

KENTUCKY BOARD OF PHARMACY
via teleconference

<https://us02web.zoom.us/j/88200407210?pwd=RWM0LzBhek5iNHQzalRmcmlwVXZndz09>

Meeting ID: 882 0040 7210 Passcode: 4GxnhT

Dial by your location

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

Meeting ID: 882 0040 7210 Passcode: 967944

Case Review Panel

August 3, 2021

9:00 a.m.

Agenda

- I. Call to Order
- II. Minutes
- III. Cases: 20-0025 A-S
- IV. Adjourn

ATTENTION: A portion of the meeting may be held in closed/executive session for the purpose of discussing and deliberating upon open investigations, which are preliminary matters that may result in litigation being filed on behalf of the Board and include the review of information required to be conducted in privacy according to federal and state law (under Agenda Items III). The specific statutory sections providing exemptions are: KRS 61.810(1)(c) KRS 61.878(1)(a) KRS 61.810(1)(j) KRS 61.878(1)(h) KRS 61.810(1)(k). Following discussion and deliberation, any and all action will be taken in open/public session.

KENTUCKY BOARD OF PHARMACY
via Zoom teleconference

CASE REVIEW PANEL
MINUTES

August 3, 2021

Peter Cohron, Vice President of the Board, called the meeting to order at 9:01 a.m. Present were: Peter Cohron, Vice President of the Board; Larry Hadley, Executive Director; Eden Davis, General Counsel; Katie Busroe, Pharmacy Inspections and Investigations Supervisor; Amanda Harding, Pharmacy and Drug Inspector; Darla Sayre, Executive Staff Advisor and Kaci Christopher, Law Clerk.

Peter Cohron moved for the Case Review Panel to go into closed session to include investigating inspectors, Eden Davis, Darla Sayre and Kaci Christopher for the purpose of reviewing, discussing and deliberating upon open investigations [20-0025 A - S] all of which are matters that may result in litigation being filed on behalf of the Board and/or require the review of information deemed confidential in accordance with state and federal law. The deliberations require the panel members to review and discuss information compiled in the course of the Board's work to detect and investigate statutory and regulatory violations (the premature release of which may harm the Board's ability to carry out its administrative adjudication or prospective law enforcement functions, if an investigation remains open and final action is not taken in this meeting) and to determine whether to initiate litigation on behalf of the Board against individual licensees, permit holders or registrants. The statutory sections providing authorizing executive session are KRS 61.810(c)(j) and (k) and KRS 61.878(1)(a) and (1)(h). Larry Hadley seconded, and the motion passed unanimously. Peter Cohron moved to come out of closed session. Larry Hadley seconded, and the motion passed unanimously.

Case 20-0025 A. Non-permitted facility allegedly:

- Operated a pharmacy without having first obtained a permit.

Alleged Violation of Law:

- KRS 315.035 (1) – permit required to operate a pharmacy.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction.

Case 20-0025 B. Pharmacy permit holder allegedly:

- Failed to provide proper oversight of pharmacy activities. Permit holder could not identify pharmacists assigned to cover clinic services.

Alleged Violation of Law:

- 201 KAR 2:074 Section 2 – hospital pharmacy administration responsibilities.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction.

Case 20-0025 C. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board;
- Engaged in unprofessional or unethical conduct by 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;
- Dispensed legend drugs not obtained through an authorized distribution channel and not in the regular course of his or her profession;
- Accepted a prescription drug for reuse;
- Dispensed adulterated drugs – drugs with labeling requiring dispensing in original container were dispensed in prescription vials;
- Engaged in unprofessional or unethical conduct by engaging in conduct, which may harm the public without or without established proof of actual injury. Expiring investigational drug was dispensed for use after expiration;
- Dispensed misbranded drugs – labeling was false or misleading;
- Dispensed misbranded drugs – prescription legend drugs not labeled with a serial number;
- Failed to provide medication guides when dispensing a drug requiring the provision of a medication guide; and
- Engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful. Pharmacist issued prescriptions via a collaborative care agreement (CCA) that was not authorized in the CCA.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may take action if found to be in violation of any provision of KRS 315, KRS 217 or their administrative regulations;
- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board;
- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury;
- KRS 217.182 (4) – possession or control of legend drugs obtained via sale or distribution by a duly licensed manufacturer, distributor, wholesaler, or pharmacy shall be lawful if it occurred in the regular course of occupation or profession of the possessor;
- KRS 217.182 (6) – no person shall dispense, prescribe, distribute or administer any legend drug except when obtained via appropriate distribution channels and as authorized by professional practice;
- 201 KAR 2:190 Section 1 – Return of prescription drugs prohibited. No pharmacist shall accept for reuse or resale a prescription drug.

