

KENTUCKY BOARD OF PHARMACY

via Zoom teleconference

<https://us02web.zoom.us/j/87304838885?pwd=ckNxZXRIQ2tJUGwrTHVuTStJWmx5QT09>

Meeting ID: 873 0483 8885

Passcode: 8whVj1

Dial by your location

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If a closed session is needed,

the teleconference will be suspended while the Board convenes a telephonic closed session.

November 5, 2020

9:00 a.m.

Board Meeting

Agenda

I. CALL TO ORDER

II. MINUTES

- A. *September 30, 2020

III. APPEARANCES

- A. *RX Crossroads by McKesson – PV2 Request

IV. BOARD REPORTS

A. Executive Director

- 1. *eMars – September 2020 and October 2020
- 2. *2021 Board Meeting Calendar
- 3. *NABP Interactive Member Forum
- 4. *Policy and Procedures Manual Annual Review

B. General Counsel

- 1. Standardization of discipline
- 2. Case Review Panel
- 3. *Training program for new Board members
- 4. *HHS Prep Act
- 5. Telehealth
- 6. *FDA Compounding MOU

C. Committee Reports

- 1. Regulation Committee
 - (a) *August 13, 2020 Minutes
 - (b) *RX Adaptation
 - (c) *RFID Tagging
 - (d) Repository
- 2. Pharmacy Technician Committee
 - (a) *September 29, 2020 Minutes

- (b) *Recommendation regarding HHS Prep Act
- 3. Diversity and Inclusion Task Force
 - (a) *September 28, 2020 Minutes
 - (b) *Mission Statement

IV. CASES

- A. *Case Review
- B. *Fines Report

V. CORRESPONDENCE

- A. *Grant County Drugs – P06853, P06979, P07334– Offsite Storage Request
- B. *Clark Drugs – P00667 – Offsite Storage Request
- C. *Clay Discount Pharmacy – P07140 – Offsite Storage Request
- D. *RX Discount Pharmacy - P06091– Offsite Storage Request
- E. *P06574 and P07819 – Donald Riley – Dual PIC Request

VI. LEGISLATION/REGULATION

- A. *201 KAR 2:380, Board Authorized Protocols.

VII. OLD BUSINESS

- A. *Medication Safety Committee
- B. *Advisory Council Member Designation

VIII. NEW BUSINESS

- A. Advisory Council Appointments
- B. Pharmacy Recovery Network Appointments
- C. APRN Council Member

IX. RECOGNITIONS

*Information included in Board Packet

MINUTES

KENTUCKY BOARD OF PHARMACY

held at

125 Holmes Street

Frankfort KY 40601

via teleconference

BOARD MEETING

November 5, 2020

CALL TO ORDER A regularly scheduled meeting was held via teleconference from the Kentucky Board of Pharmacy, Frankfort, Kentucky. President Poole called the meeting to order on November 5, 2020 at 9:00 a.m.

Members present: John Fuller, Ron Poole, Peter P. Cohron, Jill Rhodes and Craig Martin. 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; Rhonda Hamilton, 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.

Guests: Shoshana Yeager, Candice Herald, Austin Whitt, Sara Hart, Jonathan Van Lahr, Sarah Lewis, Shelby Ferrill and Christine Said.

MINUTES On motion by Craig Martin, seconded by Peter Cohron and passed unanimously, the minutes of the September 30, 2020 Board meeting was approved with the additional language requested by Ron Poole.

APPEARANCES

RX Crossroads by McKesson – Dan Deem RxCrossroads is requesting an alternative PV2 process utilizing the Parata Max+ and SKU Batch Dispensing Criteria. Dan Deem provided an overview of the verification processes being considered. After discussion, Peter Cohron moved to approve the alternative PV2 processes. John Fuller seconded, and the motion passed with Jill Rhodes opposing. Peter Cohron moved to direct the inspection staff to conduct two semi-annual reviews of the process for accuracy. Craig Martin seconded, and the motion passed with Jill Rhodes opposing.

BOARD REPORTS Mr. Hadley presented the eMars financial reports for September 2020 and October 2020 for Board review.

Mr. Hadley provided a calendar for 2021 Board meetings. Craig Martin inquired if Board meetings would be conducted via teleconference or in-person. Mr. Hadley stated that meetings would continue via teleconference until the Governor lifts the restriction of in-person meetings. John Fuller stated that there is a conflict for the January 27, 2021 meeting. The NABP

Interactive Member Forum is scheduled for the same day. Jill Rhodes stated that she has a conflict with Wednesday meetings and requested the Board consider moving to another day of the week. She also requested the possibility of having more frequent meetings. Peter Cohron moved to change the January 27, 2021 to January 28, 2021. John Fuller seconded, and the motion passed unanimously. Peter Cohron moved to the remaining meeting dates [March, May, July, September and November] from Wednesday to Tuesday. Craig Martin seconded, and the motion passed unanimously. After further discussion, Craig Martin moved to adjust the 2021 calendar to include nine meetings with the meetings to be held on the last Tuesday of the months of February, March, May, July, August, September, October and November. Peter Cohron seconded, and the motion passed with John Fuller opposing. The 2021 Board Meeting calendar dates are:

- January 28
- February 23
- March 30
- May 25
- July 27
- August 31
- September 28
- October 26
- November 30

NABP Interactive Member Forum Mr. Hadley requested a member virtually attend the NABP Interactive Member Forum on January 27, 2021. Ron Poole stated the meeting was beneficial and informative for him. Mr. Poole suggested Jill Rhodes attend the meeting. Mr. Hadley will inquire if NABP will allow additional members attend.

