

KENTUCKY BOARD OF PHARMACY

125 Holmes Street

Frankfort KY 40601

January 30, 2019

9:00 AM

Agenda

I. CALL TO ORDER

II. MINUTES

A. *December 12, 2018

III. APPEARANCES

A. *Maudie Bryant

B. *Gary Hatfield – Board Approved protocols

IV. INTERAGENCY

V. BOARD REPORTS

A. Executive Director

1. *eMars – December 2018

VI. CURRENT/PENDING CASES

A. *Case Update and Fines Report

B. *Final Orders

VII. CORRESPONDENCE

A. *Larry Stovall – Dual PIC Request

B. *Philip Almeter, UK Healthcare – Offsite Storage Request

VIII. LEGISLATION/REGULATION

A. 201 KAR 2:370 Update

IX. CONTINUING EDUCATION

A. *CE Programs – 19-01

X. OLD BUSINESS

A. *Unused Permits

B. *GoGoMeds

XI. NEW BUSINESS

A. *Standard case parameters

B. Use of ISMP for Medication Error Prevention

C. Naloxone Regulation

XII. FYI

A. 10-0007

*Information enclosed with this agenda.

MINUTES

KENTUCKY BOARD OF PHARMACY

125 Holmes Street
Frankfort KY 40601

BOARD MEETING

January 30, 2019

CALL TO ORDER A regularly scheduled meeting was held at the Kentucky Board of Pharmacy in Frankfort, Kentucky. President Martin called the meeting to order on January 30, 2019 at 9:00 a.m.

Members present: John Fuller, Ron Poole, Peter P. Cohron, Jill Rhodes, Jody Forgy and Craig Martin.

Staff: Larry Hadley, Executive Director; Katie Busroe, Pharmacy Inspections and Investigations Coordinator; Amanda Harding, Pharmacy and Drug Inspector; John Romines, Pharmacy and Drug Inspector and Darla Sayre, Executive Staff Advisor. Court Reporter Terri Pelosi recorded the meeting. Marcus Jones, Assistant Attorney General providing Board Counsel.

Guests: Chris Killmeier, Walgreens; Mark Gласper, KPhA; Chris Palutis, KPhA; Scott Dilley, PharMerica; Tammy Schlensker, PCA Pharmacy; Trish Freeman, UK College of Pharmacy;; John Carver, Baptist Health; John Long, CVS Health; Brian Fingerson, PRNC; Lindsay Villalobos, KSHP; Jody Jagers, KPhA; Carla Berreiro, APSC; Cathy Hanna, APSC; Ralph Bouvette, APSC; Joe Mashni, Medicare and Blake Vogt, CHFS OLS.

MINUTES On motion by Jill Rhodes, seconded by Ron Poole and passed unanimously, the minutes of the December 12, 2018 Board Meeting were approved.

APPEARANCE Maudie Bryant was sworn in by the court reporter, Terri Pelosi. Maudie Bryant appeared before the Board to request reinstatement of her Kentucky pharmacist license. Maudie Bryant gave a brief overview of the events leading to the surrender of her license. Maudie Bryant surrendered her Kentucky pharmacist license June 2016. Maudie Bryant signed a KYPRN agreement on December 12, 2017. She signed an Agreed Order of Surrender with the Kentucky Board of Pharmacy stipulating one year of continuous sobriety and scrupulous compliance with the directives of the KYPRN Monitoring Agreement on May 1, 2018. Her sobriety date is May 13, 2016. Brian Fingerson, chairman of the Kentucky Pharmacy Recovery Network, informed the Board that the committee voted 9-0 in favor of reinstatement.

