

**KENTUCKY BOARD OF PHARMACY**

**via Zoom teleconference**

**If a closed session is needed,**

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

<https://us02web.zoom.us/j/86499754695?pwd=Ykc2bDV0QzZ3VVNKSUVZNElydzJSdz09>

**Meeting ID: 864 9975 4695**

**Passcode: 1j8jn4**

**+1 312 626 6799 US (Chicago)**

**+1 646 558 8656 US (New York)**

**Meeting ID: 864 9975 4695**

**Passcode: 423126**

**July 29, 2020**

**9:00 a.m.**

**Board Meeting**

**Agenda**

**I. CALL TO ORDER**

**II. MINUTES**

- A. \*May 27, 2020

**III. APPEARANCE**

- A. \*Paul Mahan – Adoption of <USP> 825
- B. \*Abigail Barnes
- C. \*Blue RX – Resident pharmacy application

**IV. BOARD REPORTS**

- A. Executive Director
  - 1. \*eMars – May 2020, June 2020 and FY20 end of year
  - 2. \*COVID-19 directives
- B. General Counsel
  - 1. \*Diversity Training for staff
  - 2. \*Discuss measures KYBOP may implement to improve diversity and inclusion in pharmacy profession.
- C. Inspection Staff
  - 1. \*Non-resident pharmacy permit questions
  - 2. \*Decentralized pharmacies
  - 3. \*Supplemental Forms
    - (a) DEA Supplemental Form
    - (b) Dual PIC Request supplemental form
    - (c) Off-site storage supplemental form
  - 4. \*Dual PIC Requests cleanup
- D. Committee Reports
  - 1. \*Advisory Council - Minutes
    - (a) \*Child Fatality and Near Fatality Panel – Request for enhance safety packaging [blister packs]
    - (b) \*Education information on accidental ingestion of drugs by children

2. \*Regulation Committee – Minutes

**V. CASES**

- A. \*Case Review
- B. \*Fines Report
- C. Updates to Case Processing:
  - 1. Standardization of Fines
  - 2. Case Review Panel rework

**VI. PENDING APPLICATIONS**

- A. \*Long Prairie Pharmacy – Non-resident pharmacy application
- B. \*Vitacare – Non-resident pharmacy application
- C. \*TN Health and Wellness – Non-resident pharmacy application

**VII. CORRESPONDENCE**

- A. \*Dual PIC Requests – Rebecca Cheek:
  - 1. P07856 – CP00129, Jake Williams
  - 2. P08030 – CP00128, Steven Wagers
  - 3. P08098 - TBD, Casey Whittaker
- B. \*Dual Pharmacy space – P07730 and TBD – Philip Almeter
- C. \*Dual PIC Request – Ryan Howard
- D. \*UK Records Offsite Storage Request – P01621, P07583. P07556, P07636 and P07686
- E. \*HDM Pharmacy LLC – Offsite Storage Request P06294
- F. \*Clinic Pharmacy – P06700 – Offsite Storage Request
- G. \*Chewy Pharmacy –P08055 – Offsite Storage Request
- H. \*Chewy Pharmacy – P07685 – Offsite Storage Request

**VIII. LEGISLATION/REGULATION**

- A. \*Telehealth for the provision of pharmacy services – Regulation Draft
  - 1. \*Cardinal Health
  - 2. \*KPhA
  - 3. \*KIPA
  - 4. \*Philip Almeter – UK
  - 5. \*Chris Killmeier/Matt Martin
  - 6. \*Board Members
- B. \*201 KAR 2:270, Expungement
  - 1. \*Comment
- C. \*201 KAR 2:311, Compounding for veterinary use.
  - 1. \*Comment

**IX. NEW BUSINESS**

- A. Protocols
  - 1. \*Nutritional Supplementation Protocol
  - 2. \*Flu/Strep Protocol – Dan Grantz and Diana Klunk

(a) \*Acute Group A Streptococcal Pharyngitis Infection Protocol

(b) \*Acute Influenza Infection Antiviral Therapy Protocol

- B. \*FDA Memorandum of Understanding
- C. \*Medication Error Program
- D. \*Composition of Ad Hoc and standing Committees
- E. Implementation of new regulation and statutes regarding the practice of pharmacy
- F. \*Transfer Incentives
- G. \*Classification of Pharmacist

