

KENTUCKY BOARD OF PHARMACY

via teleconference

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Case Review Panel

September 29, 2021

9:00 a.m.

Agenda

I. Call to Order

II. Minutes – August 24, 2021

III. Cases:

- 18-0364 Revisit
- 19-0119 A and B Revisit
- 19-0277 E Revisit
- 20-0047 A and B
- 20-0120 B, D, F, H, J, L Revisit
- 20-0128 B Revisit
- 21-0076 Revisit
- 21-0089 A thru G Revisit
- 21-0142 A and B
- 21-0143 A and B
- 21-0144 A and B
- 21-0145 A and B
- 21-0146 A and B
- 21-0151 A, B and C
- 21-0163 A and B
- 21-0164 A and B
- 21-0165 A, B and C
- 21-0166 A and B
- 21-0168 A and B
- 21-0169 A and B
- 21-0172 A, B and C
- 21-0173
- 21-0174 A and B
- 21-0175 A and B
- 21-0177
- 21-0184 A, B and C
- 21-0188
- 21-0189
- 21-0190
- 21-0191 A, B and C
- 21-0192 A and B
- 21-0193 A thru I

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

September 29, 2021

Jill Rhodes, President of the Board, called the meeting to order at 9:05 a.m. Present were: Jill Rhodes, President of the Board; Peter Cohron; Chris Harlow; Larry Hadley, Executive Director; Eden Davis, General Counsel; Katie Busroe, Pharmacy Inspections and Investigations Supervisor; Amanda Harding, Pharmacy and Drug Inspector; Paul Daniels, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector; Rhonda Hamilton, Pharmacy and Drug Inspector; John Romines, Pharmacy and Drug Inspector and Darla Sayre, Executive Staff Advisor.

Jill Rhodes moved to approve the minutes of the August 24, 2021 meetings with a correction in the fine amount for 20-0122B and documentation of Amanda Harding's absence. Larry Hadley seconded, and the motion passed unanimously.

Peter Cohron moved to appoint Jill Rhodes as Chair of the Case Review Panel. Chris Harlow seconded, and the motion passed unanimously with Jill Rhodes abstaining.

Peter Cohron moved for the Case Review Panel to go into closed session to include investigating inspectors, Eden Davis, and Darla Sayre for the purpose of reviewing, discussing and deliberating upon open investigations[18-0364, 19-0119, 19-0277, 20-0120, 20-0128, 21-0076, 21-0089, 21-0142, 21-0143, 21-0144, 21-0145, 21-0146, 21-0151, 21-0163, 21-0164, 21-0165, 21-0166, 21-0168, 21-0169, 21-0172, 21-0173, 21-0174, 21-0175, 21-0177, 21-0184, 21-0188, 21-0189, 21-0190, 21-0191, 21-0192] 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). Chris Harlow seconded, and the motion passed unanimously. Chris Harlow moved to come out of closed session. Peter Cohron seconded, and the motion passed unanimously.

Case 18-0364 Alleged Violations of Law:

- KRS 315.121(c)(2) - Being convicted of, or entering an "Alford" plea or plea of nolo contendere to, irrespective of an order granting probation or suspending imposition of any sentence imposed following the conviction or entry of such plea of a violation of the

pharmacy or drug laws, rules, or administrative regulations of this state, any other state, or the federal government.

- 201 KAR 2:105(5)(4)(A) - A wholesaler shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, distribution, and disposition of prescription drugs and drug-related devices.

Proposed Resolution: Jill Rhodes moved to vacate the previous Agreed Order and the investigator is directed to conduct further investigation obtaining the DEA Settlement Agreement, the Policy and Procedures [specific to controlled substances] at the time of the alleged violation and the current Policy and Procedures [specific to controlled substances]. Chris Harlow seconded, and the motion passed unanimously.

