

MINUTES

KENTUCKY BOARD OF PHARMACY

held at

Justice and Public Safety Cabinet

1st Floor Conference Room

125 Holmes Street

Frankfort, KY 40601

and via Zoom

BOARD MEETING

January 22, 2025

10:00 a.m.

Members present: Board President Jonathan Van Lahr, Vice President Anthony Tagavi, John Fuller, Meredith Figg, Jason Belcher, Ronald Poole, and Kimberly Croley.

Staff present: Christopher Harlow, Executive Director; Eden Davis, General Counsel; Jessica Williams, Pharmacy and Drug Inspector; John Romines, Pharmacy and Drug Inspector; Hannah Rodgers, Staff Attorney; Juliana Swiney, Deputy Executive Director; and Nikki Holiday, Executive Assistant.

CALL TO ORDER: President Jonathan Van Lahr called the meeting to order at 10:00 a.m.

2024 Board President Jonathan Van Lahr Welcomed Sullivan University Pharmacy students attending via Zoom.

INSTALLATION OF OFFICERS: 2024 Board President Jonathan Van Lahr swore in the 2025 Board President Anthony Tagavi. 2024 President Jonathan Van Lahr then swore in the 2025 Vice President Meredith Figg. Ronald Poole is sworn in as a member of the Board of Pharmacy.

MINUTES: November 20th, 2024, Board meeting

Action: Kimberly Croley motioned to approve the November 20th, 2024, minutes. Meredith Figg seconded, and the motion passed unanimously.

APPEARANCES

Farah, Ali Ibrahim; MPJE Request:

Action: Jonathan Van Lahr motioned to approve; Kimberly Croley seconded the motion. Board voted to approve by unanimous vote

Collett, Lindsey (014562/21-0214); Request for Agreed Order Modification:

Action: Kimberly Croley motioned to approve the removal of restrictions in her agreed order and return her license status to “good standing. Meredith Figg seconded and the motion passed unanimously.

House, Ashley; Pharmacy Technician Application Approval Request

Action: Meredith Figg motioned to approve the application; Jonathan Van Lahr seconded the motion. The board voted to approve the application by unanimous vote.

Winkler, Shawna; Pharmacy Technician Application Approval Request

Action: Jonathan Van Lahr motioned to approve the application; Kimberly Croley seconded the motion. The Board voted to approve the application by unanimous vote.

Almac Clinical Services PA; Non-Resident Pharmacy Waiver Request

The pharmacy requested a waiver for their non-resident pharmacy, to include the following:

The non-resident pharmacy permit issued to Almac Clinical Services; LLC contains the following waivers:

1. KRS 315.0351(1)(f) requires non-resident pharmacies to open less than six (6) days per week. **Almac is permitted to be open five days per week.**

2. KRS 315.0351(1)(f) requires non-resident pharmacies to have a toll-free telephone service available to patients and that number will be printed on the label affixed to each container of drugs dispensed.

Almac is permitted to place the sponsor's toll-free number on the clinical label since the sponsor will offer counseling and can be reached for emergency situations.

3. KRS 315.0351(1)(k) requires a non-resident pharmacy to place the return address on any package shipped into Kentucky and it shall be the same as the address on file with the Kentucky Board of Pharmacy.

Almac is permitted to utilize the return address on file with the Kentucky Board of Pharmacy without the room number listed.

4. 201 KAR 2:210(1) requires the pharmacy to possess patient records, including previously dispensed drugs and known disease conditions.

Almac is permitted to not possess patient records, including previously dispensed drugs or known disease conditions since the investigator does possess these records. Almac is permitted to only have records of shipments made a patient's home, including the patient's name and address, drug name and strength, quantity, date shipped, tracking details and identify of the prescriber (investigator).

5. 201 KAR 2:210(2)(4) and (5) detail patient counseling requirements, including prospective drug use review and recording patient counseling.

Almac is permitted to not perform patient counseling since all patient instruction comes from the investigator and since the investigator is responsible for screening patients to ensure they meet the criteria of the clinical trial and obtaining informed consent.

6. 201 KAR 2:171(1) requires that specific information be captured in the pharmacy's operating system, including prescriber address and refill authorizations.