\*Information included in Board Packet

## MINUTES

### KENTUCKY BOARD OF PHARMACY

held at

125 Holmes Street

Frankfort KY 40601

via teleconference

### BOARD MEETING

July 29, 2020

**CALL TO ORDER** A regularly scheduled meeting was held via teleconference from the Kentucky Board of Pharmacy, Frankfort, Kentucky. President Poole called the meeting to order on July 29, 2020 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; Anthony Gray, General Counsel; John Romines, Pharmacy and Drug Inspector; Rhonda Hamilton, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector, Amanda Harding, Pharmacy and Drug Inspector; Katie Busroe, Pharmacy Inspections and Investigations Supervisor and Darla Sayre, Executive Staff Advisor.

Guests: Michelle Shane, KVM.

**MINUTES** On motion by Craig Martin, seconded by Peter Cohron and passed unanimously, the minutes of the May 27, 2020 Board Meeting were approved.

### APPEARANCES

**Paul Mahan – Adoption of <USP> 825** Mr. Mahan appeared before the Board to request early adoption of <USP> 825. After discussion, the Board took no action on this request.

**Abigail Barnes – Reinstatement of Licensure** Ms. Barnes appeared before the Board requesting reinstatement of her pharmacist license. At the request of Ron Poole, Ms. Barnes gave a summary of her addiction and recovery. Brian Fingerson, chair of the Kentucky Professionals Recovery Network informed the Board the committee voted 9-1 in favor of reinstatement at its July 21, 2020 meeting. Peter Cohron moved to approve the reinstatement under the standard restrictions; five year probation, inventory of controlled substances, attendance of 12 AA/NA meetings per calendar month [documentation provided to the Board monthly], quarterly inspections for two years then semi-annual inspections for three years, to be paid by Ms. Barnes, not to exceed \$500 and strict compliance to her KYPRN agreement. John Fuller seconded, and the motion passed unanimously.

**Blue RX – Resident Pharmacy Application** Craig Martin moved to deny the application due to no pharmacist in charge. The pharmacist named on the application appeared before the Board and stated she was no longer employed with the company. Peter Cohron seconded, and the

motion passed unanimously. The Board will reconsider the application once pharmacist in charge notification is received.

**BOARD REPORTS** Mr. Hadley requested the Board consider revising the directives approved at the Special Called Board meeting on March 25, 2020. He recommended deleting the first directive placing restrictions on the dispensing of chloroquine, hydroxychloroquine, mefloquine, and azithromycin. The demand for these drugs has dropped significantly. The remaining directives will be retained. Craig Martin moved to accept this recommendation. Peter Cohron seconded, and the motion passed unanimously.

**GENERAL COUNSEL** In light of recent national events transpiring over that past few months, Katie Busroe, Larry Hadley and Anthony Gray discussed diversity and inclusion in the pharmacy profession. To address this issue from a staff perspective, all staff have completed two online training courses provided through the Personnel Cabinet; Creating a Working Environment Based on Respect and Diversity Made Simple. Staff are encouraged to take additional courses as their work schedule permits.

To address this issue from a broader perspective of the pharmacy profession, we propose creating the Kentucky Board of Pharmacy Diversity and Inclusion Task Force. This task force may be an ad hoc committee comprised of six to eight members. Members should include a student representative from the University of Kentucky College of Pharmacy and Sullivan University College of Pharmacy. The goals for this task force are:

- Gather/evaluate/collect data to determine need for strategic plan to address diversity and inclusion in the Kentucky pharmacy community.
- Develop a clear cultural competency plan that addresses diversity and inclusion in the Kentucky pharmacy community.
- Implement ways to spearhead access to pharmacy services to reach those in underrepresented/underserved demographics.
- Provide diversity and cultural competency trainings (CE) pharmacists/technicians and encourage various pharmacy organizations to provide the same courses to members.
- Work with Colleges of Pharmacy to continue to recruit and retain diverse student body.