Peter Cohron moved to reinstate Maudie Bryant's pharmacist's license with stipulations as follows: five years of probation [beginning from date of the President's signature on the Agreed Order of Reinstatement]; perpetual inventory at all places of employment for Schedule II drugs; electronic tracking of Schedule III-V drugs and expired controlled substances; perpetual inventory available; audits; 12 monthly AA/NA meetings; inspections; maximum work hours

with no overtime; copy of Agreed Order to all employers and pharmacists-in-charge; KYPRN; signed release of medical records; monthly report of AA/NA meetings; observed urine, other body fluid, or hair samples for drug/alcohol screens; prohibited from accepting position as pharmacist-in-charge, power of attorney, or preceptor; attendance within 1 year of entry of her Agreed Order at Utah School or CAPTASA; monthly written self-performance evaluations. The specifics of her agreement will be detailed for Maudie Bryant later by Mr. Fingerson. Maudie Bryant stated she understood that any violation of the Agreed Order of Reinstatement shall cause her to automatically lose her license to practice pharmacy for not less than five years and one day and shall require her to petition the Board for reinstatement only after she has taken and successfully passed the entire Kentucky Board of Pharmacy licensure examination. Maudie Bryant shall not seek to amend or modify her Agreed Order. Above information shall be reported to NABP and is subject to disclosure under the Kentucky Open Records Act. President Martin cautioned Maudie Bryant that the Board requires strict compliance with all stipulations. Ron Poole seconded, and the motion passed unanimously. Katie Busroe raised concerns regarding the pharmacy practice site dispensing controlled substances.

INTERAGENCY Mark Glasper, KPhA, updated the Board on the Joint Drug Educational grant. The date of March 30, 2019 has been selected for the first Opioid Summit. The cost for the program will be \$35 pre-registration or \$50 registration at the door. The summit will feature a legislative session led by Representative Danny Bentley. Lindsay Villalobos, KSHP, invited all interested parties to attend the summit.

BOARD REPORTS Larry Hadley presented the eMars reports for December 2018 to the Board.

Larry Hadley informed the Board of the APhA meeting held in Seattle, WA on March 22-25, 2019. In the past, the Executive Director and Board President have attended. Larry Hadley stated that he will be unable to attend this year. President Martin asked the Board Members if anyone would be available to attend. Ron Poole moved to seek approval for President Martin to attend the meeting. Jody Forgy seconded, and the motion passed unanimously.

Larry Hadley informed the Board that Rhonda Hamilton, Pharmacy and Drug Inspector was approved to attend the APhA Institute on Substance Use Disorders held in Salt Lake City, UT on May 28-June 2, 2019. A portion of the cost will be paid by a NABP travel grant.

Larry Hadley stated that he had recently attended the CAPTASA meeting. He urged everyone to attend next year. The meeting was very informative and beneficial to all.

Larry Hadley informed the Board that he and Katie Busroe had met with Steve Davis, OIG on January 29, 2019 to discuss language for 201 KAR 2:370. Steve Davis will be in attendance for the discussion on the proposed regulation.

CURRENT/PENDING CASES Jill Rhodes recused herself from the meeting. Ron Poole moved to accept Case 18-0374.

18-0374. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public with or without established proof of actual injury. Pharmacist allegedly provided inaccurate drug-drug interaction information. Alleged Violation of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

Jody Forgy seconded, and the motion passed unanimously. Jill Rhodes returned to the meeting.

Ron Poole moved to accept the remainder of the Case Review Panel Recommendations for:

18-0131 A Revisit. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to maintain security of prescription records. A patient reported that pharmacy staff lost prescriptions. Alleged Violations of Law: KRS 315.121 (1)(a); 201 KAR 2:100. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0131 B Revisit. Pharmacist-in-charge allegedly failed to maintain security of prescription records. A patient reported that pharmacy staff lost prescriptions. Alleged Violation of Law: 201 KAR 2:205 Section 1. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0131 C Revisit. Pharmacist allegedly engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful. Alleged Violation of Law: KRS 315.121 (2)(j). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

18-0131 D Revisit. Pharmacist allegedly engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful. Alleged Violation of Law: KRS 315.121 (2)(j). **CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.**

