

KENTUCKY BOARD OF PHARMACY

via Zoom

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Meeting ID: 871 6068 0460 Passcode: H8GFpE

Dial by your location

+1 312 626 6799 US (Chicago)

+1 646 558 8656 US (New York)

Meeting ID: 871 6068 0460 Passcode: 862729

March 30, 2022

10:00 a.m.

AGENDA

I. CALL TO ORDER

II. MINUTES

- A. February 23, 2022

III. PUBLIC HEARING

- A. 201 KAR 2:440, Legend Drug Repository
 - 1. Comments from Sirum

IV. APPEARANCES

- A. Robert Holbrook, Reinstatement of pharmacist license
- B. Erx Automated Entry Walgreens
- C. U of L Retail and Infusion Pharmacy Dispensing Process

V. INTERAGENCY

VI. BOARD REPORTS

- A. Executive Director
 - 1. eMars, February
 - 2. Cost estimate for office remodel
 - 3. Voting delegate for NABP Annual Meeting
 - 4. 2022 Board Retreat
 - 5. APhA Report
 - 6. FDA MOU
 - 7. Expungement Requests
 - a) 01-0014
 - b) 17-0287

VII. COMMITTEE REPORTS

- A. Kentucky Professional Recovery Committee, Brian Fingerson

- B. Regulation Committee, Ralph Bouvette [For Discussion Only]
- C. Pharmacy Technician Committee, David Figg [For Discussion Only]
- D. Diversity and Inclusion Task Force, Shannon Borden and Crystal Isaacs
- E. Case Review Panel, Peter Cohron
- F. Continuous Professional Development Committee, Adrienne Matson

VIII. LEGISLATION/REGULATION

- A. 201 KAR 2:440, Legend Drug Repository
 - 1. Comments from KBVE [Received after the comment period ended; for information only]
- B. Legislative Update

IX. CORRESPONDENCE

- A. Cole Wendeln, P00917 and P06315 – Dual PIC Request
- B. Town and Country Discount Drugs, P08209 – Off-site Storage Request
- C. Baptist Health, P06933 – Expansion Request

X. OLD BUSINESS

- A. Workplace Conditions
 - 1. Journal of the American Pharmacists Association Article
 - 2. NABP Report, District 3, March 2022 Work Conditions
 - 3. Survey Update

XI. NEW BUSINESS

- A. National Treatment Delivery and Care, Non-Resident Pharmacy Application

XII. CLOSED SESSION

- A. Final Orders
 - 1. 21-0170 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

BOARD MEETING

March 30, 2022

CALL TO ORDER A regularly scheduled hybrid meeting was held at the Kentucky Board of Pharmacy, Frankfort, Kentucky. President Cohron called the meeting to order 10:00 a.m.

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

Staff: Christopher Harlow Executive Director; Martin K. Poynter, serving as General Counsel; Paul Daniels, Pharmacy and Drug Inspector; John Romines, Pharmacy and Drug Inspector; Rhonda Hamilton, Pharmacy and Drug Inspector; Amanda Harding, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector Katie Busroe, Pharmacy Inspections and Investigations Supervisor and Darla Sayre, Executive Staff Advisor.

Guests: John Long, CVS Health; Cathy Hanna, APSC; Ben Mudd, KPhA; Rich Palumbo, Express Scripts/Accredo; Robert Fink, UofL Health; Jill Lee, OIG-CHFS; Robert Benvenuti, UofL Health Counsel; Mike Burleson, Regulation Committee; and Nichole Cover, Walgreens.

MINUTES John Fuller moved to accept the minutes from the February 23, 2022 meeting. Jonathan Van Lahr seconded, and the motion passed unanimously.

APPEARANCE

George Wang, SIRUM George Wang appeared before the Board to request consideration of comments received during the comment period for 201 KAR 2:440, Legend Drug Repository. The Board considered the following:

1. 2:440 Section 3: (5) An authorized recipient shall store and maintain donated drugs in a manner that physically distinguishes them ~~separated~~ from other non-donated inventory and in a secure and temperature-controlled environment that meets the drug manufacturers' recommendations and USP standards.

Action: Jonathan Van Lahr moved to accept the amended language. Meredith Figg seconded, and the motion passed unanimously.

2. Amended language presented allowed for a handling fee to be charged for reasonable costs of participating in the program.

