## KENTUCKY BOARD OF PHARMACY via Zoom

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Meeting ID: 873 5688 7332 Passcode: dbry81 Dial by your location +1 312 626 6799 US (Chicago) +1 646 558 8656 US (New York) Meeting ID: 873 5688 7332 Passcode: 546238

# January 26, 2022 9:00 a.m. AGENDA

### I. CALL TO ORDER

### II. ELECTION OF OFFICERS

### III. ETHICS PRESENTATION, Katie Gabhart

### IV. MINUTES

- A. November 30, 2021
- B. December 15, 2021

### V. APPEARANCES

- A. Workplace Conditions
  - 1. Candace Olusola, #pizzaisnotworking
  - 2. Ben Mudd, KPhA

## VI. INTERAGENCY

### VII. BOARD REPORTS

- A. Executive Director
  - 1. eMars, November and December
  - 2. Annual Travel report submission for approval
  - 3. Chris' current work
  - 4. Dual PIC temporary request for 30 days
- B. General Counsel
  - 1. Expungement Requests
    - a) 08-0094
    - b) 18-0122 B
  - 2. Regulation Updates

### VIII. COMMITTEE REPORTS

- A. Kentucky Professional Recovery Committee, Brian Fingerson
- B. Advisory Council, Anthony Tagavi
  - 1. Final Product Verification recommendation
- C. Regulation Committee, Ralph Bouvette
  - 1. Regulation Waiver recommendations
- 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, Peter Cohron

## IX. LEGISLATION

A. 201 KAR 2:020

## X. CORRESPONDENCE

- A. ReviveRX, Non-resident Pharmacy Application
- B. Lavanya Peter, P00603 and pending application Dual PIC Request
- C. P06093, P07665, P07141, P07648, P06822 and P08073 Off-site Storage Request
- D. P07453 Off-site Storage Request

## XI. OLD BUSINESS

- A. Review of Emergency Suspension of Regulations
- B. COVID Testing with Strep/Flu

## XII. NEW BUSINESS

- A. Work from home
- B. Workflow issue/staffing shortages for pharmacists
- C. 2021 Continuing Education Requirements
- D. Protocols:
  - 1. Alcohol Use Disorder Protocol utilizing Naltrexone-based Therapy
  - 2. Opioid Use Disorder Protocol utilizing Naltrexone-based Therapy
  - 3. Self-Care Conditions Protocol: Over-the-Counter Dietary Supplement Protocol
- E. Committee Appointments and Replacements
  - a) Case Review Panel
  - b) Continuous Professional Development Committee
  - c) Advisory Council
  - d) Pharmacy Technician Committee
  - e) Advanced Practice Registered Nurse Council

#### XII. CLOSED SESSION

#### A. Final Orders

#### 1. 21-0134

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 January 26, 2022

**CALL TO ORDER** A regularly scheduled meeting was held via teleconference from the Kentucky Board of Pharmacy, Frankfort, Kentucky. Vice-President Cohron called the meeting to order 9:01 a.m.

Members present: Peter Cohron, John Fuller, Jonathan Van Lahr, Meredith Figg, Jason Belcher and Anthony Tagavi.

Staff: Christopher Harlow Executive Director; Eden Davis, General Counsel; Paul Daniels, Pharmacy and Drug Inspector; 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, Melissa Hall, Administrative Specialist III and Darla Sayre, Executive Staff Advisor.

**Guests: Nichole Cover** 

**NEW BOARD MEMBERS** Vice-President Cohron welcomed the new Board members. Melissa Hall administered the Oath of Office to Meredith Figg, Jason Belcher and Anthony Tagavi.

**ELECTION OF OFFICERS** John Fuller nominated Peter Cohron as President of the Board. With no other nominations, John Fuller moved to appoint Peter Cohron as President. Jonathan Van Lahr seconded, and the motion passed unanimously with Peter Cohron abstaining. Melissa Hall administered the Oath of Office to President Cohron.

Peter Cohron nominated John Fuller as Vice-President of the Board. With no other nominations, Peter Cohron moved to appoint John Fuller as Vice-President. Meredith Figg seconded, and the motion passed unanimously with John Fuller abstaining. Melissa Hall administered the Oath of Office to Vice-President Fuller.