Almac is permitted to retain records in a qualified computer system with appropriate security and access controls. Almac is permitted to not record the prescriber's address or any information regarding refill authorization. Almac is also permitted to only retain a redacted version of the drug order.

Action: Kimberly Croley motioned to approve the waiver request. Ronald Poole seconded the motion. Board voted to approve by unanimous vote.

Precision Compounding Pharmacy & Wellness; REVISIT

Action: Kimberly Croley motioned to approve the permit with restrictions to not permit dispensing ketamine to patients into Kentucky. Ronald Poole seconded the motion. Board voted to approve with Jonathan Van Lahr opposing the motion.

Apollo Care; Requesting Application for Outsourcing

Action: Ronald Poole motioned to table the application until the next meeting; Meredith Figg seconded the motion. The Board approved the motion unanimously. The following items were requested for follow up at March meeting: Additional Inspection Reports, Documentations from Outside Consultants, and Quality Assurance Processes.

CORRESPONDENCE

Rudd, Jesse (012915) (P00834 & P07488); Dual PIC Request

Ronald Poole motioned to temporarily approve Jesse Rudd as dual pharmacist in charge until June 30th, 2025; Jonathan Van Lahr seconded this motion. The board voted to approve the dual PIC request by unanimous vote.

George, Shelby (024165) – PA2981 & PA2957 Dual PIC Request

Meredith Figg motioned to temporarily approve Shelby George as dual pharmacist in charge until March 26th, 2025; Kimberly Croley seconded this motion. The board voted to approve the dual PIC request by unanimous vote.

201 KAR 2:370 Waiver Request – IN1604 –

Action: Request withdrawn.

INTERAGENCY/PROFESSIONAL ASSOCIATIONS

KPhA: Taylor Williams is continuing to work on senate bill 188 implementation from the pharmacy profession side. KPhA is preparing for day at the capital on February 20th. Sending out calls for board nominations that are due by March 31st.

BOARD REPORTS

Executive Director Report; Christopher Harlow: Executive Director Chris Harlow gave his report. He reviewed the eMARS financial reports which were provided to the Board in their packet(s). He also mentions that there will be some upcoming updates within the eMARs system. Throughout the rest of Harlow's report he discusses 2025 travel requests, Thoughtspan Updates (mentioning a new licensing management system- Pharmacist and Facility visibility within the licensure gateway. Continuing by going over the new renewal system that was released January 1st, 2025, and adding a survey at the end of all renewals), Senate Bill 188 Update (Discussions regarding filing complaints, and the process of compliance. Harlow wants to ensure the PBMs have the data they need. No further feedback was provided to Kentucky Board of Pharmacy on the matter)

Action: Ronald Poole motioned to approve Christopher Harlow's 2025 Travel Request dates; Kimberly Croley seconded this motion. The board voted to approve the Executive Director's 2025 travel requests by unanimous vote.

General Counsel Report: General Counsel Eden Davis gave her report which discussed a travel request for 2025 as well as two (2) expungement requests listed below with their actions.

Action: Ronald Poole motioned to approve Eden Davis's 2025 Travel Requests; Kimberly Croley seconded this motion. The board voted to approve the General Counsel's 2025 travel requests by unanimous vote.

12-0060B Expungement Request

Action: Meredith Figg motioned that this was deemed a minor offense and to approve the expungement request; Jonathan Van Lahr seconded this motion. The board voted to approve the expungement request by unanimous vote.

18-0301C Expungement Request

Action: Meredith Figg motioned that this was deemed a minor offense and to approve expungement request; Jonathan Van Lahr seconded this motion. The Board voted to approve the expungement request by unanimous vote.

COMMITTEE REPORTS

KYPRN Report: Brian Fingerson reported. The committee met via zoom January 14th, 2025 and had an introduction of the new members to committee. The committee went over the KYPRN report. Next meeting will be March 11th, 2025, 2pm via zoom.

Advisory Council: Tabitha Fischbeck reported. Met on January 14th, 2025 and went over the 201 KAR 2:070 prescription intermediary services restricted regulation. The committee discussed concerns with how proposed wording could cause unwanted implications.