3. 201 KAR 2:440 (3)(g) ~~have packaging that lists the lot number of the drug;~~
201 KAR 2:440 Section 4: (11) Drugs specified in a recall notice shall be considered recalled unless the drug has an affixed lot number to exclude it from the recall.

Action: Jonathan Van Lahr moved to accept the amended language. John Fuller seconded, and the motion passed with Anthony Tagavi opposing.

4. Amended language presented allowed for provider discretion for the expiration date cutoff of donated drugs.

5. 201 KAR 2:440 Section 3: (f) Have an expiration date of ninety days or greater, **unless the drug is in high demand, as determined by the professional judgment of the authorized recipient and can be dispensed for use prior to the drug's expiration date;**

Action: Meredith Figg moved to accept the amended language. John Fuller seconded, and the motion passed unanimously.

6. 2:440 Section 4: (7) Indigent and uninsured patients shall have priority access to drugs dispensed through the repository program. If a drug is available and no indigent or uninsured patient requests dispensing of the drug, the drug shall be made available to underinsured patients before dispensing to others. All authorized recipients shall use the Patient Eligibility Affidavit Form provided by the board **or a substantively similar physical or electronic form** when confirming a patient's status as indigent, uninsured, underinsured or other.

Action: Jonathan Van Lahr moved to accept the amended language. Anthony Tagavi seconded, and the motion passed unanimously.

7. Amended language allowed for the donation of drug samples.

8. Amended language 'if applicable,' when referencing the donor's permit number.

Action: Jonathan Van Lahr moved amend 'permit number' in the regulation to 'permit or license number'. Anthony Tagavi seconded, and the motion passed unanimously.

9. Amended language allowed for the donation of drugs from individuals.

Action: Jonathan Van Lahr moved to deny the amended language. John Fuller seconded, and the motion passed unanimously.

10. Amended language enabled pharmacist substitutions of equivalent drugs or interchangeable biological products.

Action: Anthony Tagavi moved to add language from 201 KAR 2:280 Section 1 and 2 omitting the references to third party plans. Meredith Figg seconded, and the motion passed unanimously.

11. Amended language included 'sealed' in Section 1(17).

Action: Peter Cohron moved to deny the amended language. Jonathan Van Lahr seconded, and the motion passed unanimously. Peter Cohron moved to deny the amended language in requests 2, 4 and 7 above. Jonathan Van Lahr seconded, and the motion passed unanimously.

Robert Holbrook, Request for reinstatement Robert Holbrook appeared before the Board requesting reinstatement of his pharmacist license. His Kentucky pharmacist license was voluntarily suspended December 29, 2007 pursuant to case 07-0024B. He provided a summary of his recovery and work history since his suspension. Brian Fingerson, chairperson of the Kentucky Pharmacist Recovery Committee reported the committee had voted 8-0 for recommendation of reinstatement of licensure with no restrictions.

Action: John Fuller moved approve the reinstatement request. Mr. Holbrook must satisfy all licensing requirements for initial licensure or reciprocity. Meredith Figg seconded, and the motion passed unanimously.

eRx Automated Entry, Walgreens Nichole Cover and Jon Arrends appeared before the Board with clarification on the eRx Automated Entry currently in use at Walgreens. The raised concerns on the adjudication of claims after hours. This practice has resulted in multiple complaints from patients unable to obtain medication if the pharmacy is closed. Walgreens has modified their process to allow for the prescription information to be

accessed by another Walgreens to allow cancelation of the prescription and a transfer to a different pharmacy.

Action: Anthony Tagavi moved to direct Christopher Harlow to draft a letter to Walgreens advising them to turn off the eRx automatic adjudication process while the pharmacy is closed. The Board expressed its support for technology that promotes patient safety, but further expressed their concerns that this technology, while being used during closed business hours, is unprofessional/unethical conduct by creating barriers to access to needed medication and delayed patient care. Jonathan Van Lahr seconded, and the motion passed unanimously.

UofL Retail and Infusion Pharmacy Dispensing Process Robert Benvenuti and Robert Fink appeared before the Board with additional information regarding their infusion pharmacy dispensing process.

Action: Peter Cohron moved to allow UofL to proceed with this process as presented to the Board. The practice is not prohibited at this time. If the Board amends their regulations to prohibit this practice sufficient time will be allowed to comply. A record of both labels with all documentation of preparation and/or verification processes must be readily retrievable upon request. Anthony Tagavi seconded, and the motion passed unanimously.