18-0359 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 119 dosage units of five controlled substances over a period of 13 months due to employee pilferage. Alleged Violation of Law: 201 KAR 2:100 Section 1. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0359 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 119 dosage units of five controlled substances over a period of 13 months due to employee pilferage. Alleged Violation of Law: 201 KAR 2:205. Section 2. (3)

(b). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

18-0359 C. Registered Pharmacy Technician allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without first receiving a prescription drug order for the drug. Alleged Violation of Law: KRS 315.121 (2) (f). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0372 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by employing a pharmacist who refused to dispense a prescription. Alleged Violation of Law: KRS 315.121 (1) (a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0372 B. Pharmacist-in-charge allegedly engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful. Alleged Violation of Law: KRS 315.121 (2) (j). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0373 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by employing a pharmacist who refused to dispense a prescription. Alleged Violation of Law: KRS 315.121 (1) (a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0373 B. Pharmacist-in-charge allegedly engaged in unprofessional or unethical conduct by failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful. Alleged Violation of Law: KRS 315.121 (2) (j). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0375 A. Pharmacy permit holder allegedly engaged in unprofessional conduct by failing to provide a medication to a patient after billing it to his insurance and charging him the copay. Alleged Violations of Law: KRS 315.121 (1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0375 B. Pharmacist allegedly engaged in unethical or unprofessional conduct likely to deceive, defraud, or harm the public and demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, with or without established proof of actual injury, by failing to dispense a medication to a patient after billing it to his insurance and charging him the copay. Alleged Violations of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0385 A. Pharmacy permit holder allegedly dispensed a medication without proper authorization. Pharmacy allegedly mailed a medication after the prescription had been cancelled, possibly resulting in insurance fraud and wasting healthcare dollars. Alleged Violations of Law: KRS 315.121(1)(a) and (j). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0385 B. Pharmacist-in-charge allegedly dispensed a medication without proper authorization. Pharmacist-in-charge allegedly mailed a medication after the prescription had been cancelled, possibly resulting in insurance fraud and wasting healthcare dollars. Alleged Violations of Law: KRS 315.121(2)(f). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0386 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to dispense a medication in a timely manner. Pharmacy permit holder allegedly engaged in the practice of pharmacy and allowed individuals to assist in the practice of pharmacy in an unlicensed out of state location. Alleged Violations of Law: KRS 315.121(1)(a) and KRS 315.0351 (1). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$5000 administrative fine [unlicensed location], \$1000 administration fine [failing to dispense in a timely manner].**

18-0386 B. Pharmacist in charge allegedly failed in the provision of pharmacy services. Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine.**

18-0388 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct. Alleged Violations of Law: KRS 315.121 (1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0388 B. Pharmacist in Charge allegedly engaged in unprofessional or unethical conduct by dispensing the wrong medication to a patient. Pharmacist allegedly would not dispense Timolol 10 mg tablets. Alleged Violation of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0389 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by engaging in or aiding and abetting an individual to assist in the practice of pharmacy without a license. Alleged Violation of Law: KRS 315.121 (1)(g). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative**

Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, clarify audit trail.

18-0389 B. Pharmacist in charge allegedly engaged in unprofessional or unethical conduct by engaging in or aiding an individual to assist in the practice of pharmacy without a license. Alleged Violation of Law: KRS 315.121 (1)(g). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0391 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to dispense a prescription in a timely manner. Alleged Violations of Law: KRS 315.121 (1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0391 B. Pharmacist in charge allegedly failed in the provision of pharmacy services. Alleged Violations of Law: 201 KAR 2:205 Section 2 (3)(b). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0392 A. Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of three oxycodone/APAP and two oxycodone tablets due to employee pilferage. Alleged Violation of Law: 201 KAR 2:100 Section 1. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0392 B. Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of three oxycodone/APAP and two oxycodone tablets due to employee pilferage. Alleged Violation of Law: 201 KAR 2:205 Section 2 (3)(b). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0392 C. Registered Pharmacy Technician allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without first receiving a prescription drug order for the drug. Alleged Violation of Law: KRS 315.121 (2)(f). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and revocation.**

