KENTUCKY BOARD OF PHARMACY

via Zoom

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Meeting ID: 862 0399 3121 Passcode: VRhB8R Dial by your location +1 312 626 6799 US (Chicago) +1 646 558 8656 US (New York) Meeting ID: 862 0399 3121 Passcode: 742953

September 28, 2021 9:00 a.m. AGENDA

I. CALL TO ORDER

II. MINUTES

A. August 31, 2021

III. PUBLIC HEARING

A. 201 KAR 2:411E

IV. APPEARANCES

- A. Robert Cruse Petition for Reinstatement
- B. Lindsey Collett Petition for Reciprocate License to Iowa
- C. CVS Verification Process
- D. Kentucky Pharmacists Association, Jody Jaggers Surety bond requirement exemption

V. INTERAGENCY

VI. BOARD REPORTS

- A. Executive Director
 - Update on new Staff Attorney and Administrative Assistant Board & Commissions
- B. General Counsel
 - 1. Executed FDA MOU

VII. COMMITTEE REPORTS

- A. Kentucky Professional Recovery Committee, Brian Fingerson
 - 1. Response to intern proposal
- B. Advisory Council, Matt Martin
 - 1. Review of June recommendations
- C. Regulation Committee, Ralph Bouvette

- D. Pharmacy Technician Committee, David Figg
- E. Diversity and Inclusion Task Force, Shannon Borden and Crystal Isaacs
- F. Medication Safety Committee, Elizabeth Hess
- G. Case Review Panel, Jill Rhodes

VIII. LEGISLATION/REGULATION

A. Updated Regulation Status

IX. CORRESPONDENCE

- A. P07141 and P07648 Dual PIC Request
- B. Kroger Health Connect, OH1765 Clarification on the impact of HB 219, as it pertains to remote work.

X. OLD BUSINESS

- A. Policy and Procedures Review
- B. Department of Insurance Grievances

XI. NEW BUSINESS

- A. MPJE Item Writing Committee Board to select one practicing pharmacist from applicants, one Board member and one staff member currently serving in that capacity. Practicing pharmacist applicants:
 - 1. Kim Croley
 - 2. Krystal Flaherty
 - 3. Ross Goetz
 - 4. Sophie Willis McHardy
- B. Protocols
 - 1. Colorectal Cancer [CRC] Screening Protocol
 - 2. Protocol to Initiate Dispensing of Naloxone for Opioid Overdose Prevention and Response

XII. CLOSED SESSION

A. 21-0012 C

ATTENTION: A portion of the meeting may be held in closed/executive session for the purpose of (1) deliberating as a judicial or quasi-judicial body regarding the final adjudication of the Board's pending cases; (2) 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; and (3) 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. 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)(f)KRS 61.810(1)(k). Following discussion and deliberation, any and all action will be taken in open/public session.

MINUTES

KENTUCKY BOARD OF PHARMACY held at 125 Holmes Street Frankfort KY 40601 via teleconference

BOARD MEETING

September 28, 2021

CALL TO ORDER A regularly scheduled meeting was held via teleconference from the Kentucky Board of Pharmacy, Frankfort, Kentucky. President Rhodes called the meeting to order on September 28, 2021 at 9:01 a.m.

Members: Jill Rhodes; Peter Cohron; Jonathan Van Lahr; John Fuller and Chris Harlow. Absent: Jody Forgy.

Staff: 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.

MINUTES Jonathan Van Lahr moved to accept the minutes from the August 31, 2021 meeting. John Fuller seconded, and the motion passed unanimously.

PUBLIC HEARING The Board received no comments or requests to speak on 201 KAR 2:411E. The public hearing for this regulation was canceled.

APPEARANCES

Robert Cruse Robert Cruse appeared before the Board requesting reinstatement of his pharmacist license. His Kentucky pharmacist licensed was revoked on February 2, 2018 due to Case Number 17-0297 A and B. He informed the Board that he is retired and would like to do relief work.

Action: Chris Harlow moved to approve this request with the following terms: no ownership in a pharmacy, cannot be pharmacist in charge of a pharmacy; cannot be a preceptor; must retake the MPJE and complete 60 hours of continuing education. Peter Cohron seconded. After discussion, Chris Harlow amended his motion removing the requirement to retake the MPJE and amending the 60 hours of continuing education to include at least 15 hours on pharmacy law. The amended motion passed unanimously.

Lindsey Collett Lindsey Collett appeared before the Board requesting to amend her Agreed Order of Reinstatement with Restrictions, 12-0174 removing the restriction of reciprocating her license. Ms. Collett stated that her circumstances have changed, and she has moved to Iowa. She would like to apply for reciprocity with Iowa with the Board's permission. **Action:** Peter Cohron moved to amend the Agreed Order of Reinstatement with Restrictions, 12-0174 removing the reciprocation restricting to allow Ms. Collett to proceed with applying to Iowa. Jonathan Van Lahr seconded, and the motion passed unanimously.

CVS Verification Process John Long and Joe Lavino presented an overview of the verification process currently being implemented at CVS pharmacies. The electronic process for verification is done onsite by technicians and pharmacists. After much discussion, the Board requested the following information to be provided at the next meeting:

- Workflow overview of prescriptions filled via automation,
- Medication Safety data from pilot program,
- List of all pharmacies utilizing this process in Kentucky,
- Results of the internal pilot studies conducted by CVS, and
- Legal review by General Counsel on the legality of process in Kentucky law.

Colorectal Cancer [CRC] Screening Protocol Chris Harlow moved to approve this protocol. Peter Cohron seconded, and the motion passed unanimously.