INTERAGENCY

Ben Mudd, KPhA The KPhA Annual Meeting will be held at the Campbell House in Lexington, KY on June 2-5, 2022.

BOARD REPORTS – EXECUTIVE DIRECTOR

eMars Christopher Harlow presented the February financial report to the Board.

APhA Report Christopher Harlow provided a report of the APhA Annual Meeting. This is an overview of the policy topics discussed:

1. Integration of a National Immunization Information System (IIS)
 - a. Broadens policy scope by calling for a national IIS to send and receive vaccination data from all registries to assist in patient care activities.
2. Reimbursement for Diabetes Education and Prevention
 - a. This policy is intended to support programs and services provided by pharmacists and calls on payors to reimburse pharmacists for services rendered.
3. Data to Advance Health Equity
 - a. This policy urges pharmacists to use patient-specific data and their social determinants of health to address health inequity and drive decision making in practice and advocacy.
4. Procurement Strategies and Patient Steerage
 - a. This policy addresses site of care steerage (white bagging and brown bagging) and opposes these procurement strategies if they restrict patient choice and compromise patient safety.
5. Pharmacists Prescriptive Authority and Increasing Access to Medications for Opioid Use Disorders
 - a. APhA advocates for pharmacists' independent prescriptive authority of medications indicated for opioid use disorders (MOUD) and other substance use disorders to expand patient access to treatment.
6. Pharmacy Personnel Immunization Rates
 - a. Modification of existing policy to clarify that APhA encourages federal, state, local officials, and agencies to recognize pharmacists, student pharmacists, pharmacy technicians, and pharmacy

support staff among the highest priority groups to receive medications, vaccinations, and other protective measures as essential healthcare workers.

7. Pharmacists' application of Professional Judgement

- a. This is a 4 part policy statement addressing legislation introduced in multiple states that are limiting a pharmacist's professional judgement and requiring a pharmacist to dispense certain classes of medications.
 - i. APhA supports pharmacists, as licensed healthcare professionals, in their use of professional judgement throughout the course of their practice to act in the best interest of patients.
 - ii. APhA asserts that a pharmacist's independent medication review and use of professional judgement in the medication distribution process is essential to patient safety.
 - iii. APhA opposes state and federal laws that limit a pharmacist's responsibility to exercise professional judgement in the best interest of patients.
 - iv. APhA calls for civil, criminal, and legal liability protections for pharmacists if their responsibility to use professional judgement is limited by state and federal laws.

8. Addressing AMA's policy related to pharmacists scope of practice.

- a. APhA opposes policies, practices, and statements by the American Medical Association (AMA) and other professional organizations that impede interprofessional care, patient access to pharmacist-provided care, and health equity.
- b. APhA calls on the American Medical Association (AMA) to rescind its policies opposing expanded scopes of practice for pharmacists who increase access to care, address health inequity, and improve health outcomes.
- c. APhA adamantly supports the continuation and expansion of collaborative care models among pharmacists, physicians, and other healthcare professionals to promote patient access to care and health equity.

Dr. Harlow informed the board that this may not be the final language but will notify the Board when the final polices are adopted by APhA House of Delegates.

FDA MOU Dr. Harlow reported the FDA has rescinded the MOU.

Public Hearing Dr. Harlow requested the Board's availability for a Special Called Meeting in late June. Four amended regulations will be filed with LRC in April. After discussion, the Board scheduled a Special Called Meeting for June 22, 2022 for the Public Hearing. This will be a hybrid meeting and may be canceled if no comments are received.

Expungement Requests Dr. Harlow presented Case 01-0014 for expungement.

Action: Peter Cohron moved to approve the expungement of Case 01-0014. Jonathan Van Lahr seconded, and the motion passed unanimously.

Dr. Harlow presented Case 17-0287 for expungement.

Action: Peter Cohron moved to approve the expungement of Case 17-0287. Jonathan Van Lahr seconded, and the motion passed unanimously.

NABP Annual Meeting Voting Delegate Dr. Harlow requested any Board members wishing to serve as the Board's voting delegate to email him.

COMMITTEE REPORTS

Kentucky Professional Recovery Network Brian Fingerson informed the Board that there are currently 25 known individuals being monitored and 4 unknown individuals.