- KRS 217.055 (4)(a) – drug deemed adulterated if it is mixed or packed therewith so as to reduce its quality or strength;
- KRS 217.065 (1) – drug deemed misbranded if its labeling is false or misleading in any particular;
- KRS 217.065 (11)(b) – drug deemed misbranded if its label, as originally packed, directs it be sold only on a prescription and the dispensing label does not bear a serial number;
- 21 CFR 208.24 (e) – dispenser of a prescription drug product for which a Medication Guide is required shall provide a Medication Guide directly to the patient to whom the drug product is dispensed; 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 insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice.

Case 20-0025 D. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board;
- Engaged in unprofessional or unethical conduct by 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;
- Dispensed legend drugs not obtained through an authorized distribution channel and not in the regular course of her profession;
- Accepted a prescription drug for reuse;
- Dispensed an adulterated drug – expired drug dispensed;
- Dispensed adulterated drugs – drugs with labeling requiring dispensing in original container were dispensed in prescription vials;
- Dispensed misbranded drugs – labeling was false or misleading;
- Dispensed misbranded drugs – labeling did not include an accurate statement of quantity;
- Dispensed misbranded drugs – prescription legend drugs not labeled with a serial number; and
- Failed to provide medication guides when dispensing a drug requiring the provision of a medication guide.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may take action if found to be in violation of any provision of KRS 315, KRS 217 or their administrative regulations;
- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board;
- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury;

- KRS 217.182 (4) – possession or control of legend drugs obtained via sale or distribution by a duly licensed manufacturer, distributor, wholesaler, or pharmacy shall be lawful if it occurred in the regular course of occupation or profession of the possessor;
- KRS 217.182 (6) – no person shall dispense, prescribe, distribute or administer any legend drug except when obtained via appropriate distribution channels and as authorized by professional practice;
- 201 KAR 2:190 Section 1 – Return of prescription drugs prohibited. No pharmacist shall accept for reuse or resale a prescription drug.
- KRS 217.055 (1)(a) – drug deemed adulterated if it consists in whole or part of any decomposes substance;
- KRS 217.055 (4)(a) – drug deemed adulterated if it is mixed or packed therewith so as to reduce its quality or strength;
- KRS 217.065 (1) – drug deemed misbranded if its labeling is false or misleading in any particular;
- KRS 217.065 (2)(b) – drug deemed misbranded unless its label contains an accurate statement of quantity;
- KRS 217.065 (11)(b) – drug deemed misbranded if its label, as originally packed, directs it be sold only on a prescription and the dispensing label does not bear a serial number; and
- 21 CFR 208.24 (e) – dispenser of a prescription drug product for which a Medication Guide is required shall provide a Medication Guide directly to the patient to whom the drug product is dispensed.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician’s authority pursuant to KRS 315.040.

Case 20-0025 E. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board;
- Engaged in unprofessional or unethical conduct by 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;
- Dispensed legend drugs not obtained through an authorized distribution channel and not in the regular course of his or her profession;
- Dispensed adulterated drugs – drugs with labeling requiring dispensing in original container were dispensed in prescription vials;
- Dispensed misbranded drugs – labeling was false or misleading;
- Dispensed misbranded drugs – prescription legend drugs not labeled with a serial number; and
- Failed to provide medication guides when dispensing a drug requiring the provision of a medication guide.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may take action if found to be in violation of any provision of KRS 315, KRS 217 or their administrative regulations;
- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board;
- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury;
- KRS 217.182 (4) – possession or control of legend drugs obtained via sale or distribution by a duly licensed manufacturer, distributor, wholesaler, or pharmacy shall be lawful if it occurred in the regular course of occupation or profession of the possessor;
- KRS 217.182 (6) – no person shall dispense, prescribe, distribute or administer any legend drug except when obtained via appropriate distribution channels and as authorized by professional practice;
- KRS 217.055 (4)(a) – drug deemed adulterated if it is mixed or packed therewith so as to reduce its quality or strength;
- KRS 217.065 (1) – drug deemed misbranded if its labeling is false or misleading in any particular;
- KRS 217.065 (11)(b) – drug deemed misbranded if its label, as originally packed, directs it be sold only on a prescription and the dispensing label does not bear a serial number; and
- 21 CFR 208.24 (e) – dispenser of a prescription drug product for which a Medication Guide is required shall provide a Medication Guide directly to the patient to whom the drug product is dispensed.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician’s authority pursuant to KRS 315.040.