Case 19-0119 A and B Alleged Violations 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.
- 201 KAR 2:205 Section 2 (3)(a) - The pharmacist-in-charge shall be responsible for quality assurance programs for pharmacy services designed to objectively and systematically monitor care, pursue opportunities for improvement, and resolve identified problems as may exist.
- 201 KAR 2:205 Section 2 (3)(e) - The pharmacist-in-charge shall be responsible for the making or filing of any reports required by state or federal laws or regulations.

Proposed Resolution: Jill Rhodes moved to vacate the previous Agreed Order and there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice upon issuance of a Letter of Concern. Chris Harlow seconded, and the motion passed unanimously.

Case 19-0277 E Violation of Law: KRS 315.121 (1)(g) Engaging in or aiding and abetting an individual to engage or assist in the practice of pharmacy without a license or falsely using the title of "pharmacist," "pharmacist intern," "pharmacy technician," or other term which might imply that the individual is a pharmacist, pharmacist intern, or pharmacy technician; and (i) Violation of any order issued by the board to comply with any applicable law or administrative regulations.

Proposed Resolution: Jill Rhodes moved to vacate the previous Agreed Order and 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 \$5000 administrative fine. Fine waived if respondent does not seek reinstatement of licensure to work in the pharmaceutical profession.

Fine must be paid if respondent resumes working in the pharmaceutical profession. Peter Cohron seconded, and the motion passed unanimously.

Case 20-0120 B Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b) – Pharmacist in charge is responsible for the procurement, storage, security, and disposition of drugs.

Proposed Resolution: Jill Rhodes moved to vacate the previous Letter of Reprimand and there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 20-0120 D Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b) – Pharmacist in charge is responsible for the procurement, storage, security, and disposition of drugs.

Proposed Resolution: Jill Rhodes moved to vacate the previous Letter of Reprimand and there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 20-0120 F Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b) – Pharmacist in charge is responsible for the procurement, storage, security, and disposition of drugs.

Proposed Resolution: Jill Rhodes moved to vacate the previous Letter of Reprimand and there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 20-0120 H Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b) – Pharmacist in charge is responsible for the procurement, storage, security, and disposition of drugs.

Proposed Resolution: Jill Rhodes moved to vacate the previous Letter of Reprimand and there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 20-0120 J Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b) – Pharmacist in charge is responsible for the procurement, storage, security, and disposition of drugs.

Proposed Resolution: Jill Rhodes moved to vacate the previous Letter of Reprimand and there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 20-0120 K Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b) – Pharmacist in charge is responsible for the procurement, storage, security, and disposition of drugs.

Proposed Resolution: Jill Rhodes moved to vacate the previous Letter of Reprimand and there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 20-0120 L Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b) – Pharmacist in charge is responsible for the procurement, storage, security, and disposition of drugs.

Proposed Resolution: Jill Rhodes moved to vacate the previous Letter of Reprimand and there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 20-0128 B Violation of Law: 201 KAR 2:205 Section 2 (3)(b) – Pharmacist in charge is responsible for the procurement, storage, security, and disposition of drugs.

Proposed Resolution: Jill Rhodes moved keep the Agreed Order as is with no changes. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0076 Alleged Violations of Law:

- KRS 315.121 (1)(c)(2) – being convicted of a violation of drug laws of the federal government
- KRS 315.121 (1)(a) – unprofessional or unethical conduct