Ron Poole proposed the task force be a standing committee rather than an ad hoc committee. Jill Rhodes fully supports the creation of this committee. She proposes modifying bullet point three to read:

- Implement ways to spearhead access to pharmacy services to reach those in underrepresented/underserved demographics by evaluating the disparity amongst rural and urban populations.

Jill Rhodes proposed adding the following:

- Determine methods to engage women and minorities in leadership and professional advocacy activities.

Craig Martin proposed modifying bullet point five to read:

- Work with Colleges of Pharmacy to continue to recruit and retain a more diverse student body and the pool of pharmacists serving as preceptors.

Peter Cohron moved to approve the creation of a standing Diversity and Inclusion Committee of the Kentucky Board of Pharmacy. Craig Martin seconded, and the motion passed unanimously.

**INSPECTION STAFF** Katie Busroe presented the following issues identified by inspection staff for clarification or approval by the Board.

1. Non-resident pharmacy permit questions
2. Decentralized pharmacies

After discussion, Jill Rhodes moved to direct the Regulation Committee to review these issues and provide recommendations to the Board for regulation amendments or implementing Board policy.

Katie Busroe informed the Board that one of the tasks completed by the inspection staff during the COVID travel restrictions was to identify all pharmacists serving as PIC for multiple permits and document Board approval. Three instances were located where Board approval could not be verified. Inspection staff requests the following be approved:

1. P02544 and P05082, Tonya Westmoreland
2. P05117 and P06472, Margo Ashby
3. P05064 and P06410, Andrew S. Weaver, Jr.

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

Katie Busroe requested the Board allow the inspectors to use the proposed supplemental forms for DEA Form 106, Dual PIC requests and offsite storage requests. These forms will be made available to permit holders and licensees for voluntary use only. Jill Rhodes moved to approve this request. Jody Forgy seconded, and the motion passed unanimously.

**COMMITTEE REPORTS** The approved minutes of the Advisory Council dated June 11, 2020 and the Regulation Committee dated May 8, 2020 were provided to the Board. Anthony Gray informed the Board of the recommendation from the June 18, 2020 meeting of the Advisory Council regarding Child Fatalities and Near Fatalities. The council recommended:

1. Publish an article in the quarterly BOP newsletter pertaining to medication storage recommendations, risks of accidental ingestion of medications, dispensing container options, and results in the 2019 Annual Report.
2. Concentrated education effort by Board staff, to include but not be limited to, continuing education programs and emphasis during inspections.
3. Submit a letter to the FDA requesting a requirement of child-resistant safety packaging for medications identified in accidental ingestion resulting in child fatality or hospitalization.
4. Recommend the Board promote professional organizations, colleges of pharmacy and continuing education providers to develop and provide programs on accidental ingestion resulting in child fatalities within one year.

Inspection staff provided an informational bulletin that can be provided to pharmacies during inspection. Craig Martin moved to approve recommendations 1, 2 and 4. Peter Cohron seconded, and the motion passed unanimously.

Jill Rhodes moved to approve recommendation 3 and direct the Board President and Executive Director approve the letter prior to submission. John Fuller seconded, and the motion passed unanimously.

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

**Case 17-446 A Revisit.** Pharmacy permit holder allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 449 Codeine Phosphate 30 mg tablets, 63 Alprazolam 0.25 mg tablets, 439 Alprazolam 0.5 mg tablets, 3272 Alprazolam 1 mg tablets, 757 Diazepam 10 mg tablets, 5 Diazepam 2 mg tablets, 15 Diazepam 5 mg tablets, 34 Lorazepam 0.5 mg tablets, 91 Lorazepam 1 mg tablets, 4 temazepam 15 mg capsules, 26 temazepam 30 mg capsules, 138 tramadol 50 mg tablets, and 219 Zolpidem 10 mg tablets over a period of 378 days. Alleged Violation of Law: 201 KAR 2:100 Section. **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 17-446 B Revisit.** Pharmacist in charge allegedly failed to provide adequate security and control of drugs. Pharmacy reported a loss of 449 Codeine Phosphate 30 mg tablets, 63 Alprazolam 0.25 mg tablets, 439 Alprazolam 0.5 mg tablets, 3272 Alprazolam 1 mg tablets, 757 Diazepam 10 mg tablets, 5 Diazepam 2 mg tablets, 15 Diazepam 5 mg tablets, 34 Lorazepam 0.5 mg tablets, 91 Lorazepam 1 mg tablets, 4 temazepam 15 mg capsules, 26 temazepam 30 mg capsules, 138 tramadol 50 mg tablets, and 219 Zolpidem 10 mg tablets over a period of 378 days. Pharmacist also allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering drugs for which prescription drug orders are required, without first receiving prescription drug orders for the drugs. Pharmacist allegedly engaged in unprofessional or unethical conduct by knowing or having reason to know that pharmacy technicians had engaged in or aided and abetted the unlawful distribution of legend medications, and failing to report any relevant information to the Board. Alleged Violations of Law: 201 KAR 2:205 Section 2(3)(b), KRS 315.121(2)(f), and KRS 315.121(1)(j). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$5000 administrative fine, suspension for five years and one day. CRP vote was unanimous.**