18-0396 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by aiding and abetting an individual to engage in the practice of pharmacy without a license. Alleged Violation of Law: KRS 315.121 (1)(g). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0396 B. Pharmacist in charge allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public or by engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist with or without established proof of actual injury. Pharmacist in charge allegedly failed to provide adequate supervision of an intern. Alleged Violations of Law: KRS 315.121 (2)(d) and 201 KAR 2:095 Section 3. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0396 C. Pharmacy intern allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to deceive, defraud, or harm the public or by engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacy intern with or without established proof of actual injury. Pharmacy intern allegedly practiced pharmacy without supervision by a pharmacist. Alleged Violations of Law: KRS 315.121 2(d) and 201 KAR 2:095 Section 2. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0397 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by employing a technician that discriminated against a patient due to religious affiliation. Alleged Violation of Law: KRS 315.121 (1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0397 B. Pharmacist in charge allegedly engaged in unprofessional or unethical conduct by allowing a technician to discriminate against a patient due to religious affiliation. Alleged Violation of Law: KRS 315.121 (1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0397 C. Pharmacy technician allegedly engaged in unprofessional or unethical conduct by discriminating against a patient due to religious affiliation. Alleged Violation of Law: KRS 315.121 (1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0403 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to maintain security of prescription records. A patient reported that pharmacy staff lost a written prescription dropped off at the pharmacy. Alleged Violations of Law: KRS 315.121 (1)(a); 201 KAR 2:100. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0403 B. Pharmacist-in-charge allegedly failed to maintain security of prescription records. A patient reported that pharmacy staff lost a written prescription dropped off at the pharmacy. Alleged Violation of Law: 201 KAR 2:205 Section 1. **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0403 C. Pharmacist allegedly engaged in unprofessional or unethical conduct by failing to maintain security of prescription records. A patient reported that pharmacy staff lost a

written prescription dropped off at the pharmacy. Alleged Violation of Law: KRS 315.121 (2)(d). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

18-0405 A. Pharmacy permit holder allegedly sold a misbranded drug due to medication error. Patient allegedly was dispensed a prescription for Lamotrigine that contained Labetalol. Alleged Violations of Law: KRS 217.065 (1). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine.**

18-0405 B. Pharmacist allegedly engaged in unprofessional or unethical conduct by engaging in conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Patient allegedly was dispensed a prescription for Lamotrigine that contained Labetalol. Alleged Violations of Law: KRS 315.121 (2) (d). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine.**

19-0001. Pharmacy intern allegedly violated his Kentucky Pharmacist Recovery Network Agreement (KYPRN) by consuming alcohol. Alleged Violations of Law: KRS 315.121(1)(i) and 201 KAR 2:250 Section 3(2). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and twelve drug screens a year [1 drug screen per month until licensed]. Any violation will result in revocation of intern registration. Must appear before the Board after graduation to request permission to sit for licensure examinations.**

19-0002 A. Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by employing a pharmacist who allegedly failed to perform a prospective drug utilization review on transferred prescriptions. Alleged Violations of Law: KRS 315.121(1)(a). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

19-0002 B. Pharmacist allegedly failed to perform a proper drug utilization review prior to dispensing transferred prescriptions. Alleged Violations of Law: 201 KAR 2:210 Section 4(1). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

19-0002 C. Pharmacy permit holder allegedly allowed unregistered personnel to assist with the practice of pharmacy and allegedly sold a misbranded drug due to a miscount. Alleged

Violations of Law: KRS 315.121(1)(g) and KRS 217.065(1). **CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.**

John Fuller seconded, and the motion passed with one nay vote from Peter C. Cohron.