Policy and Procedures Manual – Annual Review The Board discussed several additions and corrections to the manual. Other items discussed:

- Board Member compensation – Compensation is specified in KRS 315.171. Any increase will need to be addressed via a statutory change.
- MPJE – Jill Rhodes requested clarification on how questions are approved for the MPJE. Katie Busroe stated that two representatives attend the workshop to write the questions for the exam. This process is very structured and follow strict guidelines to enforce the integrity of the exams. John Fuller requested a representative from NABP attend the next meeting to answer questions on this procedure.
- Case Review Panel – Ron Poole requested additional language to provide the disciplinary actions steps from case investigation to case resolution. Eden Davis suggested adding a section to describe the informal process of resolving the case by an Agreed Order.

John Fuller moved to approve the changes made during the meeting. Outstanding changes will be reviewed at the next meeting. Jill Rhodes seconded, and the motion was passed unanimously.

GENERAL COUNSEL

Standardization of discipline Eden Davis stated that she is currently working on establishing a standardization of discipline for the Board. This will document will be available to the public and be beneficial during the case review process as well as providing an expectation to respondents with pending cases. Ron Poole acknowledged that the Board does use past precedent in determining disciplinary actions but an official document would allow for an easier process.

Case Review Panel After discussion, the Board requested the Regulation Committee provided amended language to remove the inspector from the voting process and add the Vice President of the Board as a voting member.

Training program for new Board members Ms. Davis is working to develop a new training program for incoming Board members. This training program will consist of:

- Resources to research policy, law and other statutes
- Review of Open Meetings Law
- Ethics training
- Definitions of law terms and overview of the regulatory/statutory process
- Policy and Procedures Manual

Joel Thornbury suggested review of the judicial process to provide insight in determining judgements.

HHS Prep Act Eden Davis provided a summary of the status. The policy behind new regulation is the decline in childhood vaccination rates. This decline has been declared a public health emergency alongside COVID19. The Prep Act is authorizing legislation for emergency action, and it provides immunity to followers of the promulgated regulations, and it provides preemption of any state law in conflict with federal regulation. Regulation 85 CFR 15198, amendment three, provides that pharmacists have the authority to order and to administer the CDC's Advisory Committee on Immunization Practices' (ACIP) recommended vaccines to children three years and older, if pharmacists comply with specific requirements. This federal rule became effective on August 24th, 2020. On October 20,, 2020, the Board received further guidance from Assistant Secretary of Health that technicians were to be included in the groups of individuals who could administer child vaccinations. This guidance also provided guidelines for technicians to be able to administer vaccines. As Kentucky prepared to adopt federal standard, guidance came on October 22, 2020 from HHS' General Counsel that said states can have less strict requirements, so long as they are allowing pharmacists and interns to vaccinate children ages 3-17. This prompted the Board to examine what the Board would like to require for pharmacists, interns and technicians to be able to order or administer childhood vaccines. The guidance from HHS' General Counsel also made clear that Pharmacists must have the authority to order vaccines and that "prescriber protocol" requirement in state law was not valid as the only means for a pharmacist to "order a vaccine." On 10/29/20, the Technician Committee discussed whether they would like to see Technicians administering childhood vaccinations. There was Consensus that techs needed to be able to administer all vaccines to

children 3-17 pursuant to specific requirements. Ms. Davis is working with the Governor's office and LRC to either get an Executive Order or an Emergency regulation through in the next 10-14 days.

Telehealth Working with Larry and Ron, Ms. Davis has been working with CHFS on their telehealth statute. CHFS is drafting legislation that creates a glossary of telehealth terminology in order to have the same definitions used across all healthcare boards. This includes minimum requirements for the proper use and security of telehealth, including confidentiality, data integrity, privacy and security, informed consent, reimbursement and establishes minimum telehealth requirements to prevent waste, fraud and abuse. The CHFS proposed statute does not allow for telepharmacy. Ron, Larry and Eden met with CHFS and they removed specific language that would have allowed for telepharmacy (i.e. distribution of prescription drugs). The Board of Pharmacy will be able to promulgate regulations under this statute relating to telehealth.

FDA MOU Ms. Davis stated that the MOU is still being reviewed. Ron Poole stated that the MOU would need to be approved after it is finalized.

COMMITTEE REPORTS

REGULATION COMMITTEE Ralph Bouvette addressed the Board to provide an update on the Regulation Committee. The Repository regulation was tabled to allow for input from a task force meeting of the NABP. Ms. Busroe attended the meeting. This item will be discussed at the next Regulation Committee meeting. Ralph Bouvette requested clarification on the RX Adaptation language sent to the committee. After discussion, Craig Martin moved to not proceed with RX Adaptation language. Jill Rhodes seconded, and the motion passed unanimously. 201 KAR 2:061 was tabled until research is obtained from General Counsel. Ralph Bouvette requested clarification on the issue or RFID tagging sent to the committee. Current regulation allows for barcode scanning. Mr. Poole stated the Board's intent was to modernize language in regulations to include advanced technology. Craig Martin suggested the language include future advances in technology.

PHARMACY TECHNICIAN COMMITTEE Jill Rhodes provided an update on the Pharmacy Technician Committee. The committee is developing a survey to gauge the interest and willingness of pharmacists to delegate specific tasks to technicians and the interest and willingness of technicians to assume these responsibilities. The survey will be sent to Kentucky pharmacists and pharmacy technicians after an initial beta test.