**Case 17-446 C Revisit.** Pharmacist allegedly engaged in unprofessional or unethical conduct by knowing or having reason to know that a pharmacy technician had engaged in or aided and abetted the unlawful distribution of legend medications, and failing to report any relevant information to the Board. Alleged Violation of Law: KRS 315.121(1)(j). **CRP Recommendation:**

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

**Case 17-446 E Revisit.** Registered pharmacy technician allegedly engaged in unprofessional or unethical conduct by selling, transferring, dispensing, ingesting, or administering drugs for which a prescription drug orders are required, without first receiving prescription drug orders for the drugs. Alleged Violation of Law: KRS 315.121(2)(f). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and status of 'Do Not Renew' CRP vote was unanimous.**

**Case 17-446 G Revisit.** 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). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and status of 'Do Not Renew' CRP vote was unanimous.**

**Case 17-446 H Revisit.** 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). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and revocation. CRP vote was unanimous.**

**CASE 19-0259 A Revisit:** Owner would like to assume liability for PIC. **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$1000 administrative fine. CRP vote was unanimous.**

**CASE 19-0259 B Revisit:** Owner would like to assume liability for PIC. **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**CASE 19-0314 B Revisit:**In order to be consistent with similar cases, a \$500 administrative fine should be added to the required continuing education. **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is**



directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 3 hours of continuing education on medication errors and their prevention, additional 3 hours of continuing education on pharmacy law. CRP vote was unanimous.

**CASE 19-0325 C Revisit:** In order to be consistent with similar cases, a \$500 administrative fine should be added to the required continuing education. **CRP Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 3 hours of continuing education on medication errors and their prevention, additional 3 hours of continuing education on pharmacy law. CRP vote was unanimous.

**Case 20-0004 A.** Pharmacy permit holder allegedly sold a misbranded drug due to a medication error. Patient was prescribed compounded progesterone 100mg vaginal suppositories but allegedly received compounded hydrocortisone/lidocaine rectal suppositories. Alleged Violation of Law: KRS 217.065(1). **CRP Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and completion of root cause analysis with ISMP's workbook within three months, follow up inspection within six months to be paid by respondent [\$500 maximum]. CRP vote was unanimous.

**Case 20-0004 B.** Pharmacist allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Patient was prescribed compounded progesterone 100mg vaginal suppositories but allegedly received compounded hydrocortisone/lidocaine rectal suppositories. Alleged Violation of Law: KRS 315.121(2)(d). **CRP Recommendation:** There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$500 administrative fine, additional 6 hours of continuing education on medication errors and their prevention. CRP vote was unanimous.

**Case 20-0026 A.** Pharmacy permit holder allegedly employed a pharmacist that showed unprofessional or unethical conduct by violating patient confidentiality. Pharmacist allegedly transferred prescriptions to another pharmacy without a patient's permission. Alleged Violation of Law: KRS 315.121(1)(a). **CRP Recommendation:** There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.