Case 20-0025 F. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board;
- Engaged in unprofessional or unethical conduct by 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;
- Dispensed legend drugs not obtained through an authorized distribution channel and not in the regular course of his or her profession;
- Dispensed adulterated drugs – drugs with labeling requiring dispensing in original container were dispensed in prescription vials;
- Dispensed misbranded drugs – labeling was false or misleading;
- Dispensed misbranded drugs – prescription legend drugs not labeled with a serial number; and
- Failed to provide medication guides when dispensing a drug requiring the provision of a medication guide.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may take action if found to be in violation of any provision of KRS 315, KRS 217 or their administrative regulations;
- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board;
 - KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury;
 - KRS 217.182 (4) – possession or control of legend drugs obtained via sale or distribution by a duly licensed manufacturer, distributor, wholesaler, or pharmacy shall be lawful if it occurred in the regular course of occupation or profession of the possessor;
 - KRS 217.182 (6) – no person shall dispense, prescribe, distribute or administer any legend drug except when obtained via appropriate distribution channels and as authorized by professional practice;
 - KRS 217.055 (4)(a) – drug deemed adulterated if it is mixed or packed therewith so as to reduce its quality or strength;
 - KRS 217.065 (1) – drug deemed misbranded if its labeling is false or misleading in any particular;
 - KRS 217.065 (11)(b) – drug deemed misbranded if its label, as originally packed, directs it be sold only on a prescription and the dispensing label does not bear a serial number; and
 - 21 CFR 208.24 (e) – dispenser of a prescription drug product for which a Medication Guide is required shall provide a Medication Guide directly to the patient to whom the drug product is dispensed.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician’s authority pursuant to KRS 315.040.

Case 20-0025 G. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board;
- Engaged in unprofessional or unethical conduct by 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;
- Dispensed legend drugs not obtained through an authorized distribution channel and not in the regular course of his or her profession;
- Dispensed adulterated drugs – drugs with labeling requiring dispensing in original container were dispensed in prescription vials;
- Dispensed misbranded drugs – labeling was false or misleading;
- Dispensed misbranded drugs – prescription legend drugs not labeled with a serial number; and

- Failed to provide medication guides when dispensing a drug requiring the provision of a medication guide.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may take action if found to be in violation of any provision of KRS 315, KRS 217 or their administrative regulations;
- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board;
- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury;
- KRS 217.182 (4) – possession or control of legend drugs obtained via sale or distribution by a duly licensed manufacturer, distributor, wholesaler, or pharmacy shall be lawful if it occurred in the regular course of occupation or profession of the possessor;
- KRS 217.182 (6) – no person shall dispense, prescribe, distribute or administer any legend drug except when obtained via appropriate distribution channels and as authorized by professional practice;
- KRS 217.055 (4)(a) – drug deemed adulterated if it is mixed or packed therewith so as to reduce its quality or strength;
- KRS 217.065 (1) – drug deemed misbranded if its labeling is false or misleading in any particular;
- KRS 217.065 (11)(b) – drug deemed misbranded if its label, as originally packed, directs it be sold only on a prescription and the dispensing label does not bear a serial number; and
- 21 CFR 208.24 (e) – dispenser of a prescription drug product for which a Medication Guide is required shall provide a Medication Guide directly to the patient to whom the drug product is dispensed.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician’s authority pursuant to KRS 315.040.

Case 20-0025 H. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board; and
- Engaged in unprofessional or unethical conduct by 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.

Alleged Violations of Law:

- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board; and

- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or 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 dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician’s authority pursuant to KRS 315.040.

Case 20-0025 I. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board;
- Engaged in unprofessional or unethical conduct by 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;
- Dispensed legend drugs not obtained through an authorized distribution channel and not in the regular course of his or her profession;
- Dispensed adulterated drugs – drugs with labeling requiring dispensing in original container were dispensed in prescription vials;
- Dispensed misbranded drugs – labeling was false or misleading; and
- Dispensed misbranded drugs – prescription legend drugs not labeled with a serial number.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may take action if found to be in violation of any provision of KRS 315, KRS 217 or their administrative regulations;
- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board;
- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury;
- KRS 217.182 (4) – possession or control of legend drugs obtained via sale or distribution by a duly licensed manufacturer, distributor, wholesaler, or pharmacy shall be lawful if it occurred in the regular course of occupation or profession of the possessor;
- KRS 217.182 (6) – no person shall dispense, prescribe, distribute or administer any legend drug except when obtained via appropriate distribution channels and as authorized by professional practice;
- KRS 217.055 (4)(a) – drug deemed adulterated if it is mixed or packed therewith so as to reduce its quality or strength;
- KRS 217.065 (1) – drug deemed misbranded if its labeling is false or misleading in any particular; and
- KRS 217.065 (11)(b) – drug deemed misbranded if its label, as originally packed, directs it be sold only on a prescription and the dispensing label does not bear a serial number.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician's authority pursuant to KRS 315.040.