The Pharmacy Technician Committee recommends the Board consider allowing a certified pharmacy technician to administer the COVID-19 vaccine according to ACIP's COVID-19 vaccine recommendations and all childhood vaccines to persons ages 3 and older according to ACIP's standard immunization schedule. The certified pharmacy technician must meet the following requirements:

- A practical training program that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines.
- Have a current certificate in basic cardiopulmonary resuscitation.
- Complete a minimum of two hours of ACPE- approved, immunization-related continuing pharmacy education.

Craig Martin moved to approve the recommendation. Jill Rhodes seconded, and the motion passed unanimously.

DIVERSITY AND INCLUSION TASK FORCE Mr. Hadley submitted the mission, vision, core values and definitions approved at the last meeting of the task force. Craig Martin requested the task force revisit these to include language to address the benefit to the public.

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

Case 17-0446 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 sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on pharmacy law. CRP vote was unanimous.

Case 20-0027 A. Pharmacy permit holder allegedly:

- Refused to fill a patient's opioid prescriptions based upon erroneous information, even after determining the information was erroneous. Pharmacy permit holder allegedly discriminated against a disabled 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. CRP vote was unanimous.

Case 20-0027 B. Pharmacist in charge allegedly:

- Refused to fill a patient's opioid prescriptions based upon erroneous information, even after determining the information was erroneous. Pharmacist in charge allegedly discriminated against a disabled patient.

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. CRP vote was unanimous.

Case 20-0027 C. Pharmacist allegedly:

- Refused to fill a patient's opioid prescriptions based upon erroneous information, even after determining the information was erroneous. Pharmacist allegedly discriminated against a disabled patient.

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. CRP vote was unanimous.

Case 20-0031 A. Pharmacy permit holder allegedly:

- Could not fill a patient's blood pressure prescription due to being out of stock and would not help the patient find elsewhere.

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. CRP vote was unanimous.

Case 20-0031 B. Pharmacist in charge allegedly:

- Could not fill a patient's blood pressure prescription due to being out of stock and would not help the patient find elsewhere.
- Engaged in unprofessional or unethical conduct by laughing at the patient and refusing to allow another associate to help the patient obtain his medication elsewhere.

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. CRP vote was unanimous.

Case 20-0033 A. Pharmacy permit holder allegedly:

- Engaged in unethical or unprofessional conduct by failing to establish appropriate contingencies to prevent interruption of patient services and delay of care during system outages.

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. CRP vote was unanimous.

Case 20-0033 B. Pharmacist in charge (PIC) allegedly:

- Failed to implement appropriate contingency plan to prevent interruption of patient services and delay of care during pharmacy system outage.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(a) – PIC of a pharmacy is responsible for resolving identified problems related to quality assurance

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0079 D Revisit. Pharmacy technician allegedly:

- Engaged in unprofessional or unethical conduct by divulging or revealing to an unauthorized person patient information without the patient’s express consent.

Alleged Violation of Law:

- KRS 315.121 (2)(b) – unprofessional or unethical conduct for violating confidentiality.

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 successfully pass the EBAS Exam [Unprofessional Conduct Section only]. If exam is not passed within six months of signed Agreed Order, revocation. CRP vote was unanimous.

Case 20-0092 A. Pharmacy permit holder allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of 2,380 Oxycodone 10mg tablets, 680 Oxycodone 20mg tablets, 101 Oxycodone 5mg tablets, and 2,298 Oxycodone 15 mg tablets over a period of 8 Months from September 1, 2019 to May 8, 2020 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.

Combined with Case 20-0092B. See below.

Case 20-0092 B. Pharmacist in charge allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of 2,380 Oxycodone 10mg tablets, 680 Oxycodone 20mg tablets, 101 Oxycodone 5mg tablets, and 2,298 Oxycodone 15 mg tablets over a period of 8 Months from September 1, 2019 to May 8, 2020 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 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 \$2,000 administrative fine, approved corrective action plan to prevent future occurrences and submission to the Board office monthly reconciliation of oxycodone products for twelve months. CRP vote was unanimous.

Case 20-0092 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. CRP vote was unanimous.

Case 20-0097 A. Pharmacy permit holder allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of 1573 hydrocodone/APAP tablets, 173 zolpidem tablets, 89 lorazepam tablets and 62 clonazepam tablets between September 2019 and May 2020.

Alleged Violations of Law:

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

CRP Recommendation: There is sufficient evidence of a violation 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 \$2,000 administrative fine, approved corrective action plan to prevent future occurrences and submission to the Board office monthly reconciliation of all strengths of hydrocodone containing products, zolpidem containing products, and all strengths of clonazepam, lorazepam, alprazolam and diazepam for twelve months. CRP vote was unanimous.

Case 20-0097 B. Pharmacist in charge allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of 1573 hydrocodone/APAP tablets, 173 zolpidem tablets, 89 lorazepam tablets and 62 clonazepam tablets between September 2019 and May 2020.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – Pharmacist in charge 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. CRP vote was unanimous.

Case 20-0097 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) – unprofessional or unethical conduct to sell, transfer, dispense, ingest, or administer a drug for which prescription order required without first receiving 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. CRP vote was unanimous.

Case 20-0098 A. Pharmacy permit holder allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of 596 tablets of various oxycodone containing medications, 60 methylphenidate tablets and 314 ml of oxycodone solution between September 2019 and June 2020.

Alleged Violation of Law:

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

CRP Recommendation: There is sufficient evidence of a violation 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, follow-up audit of oxycodone containing products in six months. CRP vote was unanimous.