**Case 20-0026 B.** Pharmacist allegedly engaged in unprofessional or unethical conduct by violating patient confidentiality. Pharmacist allegedly transferred prescriptions to another pharmacy without a patient's permission. Alleged Violation of Law: KRS 315.121(2)(b). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 20-0046 A.** Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by refusing to fill a patient's prescription for hydrocodone/apap after the patient was released from the hospital. Alleged Violation of Law: KRS 315.121(1)(a). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 20-0046 B.** Pharmacist allegedly engaged in unprofessional or unethical conduct with or without established proof of actual injury by refusing to fill a patient's prescription for hydrocodone/apap after the patient was released from the hospital. Alleged Violation of Law: KRS 315.121(2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 20-0061 A.** Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to dispense a medication in a timely manner. Alleged Violation of Law: KRS 315.121(1)(a). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 20-0061 B.** Pharmacist in charge (PIC) allegedly failed to implement quality assurance program. Alleged Violation of Law: 201 KAR 2:210 Section 2(3)(a). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 20-0062 A.** Pharmacy permit holder allegedly sold a misbranded drug due to a medication error. Patient was prescribed 25ml of prednisolone oral solution but allegedly received a prescription vial containing 15ml and no vial insert for use with an oral syringe. A different patient allegedly received an inappropriate dosage form of medication prescribed. Alleged Violations of Law: KRS 217.065(1) and KRS 315.121(1)(a). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 20-0062 B.** Pharmacist allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Patient was prescribed 25ml of prednisolone oral solution but pharmacist allegedly dispensed a prescription vial containing 15ml without a vial insert for use with an oral syringe and allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by dispensing capsules instead of liquid dosage form to a patient unable to swallow capsules. Alleged Violation of

Law: KRS 315.121(2)(d). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 20-0086 A.** Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by failing to sell a prescription in a timely manner. Alleged Violation of Law: KRS 315.121(1)(a). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 20-0086 B.** Pharmacist in charge (PIC) allegedly failed in the provision of pharmacy services. PIC did not timely order schedule II controlled substances. Alleged Violation of Law: 201 KAR 2:205 Section 2(3)(b). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 20-0087 A.** Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by delaying the provision of pharmacy services. Patient allegedly did not receive insulin when promised. Alleged Violation of Law: KRS 315.121(1)(a). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 20-0087 B.** Pharmacist in charge (PIC) allegedly failed in the provision of pharmacy services. Alleged Violation of Law: 201 KAR 2:205 Section 2(3)(b). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 20-0087 C.** Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by delaying the provision of pharmacy services. Patient allegedly did not receive insulin when promised. Alleged Violation of Law: KRS 315.121(1)(a). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 20-0087 D.** Pharmacist in charge (PIC) allegedly failed in the provision of pharmacy services and allegedly failed to provide adequate supervision. Alleged Violations of Law: 201 KAR 2:205 Section 2 (3)(b) and KRS 315.121(1)(a). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 20-0090 A.** Pharmacy permit holder allegedly engaged in unprofessional or unethical conduct by allowing a pharmacy technician to assist in the practice of pharmacy without pharmacist supervision. Alleged Violations of Law: KRS 315.121(1)(a) and KRS 315.020(4)(b). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or**

**the issuance of a Formal Complaint and Notice of Hearing. Standard terms and \$5000 administrative fine, approved corrective action plan to include a review of the job duties of the consumer medication coordinator; removing duties that assist in the practice of pharmacy or require pharmacist supervision for those duties. CRP vote was unanimous.**

**Case 20-0090 B.** Registered pharmacy technician allegedly engaged in unprofessional or unethical conduct by 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 and allegedly engaged in unprofessional or unethical conduct by ingesting a drug for which a prescription drug order is required without having first received a prescription drug order for the drug. Alleged Violations of Law: KRS 315.121(2)(b) and KRS 315.121(2)(f). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and revocation. CRP vote was unanimous.**

**Case 20-0093 A.** Pharmacy permit holder allegedly sold a misbranded drug due to a medication error. Patient was prescribed buprenorphine/naloxone 2mg/0.5mg tablets but allegedly received buprenorphine/naloxone 8mg/2mg on two separate occasions. Alleged Violation of Law: KRS 217.065(1). **CRP Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice. CRP vote was unanimous.**

