

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

May 22, 2024

10:00 a.m.

Members present: Board President Jonathan Van Lahr, Vice President Anthony Tagavi, John Fuller, Meredith Figg, Jason Belcher, Kimberly Croley. (Dr. Croley attended virtually.)

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

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

INSTALLATION OF NEW BOARD MEMBER: General Counsel Eden Davis swore in Dr. Kimberly Croley as a new Board member. President Van Lahr welcomed Dr. Croley to the Board of Pharmacy and thanked her for her willingness to serve.

PUBLIC HEARING ON 201 KAR 2:220: There were no requests to speak on this proposed regulation. The Board is still receiving written comments through the end of the month.

MINUTES: Minutes from the March 27, 2024 meeting.

Action: Anthony Tagavi motioned to accept the minutes as written from the March 27, 2024 meeting. Jason Belcher seconded, and the motion passed unanimously.

APPEARANCES

Wholesaler Application Request, Biopeptek: Representatives from Biopeptek appeared before the Board regarding their non-resident wholesaler application. This application was denied in 2023, and the representatives from the company appeared to address the concerns the Board had with their application at that time.

Attendees from Biopeptek: Biopeptek legal counsel Kalie Richardson, Biopeptek CEO Junge Zhang, and Biopeptek Vice President Shizhong Zhao.

Biopeptek representatives provided background to the Board about Biopeptek's application for a wholesale distributor license which was submitted last year. There seemed to be some deficiencies in their application at that time. Executive Director Harlow asked the representatives to give the Board an overview of their business model and relationship with the manufacturer in China, also named Biopeptek. Representatives told the Board that in 2015 they were established in Delaware and have a location in Pennsylvania. They stated that they only have a business relationship with the manufacturer in China and are the sole distributor their products. The two entities are not commonly owned. Representatives explained to the Board that they receive the product

from the manufacturer in China and do not alter the product nor repackage it. They simply put the product in boxes and ship them out to their customers. The products received are stored in the Pennsylvania location in a temperature controlled, locked facility. This facility is also licensed in Pennsylvania. The manufacturer is currently on the FDA import alert list. The Board needs to be assured that anything coming into Kentucky has been cleared by the FDA. Their Counsel explained the things that were addressed in their deficiencies. One was the label being changed so the full name and address of the manufacturer could be read, and the manufacturer updated their importer information to include Biopeptek. It was requested that should a wholesaler license be granted, that Biopeptek share quarterly reports of invoices of what was shipped into Kentucky with the Board.

Action: John Fuller motioned to approve the wholesaler application with the condition that Biopeptek submit quarterly reports as required by the Board for the next 2 years. Anthony Tagavi seconded the motion. Kimberly Croley asked if the Board is automatically notified when a shipment is quarantined by the FDA. Executive Director Harlow said it is public knowledge that can be found on a report, but that the Board is not automatically notified. She requested that Biopeptek also be required to notify the Board if they ever have any shipments quarantined for any reason by the FDA. Biopeptek's Counsel asked for clarification if Ms. Croley was referring to any time product is put on hold or anytime product is rejected. Ms. Croley responded that the Board be notified any time it is anything other than being held for random sampling. After the discussion regarding the terms of the approval as listed above, the Board voted and the motion passed unanimously.

Orr, Robert, Pharmacist Application: Mr. Orr appeared before the Board due to the fact that he indicated he did not have a criminal history. When his background check was completed, a charge did show. He explained that he did not realize that this incident appeared on his record from 2012 when he was in pharmacy school.

Action: Meredith Figg motioned to approve Mr. Orr's application. Anthony Tagavi seconded, and the motion passed unanimously.

Vidrine, Kylee Brooke, MPJE request: She was not present. The Board agreed to come back to her agenda item later.

Parekh, Ashish (I09606), Reinstatement of intern registration request: Mr. Parekh appeared before the Board to request reinstatement of his pharmacy intern registration. Mr. Parekh gave the Board background on his situation and requested to be able to sit for the NAPLEX. He must have an intern license to sit for the exam.

Action: John Fuller motioned to approve Mr. Parekh's intern registration to allow him to sit for the NAPLEX. Meredith Figg seconded, and the motion passed unanimously.

