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 24, 2024 10:00 a.m.

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

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

CALL TO ORDER: President John Fuller called the meeting to order at 10:00 a.m.

INSTALLATION OF OFFICERS: 2023 Board President John Fuller swore in the 2024 Board President Jonathan Van Lahr. President Van Lahr then swore in the 2024 Vice President Anthony Tagavi. President Van Lahr expressed his appreciation and thanked 2023 President John Fuller for his service over the past year and presented him with a gavel.

MINUTES: John Fuller had one correction to the minutes. The date of the next Protocol Review Committee meeting was incorrect.

Action: Peter Cohron moved to accept the minutes with John Fuller's amendment. John Fuller seconded, and the motion passed unanimously.

APPEARANCES

Richard Schultz, Initial Pharmacist Application: General Counsel Eden Davis gave the Board an overview of why Mr. Schultz was appearing before the Board today. Mr. Schultz had entered into an Agreed Order requiring one year of KYPRN monitoring after the Board had approved him to take his exams. He has taken and passed the NAPLEX and plans to take the MPJE in early February. The Board is to decide if he has met those terms and had one year of scrupulous compliance and if he can be released from monitoring by the KYPRN. Emily Caporal with KYPRN said his compliance has improved greatly over the past year, and she has no issues with him being licensed and released from monitoring.

Action: Anthony Tagavi motioned to release Richard Schultz from monitoring. John Fuller seconded, and the motion passed unanimously.

Austin Cole Brasfield, Pharmacy Technician application: Did not show at meeting.

Action: Peter Cohron motioned to give him one more chance to appear and defer this application to the next meeting. Meredith Figg seconded, and the motion passed unanimously.

Jaremeia Hinkle, Pharmacy Technician application: Did not show at meeting.

Action: Anthony Tagavi motioned to defer this application to the next meeting. Jason Belcher seconded, and the motion passed unanimously.

Connor Hubbell, Intern application: General Counsel Eden Davis gave the Board a summary of Mr. Hubbell's criminal history. He has a single DUI in 2023 and he completed all legal requirements. He is registered as an intern in Ohio, and the Ohio Board has taken no action.

Action: Peter Cohron motioned to approve Connor Hubbell's intern application. John Fuller seconded, and the motion passed unanimously.

Angela Moore, Pharmacy Technician application: General Counsel Eden Davis gave the Board a summary of Ms. Moore's criminal history. She had no concerning convictions relating to controlled substances or alcohol, however she does have several felony convictions for wire fraud. Ms. Moore expressed her honesty with her potential employer and has had no other offenses since.

Action: Anthony Tagavi motioned to approve Angela Moore's pharmacy technician application. Meredith Figg seconded, and the motion passed unanimously.

Keaton Scroggin, Pharmacy Technician application: Keaton Scroggin was not present at the meeting. General Counsel Eden Davis gave the Board a summary of Mr. Scroggin's criminal history. He has one conviction on his record, possession of marijuana. Mr. Scroggin was riding a bicycle and was pulled over and searched by police. Their search resulted in finding two (2) devices that Mr. Scroggin admitted were marijuana vapes. **Action:** Anthony Tagavi motioned to approve this application due to the nature of the situation. Peter Cohron seconded, and the motion passed unanimously.

Vanessa Yazell, Pharmacy Technician application: General Counsel Eden Davis gave the Board a summary of Ms. Yazell's criminal history. She has three 2022 convictions all relating to one case, attempted possession of methamphetamines, possession of marijuana, and DUI. Ms. Yazell spoke to the Board about her recovery and her boss and Big Sister were also in attendance and spoke in support of Ms. Yazell.

Action: Anthony Tagavi motioned to approve this application. Peter Cohron seconded, and the motion passed unanimously.

INTERAGENCY/PROFESSIONAL ASSOCIATIONS

KPhA: Ben Mudd, Executive Director, reminded the Board that the Board of Pharmacy application process is getting ready to start. The call for nominations will open on February 12, 2024. Any pharmacy organization that wishes to submit a letter of support for a candidate must do so by March 1st. Applications are due March 31, 2024. KPhA selects five individuals and sends that list to the Governor for appointment.