**Case 20-0093 B.** Pharmacist allegedly engaged in unprofessional or unethical conduct likely to harm the public with or without established proof of actual injury by committing a medication error. Patient was prescribed buprenorphine/naloxone 2mg/0.5mg tablets but allegedly received buprenorphine/naloxone 8mg/2mg on two separate occasions; allegedly failed to perform an appropriate drug utilization review prior to dispensing. Patient was consistently prescribed a daily maintenance dose of buprenorphine/naloxone 2mg/0.5mg approximately every 2 weeks but pharmacist allegedly dispensed buprenorphine/naloxone 8mg/2mg tablets in error on two separate occasions over the course of 5 months; and allegedly failed to provide appropriate supervision of professional acts performed by pharmacist intern. Pharmacist allegedly dispensed the wrong strength of medication pursuant to a verbal prescription received and transcribed by a fourth-year pharmacist intern. Alleged Violations of Law: KRS 315.121(2)(d); 201 KAR 2:210 Section 4; and 201 KAR 2:095 Section 3. **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and administrative fine of \$1000, and additional hours of continuing education; 6 hours on medication errors and their prevention and 6 hours of continuing education on pharmacy law. CRP vote was unanimous.**

**Case 20-0095 A.** Pharmacy permit holder allegedly sold a misbranded drug due to medication error. Patient allegedly was dispensed a prescription for Escitalopram 10 mg that contained Atorvastatin 10 mg. Alleged Violation of Law: KRS 217.065(1). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and completion of root cause analysis using ISMP's workbook within three months, follow up inspection within six months to be paid by respondent [\$500 maximum]. CRP vote was unanimous.**

**Case 20-0095 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 Escitalopram 10 mg that contained Atorvastatin 10 mg. Alleged Violation of Law: KRS 315.121(2)(d). **CRP Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and/or, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing. Standard terms and administrative fine of \$1000, and additional hours of continuing education; 12 hours on medication errors and their prevention. CRP vote was unanimous.**

Jill Rhodes seconded, and the motion passed with Peter Cohron voting no on Case 20-0004 A, Case 20-0004 B, Case 20-0093 B and Case 20-0095.

Ron Poole questioned the Board if a written document for the standardization of fines be beneficial in approving the CRP recommendations. There is a standardization of fines currently in use based on case precedent but it is not a written document. Jody Forgy moved to have Anthony Gray draft the document and present to the Board at the next meeting. The Case Review Panel will review the document prior to the meeting. Craig Martin seconded, and the motion passed unanimously.

Ron Poole informed the Board of the results from a survey sent to all state boards of pharmacy requesting information regarding disciplinary case review specifically in regards to voting members for case recommendations. Katie Busroe stated that the disciplinary regulation is under review by the Regulation Committee. The inspection staff has requested the regulation be amended to eliminate the inspector's vote. Jill Rhodes moved to direct the Regulation Committee to review the data results from the survey and other formats to remove the required vote from the inspector. Peter Cohron seconded, and the motion passed unanimously.

## **PENDING APPLICATIONS**

Craig Martin moved to approve the non-resident pharmacy application submitted by Long Prairie Pharmacy. Jody Forgy seconded, and the motion passed with one nay vote from Jill Rhodes.

Craig Martin moved to approve the non-resident pharmacy application submitted by vitaCare Prescription Services, Inc. and accept LegitScript as an accreditation for an internet pharmacy. John Fuller seconded, and the motion passed unanimously.

Jill Rhodes moved to approve the non-resident pharmacy application submitted by TN Health and Wellness with a signed Agreed Order mirroring the restrictions from Tennessee. Peter Cohron seconded, and the motion passed unanimously.

## **CORRESPONDENCE**

**Bishop Street Pharmacy, P07856/CP00129 – Jake Williams, Grace Health Pharmacy – Manchester, P08030/CP00128 – Steven Wagers, Grace Health Pharmacy – Mountain View, P08098/TBD – Casey Whitaker Dual PIC Requests** Craig Martin moved to approve these requests. John Fuller seconded, and the motion passed unanimously.

Craig Martin recused himself and was placed in a virtual waiting room.

**P07730/P08138 Shared Pharmacy Space** – Peter Cohron moved to approve this request. Jill Rhodes seconded, and the motion passed unanimously.