Keen (Noffsinger), Martia (PT00011451), Reinstatement request: Ms. Keen appeared before the Board to request the reinstatement of her pharmacy technician registration. She began working in a pharmacy and when she tried to renew her technician registration, they realized it was revoked. Staff attorney Hannah Rodgers reviewed the situation for the Board from 2014. It appears that all communication from the Board to Ms. Keen at the time were returned to sender, so it was never received by Ms. Keen.

Action: Anthony Tagavi motioned to reinstate her pharmacy technician registration. Meredith Figg seconded, and the motion passed unanimously.

Ms. Keen was notified that she must keep her information, including her address, up to date with the Board at all times.

Latham-Cox, Haley: Ms. Latham-Cox appeared before the Board to obtain a pharmacy technician registration. Due to a marijuana charge on her record she had to appear before the Board. She has an offer to work remotely with Chewy, and they are aware of her record.

Action: Anthony Tagavi motioned to approve the pharmacy technician registration. John Fuller seconded, and the motion passed unanimously.

Shively, Craig: Mr. Shively appeared before the Board to obtain a pharmacy technician registration. He would like to be a CVS delivery driver, which would require a technician registration due to the fact he will be filling automated dispensing systems as part of his job duties.

Action: Anthony Tagavi motioned to approve the pharmacy technician registration. John Fuller seconded, and the motion passed unanimously.

Mascorro, Caden: Mr. Mascorro appeared before the Board to obtain a pharmacy technician registration. He has a criminal record for public intoxication, controlled substance, and resisting arrest. He pled guilty to all charges and is currently on misdemeanor probation until July. He currently has a job offer with CVS in London, Ky, and they are aware of his criminal history. He has no additional legal incidents.

Action: John Fuller motioned to approve the pharmacy technician registration. Anthony Tagavi seconded, and the motion passed unanimously.

INTERAGENCY/PROFESSIONAL ASSOCIATIONS

KPhA: Taylor Williams gave the KPhA update to the Board. Their Annual meeting is June 6 – 9, 2024. Board Vice President Anthony Tagavi requested comments/feedback the proposed amendment to 201 KAR 2:070 for the July meeting. KPhA will have an update after their next Board meeting and will be able to provide the comments for the July meeting.

BOARD REPORTS

Executive Director Report: Executive Director Chris Harlow gave the financial (eMARS) report that was included in the Board meeting materials. The Board is on track/budget for the fiscal year 2024, which ends June 30, 2024. We are continuing to work with Thoughtspan, the new technology vendor, and are currently paying the invoice for the initial buildout of the new software. The goal is to go live in October after all the renewal cycles have ended for the year. With the new platform, all users will have to create a login for the portal to be a user. We will continue to send updates to all users that this is coming soon.

Retreat discussion: Prioritizing the list of topics for July 23rd and 24th as well as other details. The Regulation Committee has requested moving the technician topic to the top of the list. They have some questions about the policy direction from the board. After discussion, the Board decided to focus on the technician regulation first, then address the changes in compounding regulations (inspection staff will give a presentation and a question-and-answer session on this topic), 201 KAR 2:070, and temperature tracking of prescription medications. The times for the 2 days are as follows: Tuesday, July 23, 10:00 a.m. to 4:30 p.m. and Wednesday, July 24, 9:00 a.m. until 4:30 p.m. Nikki Holiday will request the Transportation building auditorium for both days.

Executive Director Harlow then gave a staffing update. Taren Robin was hired as an administrative assistant for the front desk position, and the vacant inspector staff supervisor position that will be posted this summer. He also informed the Board that the federal SCRA Guidance for Pharmacist Licensure was now posted on our website.

General Counsel Report: General Counsel Eden Davis had an expungement request for the Board to determine if they consider it a minor offense. Case # 98-0126.

Action: John Fuller made a motion to determine this case a minor offense. Meredith Figg seconded, and the motion passed unanimously. The case will be expunged.

COMMITTEE REPORTS

KYPRN Committee: Brain Fingerson gave the PRN Committee report. The committee met on May 14, 2024. There were 2 anniversary appearances. There are 23 clients known to the Board and 4 that are self-reports. Brian will be attending the APhA institute on substance use dependencies in Salt Lake City May 28 – June 2.