BOARD REPORTS

Executive Director Report: Executive Director Chris Harlow gave the financial report that was included in the Board meeting materials. He gave an update on the Budget process. Our budget request was approved by the Budget Office and Governor's Office. He explained that there is a House budget bill that differs from the Governor's budget bill. This bill does cut personnel costs. Any position that was vacant as of July 1 of last year (2023) is cut in this bill. We have two positions that fall in this category, one is currently vacant, and one is currently filled. Board staff is submitting documentation to the legislature about the importance of these positions. All of the funding for our new software platform has been approved and we are moving forward working on this.

Executive Director 2024 travel requests. Dr. Harlow added Board President Jonathan Van Lahr to the travel requests for NABP, District III, and MALTAGON. He also added that any other members who would like to attend any of these meetings to please let us know as soon as possible so we can submit the documentation needed for approval all together. Anthony Tagavi told the Board he would like to attend District III and MALTAGON.

Action: John Fuller motioned to approve the 2024 Executive Director's travel requests. Peter Cohron seconded, and the motion passed unanimously.

Executive Director Harlow then discussed potential dates for the Board retreat in July. The July Board meeting is scheduled for July 24,2024. He suggested having the retreat day either July 23 or July 25. The tentative plan would be to go to the Transportation Building for the retreat day and do a partial day of continuing education presented by our Board staff. Potential topics for this CE are pharmacy law and compounding. Dr. Harlow also plans to reach out to Sam Flynn, the Executive Director of the Office for Medical Cannabis, and see if he would be interested in providing a medical cannabis update for pharmacists. Then spend the remainder of the day focusing on a regulatory topic.

Action: Peter Cohron motioned to hold the retreat on July 23 and Board meeting on July 24, 2024, in Frankfort, agenda TBD. Meredith Figg seconded, and the motion passed unanimously.

General Counsel Report: General Counsel Eden Davis gave an overview of an Open Record Court of Appeals Decision, 2022-CA-0170-MR. This opinion is related to open records requests and your personal computers, phones, and any other devices that have Board-related material on them. They are subject to not only open records requests, but also court subpoenas. It would only relate to Board business, not the entire device. She then reviewed ethics and the training that the Board members have been assigned. She went through the major points for the Board including the following: you cannot serve in a leadership role for a state pharmacy association; if there was a concern and/or complaint filed from someone outside of the Board, what the process is [The complaint would go to the Ethics Commission where they would gather information and draft a report that would then go to the Governor for his review/action.]; you must disclose any conflict of interest either in writing or orally on the record, and recuse from the discussion and abstain from the vote/action taken on the matter. You must do this any time there is a direct or indirect interest that puts your personal interest or an interest of a direct family member in conflict with Board business or something the Board is voting on. She advised the board members that any time they have a question if something is or is not a conflict of interest to please give her a call to discuss and she will determine what the member needs to do. A Board member (or their spouse or children) may not accept any gift(s) from any licensee or permit holder, or lobbying group, or any entity attempting to influence actions of the Board, totaling more than \$25 in a calendar year. This includes meals, paying for travel, etc. Lastly, the member must always put themselves in the shoes of public protection when you are serving in this role. You have to think in terms of what is best for the public and what is best to ensure their welfare, as opposed to whatever position you hold in your private life. She again urged members to always reach out to herself or Executive Director Harlow so you can talk through it to ensure the proper steps are followed.

2024 General Counsel Travel Requests: General Counsel Eden Davis requested travel for the following: ASPL meeting, MALTAGON, FARB Regulatory Law Seminar, and the Quarles & Brady Pharmacy Law Symposium. **Action:** Meredith Figg motioned to approve the General Counsel's travel requests. Anthony Tagavi seconded, and the motion passed unanimously.

Expungement request, 19-0314B: The Board needs to determine if this is considered a minor offense. John Fuller recused from the discussion and abstained from the vote.

Action: Anthony Tagavi motioned to consider this a minor offense. Peter Cohron seconded, and the motion passed with John Fuller abstaining.