**MINUTES** Jonathan Van Lahr moved to accept the minutes from the November 30, 2021, and December 15, 2021 meetings. John Fuller seconded, and the motion passed unanimously.

**ETHICS TRAINING** Katie Gabhart, Executive Director of the Ethics Commission presented training for the new Board members on ethics within state government.

**FORMER EXECUTIVE DIRECTOR** Larry Hadley, former Executive Director of the Kentucky Board of Pharmacy expressed his appreciation to the Board members, committee members and chairs, previous Executive Directors and Board staff for the support and guidance received while serving as the Executive Director.

Action: Jonathan Van Lahr moved to express the Board's sincere appreciation to Larry Hadley for all his work while serving as the Executive Director of the Kentucky Board of Pharmacy. Anthony Tagavi seconded, and the motion passed unanimously.

**APPEARANCE – Candace Olusola, #pizzaisnotworking** Candace Olusola presented information on #pizzaisnotworking, a movement to address issues within the community pharmacy focusing on retail chain pharmacies to hold them accountable for deteriorating work conditions. Issues identified are:

- Patients returning to the hospital due to long wait times to received medications at the pharmacy.
- Medication costs rising while reimbursement is not keeping pace. Many prescriptions are dispensed at a loss to the pharmacy.
- Pharmacy staff are not protected and are afraid to speak out.

The movement is approaching national Boards of Pharmacy to voice these concerns.

**Ben Mudd, Kentucky Pharmacist's Association** Ben Mudd, Executive Directed presented the findings of a recent poll conducted by the Pharmacy Work Environment Advisory Committee. The Board requested the work designation of pharmacists responding to the poll.

## **BOARD REPORTS – EXECUTIVE DIRECTOR**

eMars Christopher Harlow presented the November and December financial reports to the Board.

Annual Travel Christopher Harlow requested approval for the following meeting dates in 2022.

- American Pharmacists Association (APhA) Annual Meeting, San Antonio March 18-22
- Rx Drug Abuse Summit, Atlanta April 18-21
- Kentucky Society of Health System Pharmacists (KSHP) Spring Meeting, May 17
- National Association of Boards of Pharmacy (NABP) Annual Meeting, Phoenix May 19-21
- Kentucky Pharmacists Association (KPhA) Annual Meeting, June 3-5
- National Association of Boards of Pharmacy (NABP) District 3 Meeting, Flowood, MS August 7-10
- National Association of Boards of Pharmacy (NABP) Executive Officer Orientation, Chicago September 28-30
- Kentucky Society of Health System Pharmacists (KSHP), Fall Meeting, October 6-7
- Kentucky Pharmacists Association Legislative Conference, Date TBD
- MALTA-GON, New Orleans, LA September 18-21, 2022

Action: Anthony Tagavi moved to approve all travel requests as presented. John Fuller seconded, and the motion passed unanimously.

**Executive Director Progress Report** Dr. Harlow provided an update to the Board on his progress since his effective date of January 15, 2022. He has met with office staff and is scheduling inspections with the inspectors. He is working on drafting a Board Processes Manual to document the processes used by the Board.

**30 Day Temporary Dual PIC Form** Dr. Harlow presented a 30 Day Temporary Dual PIC Form to the Board. He advised that several pharmacies are without a pharmacist-in-charge due to staffing issues. He requested the Board allow use of this form for the Executive Director to approve. This will be for a temporary 30-day period. Requests for a longer period must be submitted to the Board at the next regularly scheduled Board meeting for approval.

**Action:** Jonathan Van Lahr moved to approve this form and allow the Executive Director to approve for a 30-day period with no extensions. John Fuller seconded, and the motion passed unanimously.

### **BOARD REPORTS – GENERAL COUNSEL**

Expungement Requests Eden Davis presented Cases 08-0094 and 18-0122 B for expungement.

**Action:** Jonathan Van Lahr moved to approve the expungement of Case 08-0094. John Fuller seconded, and the motion passed unanimously. Anthony Tagavi moved to approve the expungement of Case 18-0122 B. Jonathan Van Lahr seconded, and the motion passed with Meredith Figg abstaining. Joel Thornbury requested the Board address the prescribing of controlled substances for a more uniform prescriber law.

**Regulation Updates** Ms. Davis provided a status report on regulations. She advised that 201 KAR 2:020 is set to expire this year.