Jill Rhodes moved to accept the Hearing Officer's Recommended Order, and issue the Final Order for:

18-0123 Special pharmacy permit holder allegedly failed to provide written notification to the Board of Pharmacy 15 days prior to permanent closure. Alleged Violation of Law: 201 KAR 2:106 Section 2 (1)(c). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine. Recommended Order of Default – 12/13/2018; Motion for Default Judgment – 11/28/2018**

18-0286 B Pharmacy technician assisted in the practice of pharmacy without a pharmacy technician registration from 3/31/2018 to 4/4/2018. Alleged Violation of Law: 315.138[g]. **Standard Parameters: 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 administrative fine. Recommended Order of Default – 11/21/2018; Motion for Default Judgment – 11/15/2018**

18-0286 A Finalized 6/26/2018

18-0303 Permit holder allegedly failed to provide written notification to the Kentucky Board of Pharmacy 15 days prior to permanent closure. Alleged Violation of Law: 201 KAR 2:106 Section 2 (1)(c). **CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine.**

Recommended Order of Default – 11/19/2018; Motion for Default Judgment – 10/22/2018

Ron Poole seconded, and the motion passed unanimously.

CORRESPONDENCE

Larry Stovall, Dual PIC Request – Ron Poole moved to deny this request. Peter C. Cohron seconded, and the motion passed with one nay vote from Jill Rhodes.

President Martin recused himself from the meeting. Vice President Poole chaired the meeting in President Martin's absence.

Philip Almeter, UK Healthcare, Offsite Storage Request – Jill Rhodes moved to approve this request stipulating that any future pharmacy permits must seek approval from the Board. John Fuller seconded, and the motion passed unanimously.

President Martin returned and assumed chair of the meeting.

CONTINUING EDUCATION Ron Poole moved to approve 19-01. Peter C. Cohron seconded, and the motion passed unanimously.

OLD BUSINESS

Unused Permits – Katie Busroe presented the information requested at the last meeting on a summary of how other states handle the issue of unused permits. After much discussion, it was determined that a time frame should be established for facilities to be in operation after issuance due to a delay with Medicaid. The proposed time frame was 9 months for a pharmacy permit and 6 months for a wholesale distributor license. Facilities may petition the Board for an extension at that time. Jill Rhodes moved to direct the Advisory Council to evaluate this issue and determine if the council could provide a recommendation to the Board by the July 2019 Board meeting. Ron Poole seconded, and the motion passed unanimously.

GoGoMeds – Katie Busroe presented the information requested at the last meeting on the pharmacy practice at GoGoMeds. Katie Busroe and Paul Daniels, Pharmacy and Drug Inspector, toured the site on December 20, 2018 to review pharmacy practices. They determined that this pharmacy was operating two different business models under one pharmacy permit. After much discussion, Ron Poole moved that this pharmacy practice constituted no violation of the law. John Fuller seconded, and the motion passed unanimously.

NEW BUSINESS

Standard Case Parameters – Katie Busroe requested the Board review standard cases and set parameters for office case management rather than referring them to the Case Review Panel. The proposed standard case and parameters are:

- Closure - \$500 fine on permit holder (pharmacy, wholesaler, manufacturer, med gas)
- Late renewals and continuing to practice - \$500 fine on pharmacist, pharmacy, wholesaler, manufacturer, med gas
- Shipping into Kentucky without a pharmacy permit - \$50 fine/prescription shipped into Kentucky
- Shipping into Kentucky without a wholesaler license - \$500 fine/month or any portion of a month shipped into Kentucky
- Pharmacist violating an Agreed Order that required extra CE - \$1000 fine plus double the CE that was short.

- Failure to name a PIC in 14 days: \$500 fine/month or any portion of a month without a PIC on the permit holder.

Any cases that fall outside of the standard case parameter will be presented to the Case Review Panel. Any standard cases that receive requests or appeals by the respondent will be presented to the Board for their determination.

Peter C. Cohron moved to accept the standard case parameters and allow for office case management. John Fuller seconded, and the motion passed unanimously.