Regulation Status Update: General Counsel provided an update and the regulation spreadsheet to the Board members in their meeting materials. This includes updating the facility applications and we now have a resident and a non-resident application for every type of facility license we have. There is currently one regulation at LRC. It has gone before ARRS and now needs to go before the Health Services Committee. 201 KAR 2:165 – amendments align regulation with Federal law regarding controlled substances prescribing. There are three regulations that the Regulation Committee is working on that are sunsetting and have been certified. 201 KAR 2:070, 201 KAR 2:220, and 201 KAR 2:045. The Regulation Committee will report on these in their report.

Proposed Change of Ownership Regulation: General Counsel gave the Board an update on our work on the new Change of Ownership regulation. The intent is not to change practice, but to capture it in a rule. This would provide stakeholders with somewhere to go to reference the rules when there is a potential change of ownership.

Action: Anthony Tagavi motioned to send this regulation to the Regulation Committee. Meredith Figg seconded, and the motion passed unanimously.

Action: Anthony Tagavi motioned to prioritize the regulations that the Regulation Committee currently has as follows: 1) change of ownership, 2) pharmacy technician, 3) records retention.

Deputy Executive Director/Inspection Staff: No updates this meeting.

COMMITTEE REPORTS

KYPRN Committee: Emily Caporal gave the KYPRN Committee report. The Committee met on January 9, 2024, and they had one appearance, Daniel Justin. The Committee voted 7 – 1 in support of reinstatement of his license with a recommended 5 years continued monitoring after reinstatement and work in an environment with no controlled substances. This will be discussed in closed session later in the meeting. There are currently 24 individuals being monitored, 20 of which are known to the Board. Ms. Caporal reminded the Board about the CAPTASA conference coming up. The next meeting is March 12, 2024 at 2:00 p.m.

Regulation Committee: Mike Burleson gave the Regulation Committee report. The Committee met on January 12, 2024. The Committee voted to send 201 KAR 2:220, Collaborative Care Agreements, to LRC with technical changes to keep it from sunsetting. The Committee will revisit this regulation in approximately 6 months. 201 KAR 2:070, Pharmacy Intermediary Services was also reviewed by the Committee. There were some small wording changes made and the Committee voted to send it to the Board for review. The Committee did begin conversation about the Pharmacy Technician regulation, but they decided to table that until their next meeting. Next meeting is March 15, 2024.

Action: Peter Cohron motioned to approve the amended version with the technical change of 201 KAR 2:220. John Fuller seconded, and the motion passed unanimously.

Executive Director Chris Harlow suggested that CCAs could be a potential retreat topic as the timeline falls in line with the retreat.

201 KAR 2:070: Board members discussed the language and concerns on how it could affect health systems and other licensees. Executive Director Chris Harlow told the Board that the intent was not to change the way the rule is enforced, but to provide clarity. After discussion, General Counsel Eden Davis suggested certifying the regulation for amendment so the Board has time to research their concerns. This regulation has not been amended since 1974.

Action: Meredith Figg motioned to certify 201 KAR 2:070 for amendment. John Fuller seconded, and the motion passed unanimously.

Action: Anthony Tagavi motioned to refer 201 KAR 2:070 to the Advisory Council and solicit comments via KPhA and KHA on how potential changes could affect stakeholders. Peter Cohron seconded, and the motion passed unanimously.

Advisory Council: Executive Director Harlow gave the Advisory Council report. Their next meeting is February 13, 2024 at 9:00 a.m. They will also meet again in March prior to the March 27, 2024 Board meeting. They currently have the following, in order of priority, on their agenda: Telework, Centralized Prescription Processing, and Final Product Verification. The intent was to keep these three topics together since they are related. We will address all three of those recommendations at the March meeting.

Protocol Review Committee: Joel Thornbury gave the Protocol Review Committee report. The Committee has two protocols completed. They have been working on the formalization of what the protocols will look like in terms of headers, footers, the modernization of the language, and standardize the way in which medications are presented in the protocols. The two protocols presented to the Board today are the following: Acute Group A Streptococcal Pharyngitis and Acute Influenza Infection Antiviral Therapy. Next meeting is February 6, 2024.

Action: John Fuller motioned to approve both protocols [Acute Group A Streptococcal Pharyngitis and Acute Influenza Infection Antiviral Therapy]. Anthony Tagavi seconded, and the motion passed unanimously. Executive Director Chris Harlow explained the process to the Board. Once these protocols are updated, the most recent version will be available on our website and they will replace the old versions. While it is not required to use the most recent version, it will be considered best practices to utilize the newest versions.