Action: Kimberly Croley voted to direct staff to incorporate exceptions within pharmacy delivery model addressing stakeholder concerns and present at the next meeting. Ronald Poole seconded this motion. Board voted to pass the motion by unanimous vote.

PROTOCOL REVIEW COMMITTEE

They have continued to work on the draft of proposed PrEP protocol. Preparing to bring a motion to the board for the next meeting. No action recorded or needed.

OLD BUSINESS

Executive Director, Christopher Harlow gave an update on Non-Sterile Compounding Compliance. It was reported that a survey was put together to assess for readiness for compliance and potential barriers. Oral comments made by Ronald Poole, Kimberly Croley, and John Fuller, Eden Davis, Meredith Figg, and Jonathan Van Lahr on the update.

Action: Jonathan Van Lahr motioned to ensure there is publicizing on the waiver process for Regulation 076 regarding USP standards. Kimberly Croley seconded the motion. Board voted to pass the motion by unanimous vote.

201 KAR 2:045 Amendment

Action: Kimberly Croley motioned to approve 201 KAR 2:045 with changes presented and discussed. Ronald Poole seconded this motion. Motion passes with Jonathan Van Lahr opposing the motion.

201 KAR 2:165

Action: Kimberly Croley motioned to approve 201 KAR 2:165 with changes presented and discussed. This motion was seconded by Ronald Poole. The Board voted to pass the motion by unanimous vote.

NEW BUSINESS: None

CLOSED SESSION

Action: Kimberly Croley Motioned to enter close session. Ronald Poole seconded, and the motion passed unanimously. Kimberly Croley, Ronald Poole and Anthony Tagavi left the room.

Action: Kimberly Croley Motioned to open session. Ronald Poole seconded, and the motion passed unanimously

CLOSED SESSION DISCUSSION: No action was taken while in closed session

23-0539(A): The 2024 CRP panel discussed and determined that a modification should be made, and an agreed order should be issued to the permit holder with a fine of \$75,000, three (3) years' probation, bi-annually dispensing reports requirement throughout the probation period and not further violations of 201-KAR2076.

23-0539(B): The 2024 CRP panel determined that an interim agreed order should be issued with a \$500 fine, six (6) hours C.E. on pharmacy law(s), and six (6) hours C.E. on compounding law (3) for a total of twelve (12) hours. Term of the interim agreed order shall be 12 months.

24-0025 & 240039: The 2024 CRP panel determined that an interim agree order shall be issued for a term of 12 months, with a \$7,500 fine and a corrective action plan. Respondent shall have no further discipline, and the interim agree order shall convert to an agreed order, if the party *does* have discipline.

Action: Meredith Figg motioned to approve. Jonathan Van Lahr seconded, and the motion passes unanimously. Kimberly Croley, Ronald Poole and Anthony Tagavi abstained from the vote.

24-0074 (A): The panel determined that an agreed order for probations shall be issued for a term of three (3) years with a \$1,000 fine; all ordering must be completed by the pharmacist in charge (PIC) or the certified pharmacy technician under their individual credentials. The PIC must be responsible for any changes in controlled substance inventory and any modifications or verifications of such modifications must be completed on the same day by the PIC. A controlled substance audit of all scheduled to drugs to be done every six (6) months and schedules 3-5 to be done annually for a period of three (3) years. Corrective action plan and an order reconciliation POA shall remain with the PIC and any board approval must be solved for any PIC changes.

Action: Meredith Figg motioned to accept terms presented by counsel. Jason Belcher seconded this motion. Jonathan Van Lahr, Kimberly Croley, Ronald Poole and Anthony Tagavi abstained. Christopher Harlow replaced Jonathan Van Lahr as the voting member per 201 KAR 2:061. Motion passed unanimously.

NEXT MEETING: March 26th, 2025

ADJOURNMENT – 3:44 p.m.

Action: Jonathan Van Lahr motioned to adjourn the meeting. Ronald Poole seconded, and the motion passed unanimously

AUDIO/VIDEO TRANSCRIPT AVAILABLE UPON REQUEST