Case 20-0025 J. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board;
- Engaged in unprofessional or unethical conduct by 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;
- Dispensed legend drugs not obtained through an authorized distribution channel and not in the regular course of her profession;
- Dispensed an adulterated drug – expired drug dispensed;
- Dispensed misbranded drugs – labeling was false or misleading; and
- Dispensed misbranded drugs – prescription legend drugs not labeled with a serial number; and
- Failed to provide medication guides when dispensing a drug requiring the provision of a medication guide.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may take action if found to be in violation of any provision of KRS 315, KRS 217 or their administrative regulations;
- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board;
- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury;
- KRS 217.182 (4) – possession or control of legend drugs obtained via sale or distribution by a duly licensed manufacturer, distributor, wholesaler, or pharmacy shall be lawful if it occurred in the regular course of occupation or profession of the possessor;
- KRS 217.182 (6) – no person shall dispense, prescribe, distribute or administer any legend drug except when obtained via appropriate distribution channels and as authorized by professional practice;
- KRS 217.055 (1)(a) – drug deemed adulterated if it consists in whole or part of any decomposes substance;
- KRS 217.065 (1) – drug deemed misbranded if its labeling is false or misleading in any particular;
- KRS 217.065 (11)(b) – drug deemed misbranded if its label, as originally packed, directs it be sold only on a prescription and the dispensing label does not bear a serial number; and

- 21 CFR 208.24 (e) – dispenser of a prescription drug product for which a Medication Guide is required shall provide a Medication Guide directly to the patient to whom the drug product is dispensed.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician’s authority pursuant to KRS 315.040.

Case 20-0025 K. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board;
- Engaged in unprofessional or unethical conduct by 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;
- Dispensed legend drugs not obtained through an authorized distribution channel and not in the regular course of his profession;
- Dispensed misbranded drugs – labeling was false or misleading; and
- Dispensed misbranded drugs – prescription legend drugs not labeled with a serial number.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may take action if found to be in violation of any provision of KRS 315, KRS 217 or their administrative regulations;
- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board;
- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury;
- KRS 217.182 (4) – possession or control of legend drugs obtained via sale or distribution by a duly licensed manufacturer, distributor, wholesaler, or pharmacy shall be lawful if it occurred in the regular course of occupation or profession of the possessor;
- KRS 217.182 (6) – no person shall dispense, prescribe, distribute or administer any legend drug except when obtained via appropriate distribution channels and as authorized by professional practice;
- KRS 217.065 (1) – drug deemed misbranded if its labeling is false or misleading in any particular; and
- KRS 217.065 (11)(b) – drug deemed misbranded if its label, as originally packed, directs it be sold only on a prescription and the dispensing label does not bear a serial number.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician's authority pursuant to KRS 315.040.

Case 20-0025 L. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board;
- Engaged in unprofessional or unethical conduct by 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;
- Dispensed legend drugs not obtained through an authorized distribution channel and not in the regular course of his or her profession;
- Dispensed adulterated drugs – drugs with labeling requiring dispensing in original container were dispensed in prescription vials;
- Dispensed misbranded drugs – labeling was false or misleading;
- Dispensed misbranded drugs – prescription legend drugs not labeled with a serial number; and
- Failed to provide medication guides when dispensing a drug requiring the provision of a medication guide.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may take action if found to be in violation of any provision of KRS 315, KRS 217 or their administrative regulations;
- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board;
- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury;
- KRS 217.182 (4) – possession or control of legend drugs obtained via sale or distribution by a duly licensed manufacturer, distributor, wholesaler, or pharmacy shall be lawful if it occurred in the regular course of occupation or profession of the possessor;
- KRS 217.182 (6) – no person shall dispense, prescribe, distribute or administer any legend drug except when obtained via appropriate distribution channels and as authorized by professional practice;
- KRS 217.055 (4)(a) – drug deemed adulterated if it is mixed or packed therewith so as to reduce its quality or strength;
- KRS 217.065 (1) – drug deemed misbranded if its labeling is false or misleading in any particular;
- KRS 217.065 (11)(b) – drug deemed misbranded if its label, as originally packed, directs it be sold only on a prescription and the dispensing label does not bear a serial number; and
- 21 CFR 208.24 (e) – dispenser of a prescription drug product for which a Medication Guide is required shall provide a Medication Guide directly to the patient to whom the drug product is dispensed.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician's authority pursuant to KRS 315.040.