**UK Offsite Storage Request, P01621, P07583, P07556, P07636 and P07686** – Jill Rhodes moved to approve this request. John Fuller seconded, and the motion passed unanimously.

Craig Martin returned to the meeting.

**P08032/P08033 – Ryan Howard Dual PIC Requests** John Fuller moved to approve this request. Peter Cohron seconded, and the motion passed unanimously.

**HDM Pharmacy LLC, P06294 Offsite Storage Request** Craig Martin moved to approve this request. John Fuller seconded, and the motion passed unanimously.

Craig Martin recused himself and was placed in a waiting room.

**Clinic Pharmacy, P06700 Offsite Storage Request** Peter Cohron moved to approve this request. John Fuller seconded, and the motion passed unanimously.

Craig Martin returned to the meeting.

**Chewy Pharmacy, P08055 and P07685 Offsite Storage Request** Craig Martin moved to approve this request with a clarification regarding access to records allowing for licensed or registered individuals. Jill Rhodes seconded, and the motion passed unanimously.

## **LEGISLATION/REGULATION**

**Telehealth for the provision of pharmacy** The Board reviewed the proposed regulation provided by the Advisory Council. The following individuals appeared before the Board to comment.

- Adam Chesler, Cardinal Health
- Mark Glasper, KPhA
- Philip Almeter, UK
- Chris Killmeier
- Rosemary Smith, KIPA
- Matt Martin, Chairperson of the Advisory Council

Board members were allowed to comment on the proposed regulation. Peter Cohron moved to forego any implementation of telehealth regulation. Jill Rhodes seconded, and the motion passed unanimously.

**201 KAR 2:270, Expungement.** Larry Hadley informed the Board that comments received regarding this regulation amendment had not previously been presented to the Board. Peter Cohron moved to direct the Regulation Committee to review the comments and insert them into the regulation. Craig Martin seconded, and the motion passed unanimously.

**201 KAR 2:311, Compounding for veterinary use.** Aaron Lopez appeared before the Board requesting the Board review the language for clarification. After discussion, Larry Hadley informed the Board this regulation will be returned to the Board after review and consideration.

## **NEW BUSINESS**

**Nutritional Supplementation Protocol** Jill Rhodes moved to approve this protocol. Craig Martin seconded, and the motion passed unanimously.

**Acute Group A Streptococcal Pharyngitis Infection Protocol and Acute Influenza Infection Antiviral Therapy Protocol** Peter Cohron moved to approve the revision of these protocols to testing with a CLIA waived real-time PCR test. John Fuller seconded, and the motion passed unanimously.

**FDA Memorandum of Understanding** Larry Hadley presented the FDA MOU. The language is final but there is no need to take action at this time.

**Medication Error Program** Jill Rhodes proposed the creation of an ad hoc Medication Safety Committee comprised of pharmacists with expertise in medication safety to advise the board on medication error matters that include:

1. Considering application of a tool to assign harm level for medication errors that occur and are investigated by the board  
(<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6647434/#!po=40.9091> )

2. Categorize the types of errors that occur and develop a standardized remediation plan/assignment for the board to employ with a disciplinary action for a medication error
3. Provide an opinion on the disciplinary action recommended for first time medication error offense that causes no harm v. medication errors that cause harm
  - Informal discipline
  - Letter of reprimand
  - Unethical/unprofessional conduct
  - One of the above PLUS remediation plan
  - Other
4. Consider the idea of developing a repository database for Kentucky pharmacists to safely and anonymously report medication errors and concerns for patient welfare (no specific pharmacies or pharmacists would be reported – data collected would be categorized to type of practice setting, etc.)
  - For med error review and discussion by the ad hoc committee to identify patterns of concern for our state and recommend corresponding corrective action plans / remediation support for the board to consider for the profession
  - Partner with an expert organization for a state pilot? (ex. ISMP)
  - Note: There are already programs available for reporting <https://www.ismp.org/report-medication-error> ) and internal QA programs pharmacies have developed. This is not intended to supplant those programs or interfere. This is proposed as an idea to specifically look at our state’s individual medication error profile and address the needs, if identified, in our state to support the profession and optimize the safety and welfare of our Commonwealth. It may also provide a safe venue for pharmacists to report errors that they feel otherwise uncomfortable with reporting and feel safety concerns exist without subjecting themselves to potential disciplinary action in the process.