Proposed Resolution: Jill Rhodes moved to vacate the previous Agreed Order and there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice upon issuance of a Letter of Concern. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0089 A Alleged Violation of Law: KRS 315.121 (1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons:
Unprofessional or unethical conduct.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice upon issuance of a Letter of Concern. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0089 B Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b) – The Pharmacist in charge shall be responsible for: The procurement, storage, security, and disposition of drugs and the provision of pharmacy services.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice upon issuance of a Letter of Concern. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0089 C Alleged Violation of Law: KRS 315.121 (2)(d) – Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist, pharmacist intern, or pharmacy technician: 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.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice upon issuance of a Letter of Concern. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0089 D Alleged Violation of Law: KRS 315.121 (1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: Unprofessional or unethical conduct.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice upon issuance of a Letter of Concern. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0089 E Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b) – The Pharmacist in charge shall be responsible for: The procurement, storage, security, and disposition of drugs and the provision of pharmacy services.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice upon issuance of a Letter of Concern. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0090 F Alleged Violations of Law: 201 KAR 2:210 Section 4 (1), (2), and (3) – Prospective Drug Use Review. (1) A prospective drug use review shall be conducted by a pharmacist prior to dispensing. (2) It shall include an assessment of a patient’s drug therapy and the prescription order. (3) A prospective drug use review shall include a review by the pharmacist of the following: Known allergies; Rationale for use; Proper dose, route of administration, and directions; Synergism with currently employed modalities; Interaction or adverse reaction with applicable: Drugs, Foods, or Known disease states; Proper utilization for optimum therapeutic outcomes; and Clinical misuse or abuse.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice upon issuance of a Letter of Concern. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0089 G Alleged Violation of Law: KRS 315.121 (1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: Unprofessional or unethical conduct.

Proposed Resolution: Jill Rhodes moved there is sufficient evidence developed and the investigator is directed to conduct further investigation working with the New Jersey Board of Pharmacy. The results of the investigation will be presented to the Board for their review and resolution. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0142 A Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that

- (I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
- (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
- (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);

Proposed Resolution: Jill Rhodes moved to send a warning letter prohibiting shipment of compounded pharmaceuticals using restricted pharmaceuticals in 42 USC 262 and 21 USC 353, refer this case to the FDA and obtain California laws on compounding of peptides and bulk powders. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0142 B Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.
- 201 KAR 2:205 Section 3(b) – Section 2. Duties and Responsibilities. The pharmacist-in-charge shall be responsible for: (b) The procurement, storage, security, and disposition of drugs and the provision of pharmacy services.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product.
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that
 - (I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
 - (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
 - (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);

Proposed Resolution: Jill Rhodes moved to send a warning letter prohibiting shipment of compounded pharmaceuticals using restricted pharmaceuticals in 42 USC 262 and 21 USC 353. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0143 A Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.

- KRS 315.342(14) - Each out-of-state outsourcing facility shall compound in compliance with the requirements of state and federal law and regulations, to include all applicable guidance documents and Current Good Manufacturing Practices published by the United States Food and Drug Administration.
- 21 USC 353b(a)(2)(A)(i)(I)(II)(III) and (ii) – §353b. Outsourcing facilities

(a) In general

Sections 352(f)(1), 355, and 360eee–1 of this title shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met:

(2) Bulk drug substances

The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;

(II) providing a period of not less than 60 calendar days for comment on the notice; and

(III) publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or

(ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing;

Proposed Resolution: Jill Rhodes moved to send a warning letter prohibiting shipment of compounded pharmaceuticals using restricted pharmaceuticals in 42 USC 262 and 21 USC 353, refer this case to the FDA and obtain California laws on compounding of peptides and bulk powders. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0143 B Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- 21 USC 353b(a)(2)(A)(i)(I)(II)(III) and (ii) – §353b. Outsourcing facilities

(a) In general

Sections 352(f)(1), 355, and 360eee–1 of this title shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a

facility that elects to register as an outsourcing facility if each of the following conditions is met:

(2) Bulk drug substances

The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;

(II) providing a period of not less than 60 calendar days for comment on the notice; and

(III) publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or

(ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 356e of this title at the time of compounding, distribution, and dispensing;

Proposed Resolution: Jill Rhodes moved to send a warning letter prohibiting shipment of compounded pharmaceuticals using restricted pharmaceuticals in 42 USC 262 and 21 USC 353. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0144 A Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that
 - (I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
 - (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
 - (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);