Case 20-0098 B. Pharmacist in charge allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of 596 tablets of various oxycodone containing medications, 60 methylphenidate tablets and 314 ml of oxycodone solution between September 2019 and June 2020.

Alleged Violation of Law:

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

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. CRP vote was unanimous.

Case 20-0099 A. Pharmacy permit holder allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of 2601 hydrocodone/APAP tablets and 1347 oxycodone/APAP tablets between June 2019 and May 2020.

Alleged Violation of Law:

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

CRP Recommendation: There is sufficient evidence of a violation 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, follow-up audit of oxycodone containing products and hydrocodone containing products in six months. CRP vote was unanimous.

Case 20-0099 B. Pharmacist in charge allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of 2601 hydrocodone/APAP tablets and 1347 oxycodone/APAP tablets between June 2019 and May 2020.

Alleged Violation of Law:

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

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. CRP vote was unanimous.

Case 20-0100. Licensed wholesale distributor allegedly:

- Engaged in fraud in connection with the wholesale distribution of drugs;
- Failed to maintain accurate records of all drugs handled; and
- Failed to make records available to agents of the board for inspection upon request.

Alleged Violations of Law:

- KRS 315.121 (1)(f) – Engaging in fraud in connection with wholesale distribution of drugs;
- KRS 315.402 (2) – wholesale distributor requirement to maintain records and make available for inspection;
- 201 KAR 2:105 Section 2 (4)(c) – requirements for wholesale distributor to demonstrate acceptable operational procedures to include accurate records;
- 201 KAR 2:105 Section 5 (3) (a) – Recordkeeping retention requirements; and
- 201 KAR 2:105 Section 5 (3)(b) – Recordkeeping availability requirements.

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, permit holder is prohibited from obtaining a Kentucky permit in the future. CRP vote was unanimous.

Case 20-0101. Wholesale Distributor Licensee allegedly:

- Failed to notify the Board of cessation of business activity at facility and failed to follow procedures for closure in order to keep wholesale distribution license active.
- Failed to demonstrate facility is adequately maintained to ensure proper lighting, ventilation, sanitation, and security.

Alleged Violations of Law:

- 201 KAR 2:106 Section 2 (2)(a) – wholesale distributor licensed by the Kentucky Board of Pharmacy whose hours of operation have deviated over a period of five (5) consecutive working days from those of record at the Board of Pharmacy office shall immediately notify the board, verbally and in writing of the reason for the deviation and the anticipated period of continuance.
- 201 KAR 2:105 Section 2 (4)(a) - demonstration of acceptable operational procedures, including adequate maintenance and storage conditions to ensure proper lighting, ventilation, temperature and humidity control, sanitation, and security.
- 201 KAR 2:105 Section 5 (1)(a) - buildings shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.

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. CRP vote was unanimous.

Case 20-0102 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by employing pharmacists and technician that behave in unprofessional manner; and
- Failed to have a prescription record capable of recording the dispensing of a one-time emergency refill of up to 72-hour supply of maintenance medication.

Alleged Violations of Law:

- KRS 315.121 (1)(a) – general unprofessional or unethical conduct;
- KRS 315.121 (1)(h) - violation of administrative regulations;
- 201 KAR 2:175 Section 1 (1)(d) – emergency refill requirement for pharmacist to record date, quantity dispensed, and pharmacist’s name or initials; and
- 201 KAR 2:170 Section 1 (9) – computerized recordkeeping required to have auxiliary recordkeeping system if automated data processing system is inoperative for any reason.

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 \$2,500 administrative fine. CRP vote was unanimous.

20-0102 B. Pharmacist in charge allegedly:

- Engaged in unprofessional or unethical conduct by harassing a patient;
- Engaged in unprofessional or unethical conduct by failing to properly supervise technicians that are behaving in unprofessional manner by harassing a patient.

Alleged Violation of Law:

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

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0103 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by employing individuals who did not transfer a call to a pharmacist upon request of a consumer.
- Engaged in unprofessional or unethical conduct by delaying pharmacy care.

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. CRP vote was unanimous.

Case 20-0103 B. Pharmacist in charge allegedly:

- Failed in the provision of pharmacy services.
- Failed to implement an adequate quality assurance program.

Alleged Violations of Law:

- 201 KAR 2:205 Section 2 (3)(a) – pharmacist in charge responsible for quality assurance program; and
- 201 KAR 2:205 Section 2 (3)(b) – pharmacist in charge 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. CRP vote was unanimous.

Case 20-0103 C. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by dispensing misbranded prescriptions. Prescriptions were dispensed with the incorrect prescriber name.

Alleged Violation of Law:

- KRS 217.065 (11)(b) – labeling of prescription must bear name of licensed practitioner

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0103 D. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without proof of actual injury. Prescriptions were dispensed with the incorrect prescriber name.

Alleged Violation of Law:

- KRS 315.121 (2)(d) – unprofessional or unethical conduct likely to deceive public

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0106 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct. Pharmacy employees allegedly lied to patient about insurance coverage and falsely claimed to have no medication in stock to avoid filling patient's prescription.

Alleged Violation of Law:

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

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0106 B. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by refusing to transfer patient's prescription to another pharmacy to avoid a delay in 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, 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. CRP vote was unanimous.

Case 20-0107 A. Pharmacy permit holder allegedly:

- Sold misbranded drugs due to a medication error. Patient allegedly received 27 prednisone 10 mg tablets in a bottle labeled as quantity 40.

Alleged Violation of Law:

- KRS 217.065(1) – misbranding.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0107 B. 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. CRP vote was unanimous.

