient's prescriptions.

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 20-0119 B. Pharmacist in charge allegedly:

- Engaged in unprofessional or unethical conduct.
- Divulged or revealed patient information to unauthorized persons when she spoke too loudly about a patient's prescriptions.

Alleged Violation of Law:

- KRS 315.121(2)(b) - Divulging or revealing to unauthorized persons patient information or the nature of professional services rendered without the patient's express consent.

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 20-0128 A. Pharmacy permit holder allegedly:

- Failed to provide adequate security and control of drugs. The pharmacy reported a loss of 158 hydrocodone/apap 5mg/325mg, 394 hydrocodone/apap 7.5mg/325mg, and 1085 hydrocodone/apap 10mg/325mg, for a total of 1,637 tablets over approximately a 5 month period via a DEA 106 form.

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 20-0128 B. Pharmacist in charge allegedly:

- Failed to provide adequate security and control of drugs. The pharmacy reported a loss of 158 hydrocodone/apap 5mg/325mg, 394 hydrocodone/apap 7.5mg/325mg, and 1085 hydrocodone/apap 10mg/325mg, for a total of 1,637 tablets over approximately a 5 month period via a DEA 106 form.

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 and the 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 quality assurance or drug diversion. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

Case 20-0128 C. Pharmacy technician allegedly:

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

Alleged Violation of Law:

- KRS 315.121 (2)(f)—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 20-0205 D Revisit. Non-resident pharmacy, with a pending non-resident pharmacy permit application, allegedly:

- Engaged in unprofessional or unethical conduct by engaging in the wholesale distribution of drugs without a permit.
- Non-resident pharmacy 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
- KRS 315.420 – a wholesale distributor shall be licensed by the Board prior to engaging in the wholesale distribution of prescription drugs in the Commonwealth.

Finding: No action taken. Motion to send to Board for further determination. 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.

Finding: No action taken. Motion to send to Board for further determination. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

Case 20-0205 G Revisit. Non-resident pharmacy, with no pending non-resident pharmacy permit application, allegedly:

- Engaged in unprofessional or unethical conduct by selling prescription drugs to a wholesale distributor located in Kentucky 209 times from April 2018 through April 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
- KRS 315.420 – a wholesale distributor shall be licensed by the Board prior to engaging in the wholesale distribution of prescription drugs in the Commonwealth.

Finding: No action taken. Motion to send to Board for further determination. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

Case 20-0205 I Revisit. Non-resident pharmacy, with no pending non-resident pharmacy permit application, allegedly:

- Engaged in unprofessional or unethical conduct by selling prescription drugs to a wholesale distributor located in Kentucky 215 times from April 2018 through April 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
- KRS 315.420 – a wholesale distributor shall be licensed by the Board prior to engaging in the wholesale distribution of prescription drugs in the Commonwealth.
- KRS 315.121(1)(f) – engaging in fraud in the wholesale distribution of drugs by falsifying transaction data

Finding: No action taken. Motion to send to Board for further determination. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

Case 20-0212 A. Special pharmacy permit holder for medical gases allegedly:

- Engaged in the practice of special pharmacy services from an unlicensed location due to moving without notification to the Board.

Alleged Violation of Law:

- KRS 315.035 (5) – Permits to operate shall be issued only for the premises and persons named in the application.

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 20-0212 B. Pharmacist-in-charge allegedly:

- Engaged in the practice of special pharmacy services from an unlicensed location due to moving without notification to the Board.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3) (e) – The pharmacist in charge shall be responsible for making or filing any reports required by state or federal laws or 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 20-0217 A. Pharmacy permit holder allegedly:

- Failed to provide adequate security and control of controlled substances. Pharmacy reported a loss of 1919 hydrocodone/acetaminophen (APAP) and 1601 oxycodone/APAP tablets, for 3520 total tablets in an audit period of approximately 18 months due to employee pilferage.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – violation of any provision of KRS Chapters 217, 218A, 315 or regulations promulgated pursuant to the chapters; and
- 201 KAR 2:100 Section 1 – security and control regulation.