FACILITY APPLICATIONS

Non-resident pharmacy application, Express Med Pharmaceuticals, d/b/a SelectRx PA: Kyle Decker (in person) and Janelle Martens (via Zoom) attended to answer any questions regarding this application. Deputy Executive Director Juliana Swiney gave the Board an overview of the application and the application and supporting documents were provided to the Board in their meeting materials. Mr. Decker explained the disciplinary action (citation) included in their application regarding expired medications. The Board members had questions about their business model and how they obtain customers/patients. Mr. Decker explained how their business model operates. Ms. Martens also gave information about their platform, Population Health, which offers a wide variety of services to members, with SelectRx being one of them. (This includes compliance packaging/pouch packaging and the people who take 6 or more medications are the ones who "qualify" for this service.) After lengthy discussion, the Board requested to see the exact script that they use with potential patients, and they would like to see this prior to approving their application. **Action:** Meredith Figg motioned to table this application until the next meeting and upon SelectRx providing the exact verbiage of the script they use when they call potential patients. Peter Cohron seconded. John Fuller requested to also get information from the Indiana facility that is already permitted in Kentucky. The motion with Mr. Fuller's additional request passed unanimously.

Non-resident pharmacy application, Almac Clinical Services LLC: Deputy Executive Director Juliana Swiney gave the Board an overview of the pharmacy application. They are strictly a clinical trial packager and are requesting a pharmacy and wholesaler be permitted at the same address. They have seen an uptick in requests from customers (hospitals, clinics, etc) that have asked them to ship directly to the patient. Troy Sussmuth and Frances Smith attended via Zoom representing the pharmacy/wholesaler. They do not hold patient information. The provider who is participating in the clinical trial has the patient information. Action: Peter Cohron motioned to table this until the March meeting so that the Board can figure out everything that they need to waive or adjust in order to accommodate a unique situation. Meredith Figg seconded, and the motion passed unanimously.

Anthony Tagavi also requested information on how they are licensed in other states.

CORRESPONDENCE

Offsite Storage Request: Pikeville Medical Center (P06519)

Action: Peter Cohron motioned to approve the off-site storage request. Anthony Tagavi seconded, and the motion passed unanimously.

Dual PIC Request: AZ2831 and AZ2841 – revise form to state 60 hours total, not 60 hours at each pharmacy. **Action:** John Fuller motioned to approve for 6 months with hours not to exceed 60 hours per week total. Anthony Tagavi seconded, and the motion passed unanimously.

Dual PIC Request: P08295 and CP00143

Action: Anthony Tagavi motioned to approve the dual PIC request. John Fuller seconded, and the motion passed unanimously.

Non-resident pharmacy permit waiver request – Monroe Pharmacy: This item was moved until after old business.

OLD BUSINESS

201 KAR 2:460, Out-of- State Pharmacy Permit, 201 KAR 2:030, License Transfer and Non-Resident Pharmacist License Amended Regulation and 201 KAR 2:050 Licenses and permits; fees: Executive Director Chris Harlow addressed all three of these regulations collectively and gave an overview of the history and recommendations from the Advisory Council. This regulation was originally filed then withdrawn, and the Advisory Council has recommended to the Board that it be refiled with their proposed changes. The Advisory Council recommended a lower application fee for this process using the NABP Verify program. They recommended a \$50 initial fee and a \$50 renewal fee and a separate application process. The definition of limited transactions was discussed and how the Board would like to handle the waiver request on the agenda today. Executive Director Chris Harlow stated that there was no definition for what "good standing" means and recommended that the Board define this prior to filing. There was no action taken on these regulations today, as work continues on them, and the application incorporated by reference.

Non-resident pharmacy permit waiver request – Monroe Pharmacy: This non-resident pharmacy is seeking a waiver to ship into Kentucky because they are only shipping two products which are specialty medications. They have already shipped into Kentucky without a permit. The Board wanted to know why it would be problematic to obtain licensure in Kentucky.

Action: Peter Cohron motioned to deny the waiver. John Fuller seconded, and the motion passed unanimously.