### **COMMITTEE REPORTS**

**Kentucky Professional Recovery Network** Brian Fingerson informed the Board that there are currently 24 known individuals being monitored and 4 unknown individuals.

**Advisory Council** Anthony Tagavi presented to the Board two recommendations from the Advisory Council. Regarding the charge of the Opioid Use Disorder, the council recommends requiring one hour of continuing education specific to opioid use disorder.

Action: John Fuller moved to defer this recommendation to the February meeting. Jonathon Van Lahr seconded, and the motion passed with Anthony Tagavi abstaining.

Regarding visual product inspection, the council recommends that visual product inspection of a prescription cannot be performed prior to final product verification unless approved by the Kentucky Board of Pharmacy.

Action: Jonathan Van Lahr moved to defer this recommendation to the February meeting. John Fuller seconded, and the motion passed with Anthony Tagavi abstaining.

**Regulation Committee** Cathy Hanna presented the committee's recommendations of regulations waived during the current state of emergency. The committee recommended a statutory change to allow pharmacists to order a COVID test without a prescriber's order. President Cohron requested deferring the remaining recommendations until the February meeting.

Actions: Jonathan Van Lahr moved to direct the Executive Director and Board Counsel to begin the process of this statutory change. Meredith Figg seconded, and the motion passed unanimously.

Peter Cohron moved to direct Board staff to post a list of authorized recipient pharmacies on the website once available. Jonathan Van Lahr seconded, and the motion passed unanimously.

**Pharmacy Technician Committee** David Figg reported the committee continues to work on enhanced pharmacy technician duties regarding training and what other states are utilizing. Sullivan University College of Pharmacy has agreed to partner with the committee to establish this training.

Diversity and Inclusion Task Force No information to report.

**Medication Safety Committee** Liz Hess reported the committee continues to work on their charge. They are exploring methods in which pharmacy staff may report medication errors or near errors without facing discipline.

## LEGISLATION

**201 KAR 2:020, Examination** Eden Davis presented a revised draft of the regulation after comments received from the Inspection staff. Dr. Harlow stated that the Board needs to look at 201 KAR 2:050 to amend that language 'pharmacist examination fee' to 'application fee.' The Board discussed the decision of NABP to stop provided actual test scores to the Board and/or the applicant.

Action: Peter Cohron directed Dr. Harlow to request a representative from NABP be available at the February Board meeting to discuss this issue.

## CORRESPONDENCE

Actions:

**ReviveRX, Non-resident Pharmacy Application** Jonathan Van Lahr moved to deny this application stating the reason of deviation of accepted best practices of the FDA. John Fuller seconded, and the motion passed unanimously. Dr. Harlow requested the Board consider rules or regulation around the FDA warning letters.

Lavanya Peter, P00603 and P08222, Dual PIC Request Anthony Tagavi moved to approve this request with a deadline of June 1, 2022. Jonathan Van Lahr seconded, and the motion passed unanimously.

**P06093, P07665, P07141, P07648, P06822 and P08073 – Off-site Storage Requests** John Fuller moved to approve this request. Jonathan Van Lahr seconded, and the motion passed unanimously.

**P07453** – **Off-site Storage Request** John Fuller moved to approve this request. Jonathan Van Lahr seconded, and the motion passed unanimously.

## **OLD BUSINESS**

**Review of Emergency Suspension of Regulations** Eden Davis advised that the document issued by the Board April 8, 2020, referencing the state of emergency under Executive Order is no longer valid.

Action: Jonathan Van Lahr moved to amend the declaration on this document to read 'State of Emergency by General Assembly exists' and to allow the remainder of the document to remain as is. John Fuller seconded, and the motion passed unanimously.

## **NEW BUSINESS**

**Work from home** President Cohron stated this issue is pharmacists taking verbal prescriptions outside the pharmacy while working remotely then entering the prescriptions in the pharmacy system to be printed in the pharmacy. Eden Davis suggested the Board draft a Declaratory Opinion as this will impact all pharmacies.