Regulation Committee: Cathy Hanna gave the Regulation Committee report. The committee met on May 10, 2024 and approved the change of ownership draft regulation. The Committee asked the Board for direction on the Technician proposed rule(s) amendments, as well as to move this topic to the top of the list at the retreat.

Advisory Council: General Counsel Eden Davis gave the Advisory Council report. The council is working on temperature tracking of prescription medications. They are looking at other state to put together a framework, specifically Texas and Georgia.

Diversity & Inclusion Task Force: Shannon Borden gave the Diversity & Inclusion Task Force report. The Task Force met on March 28, 2024. Their May meeting was cancelled due to state office building closures. They continue to work on podcast creation and implementation. The 3 topics they are currently working on now are race, LGBTQIA+, and disabilities.

Protocol Review Committee: Cassie Hobbs gave the Protocol Review Committee report. She was prepared to present 3 protocols to the Board for approval, however Mr. Tagavi had some questions about the strike throughs on the education pieces, but that section was moved to the bottom of the page. Ms. Hobbs stated that was a formatting issue, as the committee is trying to make all the protocols look very similar in nature. Mr. Tagavi pointed out that the self-care protocol still had that listed at the top, so they do not seem to be consistent. The Board requested that these issues be corrected, and the committee provide them with both the strike-through versions as well as the final versions so they can see what has been struck through. No action was taken on these protocols.

CORRESPONDENCE

Closure of Permit (non-use) Extension Request – Owensboro Health Community Pharmacy (P08277): Jason Collins addressed the Board and explained that they had originally planned to be able to move in and begin operations in the building they purchased, however the prior tenant did not leave the property in the manner in which they expected it to be. They have had to do much more construction on the property than they anticipated, and it is taking longer than expected. They are hoping for a Aug 21 – 26, 2024 opening, which will put them just over a year without their permit being used so they are requesting an extension.

Action: Anthony Tagavi motioned to extend the permit until September 30, 2024. Meredith Figg seconded, and the motion passed unanimously.

Shared sink request, St. Matthews Community Pharmacy (P07821) and St. Matthews Specialty (P07869): This item was skipped due to no one attending from the entity.

Dual PIC Request: Jordan Smith (018455); P02542 and CP00154 – Dr. Smith would like to continue her PIC role at P02542, but also open a consulting/non-dispensing clinical pharmacy.

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

Dual PIC Request: Richard Slone (008306); P07140 and P06091. Mr. Slone had a PIC suddenly resign and he is seeking temporary dual PIC approval until he can find a replacement PIC.

Action: Anthony Tagavi motioned to approve the request for 6 months. Meredith Figg seconded, and the motion passed unanimously.

Returned to Vidrine, Kylee; MPJE Request: Ms. Vidrine owns a compounding pharmacy in Lake Charles, Louisiana, and she is trying to get licensed in KY so she can ship into the state. There was action taken against the applicant in Louisiana and she completed a corrective action plan in Louisiana, took additional training, and hired a compounding specialist as a consultant. Once she obtains licensure for herself in KY she plans on submitting an application for a KY non-resident pharmacy permit

Action: Anthony Tagavi motioned to approve the MPJE request. Meredith Figg seconded, and the motion passed unanimously.

OLD BUSINESS

201 KAR 2:370 Amendment: Pharmacy Services in long-term care facility: Executive Director Harlow gave the Board background on the existing regulation and the intent that was previously discussed about the “closed system” in automated dispensing systems language in the regulation. Once the pharmacist had checked the device, then it was not meant to be manipulated in any way before being put in the system. At the last meeting Board staff was directed to make that clearer in the definition in this regulation, which legal staff has done. “Tamper-resistant secure container” was the new definition that was added. The only other change to the regulation was the exclusion of assisted living communities and the definition of long-term care. Two years ago, the Legislature added assisted living communities and the definition of long-term care. That was brought before the Board at that time, but no regulation was ever filed with this update because the Board was working on technician regulation(s) at that time.

*Continued discussion was held on this topic until after lunch. The Board moved to the New Business section of the agenda, starting with the appointment of a pharmacist to the Board of Physicians and Advisors.