Proposed Resolution: Jill Rhodes moved to send a warning letter prohibiting shipment of compounded pharmaceuticals using restricted pharmaceuticals in 42 USC 262 and 21 USC 353, refer this case to the FDA and obtain California laws on compounding of peptides and bulk powders. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0144 B Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- 201 KAR 2:205 Section 3(b) – Section 2. Duties and Responsibilities. The pharmacist-in-charge shall be responsible for: (b) The procurement, storage, security, and disposition of drugs and the provision of pharmacy services.
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that
 - (I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
 - (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
 - (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);

Proposed Resolution: Jill Rhodes moved to send a warning letter prohibiting shipment of compounded pharmaceuticals using restricted pharmaceuticals in 42 USC 262 and 21 USC 353. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0145 A Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician compounds the drug

product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that

- (I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
- (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
- (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);

Proposed Resolution: Jill Rhodes moved to send a warning letter prohibiting shipment of compounded pharmaceuticals using restricted pharmaceuticals in 42 USC 262 and 21 USC 353, refer this case to the FDA and obtain California laws on compounding of peptides and bulk powders. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0145 B Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- 201 KAR 2:205 Section 3(b) – Section 2. Duties and Responsibilities. The pharmacist-in-charge shall be responsible for: (b) The procurement, storage, security, and disposition of drugs and the provision of pharmacy services.
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that

- (I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
- (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
- (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);

Proposed Resolution: Jill Rhodes moved to send a warning letter prohibiting shipment of compounded pharmaceuticals using restricted pharmaceuticals in 42 USC 262 and 21 USC 353. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0146 A Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that
 - (I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
 - (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
 - (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);

Proposed Resolution: Jill Rhodes moved to send a warning letter prohibiting shipment of compounded pharmaceuticals using restricted pharmaceuticals in 42 USC 262 and 21 USC 353, refer this case to the FDA and obtain California laws on compounding of peptides and bulk powders. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0146 B Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.

- 201 KAR 2:205 Section 3(b) – Section 2. Duties and Responsibilities. The pharmacist-in-charge shall be responsible for: (b) The procurement, storage, security, and disposition of drugs and the provision of pharmacy services.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that

- (I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
- (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
- (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);

Proposed Resolution: Jill Rhodes moved to send a warning letter prohibiting shipment of compounded pharmaceuticals using restricted pharmaceuticals in 42 USC 262 and 21 USC 353. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0151 A Alleged Violation of Law: KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice upon issuance of a Letter of Concern for inconsistency of posted store hours due to staffing shortages. Chris Harlow seconded, and the motion passed unanimously.

Case 21-0151 B Alleged Violation of Law: 201 KAR 2:205 Section 3(b) – Section 2. Duties and Responsibilities. The pharmacist-in-charge shall be responsible for: (b) The procurement, storage, security, and disposition of drugs and the provision of pharmacy services.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Chris Harlow seconded, and the motion passed unanimously.

Case 21-0151 C Alleged Violation of Law: KRS 315.121 (2)(d) – Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist, pharmacist intern, or pharmacy technician: 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.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Chris Harlow seconded, and the motion passed unanimously.

Case 21-0163 A Violations of Law:

- KRS 315.121 (1)(a) – unprofessional or unethical conduct.
- 201 KAR 2:180 Section 5 – proper temperatures shall be maintained for compounding and dispensing of drugs and medicines.

Proposed Resolution: Jill Rhodes moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand recommending a tracking method for air issues and to report to the Board upon resolution of the issue. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0163 B Alleged Violation of Law: 201 KAR 2:205 Section 2(3)(b) – PIC responsible for the procurement, storage, security, and disposition of drugs.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0164 A Alleged Violations of Law:

- KRS 315.121 (1)(h) - The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: Being found by the board to be in violation of any provision of this chapter, KRS Chapter 217, KRS Chapter 218A, or the administrative regulations promulgated pursuant to these chapters.
- KRS 217.065 (1) – Except for violations of KRS 218A.350, a drug or device shall be deemed to be misbranded: If its labeling is false or misleading in any particular.
- KRS 217.065 (2)(b) – Except for violations of KRS 218A.350, a drug or device shall be deemed to be misbranded: If in package form unless it bears a label containing: An accurate statement of the quantity of the contents in terms of weight, measure, or

numerical count; provided that reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the secretary.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0164 B Alleged Violation of Law: KRS 315.121 (2)(d) – Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist, pharmacist intern, or pharmacy technician: 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.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0165 A Alleged Violation of Law: KRS 315.121 (1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons:
Unprofessional or unethical conduct.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0165 B Violations of Law:

- KRS 315.121 (2)(d) – Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist, pharmacist intern, or pharmacy technician: 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.
- 201 KAR 2:210 Section 4 (1), (2), and (3) – Prospective Drug Use Review.
 - (1) A prospective drug use review shall be conducted by a pharmacist prior to dispensing.
 - (2) It shall include an assessment of a patient’s drug therapy and the prescription

order.

(3) A prospective drug use review shall include a review by the pharmacist of the following: Known allergies; Rationale for use; Proper dose, route of administration, and directions; Synergism with currently employed modalities; Interaction or adverse reaction with applicable: Drugs, Foods, or Known disease states; Proper utilization for optimum therapeutic outcomes; and Clinical misuse or abuse.

Proposed Resolution: Jill Rhodes moved 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, approved corrective action plan developed by the PIC to prevent future occurrences regarding auto refill upon dosage change, documentation of hard and soft stop overrides. A report of the progress must be submitted to the inspector three months after issuance of Agreed Order. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0165 C Violations of Law:

- KRS 315.121 (2)(d) – Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist, pharmacist intern, or pharmacy technician: 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.
- 201 KAR 2:210 Section 4 (1) – Prospective Drug Use Review. A prospective drug use review shall be conducted by a pharmacist prior to dispensing.
- 201 KAR 2:210 Section 4 (2) – Prospective Drug Use Review. It shall include an assessment of a patient’s drug therapy and the prescription order.
- 201 KAR 2:210 Section 4 (3) – Prospective Drug Use Review. A prospective drug use review shall include a review by the pharmacist of the following: Known allergies; Rationale for use; Proper dose, route of administration, and directions; Synergism with currently employed modalities; Interaction or adverse reaction with applicable: Drugs, Foods, or Known disease states; Proper utilization for optimum therapeutic outcomes; and Clinical misuse or abuse.

Proposed Resolution: Jill Rhodes moved 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. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0166 A Alleged Violation of Law: KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0166 B Alleged Violations of Law:

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

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0168 A Violations of Law:

- KRS 315.020 (1) – No owner of a pharmacy who is not a pharmacist shall fail to place a pharmacist in charge of his or her pharmacy or shall permit any person to compound or dispense prescription drugs, medicines, or pharmaceuticals in his or her place of business except in the presence and under the immediate supervision of a pharmacist.

Proposed Resolution: Jill Rhodes moved 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 \$25,000 administrative fine, approved corrective action plan on pharmacist in charge replacement within three months. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0168 B Alleged Violation of Law: KRS 315.121 (2)(b) – Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist, pharmacist intern, or pharmacy technician: Divulging or revealing to unauthorized persons patient information or the nature of professional services rendered without the patient's express consent or without order or direction of a court. In addition to members, inspectors, or agents of the board, the following are considered authorized persons: The patient, patient's agent, or another pharmacist acting on behalf of the patient; Certified of licensed health-care personnel who are responsible for

care of the patient; Designated agents of the Cabinet for Health and Family Services for the purposes of enforcing the provisions of KRS Chapter 218A; Any federal, state, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person; or An agency of government charged with the responsibility of providing medical care for the patient, upon written request by an authorized representative of the agency requesting such information.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0169 A Alleged Violations of Law:

- KRS 315.121 (1)(a)—unprofessional or unethical conduct
- KRS 315.121 (1)(h)—being found by the board to be in violation of any provision of this chapter, KRS Chapter 217, KRS Chapter 218A, or the administrative regulations promulgated pursuant to these chapters by violating KRS 218A.180(4)—All written, facsimile, and electronic prescriptions for controlled substances shall be dated and signed by the practitioner on the date issued.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0169 B Violations of Law:

- KRS 315.121 (1)(h)—being found by the board to be in violation of any provision of this chapter, KRS Chapter 217, KRS Chapter 218A, or the administrative regulations promulgated pursuant to these chapters by violating KRS 218A.180(4)—All written, facsimile, and electronic prescriptions for controlled substances shall be dated and signed by the practitioner on the date issued.

Proposed Resolution: Jill Rhodes moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0172 A Violations of Law:

- KRS 315.121 (1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: Unprofessional or unethical conduct.
- KRS 315.121 (1)(h) - The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: Being found by

the board to be in violation of any provision of this chapter, KRS Chapter 217, KRS Chapter 218A, or the administrative regulations promulgated pursuant to these chapters.

- KRS 217.065 (1) – Except for violations of KRS 218A.350, a drug or device shall be deemed to be misbranded: If its labeling is false or misleading in any particular.

Proposed Resolution: Jill Rhodes moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0172 B Violations of Law:

- KRS 315.121 (2)(d) – Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist, pharmacist intern, or pharmacy technician: 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.
- 201 KAR 2:205 Section 2 (3)(b) – The pharmacist-in-charge shall be responsible for: The procurement, storage, security, and disposition of drugs and the provision of pharmacy services.

Proposed Resolution: Jill Rhodes moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0172 C Alleged Violation of Law: KRS 315.121 (2)(d) – Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist, pharmacist intern, or pharmacy technician: 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.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0173 Violation of Law: KRS 315.020 (1) – requirement to place a pharmacist in charge of pharmacy.

Proposed Resolution: Jill Rhodes moved 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, approved corrective action plan on pharmacist in charge

replacement within three months. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0174 A Violation of Law: KRS 315.035(4) – each permit to operate a pharmacy shall expire on June 30 and be renewable annually

Proposed Resolution: Jill Rhodes moved 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, maintain appropriate contact information with the Board and notification upon a change in scheduled hours of operation. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0174 B Violation of Law: 201 KAR 2:205 Section (2)(e) – responsible for filing required reports

Proposed Resolution: Jill Rhodes moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0175 A

Violations of Law:

- KRS 315.035(4) – each permit to operate a pharmacy shall expire on June 30 and be renewable annually
- 201 KAR 2:225 Section 4 – renewal application and appropriate fee shall be submitted to the Board office

Proposed Resolution: Jill Rhodes moved 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. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0175 B Violation of Law: 201 KAR 2:205 Section (2)(e) – responsible for filing required reports

Proposed Resolution: Jill Rhodes moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0177 Alleged Violation of Law: KRS 315.121 (1)(a): The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons:
Unprofessional or unethical conduct.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0184 A Alleged Violation of Law: KRS 315.121 (1)(a): The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons:
Unprofessional or unethical conduct.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0184 B Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b) – The pharmacist-in-charge shall be responsible for: The procurement, storage, security, and disposition of drugs and the provision of pharmacy services.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0184 C Violations of Law:

- KRS 315.121 (2)(d) – Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist, pharmacist intern, or pharmacy technician: 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.
- 201 KAR 2:210 Section 4 (1) – Prospective Drug Use Review. A prospective drug use review shall be conducted by a pharmacist prior to dispensing.
- 201 KAR 2:210 Section 4 (2) – Prospective Drug Use Review. It shall include an assessment of a patient’s drug therapy and the prescription order.
- 201 KAR 2:210 Section 4 (3) – Prospective Drug Use Review. A prospective drug use review shall include a review by the pharmacist of the following: Known allergies; Rationale for use; Proper dose, route of administration, and directions; Synergism with currently employed modalities; Interaction or adverse reaction with applicable: Drugs, Foods, or Known disease states; Proper utilization for optimum therapeutic outcomes; and Clinical misuse or abuse.