CRP Recommendation: There is sufficient evidence of a violation, however, the disposition 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 20-0217 B. Pharmacist in charge allegedly:

- Failed to provide adequate security and control of controlled substances. Pharmacy reported a loss of 1919 hydrocodone/acetaminophen (APAP) and 1601 oxycodone/APAP tablets, for 3520 total tablets in an audit period of approximately 18 months due to employee pilferage.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – violation of any provision of KRS Chapters 217, 218A, 315 or regulations promulgated pursuant to the chapters; and
- 201 KAR 2:205 Section 2 (3)(b) – PIC requirement to provide drug security.

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 quality assurance or drug diversion. Vote was unanimous with the investigator abstaining from the vote to limit their role to that of a factfinder.

Case 20-0217 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 Violations of Law:

- KRS 315.121 (1)(h) – violation of any provision of KRS Chapters 217, 218A, 315 or regulations promulgated pursuant to the chapters; and
- KRS 315.121 (2)(f) – unprofessional conduct to sell or ingest a drug requiring a prescription drug order without a prescription drug order.

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 20-0221 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 20-0221 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 20-0221 C. 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 20-0221 D. 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.

Case 20-0223 A. Pharmacy permit holder allegedly:

- Sold a misbranded drug due to a medication error. An antibiotic was dispensed with incorrect directions. Amox-Clav prescribed to be taken every 12 hours was labeled with directions to take every 2 hours.

Alleged Violation of Law:

- KRS 217.065 (1) – drug misbranded if 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 20-0223 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. An antibiotic was dispensed with incorrect directions. Amox-Clav prescribed to be taken every 12 hours was labeled with directions to take every 2 hours.

Alleged Violation of Law:

- KRS 315.121 (2)(d) – Unprofessional or unethical conduct for conduct likely to harm public 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 21-0001 A. Pharmacy permit holder allegedly:

- Sold a misbranded drug due to a medication error. Patient allegedly was dispensed a prescription for aripiprazole 5 mg tablets that contained aripiprazole 15 mg tablets.

Alleged Violation of Law:

- KRS 217.065 (1) – Misbranded for false or misleading labeling.

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 21-0001 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 was dispensed a prescription for aripiprazole 5 mg tablets that contained aripiprazole 15 mg tablets.

Alleged Violation of Law:

- KRS 315.121 (2)(d) – Unprofessional or unethical conduct for conduct likely to harm public 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.

Peter Cohron moved to go into closed session pursuant to KRS 61.810(1)(c) and (j) to discuss proposed or pending litigation on Cases 20-0198 A, 20-0205 D, 20-0205 E, 20-0205 G and 20-0205 I to include the Board, Larry Hadley, Katie Busroe, Paul Daniels, 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 pending discipline for Cases 20-0198 A, 20-0205 D, 20-0205 E, 20-0205 G and 20-0205 I. Jonathan Van Lahr seconded, and the motion passed unanimously.

Case 20-0198 A. Chris Harlow moved to refer the case back to the Case Review Panel. Peter Cohron seconded, and the motion passed unanimously.

Case 20-0205 D. Chris Harlow moved to deny the pending non-resident permit and refer this violation to the FDA. Peter Cohron seconded, and the motion passed unanimously.

Case 20-0205 E. Chris Harlow moved to refer the case back to the Case Review Panel. Peter Cohron seconded, and the motion passed unanimously.

Case 20-0205 G. Peter Cohron moved to refer this violation to the FDA. Jonathan Van Lahr seconded, and the motion passed unanimously.

Case 20-0205 I. Peter Cohron moved to refer this violation to the FDA. Jonathan Van Lahr seconded, and the motion passed unanimously.

Chris Harlow moved to dismiss the disciplinary actions for Cases 20-0205 D, 20-0205 E, 20-0205 G and 20-0205 I approved prior to today's meeting due to the respondents not having a Kentucky permit. Jonathan Van Lahr seconded, and the motion passed unanimously.

CORRESPONDENCE John Fuller moved to approve the off-site storage request submitted by Med Care Pharmacy, P07782. Jonathan Van Lahr seconded, and the motion passed unanimously. President Rhodes recused and was placed in the Waiting Room. Vice President Cohron presided over the meeting in her absence. Chris Harlow moved to approve the dual PIC request submitted by Adam Crone, P08082 and P08108. John Fuller seconded, and the motion passed unanimously. President Rhodes returned to the meeting. Chris Harlow moved to approve the dual PIC request submitted by Lisa Patton, P05150 and P08168. John Fuller seconded, and the motion passed unanimously.