NEW BUSINESS

Board of Physicians and Advisors Appointment (One Appointment)

The following individuals applied for this appointment:

Baum, Regan A (015978)

Booker, Antonio (019273)

Cann, Amber (012015)

Carrico, Matt (015231)

Kebodeaux, Clark (015036)

Kramer, Andrea (015973)

Moore, Daniel (015588)

There were 2 rounds of confidential ballot voting by the Board members. Dr. Croley voted by private chat to Executive Assistant Nikki Holiday via Zoom. After the first round of voting the 2 individuals that did not get a vote were Antonio Book and Andrea Kramer. They were eliminated from the second round of voting. The Board members then voted again on the remainder of the applicants. The person with the most votes after the 2 rounds of votes was Dr. Matt Carrico.

Action: Kim Croley motioned to accept Dr. Carrico as the appointee to the Board of Physicians and Advisors. Anthony Tagavi seconded, and the motion passed unanimously.

Declaratory Opinion – Guidance for Kentucky Pharmacies Acquiring Human Compounded Products from 503B Outsourcing Facilities:

Executive Director Harlow reviewed the draft guidance published by the FDA on this matter. The FDA has interpreted that outsourcing facilities may provide compounded products to pharmacies for dispensing, so long as there is no further resale of that product. The Board has addressed this before, but we were just waiting for FDA guidance. The FDA has determined this is a wholesale exemption. Board staff provided guidance in a declaratory opinion for review and approval by the Board. (See attached).

Action: Anthony Tagavi motioned to accept the declaratory opinion. John Fuller seconded, and the motion passed unanimously.

LUNCH BREAK

THE BOARD RETURNED TO OLD BUSINESS AFTER LUNCH

201 KAR 2:370 Amendment: Pharmacy Services in long-term care facility (continued): the Board continued their discussion on the amendments to this regulation.

Action: Anthony Tagavi motioned to approve the amendments to this regulation. Meredith Figg seconded, and the motion passed unanimously.

The Board scheduled a special-called meeting for August 28, 2024 at 10:00 a.m. eastern time for public comment on any regulations approved today that will be filed.

201 KAR 2:480 New Regulation: Telework: General Counsel Eden Davis shared her screen so she could make any potential changes the Board may require. Executive Director Harlow reviewed comments received and the comments were discussed by the Board members.

Action: Meredith Figg motioned to file this regulation as written. John Fuller seconded, and the motion passed unanimously.

201 KAR 2:210 Amendment: Patient records, drug regimen review, patient counseling, and final product verification: General Counsel Eden Davis shared her screen so she could make any potential changes the Board may require. Executive Director Harlow reviewed comments received and the comments were discussed by the Board members.

Action: John Fuller motioned to file this regulation as written. Meredith Figg Seconded, and the motion passed unanimously.

201 KAR 2:470 New Regulation: Change of Ownership: General Counsel Eden Davis shared her screen so she could make any potential changes the Board may require. Executive Director Harlow reviewed comments received and the comments were discussed by the Board members.

Action: Anthony Tagavi motioned to file this regulation as written. Kim Croley seconded, and the motion passed unanimously.

Jennifer Wintergerst, Legal Counsel for clients in cases 22-0029/22-0106 addressed the Board prior to going into Closed Session for their discussion on these cases.

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

CLOSED SESSION

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

2023 CRP Settlement Review: 22-0029 / 22-0106

Action: Anthony Tagavi motioned to dismiss the above referenced cases. John Fuller seconded. Kim Croley, Jason Belcher, Meredith Figg, and Jonathan Van Lahr abstained from the vote. The motion passed.

Action: Meredith Figg motioned to enter closed session. Jason Belcher seconded, and the motion passed unanimously.

CLOSED SESSION

Action: Meredith Figg motioned to exit closed session. Jason Belcher seconded, and the motion passed unanimously.

2024 CRP Evidentiary Review: 24-0049A

Action: Meredith Figg motioned for an interim suspension order. Jonathan Van Lahr seconded. Kim Croley, John Fuller, and Anthony Tagavi abstained. The motion passed.

NEXT MEETING: July 24, 2024 (Retreat July 23, 2024)

ADJOURNMENT

Action: Meredith Figg motioned to adjourn the meeting. Anthony Tagavi seconded, and the meeting adjourned at 2:17 p.m.