Proposed Resolution: Proposed Resolution: Jill Rhodes moved 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 immunizations [must be completed by December 31, 2021]. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0188 Violation of Law: KRS 315.020 (1) – No owner of a pharmacy who is not a pharmacist shall fail to place a pharmacist in charge of his or her pharmacy or shall permit any person to compound or dispense prescription drugs, medicines, or pharmaceuticals in his or her place of business except in the presence and under the immediate supervision of a pharmacist.

Proposed Resolution: Jill Rhodes moved 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, approved corrective action plan on pharmacist in charge replacement within three months. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0189 Violations of Law:

- KRS 315.020 (1) – No owner of a pharmacy who is not a pharmacist shall fail to place a pharmacist in charge of his or her pharmacy or shall permit any person to compound or dispense prescription drugs, medicines, or pharmaceuticals in his or her place of business except in the presence and under the immediate supervision of a pharmacist.
- KRS 315.121 (1)(e) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: Knowingly making or causing to be made any false, fraudulent, or forged statement or misrepresentation of a material fact in securing issuance or renewal of a license, permit, or certificate.

Proposed Resolution: Jill Rhodes moved 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 \$25,000 administrative fine, approved corrective action plan on pharmacist in charge replacement within three months. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0190 Violation of Law: KRS 315.020 (1) – No owner of a pharmacy who is not a pharmacist shall fail to place a pharmacist in charge of his or her pharmacy or shall permit any person to compound or dispense prescription drugs, medicines, or pharmaceuticals in his or her place of business except in the presence and under the immediate supervision of a pharmacist.

Proposed Resolution: Jill Rhodes moved 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 \$25,000 administrative fine, approved corrective action plan on pharmacist in charge replacement within three months. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0191 A Alleged Violations of Law: KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0191 B Alleged Violations of Law:

- KRS 315.121 (1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: Unprofessional or unethical conduct.
- KRS 315.121 (2)(d) – Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist, pharmacist intern, or pharmacy technician: 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.
- 201 KAR 2:205 Section 2 (3)(b) – The pharmacist-in-charge shall be responsible for: The procurement, storage, security, and disposition of drugs and the provision of pharmacy services

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0191 C Alleged Violations of Law:

- KRS 315.121 (1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: Unprofessional or unethical conduct.
- KRS 315.121 (2)(d) – Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist, pharmacist intern, or pharmacy technician: 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.

Proposed Resolution: Jill Rhodes moved there is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0192 A Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product.
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that
 - (I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
 - (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
 - (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c).

Proposed Resolution: Jill Rhodes moved to send a warning letter prohibiting shipment of compounded pharmaceuticals using restricted pharmaceuticals in 42 USC 262 and 21 USC 353, refer this case to the FDA and obtain California laws on compounding of peptides and bulk powders. Peter Cohron seconded, and the motion passed unanimously.

Case 21-0192 B Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.
- 201 KAR 2:205 Section 3(b) – Section 2. Duties and Responsibilities. The pharmacist-in-charge shall be responsible for: (b) The procurement, storage, security, and disposition of drugs and the provision of pharmacy services.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c).

Proposed Resolution: Jill Rhodes moved to send a warning letter prohibiting shipment of compounded pharmaceuticals using restricted pharmaceuticals in 42 USC 262 and 21 USC 353. Peter Cohron seconded, and the motion passed unanimously.

Peter Cohron recused himself from discussion for cases 20-0047 and 21-0193. Jill Rhodes recused herself from case 20-0047. Larry Hadley will serve in their capacity on the panel.

Jill Rhodes moved for the Case Review Panel to go into closed session to include investigating inspectors, Eden Davis, and Darla Sayre for the purpose of reviewing, discussing and deliberating upon open investigations [21-0193, 20-0047] 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). Peter Cohron seconded, and the motion passed unanimously.