Action: Jonathan Van Lahr moved to direct Eden Davis draft a Declaratory Opinion with the following criteria outlined:

- Exercise best practices enter electronically repeating the prescription to the prescriber for accuracy;
- Signature must contain full name not only initials;
- Hard copy notes to be scanned into pharmacy system then destroyed per HIPAA guidelines; and
- Does not preclude pharmacist from taking handwritten notes prior to electronic entry.

John Fuller seconded, and the motion passed unanimously.

**2021 Continuing Education Requirements** Dr. Harlow advised the Board review how to proceed with the 2020-2021 continuing education requirement deficiencies. Due to the extension to obtain 2020 CE credits, the Board is requesting confirmation of 30 CE credits obtained from January 1, 2020 through December 31, 2021 on the 2022 pharmacist renewals. After discussion, Dr. Harlow will provide a total of those pharmacists self-reporting non-completion of the required continuing education.

**Committee Appointments and Replacements** Dr. Harlow advised the Board of vacancies on several committees due to his appointment as Executive Director and Anthony Tagavi's appointment to the Board.

## Actions:

**Case Review Panel** President Cohron and Jonathan Van Lahr agreed to serve on this panel for the remainder of the year. John Fuller moved to appoint Anthony Tagavi to the panel replacing Christopher Harlow. Meredith Figg seconded, and the motion passed with Anthony Tagavi abstaining.

**Continuous Professional Development Committee Appointment** Jonathan Van Lahr moved to appoint Meredith Figg to this committee replacing Christopher Harlow. Anthony Tagavi seconded, and the motion passed unanimously with Meredith Figg abstaining.

moved to approve this appointment. Chris Harlow seconded, and the motion passed unanimously.

**Advanced Practice Registered Nurse Council** John Fuller moved to appoint Jonathan Van Lahr to this council replacing Christopher Harlow. Anthony Tagavi seconded, and the motion passed unanimously with Jonathan Van Lahr abstaining.

**Advisory Council** Dr. Harlow advised that applications for the vacancy will be presented at the February Board meeting.

**Pharmacy Technician Committee** Jonathan Van Lahr moved to appoint John Fuller to this committee. Meredith Figg seconded, and the motion passed unanimously with John Fuller abstaining.

**Opioid Use Disorder Protocol utilizing Naltrexone-based Therapy** Jonathan Van Lahr moved to approve the changes to this protocol. John Fuller seconded, and the motion passed unanimously.

**Self-Care Conditions Protocol: Over-the-Counter Dietary Supplement Protocol** Anthony Tagavi moved to approve this protocol. John Fuller seconded, and the motion passed unanimously.

**Workflow issue/staffing shortages for pharmacists** Dr. Harlow presented several requests to the Board advising them of workflow issues due to staffing shortages. Work conditions have decreased during the pandemic. John Fuller stated that by rising to the challenges of COVID pharmacists have increased their workload to accommodate patients. This increased workload has resulted in burnout and staffing issues. Dr. Harlow suggested convening a work group to study this issue and provide recommendations to the Board. Peter Cohron proposed the development of a survey by the Board requesting feedback from pharmacists to identify the issues. The issues will then be sent as a high priority charge to the Regulation Committee for regulation changes or development. Katie Busroe advised the inspection staff can provide staffing data. She stated this is a public safety issue. Staffing issues increase the likelihood of medication errors or near misses.

Action: Peter Cohron moved to direct staff to develop a survey to identify workflow issues resulting in staffing shortages. Possible questions for the survey should be sent to Dr. Harlow by email. The proposed survey will be presented at the February meeting for approval. Jonathan Van Lahr seconded, and the motion passed unanimously.

**CLOSED SESSION** Jonathan Van Lahr moved to go into closed session to include Christopher Harlow, Eden Davis and Darla Sayre for the purpose of reviewing, discussing and deliberating upon open investigations [21-0134] 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). John Fuller seconded, and the motion passed unanimously. Anthony Tagavi moved to come out of closed session after a discussion of 21-0134. Jonathan Van Lahr seconded, and the motion passed unanimously.

**Action:** Jonathan Van Lahr moved to accept the Attorney General's recommendation for 21-0134 of issuance of final order as incorporated by the Attorney General's office. John Fuller seconded, and the motion passed unanimously.

**ADJOURNMENT** Jonathan Van Lahr moved to adjourn. John Fuller seconded, and the motion passed unanimously. President Cohron adjourned the meeting at 3:00 p.m.