Case 20-0025 M. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board;
- Engaged in unprofessional or unethical conduct by 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;
- Dispensed legend drugs not obtained through an authorized distribution channel and not in the regular course of his or her profession;
- Dispensed adulterated drugs – drugs with labeling requiring dispensing in original container were dispensed in prescription vials;
- Dispensed misbranded drugs – labeling was false or misleading; and
- Dispensed misbranded drugs – prescription legend drugs not labeled with a serial number.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may take action if found to be in violation of any provision of KRS 315, KRS 217 or their administrative regulations;
- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board;
- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury;
- KRS 217.182 (4) – possession or control of legend drugs obtained via sale or distribution by a duly licensed manufacturer, distributor, wholesaler, or pharmacy shall be lawful if it occurred in the regular course of occupation or profession of the possessor;
- KRS 217.182 (6) – no person shall dispense, prescribe, distribute or administer any legend drug except when obtained via appropriate distribution channels and as authorized by professional practice;
- KRS 217.055 (4)(a) – drug deemed adulterated if it is mixed or packed therewith so as to reduce its quality or strength;
- KRS 217.065 (1) – drug deemed misbranded if its labeling is false or misleading in any particular; and
- KRS 217.065 (11)(b) – drug deemed misbranded if its label, as originally packed, directs it be sold only on a prescription and the dispensing label does not bear a serial number.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician's authority pursuant to KRS 315.040.

Case 20-0025 N. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board;
- Engaged in unprofessional or unethical conduct by 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;
- Dispensed legend drugs not obtained through an authorized distribution channel and not in the regular course of his or her profession;
- Dispensed adulterated drugs – drugs with labeling requiring dispensing in original container were dispensed in prescription vials;
- Dispensed misbranded drugs – labeling was false or misleading;
- Dispensed misbranded drugs – prescription legend drugs not labeled with a serial number; and
- Failed to provide medication guides when dispensing a drug requiring the provision of a medication guide.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may take action if found to be in violation of any provision of KRS 315, KRS 217 or their administrative regulations;
- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board;
- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury;
- KRS 217.182 (4) – possession or control of legend drugs obtained via sale or distribution by a duly licensed manufacturer, distributor, wholesaler, or pharmacy shall be lawful if it occurred in the regular course of occupation or profession of the possessor;
- KRS 217.182 (6) – no person shall dispense, prescribe, distribute or administer any legend drug except when obtained via appropriate distribution channels and as authorized by professional practice;
- KRS 217.055 (4)(a) – drug deemed adulterated if it is mixed or packed therewith so as to reduce its quality or strength;
- KRS 217.065 (1) – drug deemed misbranded if its labeling is false or misleading in any particular;
- KRS 217.065 (11)(b) – drug deemed misbranded if its label, as originally packed, directs it be sold only on a prescription and the dispensing label does not bear a serial number; and
- 21 CFR 208.24 (e) – dispenser of a prescription drug product for which a Medication Guide is required shall provide a Medication Guide directly to the patient to whom the drug product is dispensed.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician's authority pursuant to KRS 315.040.

Case 20-0025 O. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board;
- Engaged in unprofessional or unethical conduct by 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;
- Dispensed legend drugs not obtained through an authorized distribution channel and not in the regular course of his or her profession;
- Dispensed adulterated drugs – drugs with labeling requiring dispensing in original container were dispensed in prescription vials;
- Dispensed misbranded drugs – labeling was false or misleading;
- Dispensed misbranded drugs – prescription legend drugs not labeled with a serial number; and
- Failed to provide medication guides when dispensing a drug requiring the provision of a medication guide.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may take action if found to be in violation of any provision of KRS 315, KRS 217 or their administrative regulations;
- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board;
- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury;
- KRS 217.182 (4) – possession or control of legend drugs obtained via sale or distribution by a duly licensed manufacturer, distributor, wholesaler, or pharmacy shall be lawful if it occurred in the regular course of occupation or profession of the possessor;
- KRS 217.182 (6) – no person shall dispense, prescribe, distribute or administer any legend drug except when obtained via appropriate distribution channels and as authorized by professional practice;
- KRS 217.055 (4)(a) – drug deemed adulterated if it is mixed or packed therewith so as to reduce its quality or strength;
- KRS 217.065 (1) – drug deemed misbranded if its labeling is false or misleading in any particular;
- KRS 217.065 (11)(b) – drug deemed misbranded if its label, as originally packed, directs it be sold only on a prescription and the dispensing label does not bear a serial number; and