Case 20-0107 C. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive or harm the public with or without established proof of actual injury by committing a medication error.
- Patient allegedly received 27 prednisone 10 mg tablets in a bottle labeled as quantity 40.

Alleged Violations of Law:

- KRS 315.121 (2)(d) – conduct likely to deceive or harm the public with or without proof of injury.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0110 A. Pharmacy permit holder allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of 1080 alprazolam ER tablets and 6,622 ml of promethazine with codeine syrup over a period of approximately 5 weeks.

Alleged Violation of Law:

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

CRP Recommendation: There is sufficient evidence of a violation 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 \$2,000 administrative fine, approved corrective action plan to prevent future occurrences and submission to the Board office monthly reconciliation of promethazine with codeine, and all strengths of clonazepam, lorazepam, alprazolam and diazepam for twelve months. CRP vote was unanimous.

Case 20-0110 B. Pharmacist in charge allegedly:

- Failed to provide adequate security and control of drugs. Pharmacy reported a loss of 1080 alprazolam ER tablets and 6,622 ml of promethazine with codeine syrup over a period of approximately 5 weeks.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(b) – pharmacist in charge 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. CRP vote was unanimous.

Case 20-0110 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) – unprofessional or unethical conduct to sell, transfer, dispense, ingest, or administer a drug for which prescription order required without first receiving 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. CRP vote was unanimous.

Case 20-0112 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by employing individuals who do not wear personal protective equipment (PPE) when delivering prescriptions during the 2020 coronavirus state of emergency.
- Engaged in unprofessional or unethical conduct by aiding and abetting an individual to engage in the practice of pharmacy without a license. A registered nurse (RN) transferred a prescription to another pharmacy.
- Engaged in unprofessional or unethical conduct by selling prescriptions without first receiving a legitimate prescription order. Prescription drug orders issued through an collaborative care agreement (CCA) after the expiration of the effective date in the agreement
- Sold misbranded prescriptions. Prescriptions dispensed labeled with the incorrect prescriber.

Alleged Violations of Law:

- KRS 315.121 (1)(a) – general unprofessional or unethical conduct;
- KRS 315.121 (1)(g) – aiding and abetting an individual to engage in the practice of pharmacy without a license; and
- KRS 217.065 (11)(b) – misbranded if prescription label does not bear the name of the licensed prescribing practitioner.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0112 B. Pharmacist in charge allegedly:

- Failed to implement a quality assurance program that objectively and systematically monitors care. A pharmacy delivery driver did not wear PPE when delivering medications.
- Engaged in unprofessional or unethical conduct by aiding and abetting an individual to engage in the practice of pharmacy without a license. A registered nurse (RN) transferred a prescription to another pharmacy.
- Failed in the provision of pharmacy services. Prescriptions were dispensed issued through a CCA after the expiration of the effective date in the agreement.

Alleged Violations of Law:

- KRS 315.121 (1)(g) – aiding and abetting an individual to engage in the practice of pharmacy without a license;
- 201 KAR 2:205 Section 2 (3)(a) – pharmacist in charge responsibility for quality assurance programs; and
- 201 KAR 2:205 Section 2 (3)(b) – pharmacist in charge responsibility for 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 \$1,000 administrative fine, additional 6 hours of continuing education on pharmacy law. CRP vote was unanimous.

Case 20-0112 C. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by dispensing a drug for which a prescription drug order is required without having first received a prescription drug order for the drug. Six (6) prescriptions were dispensed issued through a CCA after the expiration of the effective date in the agreement.
- Engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof or actual injury. Prescription dispensed labeled with the incorrect prescriber.

Alleged Violations of Law:

- KRS 315.121 (2)(d) – unprofessional or unethical conduct to deceive the public with or without proof of actual injury;
- 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 217.065 (11)(b) – misbranded if prescription label does not bear the name of the licensed prescribing practitioner.

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 \$1,000 administrative fine, additional 6 hours of continuing education on pharmacy law. CRP vote was unanimous.

Case 20-0112 D. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by dispensing a drug for which a prescription drug order is required without having first received a prescription drug order for the drug. Six (6) prescriptions were dispensed issued through a CCA after the expiration of the effective date in the agreement.

Alleged 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.

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

Case 20-0112 E. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by dispensing a drug for which a prescription drug order is required without having first received a prescription drug order for the drug. Two (2) prescriptions were dispensed issued through a CCA after the expiration of the effective date in the agreement.
- Engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive the public with or without established proof or actual injury. Prescription dispensed labeled with the incorrect prescriber.

Alleged Violations of Law:

- KRS 315.121 (2)(d) – unprofessional or unethical conduct to deceive the public with or without proof of actual injury;
- 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 217.065 (11)(b) – misbranded if prescription label does not bear the name of the licensed prescribing practitioner.

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 \$1,000

administrative fine, additional 6 hours of continuing education on pharmacy law. CRP vote was unanimous.

Case 20-0112 F. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by dispensing a drug for which a prescription drug order is required without having first received a prescription drug order for the drug. Four (4) prescriptions were dispensed without prescription drug order. Pharmacist is not party to a CCA with the prescriber on the dispense date.
- Engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful. Pharmacist is not party to a CCA with the prescriber on the dispense date.

Alleged Violations 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 to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on pharmacy law. CRP vote was unanimous.

Case 20-0113 A, B, and C.