NEW BUSINESS

APRN Council Appointment: Board President Jonathan Van Lahr stepped down from his appointment to the APRN Council and another Board member must be appointed.

Action: Anthony Tagavi motioned to appoint Peter Cohron to the APRN Council. John Fuller seconded, and the motion passed unanimously.

Pharmacist Recovery Network Committee Member Applications (2 vacancies): The following individuals submitted their application for appointment to the PRN Committee. The Board voted on the following applicants and Kristin Karrick and Rheagan Wills received the most votes.

- i. Akins, Tonya
- ii. Ali, Brittany
- iii. Anderson, Heather
- iv. Ashley, Kailen
- v. Awudu, Rekiyatu
- vi. Babb, Ryan
- vii. Blair, Amanda
- viii. Bolton, Spencer
- ix. Byrd, Brooke
- x. Cantrell, Michael
- xi. Craycraft, Lauren
- xii. David, Gary
- xiii. Divers, Cari
- xiv. Eatmon, Courtney
- xv. Epps, Amy
- xvi. Hancock, Brian
- xvii. Hankinson, Willaim
- xviii. Honerlaw, David
- xix. Karrick, Kristina
- xx. Keller, Kimberly
- xxi. Kramer, Andrea
- xxii. Lamkin, Lynn
- xxiii. Lockwood, Anna
- xxiv. Lyles, Jacob
- xxv. Lyons, Allie
- xxvi. Mahan, Jamie
- xxvii. McMahon, Laura
- xxviii. Newsome, Colby
- xxix. Schreihofer, Amber
- xxx. Szesny, Derek
- xxxi. Taylor, Durran
- xxxii. Warren, Dalton
- xxxiii. Whisman, Emma
- xxxiv. White, Jessalynn
- xxxv. Wills, Rheagan

Action: Antohny Tagavi motioned to appoint Kristin Karrick and Rheagan Wills to the PRN Committee. Jason Belcher seconded, and the motion passed unanimously.

Daniel Justin, 20-01210 (O) Reinstatement. General Counsel Eden Davis gave the Board an overview of Mr. Justin's reinstatement request, including the recommendations of the PRN Committee. Those recommendations were continued monitoring for 5 years and not allowed to work in a setting with access to controlled substances.

Action: John fuller motioned to reinstate Daniel Justin's license with the PRN Committee recommendations and including the following conditions: *Shall provide a copy of this AO to all employers and Pharmacist-in-*

charge (PIC). Submit with application for reinstatement a signed copy of the AO by the PIC and shall notify the Board of change of home address, telephone number, and/or email within 7 days of change.

CLOSED SESSION

Action: Meredith Figg motioned to go into closed session. Anthony Tagavi seconded, and the motion passed unanimously.

Action: Peter Cohron motioned to come out of closed session. Meredith Figg seconded, and the motion passed unanimously.

Action: Peter Cohron motioned to issue the recommended order of the hearing officer as the Board final order in case #23-0132. Jason Belcher seconded, Meredith Figg, Anthony Tagavi, and John Fuller abstained, and the motion passed.

Action: Meredith Figg motioned to go into closed session. Anthony Tagavi seconded, and the motion passed unanimously.

Action: Anthony Tagavi motioned to come out of closed session. Jonathan Van Lahr seconded, and the motion passed unanimously.

Action: Anthony Tagavi motioned to adopt/accept the settlement agreements for 22-0005A and 22-0069. Jonathan Van Lahr seconded, and the motion passed unanimously.

Action: Anthony Tagavi motioned to go into closed session. Peter Cohron seconded, and the motion passed unanimously.

Action: Anthony Tagavi motioned to come out of closed session. John Fuller seconded, and the motion passed unanimously.

Action: Meredith Figg motioned to reduce the agreed order from 5 years and a day to 5 years in case #23-0023. Anthony Tagavi seconded, and the motion passed unanimously.

NEXT MEETING: The next meeting of the Kentucky Board of Pharmacy will be March 27, 2024 at 10:00 a.m.

ADJOURNMENT

Action: Anthony Tagavi motioned to adjourn the meeting at 2:16 p.m. Jason Belcher seconded, and the motion passed unanimously. Meeting adjourned at 2:16 p.m.