- 21 CFR 208.24 (e) – dispenser of a prescription drug product for which a Medication Guide is required shall provide a Medication Guide directly to the patient to whom the drug product is dispensed.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician’s authority pursuant to KRS 315.040.

Case 20-0025 P. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board;
- Engaged in unprofessional or unethical conduct by 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;
- Dispensed legend drugs not obtained through an authorized distribution channel and not in the regular course of his or her profession;
- Dispensed adulterated drugs – drugs with labeling requiring dispensing in original container were dispensed in prescription vials;
- Dispensed misbranded drugs – labeling was false or misleading;
- Dispensed misbranded drugs – prescription legend drugs not labeled with a serial number; and
- Failed to provide medication guides when dispensing a drug requiring the provision of a medication guide.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may take action if found to be in violation of any provision of KRS 315, KRS 217 or their administrative regulations;
- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board;
- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury;
- KRS 217.182 (4) – possession or control of legend drugs obtained via sale or distribution by a duly licensed manufacturer, distributor, wholesaler, or pharmacy shall be lawful if it occurred in the regular course of occupation or profession of the possessor;
- KRS 217.182 (6) – no person shall dispense, prescribe, distribute or administer any legend drug except when obtained via appropriate distribution channels and as authorized by professional practice;
- KRS 217.055 (4)(a) – drug deemed adulterated if it is mixed or packed therewith so as to reduce its quality or strength;
- KRS 217.065 (1) – drug deemed misbranded if its labeling is false or misleading in any particular;

- KRS 217.065 (11)(b) – drug deemed misbranded if its label, as originally packed, directs it be sold only on a prescription and the dispensing label does not bear a serial number; and
- 21 CFR 208.24 (e) – dispenser of a prescription drug product for which a Medication Guide is required shall provide a Medication Guide directly to the patient to whom the drug product is dispensed.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician’s authority pursuant to KRS 315.040.

Case 20-0025 Q. Pharmacist allegedly:

- Knew or had reason to know that a pharmacist had engaged in or aided and abetted the unlawful distribution of legend medications and failed to report any relevant information to the board;
- Engaged in unprofessional or unethical conduct by 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;
- Dispensed misbranded drugs – labeling was false or misleading; and
- Dispensed misbranded drugs – labeling did not include an accurate statement of quantity.

Alleged Violations of Law:

- KRS 315.121 (1)(h) – Board may take action if found to be in violation of any provision of KRS 315, KRS 217 or their administrative regulations;
- KRS 315.121 (1)(j) – Board may take action if licensee knew or had reason to know that a pharmacist engaged in unlawful distribution of legend medications and failed to report information to the board;
- KRS 315.121 (2)(d) – unprofessional or unethical conduct by engaging in conduct which may harm the public or which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury;
- KRS 217.065 (1) – drug deemed misbranded if its labeling is false or misleading in any particular; and
- KRS 217.065 (2)(b) – drug deemed misbranded unless its label contains an accurate statement of quantity.

CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician’s authority pursuant to KRS 315.040.

Case 20-0025 R. Pharmacist allegedly:

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

issued prescriptions via a collaborative care agreement (CCA) that were not authorized in the CCA.

Alleged Violation of Law:

- 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 insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician’s authority pursuant to KRS 315.040.

Case 20-0025 S. Pharmacist allegedly:

- Engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful. Pharmacist issued prescriptions via a collaborative care agreement (CCA) that were not authorized in the CCA.

Alleged Violation of Law:

- 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 insufficient evidence of a violation to warrant disciplinary action and the case is dismissed without prejudice due to lack of jurisdiction. Respondent was operating under the physician’s authority pursuant to KRS 315.040.

Peter Cohron moved to submit the recommendations listed above for Case 20-0025 A - S to the Board for approval. Larry Hadley seconded, and the motion passed unanimously with Amanda Harding abstaining from the vote to limit their role to that of a factfinder.

Larry Hadley moved to adjourn. Peter Cohron seconded, and the motion passed unanimously. Peter Cohron adjourned the meeting at 9:51 a.m.