SUMMARY:

- Consumer complaint that pharmacy dispensed prescription items without a valid prescription.
- Consumer receives both prescription drugs and veterinary diet products requiring practitioner authorization from an internet retailer.
- Prescriptions for all items, three for drugs and two for diet products, mailed to pharmacy.
- Prescriptions received while pharmacist B was pharmacist in charge.
- Pharmacy only dispenses prescription drugs. Prescriptions for diet products not forwarded to appropriate group within company.
- Consumer mailed copy of one veterinary diet product prescription to pharmacy while pharmacist C was pharmacist in charge.
- The copy of the veterinary diet prescription was destroyed and not forwarded to appropriate group within company. According to company website, copies of diet products acceptable for authorization.

Case 20-0113 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by not maintaining hard copy prescriptions mailed to the pharmacy.
- Failed to provide adequate security and control of prescriptions mailed to the pharmacy.
- Engaged in unprofessional or unethical conduct by publication of misleading statements concerning the practice of pharmacy.

Alleged Violations of Law:

- KRS 315.121 (1)(a) – general unprofessional or unethical conduct; and
- 201 KAR 2:100 Section 2 – security and control of prescription files.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0113 B. Pharmacist in charge allegedly:

- Failed to implement an effective quality assurance program to ensure the security of prescriptions mailed to the pharmacy.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(a) – pharmacist in charge responsible for quality assurance program.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0113 C. Pharmacist in charge allegedly:

- Failed to implement an effective quality assurance program to ensure the security of prescriptions mailed to the pharmacy.

Alleged Violation of Law:

- 201 KAR 2:205 Section 2 (3)(a) – pharmacist in charge responsible for quality assurance program.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0114 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by employing a pharmacist that provided false, misleading, or deceptive statements concerning the practice of pharmacy.

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. CRP vote was unanimous.

Case 20-0114 B. Pharmacy permit holder allegedly:

- Dispensed misbranded prescriptions.
- Patient allegedly received an oxycodone-acetaminophen prescription labeled for a quantity of 90 tablets but containing a quantity of 86 tablets.
- Patient allegedly received a prescription labeled as oxycodone-acetaminophen but containing some unknown drug.

Alleged Violations of Law:

- KRS 217.065 (1) – drug misbranded if labeling false or misleading in any particular; and
- KRS 217.065 (2)(b) – drug misbranded unless accurate statement of the quantity of the contents.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0114 C. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by circulating false, misleading, or deceptive statements concerning the practice of pharmacy. Pharmacist refused to return prescription to patient.
- Engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public with or without established proof of actual injury. Pharmacy dispensed misbranded prescriptions.
- 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)(a) – unprofessional or unethical conduct to circulate false, misleading, or deceptive statements concerning the practice of pharmacy;
- KRS 315.121 (2)(d) – unprofessional or unethical conduct to engage in conduct likely to deceive the public with or without established proof of actual injury; and
- KRS 315.121 (2)(j) – unprofessional or unethical conduct to fail 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. CRP vote was unanimous.

Case 20-0115 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by selling prescription active pharmaceutical ingredient (API), including a schedule V controlled substance API, to a person not licensed to dispense, distribute, or possess a legend drug or controlled substance.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may discipline for violations of KRS Chapter 217 or Chapter 218A;

- KRS 217.182 (2)(b) – may sell or distribute legend drug to a person licensed to administer, dispense, distribute, or possess a legend drug; and
- KRS 218A.170 (2)(b) – may sell or distribute a controlled substance to a person registered pursuant to federal controlled substances laws.

Combined with Case 20-0115 B. See below.

Case 20-0115 B. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by selling prescription active pharmaceutical ingredient (API), including a schedule V controlled substance API, to a person not licensed to dispense, distribute, or possess a legend drug or controlled substance.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may discipline for violations of KRS Chapter 217 or Chapter 218A;
- KRS 217.182 (2)(b) – may sell or distribute legend drug to a person licensed to administer, dispense, distribute, or possess a legend drug; and
- KRS 218A.170 (2)(b) – may sell or distribute a controlled substance to a person registered pursuant to federal controlled substances laws.

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 \$1,000 administrative fine, additional 6 hours of continuing education on pharmacy law. CRP vote was unanimous.

Case 20-0117 A. Pharmacy permit holder allegedly:

- Sold a misbranded drug due to a medication error. Patient was allegedly dispensed a prescription and refill for Ergocalciferol 1.25mg (Vitamin D2 50,000 IU) with directions to take 1 capsule twice a week that was labeled with directions to take 1 capsule twice a day.

Alleged Violation of Law:

- KRS 217.065 (1) – Drug misbranded if labeling 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. CRP vote was unanimous.

Case 20-0117 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; and

- Failed to perform a proper prospective drug use review prior to dispensing a refilled prescription.

Alleged Violations of Law:

- KRS 315.121 (2)(d) – Unprofessional or unethical conduct for conduct likely to harm the public; and
- 201 KAR 2:210 Section 4 (1) – Requirement to perform a prospective drug use review 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. CRP vote was unanimous.

Case 20-0117 C. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by committing a medication error; and
- Failed to perform a proper prospective drug use review prior to dispensing a new prescription.

Alleged Violations of Law:

- KRS 315.121 (2)(d) – Unprofessional or unethical conduct for conduct likely to harm the public; and
- 201 KAR 2:210 Section 4 (1) – Requirement to perform a prospective drug use review 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. CRP vote was unanimous.

Case 20-0118 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by instituting a corporate process that resulted in a patient receiving a 7-day supply of an opioid prescription.

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. CRP vote was unanimous.

Case 20-0118 B. Pharmacist in charge allegedly:

- Failed in the proper provision of pharmacy services. Due to implementation of a corporate process, patient was dispensed a 7-day supply of an opioid prescription instead of the full amount.
- Failed in the proper supervision of a pharmacist intern.