Peter Cohron was placed in the waiting room. Jill Rhodes will be placed in the waiting room during closed session for case 21-0193.

Chris Harlow moved to come out of closed session. Larry Hadley seconded, and the motion passed unanimously.

Jill Rhodes and Peter Cohron returned to the meeting.

Case 20-0047 A Violation of Law: KRS 217.065 (1) – a drug is deemed misbranded when its labeling is false or misleading.

Proposed Resolution: Chris Harlow moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Larry Hadley seconded, and the motion passed unanimously with Jill Rhodes and Peter Cohron abstaining.

Case 20-0047 B 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.

Proposed Resolution: Chris Harlow moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Larry Hadley seconded, and the motion passed unanimously with Jill Rhodes and Peter Cohron abstaining.

Case 21-0193 A Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any

biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product.

- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician—(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c).

Proposed Resolution: Jill Rhodes moved 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 \$200,000 administrative fine and the respondent may not own any license or permit issued by the Board in the future. Chris Harlow seconded, and the motion passed with Peter Cohron abstaining.

Case 21-0193 B Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.
- 201 KAR 2:205 Section 3(b) – Section 2. Duties and Responsibilities. The pharmacist-in-charge shall be responsible for: (b) The procurement, storage, security, and disposition of drugs and the provision of pharmacy services.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product

- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that
 - (I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
 - (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
 - (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c).

Proposed Resolution: Jill Rhodes moved 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 5 hours of continuing education on pharmacy law annually for five years, respondent may not be pharmacist in charge for five years from issuance of the Agreed Order. Chris Harlow seconded, and the motion passed with Peter Cohron abstaining.

Case 21-0193 C Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c).

Proposed Resolution: Jill Rhodes moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Chris Harlow seconded, and the motion passed unanimously with Peter Cohron abstaining.

Case 21-0193 D Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c).

Proposed Resolution: Jill Rhodes moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Chris Harlow seconded, and the motion passed unanimously with Peter Cohron abstaining.

Case 21-0193 E Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that
 - (I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
 - (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
 - (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c).

Proposed Resolution: Jill Rhodes moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Chris Harlow seconded, and the motion passed unanimously with Peter Cohron abstaining.

Case 21-0193 F Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.

- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that
 - (I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
 - (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
 - (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c).

Proposed Resolution: Jill Rhodes moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Chris Harlow seconded, and the motion passed unanimously with Peter Cohron abstaining.

Case 21-0193 G Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-(A) compounds the drug

product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c).

Proposed Resolution: Jill Rhodes moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Chris Harlow seconded, and the motion passed unanimously with Peter Cohron abstaining.

Case 21-0193 H Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed

by the Secretary through regulations issued by the Secretary under subsection (c).

Proposed Resolution: Jill Rhodes moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Chris Harlow seconded, and the motion passed unanimously with Peter Cohron abstaining.

Case 21-0193 I Violations of Law:

- KRS 315.121(1)(a) – The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons: (a) Unprofessional or unethical conduct.
- KRS 217.075 (1)(a) - No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless: (a) An application with respect thereto has become effective under the federal act.
- 42 USC 262(a)(1)(A) – Regulation of biological products (a) Biologics license (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless (A) a biologics license under this subsection or subsection (k) is in effect for the biological product
- 21 USC 353a(b)(1)(A)(i)(I)(II) and (III) – Pharmacy Compounding. Compounded drug. Licensed pharmacist and licensed physician. A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that
 - (I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;
 - (II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
 - (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c).

Proposed Resolution: Jill Rhodes moved there is sufficient evidence of a violation, however, the penalty shall be the issuance of a Letter of Reprimand. Chris Harlow seconded, and the motion passed unanimously with Peter Cohron abstaining.

Jill Rhodes moved to adjourn. Chris Harlow seconded, and the motion passed unanimously. Jill Rhodes adjourned the meeting at 3:00 p.m.