Regulation Committee Mike Burlison presented the following:

1. Draft regulation for 201 KAR 2:???, a new regulation for out of state pharmacy permits. This draft regulation will be discussed at the July Board Retreat.
2. The recommendation to add 201 KAR 2:230, Central Fill to the July Board Retreat. Facilities interested in submitting a business model for determination must submit a presentation at least thirty days prior to the retreat. This regulation could be included in the discussion of remote work, verification, common database and central fill.
3. Recommend additional time to review 201 KAR 2:450, sterile water and sterile saline; allowance to review 201 KAR 2:205 for possible amendments and extend this charge for a more in-depth study.

Action: Meredith Figg moved approve the recommendations of the Regulation Committee. Jonathan Van Lahr seconded, and the motion passed unanimously.

Pharmacy Technician Committee David Figg provided the recommendation to the Board for training of Enhanced Pharmacy Technicians. This item will be discussed at the July Board Retreat.

Diversity and Inclusion Task Force Dr. Harlow advised the Task Force is proceeding with their charge. They have requested Board approval to develop and present a Diversity and Inclusion Panel Discussion at the KPhA Annual Meeting, June 2-5, 2022 in Lexington.

Action: John Fuller moved to approve this recommendation. Jonathan Van Lahr seconded, and the motion passed unanimously.

Case Review Panel Peter Cohron reported that the Panel continues to see several cases resulting from the lack of a pharmacist-in-charge. The panel is currently using a \$500 administrative fine per week without the PIC as a base for these cases.

Continuous Professional Development Committee Katie Busroe reported the committee met for the first time on March 9, 2022. They have requested a representative from ACPE to appear at their next meeting to report on their findings regarding professional development.

LEGISLATION/REGULATION

201 KAR 2:440, Legend Drug Repository Dr. Harlow advised that comments from the Kentucky Board of Veterinary Examiners were received after the comment period expired. Michelle Shayne advised that they were not notified of this regulation upon filing. The Board directed Dr. Harlow to followup with KVE regarding the notifications and their comments. The Board reviewed the comments with no action taken.

Legislative Update Christopher Harlow provided an update from the current legislative session listing all proposed legislation that has potential to impact pharmacy practice.

CORRESPONDENCE

Actions:

Cole Wendeln, P00971 and P06315 - Dual PIC Request John Fuller moved to approve this request. Jonathan Van Lahr seconded, and the motion passed unanimously.

Town and Country Discount Drugs, P08209 – Offsite Storage Request Anthony Tagavi moved to approve this request. Meredith Figg seconded, and the motion passed unanimously.

Baptist Health, P06933 – Expansion Request John Fuller moved to approve this request. Jonathan Van Lahr seconded, and the motion passed unanimously.

OLD BUSINESS

Workflow issues/staffing shortages Christopher Harlow advised that the survey results are currently being analyzed. The results will be presented to the Board at the June Board meeting.

NEW BUSINESS

National Treatment Delivery and Care, Non-resident Pharmacy Application Katie Busroe presented the application to the Board for review.

Action: Anthony Tagavi moved to direct the inspector to obtain additional information from the pharmacy; complete dispensing records, other products dispensed, patient data for inability to take commercially available products and where the prescriptions are obtained. Jonathan Van Lahr seconded, and the motion passed unanimously.

Board Retreat Dr. Harlow requested the Board to prioritize the topics for discussion at the Board Retreat. The Board requested Dr. Harlow to provide a survey for the Board members to rank the topics on the Agenda for the Board Retreat. Topics will be discussed in that order as time allows.

CLOSED SESSION Peter Cohron moved to go into closed session to include Christopher Harlow, Keith Poynter and Darla Sayre for the purpose of reviewing, discussing and deliberating upon open investigations [termination of KYPRN agreement] 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). Jonathan Van Lahr seconded, and the motion passed unanimously. Peter Cohron moved to come out of closed session after a discussion regarding a Final Order. Jonathan Van Lahr seconded, and the motion passed unanimously.

Action: Jonathan Van Lahr moved to accept the recommended Final Order for case 21-0170 C. John Fuller seconded, and the motion passed unanimously.

ADJOURNMENT John Fuller moved to adjourn. Meredith Figg seconded, and the motion passed unanimously. President Cohron adjourned the meeting at 2:00 p.m.