Alleged Violations of Law:

- KRS 315.121 (1)(a) – general unprofessional or unethical conduct;
- KRS 315.020 (4)(a) – pharmacist interns perform professional practice activities under supervision; and
- 201 KAR 2:205 Section 2 (3)(b) – provision of pharmacy services responsibility of pharmacist in charge.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0121 A. Pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by selling a prescription without a legitimate prescription drug order.
- Engaged in unprofessional or unethical conduct by obtaining a prescription through an intermediary service.

Alleged Violations of Law:

- KRS 315.121 (1)(a) – general unprofessional or unethical conduct; and
- 201 KAR 2:070 Section 1 – prohibition of filling or dispensing prescriptions obtained via an intermediary service

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0121 B. Pharmacist in charge allegedly:

- Failed to implement an appropriate quality assurance program.
- Dispensed prescriptions obtained through an intermediary service.

Alleged Violations of Law:

- 201 KAR 2:205 Section 2 (3)(a) – pharmacist in charge responsibility for quality assurance program;
- 201 KAR 2:205 Section 2 (3)(b) – pharmacist in charge responsibility for provision of pharmacy services; and
- 201 KAR 2:070 Section 1 – prohibition of filling or dispensing prescriptions obtained via an intermediary service.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

Case 20-0123. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct. Pharmacist attempted to call in a prescription to another pharmacy for his girlfriend.

Alleged Violations of Law:

- KRS 315.121(1)(a) – Unprofessional or unethical conduct;
- 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;
- 201 KAR 2:165 Section 1, Part 2 – Failing to record transfer information, and
- 201 KAR 2:170 Section 1 – Failing to maintain prescription records.

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

Case 20-0204. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct
- Violated terms of the current Agreed Order of Restrictions

Alleged Violations of Law:

- KRS 315.121 (1)(a), (i) – unprofessional or unethical conduct; 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 of an Agreed Order with Restrictions, in addition to the current Agreed Order, to include 10 year probation from date of previous Agreed Order, KYPRN monitoring agreement, limit of two work locations, work locations must be within a 50 mile radius of home residence, work locations must be approved by the Board or Board President after consultation with Pharmacy and Drug Inspector, shall work a maximum of 45 hours per week or ninety hours within two weeks, with a maximum of fifty hours in any seven consecutive days with no overtime, with strict wording to reflect no modifications to the Agreed Order. CRP vote was unanimous.

Case 20-0205 A. Non-resident pharmacy permit holder allegedly:

- Engaged in unprofessional or unethical conduct by engaging in the wholesale distribution of prescription drugs.
- Permit holder allegedly sold prescription drugs to a wholesale distributor located in Kentucky 247 times from March 2017 through June 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.

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. CRP vote was unanimous.

Case 20-0205 B. Non-resident pharmacist-in-charge (PIC) allegedly:

- Engaged in unprofessional or unethical conduct by engaging in the wholesale distribution of prescription drugs.
- PIC of non-resident pharmacy permit holder allegedly sold prescription drugs to a wholesale distributor located in Kentucky 247 times from March 2017 through June 2020.

Alleged Violations of Law:

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

CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$10,000 administrative fine, additional 6 hours of continuing education on pharmacy law. CRP vote was unanimous.

Case 20-0205 C. Non-resident wholesale distributor allegedly:

- Engaged in unprofessional or unethical conduct by obtaining a Kentucky Board of Pharmacy license but using the Kentucky non-resident pharmacy permit located in the same physical space to obtain and sell prescription drugs.

Alleged Violation of Law:

- KRS 315.121(1)(a) – unprofessional or unethical conduct by obtaining a Kentucky Board of Pharmacy license but using the Kentucky non-resident pharmacy permit located in the same physical space to obtain and sell prescription drugs.

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. CRP vote was unanimous.

Case 20-0205 D. 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.

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 deny pending application, Board will not grant any future applications. CRP vote was unanimous.

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

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

Alleged Violations of Law:

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

CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$10,000 administrative fine, additional 6 hours of continuing education on pharmacy law. CRP vote was unanimous.

Case 20-0205 F. Non-resident wholesale distributor allegedly:

- Engaged in unprofessional or unethical conduct by obtaining a Kentucky license but using the pharmacy permit located in the same physical space to obtain and sell prescription drugs.

Alleged Violation of Law:

- KRS 315.121(1)(a) – unprofessional or unethical conduct by obtaining a Kentucky Board of Pharmacy license but using the Kentucky non-resident pharmacy permit located in the same physical space to obtain and sell prescription drugs.

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. CRP vote was unanimous.

Case 20-0205 G. 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.

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 deny pending application, Board will not grant any future applications. CRP vote was unanimous.

Case 20-0205 H. Non-resident wholesale distributor allegedly:

- Engaged in unprofessional or unethical conduct by obtaining a Kentucky license but using the pharmacy permit located in the same physical space to obtain and sell prescription drugs.

Alleged Violation of Law:

- KRS 315.121(1)(a) – unprofessional or unethical conduct by obtaining a Kentucky Board of Pharmacy license but using the Kentucky non-resident pharmacy permit located in the same physical space to obtain and sell prescription drugs.

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. CRP vote was unanimous.

Case 20-0205 I. 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

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 deny pending application, Board will not grant any future applications. CRP vote was unanimous.