Use of ISMP for Medication Error Prevention – President Martin requested the Board look at the method used for medication errors. Currently those determined to have committed a medication error receive a \$500 administrative fine and must complete an additional 6 hours of continuing education on medication errors and their prevention. Katie Busroe informed the Board that years ago, Melinda Joyce chaired a committee on this issue which resulted in no changes from the Board. President Martin suggested the ISMP Medication Safety Self-Assessment in lieu of the continuing education requirement. Katie Busroe stated that this assessment was a more time intensive, exhaustive and educational approach than continuing education. After much discussion, President Martin offered to work with staff to provide the Board a more detailed proposal. Jill Rhodes moved to direct President Martin and staff to propose language for future medication error cases. Ron Poole seconded, and the motion passed unanimously.

Naloxone Regulation – Larry Hadley informed the Board that he had been approached by various individuals regarding the current naloxone regulation. There is a push for naloxone to be made available over the counter to allow for greater access to the public in light of the current opioid crisis. Blake Vogt, Assistant Counsel, CHFS OLS, reported that nurses are questioning the dispensing without a patient name on the label. Trish Freeman stated that KRS 217.186 specifies that you can dispense to an individual or an agency. It does not allow for the distribution of the medication without a prescription. Jody Jagers, KPhA, informed the Board that many pharmacists are hesitant to dispense naloxone to an agency. He requested the Board to allow pharmacies to hold events to dispense naloxone outside of the permitted pharmacy. Previous opinion from the Kentucky Board of Pharmacy did not allow for dispensing outside of the permitted pharmacy. Trish Freeman requested the Board to revisit this opinion to allow pharmacists to preprint prescription labels, dispense naloxone at a community event and update the prescription label record with the patient's name at a later time. Concerns were raised regarding the training of the individual for the administration of naloxone. Jody Jagers stated that training in the administration of naloxone was included during patient consultation at the naloxone clinics sponsored by KPhA. President Martin proposed tabling this issue until a later date to allow for input and review from the General Counsel.

President Martin recessed the meeting for lunch. The meeting will resume at 1:00 p.m. for a discussion on 201 KAR 2:370 and personal care homes. President Martin reconvened the meeting at 1:00 p.m.

LEGISLATION/REGULATION

201 KAR 2:370 – Pharmacy services in long-term care facility (LTCF)

President Martin reviewed the status of the proposed regulation change for 201 KAR 2:370. Comments were received after the Board’s approval to submit this regulation to LRC. The regulation was withdrawn to address those concerns. He cautioned the audience that only the section regarding personal care homes was up for discussion. After much discussion, Ron Poole moved to accept the following changes from the proposed draft and to direct Larry Hadley to file with LRC:

Amend Section 1 (5) “Long-term care facility” (“LTCF”) is defined by KRS 216.510(1), excluding family-care homes.

Strike Section 1 (5)(a)(b)(c)(d)(e).

Amend Section 2 (1) The pharmacist-in-charge of the dispensing pharmacy shall be responsible for policies and procedures governing the procurement, distribution, storage, security, access, administration, and control of all drugs that are provided to a LTCF, and shall review all policies and procedures at least once every twelve (12) months.

Insert Section 2 (5)(i) An EMK shall not be stocked in a personal care home without personnel lawfully licensed to administer medications.

Amend Section 2 (6)(a) Excluding personal care homes, LTCF drug stock of drugs shall not exceed fifteen (15) individual doses each of 150 non-controlled substances.

Insert Section 2 (b) LTCF drug stock in a personal care home shall not exceed five (5) individual doses each of thirty (30) non-controlled substances.

Amend remaining lines in Section 2 (c)(d)(e)(f)(g) to reflect the insertion of a new line Section 2 (b) as referenced above.

Peter C. Cohron seconded, and the motion passed unanimously.

ADJOURNMENT On motion by Ron Poole, seconded by Peter C. Cohron and passed unanimously, President Martin adjourned the meeting at 2:25 p.m. The next regularly scheduled meeting begins at 9:00 am on March 27, 2019 at the Board Office in Frankfort, Kentucky.

Larry A. Hadley

Executive Director