John Fuller requested tabling this proposal until the next Board meeting to allow for further review.

**Composition of Ad Hoc and Standing Committees [pertaining to writing regulations]** In order to be respectful of pharmacists donating their time and money to serve on a committee, when a committee is formed, it will be composed of practicing pharmacists or experienced pharmacists in that topic discipline without a conflict of interest. Board Members may be appointed to serve on these committees; however, the committees will not be composed of Kentucky Board of Pharmacy employees in order for the committee to concentrate on the main topic at hand. Certainly, the chair of the committee may ask a Kentucky Board of Pharmacy employee to assist in any manner necessary when needed. If a regulation is to be submitted to the Kentucky Board of Pharmacy, the committee will first submit their document to the sitting Regulation Committee where this committee will review it for its legal ramifications and wording. During this legal review by the sitting Regulation Committee, any employee of the Board of Pharmacy can also submit comments to the Regulation Committee for consideration



concerning the document. The Regulation Committee will then return its recommendations to the ad hoc Committee. The ad hoc Committee will then consider each recommendation for completion of the document to be submitted to the Board. This should allow for a more expedited procedure for submitting documents for Board review and approval. Craig Martin moved to approve this recommendation and establish it as Board Policy. Jill Rhodes seconded, and the motion passed unanimously.

**Implementation of new regulations or statutes regarding the practice of pharmacy** When new regulations or statutes are passed in the General Assembly including those by other agencies that effect the practice of pharmacy, the General Counsel will give a presentation to the Board. The presentation will include a summary of the regulation or statute, interpretation of the regulation or statute from the submitting governing agency, staff input on implementation and the unintended consequences in pharmacy resulting in the inability to take care of patients. The Board will then properly vet and take action on how the new regulations or statutes will be implemented before inspection staff educates pharmacists during inspections, Board newsletter or continuing education. Jill Rhodes moved to establish as Board Policy that new changes to the practice of pharmacy from regulations and statutes be presented to the Board by the General Counsel for review. Peter Cohron seconded, and the motion passed unanimously.

**Transfer Incentives** Larry Hadley presented proposed language to amend 201 KAR 2:165, Transfer of Prescription Information. This amendment would prohibit a pharmacist from using incentives to induce the transfer of a prescription absent the exercise of professional judgment in accordance with KRS 315.202 (1). Craig Martin addressed a concern regarding restriction of a pharmacy promoting their business. Peter Cohron moved to forego implementation for a review from other entities and language revisions to address Dr. Martin's concerns. Craig Martin seconded, and the motion passed unanimously.

**Classification of Pharmacist** Ron Poole proposed the establishment of a list to designate the classification of a pharmacist. This classification would be stored in the Kentucky Board of Pharmacy database. The information will be gathered during annual renewal and updated outside of the renewal period with a form submitted to the Board office. Pharmacists will choose one or multiple from the following:

- Chain Community
- Independent Community
- Hospital
- Consultant - LTC
- Consultant – Business/Legal
- Managed Care
- Industry
- Academia
- Online/Mail Order
- Compounding Only

- Nuclear
- Other \_\_\_\_\_

Peter Cohron moved to approve this recommendation. Craig Martin seconded, and the motion passed unanimously.

**Closed Session** Peter Cohron moved to go into closed session pursuant to KRS 61.810 (1)(f) for discussions or hearings which might lead to the appointment, discipline, or dismissal of an individual employee, member, or student without restricting that employee's, member's, or student's right to a public hearing if requested. This exception shall not be interpreted to permit discussion of general personnel matters in secret. Craig Martin seconded, and the motion passed unanimously. Peter Cohron moved to come out of closed session. Craig Martin seconded, and the motion passed unanimously.

**ADJOURNMENT** On motion by Jill Rhodes, seconded by Craig Martin and passed unanimously, President Poole adjourned the meeting at 2:34 p.m. The next regularly scheduled meeting begins at 9:00 am on September 30, 2020 at the Kentucky Board of Pharmacy in Frankfort, KY or via teleconference.

Larry A. Hadley  
Executive Director