201 KAR 2:061 Ralph Bouvette, Chairperson of the Regulation committee advised the Board that 201 KAR 2:061 was still under review. Constitutional concerns were raised regarding due process. The current proposed amendments include:

- Notification of respondent upon investigation
- Case resolution within 100 days
- CRP comprised of Board President and two assigned Board members. The Executive Director, case inspector and Board counsel would be non-voting members.
- Notification within 30 days of CRP decision
- Administrative Conferences
- Non-adverse disciplinary process

LETTER OF REPRIMAND Board Counsel Opinion Eden Davis presented the requested opinion on the use of reprimand as a method of taking non-adverse action on a licensee, permit holder or registrant.

EMERGENCY REGULATION FILING Eden Davis advised that 201 KAR 2:410E as amended became effective at noon, February 22, 2021.

GENERAL ASSEMBLY LEGISLATIVE UPDATE Larry Hadley provided an update on the legislative session. Representative Bentley has an insulin bill on the floor that caps copays at \$35. KRS 217.177 has amendments to remove some restrictions on the retail sales of syringes and needles as a public health initiative. House Bill 219 has an amendment to allow pharmacists, pharmacist interns and pharmacy technicians to practice in a remote setting under appropriate conditions. There may be an additional cost to the Board for inspection of these facilities. This practice will be included in the directive to the Advisory Council regarding Emergency Preparedness. The Kentucky Board of Nursing allowed 201 KAR 2:059 to expire. Pursuant to KRS 13A.3102, administrative regulation 201 KAR 20:059 expired on 6/19/2020. Carisoprodol, alprazolam, lorazepam, clonazepam and diazepam are now subject to same APRN prescribing limitations as all other schedule IV controlled substances. Pursuant to KRS 314.011(8)(b), Kentucky APRNs who are authorized to prescribe controlled substances may prescribe a 30 day supply of any Schedule IV controlled substance, with up to five refills. Alternatively, such APRNs may prescribe a full 6 month supply, subject to any restriction that may be imposed by a third party payer.

ADVISORY COUNCIL CONSUMER MEMBER President Rhodes informed the Board that there was one application received for the vacant consumer member appointment on the Advisory Council. Peter Cohron moved to appoint Donna Drury to the vacant position. Chris Harlow seconded, and the motion passed unanimously.

POLICY AND PROCEDURES MANUAL Chris Harlow moved to approve all the amendments and additions excluding the MPJE section. Jonathan Van Lahr seconded, and the motion passed unanimously. Peter Cohron suggested the Executive Director appoint two representatives with staggered terms for the NABP MPJE Item Writing. At least one of these representatives should be a practicing pharmacist. The terms would be for 3 or 4 years. Peter Cohron moved for the Board to direct himself to propose language for this section to be reviewed at the March meeting. Chris Harlow seconded, and the motion passed unanimously.

FDA COMPOUNDING MOU Eden Davis gave a brief overview of the FDA Compounding Memorandum of Understanding that would require 503A facilities dispensing or distributing greater than 50% of compounding human products to report adverse events for information sharing purposes between states. The Board reviewed comments provided by pharmacies that would be impacted by this agreement. Katie Busroe stated that the inspection staff does not anticipate any change to their workload if Kentucky chooses to participate. President Rhodes asked how inspections of provider offices would be conducted. Ms. Busroe advised that the current version of the MOU does not require the state boards of pharmacy to inspect those facilities only notify the FDA if an issue is discovered. This item was tabled until the March meeting.

SELF CARE CONDITIONS PROTOCOL DIABETES TESTING AND INJECTION SUPPLIES Emily Followell presented the amended Pharmacist Diabetes Testing and Injection Supplies Protocol to the Board. Chris Harlow moved to approve the amended version. Peter Cohron seconded, and the motion passed unanimously.

MOCK PRNC MEETING Brian Fingerson, Chairperson presented an overview of a typical Professional Recovery Network Committee meeting. Mr. Fingerson provided the Board with the documents used during the meeting. Joel Thornbury spoke on his experience serving on the committee.

LAW REVIEW BASICS Eden Davis, Board Counsel presented a law review presentation to the Board. This information is also included in the Policy and Procedures Manual.

MOCK CASE REVIEW PANEL Katie Busroe presented an overview of a typical Case Review Panel meeting. Ms. Busroe provided a summary of the case investigation process, a summary of past cases and a timeline of the investigation. President Rhodes thanked the inspection staff for the information and their hard work. The Board requested an annual summary report of cases.