Case 20-0205 J. Non-resident wholesale distributor allegedly:

- Engaged in unprofessional or unethical conduct by obtaining a Kentucky license but using the pharmacy permit located in the same physical space to obtain and sell prescription drugs.
- Wholesale distributor allegedly falsified transaction records by indicating the wholesale distributor bought and sold 215 times when invoices from originating wholesale distributor and to the final wholesale distributor indicate the pharmacy permit holder bought and sold the prescription drugs from April 2018 through April 2020.

Alleged Violations of Law:

- KRS 315.121(1)(a) – unprofessional or unethical conduct by obtaining a Kentucky Board of Pharmacy license but using the Kentucky non-resident pharmacy permit located in the same physical space to obtain and sell prescription drugs.

- KRS 315.121(1)(f) – engaging in fraud in the wholesale distribution of drugs by falsifying transaction data

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. CRP vote was unanimous.

Case 20-0205 K. Resident wholesale distributor allegedly:

- Engaged in unprofessional or unethical conduct by purchasing prescription drugs 247 times from a non-resident pharmacy permit holder and prescription drugs 434 times from non-resident pharmacies without Kentucky pharmacy permits.

Alleged Violations of Law:

- KRS 315.121(1)(a) – unprofessional or unethical conduct for failing to perform due diligence for the source of prescription drugs

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

John Fuller seconded, and the motion passed unanimously.

CORRESPONDENCE

Grant County Drugs, P06853, P06979, P07334 Offsite Storage Request Craig Martin moved to approve this request with the stipulation that only pharmacy records [prescription/financial] be stored at the facility and only pharmacy personnel may have access to the facility. Peter Cohron seconded, and the motion passed unanimously.

Clark Drugs, P00667 Offsite Storage Request –John Fuller moved to approve this request. Jill Rhodes seconded, and the motion passed unanimously.

Clay Discount Pharmacy, P07140 and RX Discount Pharmacy, P06091 Offsite Storage Request – Craig Martin moved to approve this request with the stipulation that only prescription records older than two years be stored offsite. Jill Rhodes seconded, and the motion passed unanimously.

P06574 and P07819, Donald Riley Dual PIC Request – Craig Martin moved to approve this request until December 16, 2020. Peter Cohron seconded, and the motion passed unanimously.

LEGISLATION/REGULATION

201 KAR 2:380, Board Authorized Protocols Trish Freeman presented an amended draft of the regulation for Board approval. These amendments include the addition of colon cancer screening to the list of authorized conditions and correct oversights in the initial drafting. Craig Martin moved to approve the amended regulation as corrected during the meeting and submit to LRC. Peter Cohron seconded, and the motion passed unanimously with Jill Rhodes abstaining.

OLD BUSINESS

Medication Safety Committee Jill Rhodes proposed the creation of an ad hoc Medication Safety Committee comprised of pharmacists with expertise in medication safety to advise the board on medication error matters. This item was tabled at the previous meeting to allow for more review. Peter Cohron moved to create this committee based on the proposal. John Fuller seconded, and the motion passed unanimously.

Advisory Council Member Designation Larry Hadley advised the Board that member designation approved at the April 28, 2020 needs to be amended to include the addition of a public member. Craig Martin moved to require members of the Advisory Council consist of at least one each of the following designations; retail pharmacist, independent pharmacist, hospital pharmacist, academia pharmacist, consultant pharmacist, industry pharmacist and public non-pharmacist. Jill Rhodes seconded, and the motion passed unanimously.

NEW BUSINESS

Advisory Council Appointments Larry Hadley presented the top two applicants receiving votes for the Advisory Council; Cindy Cummings and Lauren Adams. Jill Rhodes moved to appoint these individuals to the Advisory Council. John Fuller seconded, and the motion passed unanimously.

Professional Recovery Network Committee Larry Hadley presented the top three applicants receiving votes for the committee; Karen Blumenschein, Andraya Clark and Courtney Eatmon. Peter Cohron moved to approve these individuals to the committee. Craig Martin seconded, and the motion passed unanimously. Joel Thornbury challenged the Board to promote the work of this committee to better serve those in the pharmacy profession suffering from impairment. Ron Poole suggested Brian Fingerson develop a presentation that may be considered for continuing education credit approved by the Board. Jill Rhodes moved to direct the committee to develop a one hours CE presentation for Board approval. Peter Cohron seconded, and the motion passed unanimously.

APRN Council Member Ron Poole gave an overview of his representation on the council. He suggested that the Board establish a two year term for future pharmacy representatives. Applications will be requested for pharmacy representation on this council. Applications will be reviewed at the next scheduled meeting.

RECOGNITIONS Larry Hadley recognized the following:

- Shannon Stiglitz has served a four year term on the Advisory Council. Her term expires December 31, 2020.
- Kelly Whitaker has served a four year term on the Advisory Council. Her term expires December 31, 2020.
- Michel Wyant has served a four year term on the Advisory Council. His term expires December 31, 2020.
- Chris Killmeier has served an eight year term on the Pharmacy Recovery Network Committee. His term expires December 31, 2020.
- Joel Thornbury has served a four year term on the Pharmacy Recovery Network Committee. His term expires December 31, 2020.
- Ron Poole has served as President of the Board for 2020 and has served a four year term on the Kentucky Board of Pharmacy. His term expires December 31, 2020.
- Craig Martin has served a five year term on the Kentucky Board of Pharmacy. His term expires December 31, 2020.

Mr. Hadley thanked them for the service and dedication to the Board.

ADJOURNMENT On motion by Craig Martin, seconded by John Fuller and passed unanimously, President Poole adjourned the meeting at 2:20 p.m. The next regularly scheduled meeting begins at 9:00 am on January 28, 2021 via teleconference.

Larry A. Hadley
Executive Director