Kentucky Pharmacists Association Jody Jaggers requested an exemption or extension of the security bond requirement for a wholesale license. Dr. Jaggers stated the license is not being utilized but is held for future use in the event of an emergency in which medications would need to be stockpiled.

Action: John Fuller moved to approve this extension request with submission of a letter of credit within 30 days and a letter requesting to extend the inactive wholesaler license. Jonathan Van Lahr seconded, and the motion passed unanimously.

Jill Rhodes recognized the students from the University of Kentucky College of Pharmacy.

Professional Development Committee President Rhodes reminded the following organizations to submit their nominations for the committee by October 19, 2021:

- University of Kentucky College of Pharmacy;
- Sullivan University College of Pharmacy and Health Sciences;
- Kentucky Pharmacists Association; and
- Kentucky Society of Health System Pharmacists.

BOARD REPORTS

Executive Director Larry Hadley reported the new Staff Attorney and Administrative Assistant positions cannot be filled until July 1, 2022 due to not being included in the current fiscal year budget.

Action: The Board directed staff to explore options to obtain additional legal staff in the interim.

General Counsel Eden Davis informed the Board that the FDA MOU was signed by the Board President on September 10, 2021 and submitted to the FDA.

COMMITTEE REPORTS

Kentucky Professional Recovery Network Brian Fingerson reported to the Board that there are currently 30 participants being monitored. Of which the breakdown is: 26 Board ordered and 4 self-referred [unknown to the Board]. One participate completed their term and has been removed from the program. He provided the response from Sullivan University College of Pharmacy on the recommended proposal for student participation in KYPRN.

Action: Jill Rhodes requested the committee provide an amended recommendation for the November Board meeting. Eden Davis is to provide the legal requirements for notifying the Board of DUIs at the next PRN meeting.

Advisory Council The Board reviewed the recommendations provided by the Advisory Council on COVID-19 State of Emergency changes in the Board of Pharmacy regulations and enforcement.

Action: Jonathan Van Lahr moved to submit these recommendations to the Regulation Committee with the note of opposition to the amendment of 201 KAR 2:205, Section 3 [d][3]. Chris Harlow seconded, and the motion passed unanimously.

Regulation Committee Ralph Bouvette reported to the Board that the committee continues to work on development of a non-resident pharmacy regulation, repository regulation and the review of 201 KAR 2:230. The next meeting will be held October 20, 2021.

Pharmacy Technician Committee No information to report.

Diversity and Inclusion Task Force Eden Davis advised that the task force has not met due to a lack of quorum. The committee chairs request the voting members be reduced to better obtain a quorum.

Action: Chris Harlow moved to reduce the voting members to 14. The committee chairs will determine the voting members via past meeting attendance. Peter Cohron seconded, and the motion passed unanimously.

Medication Safety Committee No information to report.

Case Review Panel No information to report.

LEGISLATION/REGULATION Eden Davis provided a status report on Board of Pharmacy regulations.

CORRESPONDENCE

Actions:

P07141 and P07648 - Dual PIC Request Peter Cohron moved to approve this request. Chris Harlow seconded, and the motion passed unanimously.

John Fuller recused himself and was placed in the waiting room.

Kroger Health Connect, OH1765 – Clarification on the impact of HB 219 pertaining to remote work Shannon Stiglitz, Kentucky Retail Federation stated the intent of HB 219 was not to prohibit current practices. Chris Harlow moved to table this discussion until the next meeting. Jonathan Van Lahr seconded, and the motion passed unanimously.

OLD BUSINESS

Policy and Procedures Review The requested updates for the Policy and Procedures Manual were reviewed. During the review, Jonathan Van Lahr requested the Board review 201 KAR 2:015, Continuing Education.

Action: Chris Harlow moved to approve the updates. Jonathan Van Lahr seconded, and the motion passed unanimously.

Department of Insurance Grievances Larry Hadley reported that there was no new information at this time.

NEW BUSINESS

MPJE Item Writing Committee President Rhodes requested Board members submit their votes for the appointment of the practicing pharmacist member by using Chat or verbally. Votes received [majority indicated with an asterisk]:

- Kim Croley 1
- Krystal Flaherty 1
- Ross Goetz 1
- Sophie Willis McHardy 2*

Action: Chris Harlow moved to appoint Sophie Willis McHardy as the practicing member of the MPJE Item Writing Committee. Peter Cohron seconded, and the motion passed unanimously. Chris Harlow moved to appoint Jonathan Van Lahr to the committee. John Fuller seconded, and the motion passed unanimously. Peter Cohron moved to appoint Amanda Harding to the committee. Chris Harlow seconded, and the motion passed unanimously.

Protocol to Initiate Dispensing of Naloxone for Opioid Overdose Prevention and Response. Trish Freeman presented the updated protocol to the Board.

Action: Jonathan Van Lahr moved to approve this protocol. Peter Cohron seconded, and the motion passed unanimously.

CLOSED SESSION Peter Cohron moved to go into closed session to include investigating inspector, Larry Hadley, Eden Davis, and Darla Sayre for the purpose of reviewing, discussing

and deliberating upon open investigations [21-0012C] 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. Peter Cohron moved to come out of closed session after a discussion of 21-0012C. Jonathan Van Lahr seconded, and the motion passed unanimously.

Action: Peter Cohron moved to accept the Hearing Officer's recommendation for the pharmacy technician registration to not be issued or renewed. John Fuller seconded, and the motion passed unanimously.

ADJOURNMENT Jonathan Van Lahr moved to adjourn. Peter Cohron seconded, and the motion passed unanimously. President Rhodes adjourned the meeting at 1:25 p.m.