BUDGET Larry Hadley answered questions regarding the budget process and finances of the Board. Reports of monthly revenue and expenditures are provided for Board review at each meeting of the Board.

REVIEW OF BOARD STAFF AND DUTIES The Board reviewed the job descriptions for office and inspection staff.

REVIEW OF COMMITTEES AND THEIR RESPONSIBILITIES/BOARD LIAISONS The Board discussed the tabled item from January regarding Board Liaisons to the committees. President Rhodes advised that after further review it appeared that each committee was represented by the Board or the Executive Director. Larry Hadley invited the Board to join the meetings at their convenience. The Board was advised that attendance would be restricted so a quorum of the Board is not established.

ADVISORY COUNCIL CHARGE-EMERGENCY PREPAREDNESS RESPONSE President Rhodes presented the following as a proposed 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;
- Evaluate and recommend permanent practice changes that are temporarily being done at this time to meet the demands of the pandemic;
- 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;
- 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 evoked in an emergency pharmacy powers regulation; and
- Consider including the board inspection/ ED/board staff in emergency preparedness response.

Additionally, President Rhodes requested the Advisory Council review participation in the NABP Passport Program.

- Create a readily usable and UTD robust pharmacy / pharmacist database so recognize the pharmacists who can be called upon to assist based on their capacity, i.e. certifications, job expertise and work location; and
- Create a process to allow retired pharmacists to re-enter the workforce to meet the patient care demands of various types of emergencies

Jonathan Van Lahr suggested a review of hand sanitizer issues during the ongoing pandemic. President Rhodes agreed to further refine the above charges to be reviewed at the March meeting with any additions received from Board members or staff.

DISCIPLINARY STANDARDIZATION DOCUMENT Eden Davis presented a spreadsheet of past cases with disciplinary actions. She advised that this was a work in progress. The Board requested the addition of disciplinary actions taken against wholesalers, manufacturers and third party logistic provider.

NABP MEETING REPORT President Rhodes and Vice President Cohron provided a report of their attendance at the NABP Interactive Member Forum. Topics discussed included:

- Medication re-use task force

- Working from home – post pandemic
- Tennessee survey on workplace safety conditions
- Pharmacy practice changes in Idaho and Washington

INTEREST/CONCERNS Jonathan Van Lahr expressed concerns of the integrity of shipped prescriptions. There are no storage requirements to insure the integrity of the products during transit to the consumer. Chris Harlow proposed looking at other state regulations for guidance. President Rhodes requested Jonathan Van Lahr to draft an outline for review at the March meeting. A charge to the Advisory Council will be drafted at that time.

The inspection staff expressed concern as follows:

1. Appropriateness of mailing OTC syringes – A letter requesting a ruling was directed to the Cabinet for Health and Family Services was sent in 2018. No response was received. The Board directed Eden Davis to send another letter requesting a ruling.
2. 201 KAR 2:250 – Inspection staff request the Board review the inclusion of pharmacist interns in the KYPRN as an ‘unknown’ and the participation in KYPRN without acknowledgement of a substance abuse problem. President Rhodes requested additional information from Brian Fingerson, UK College of Pharmacy and Sullivan University College of Pharmacy.
3. Inspection software upgrade for better functionality to meet the current and future needs of the staff.
4. 201 KAR 2:330 – Utilization of the inspection staff in emergency preparedness. This will be included in the charge to the Advisory Council.
5. 201 KAR 2:015 and KRS 315.065 - Move from Continuing Education to Professional Development. The Board would like to revisit this discussion at the March meeting. This will require a statutory change.
6. KRS 315.150 – Expansion of the Board of Pharmacy for better representation of the pharmaceutical community, to address diversity and inclusion and to better address the ever changing scope of pharmacy practice. The Board would like to revisit this discussion at the March meeting.

Joel Thornbury introduced Ben Mudd as the new Executive Director of the Kentucky Pharmacist Association. Dr. Mudd advised that the KPhA Annual Meeting will be held June 3-6, 2021. This will be both in-person and virtual.

President Rhodes advised the next meeting will be March 30, 2021 beginning at 9:00 a.m.

ADJOURNMENT Jonathan Van Lahr moved to adjourn. Peter Cohron seconded and the motion passed unanimously. President Rhodes adjourned the meeting at 3:53 p.m.