

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

March 27, 2024

10:00 a.m.

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

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; 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 10:01 a.m.

President Van Lahr informed the Board and the public that Peter Cohron has resigned from the Board of Pharmacy.

MINUTES: Minutes from the January 24, 2024 meeting.

Action: Anthony Tagavi motioned to accept the minutes from the January 24, 2024 meeting. John Fuller seconded, and the motion passed unanimously.

APPEARANCES

Child Fatality and Near Fatality External Review Panel: Dr. Melissa Currie, Child Abuse Pediatrician with Norton Children's Pediatric Protection Specialists, and Professor at the University of Louisville School of Medicine, gave a presentation to the Board about the Panel's findings about child fatalities and near fatalities.

Adams, James Pruett, Pharmacist License Transfer: Mr. Adams spoke to the Board and explained his criminal history and why he was before them requesting a license transfer.

Action: Anthony Tagavi motioned to approve the license transfer application. Meredith Figg seconded, and the motion passed unanimously.

Henderson, Leann, Pharmacist License Reinstatement: Ms. Henderson appeared before the Board for her pharmacist license reinstatement. She appeared before the KYPRN Committee at their March 9, 2024 meeting, and the Committee recommended that the Board approve her to sit for the NAPLEX and MPJE. Once she passes both exams she is to come back before the Board for them to determine what the terms should be with her license.

Action: Anthony Tagavi motioned to approve the KYPRN recommendations and allow Ms. Henderson to sit for exams. John Fuller seconded, and the motion passed unanimously.

Kokoszka, Robert, Pharmacist License Transfer: Mr. Kokoszka appeared before the Board and spoke about his history and issues in both Georgia and Tennessee. He is involved in the Tennessee Recovery program and is currently being monitored there. License transfer was authorized. He does not have to retake the MPJE and must sign an agreed order mirroring the terms of his Tennessee consent order.

Action: Anthony Tagavi motioned to approve his license transfer with an agreed order that mirrors his Tennessee agreement. John Fuller seconded, and the motion passed unanimously.

Hinkle, Jaremeia, Pharmacy Technician application: Ms. Hinkle attended virtually and explained her criminal history to the Board. She is currently seeking employment at a clinical practice pharmacy where she will work remotely therefore there are no drugs on site.

Action: Meredith Figg motioned to approve Ms. Hinkle's technician application only for her current employer. If she wishes to work somewhere else, she must come before the Board for approval. If she has no further drug charges in the next 2 years, that condition sunsets. Anthony Tagavi seconded, and the motion passed unanimously.

Whitman, Danisha, Pharmacy Technician application: Ms. Whitman attended virtually and explained her criminal history to the Board. She stated that she is in the process of getting her record expunged. She currently works at Knipper Rx in an office/administrative setting with no drugs on site.

Action: John Fuller motioned to approve Ms. Whitman's technician application with no conditions. Anthony Tagavi seconded, and the motion passed unanimously.

CVS Air Support: John Long, Director of Regulatory Affairs for CVS gave the introduction for the presentation as well as introduced Joe Lavino, Attorney in the CVS Regulatory Affairs Department, and Todd Picklesimer, Senior Manager in Operations overseeing the Air Support project. Mr. Picklesimer presented virtually on CVS's air support program, how it operates and where it is currently being used. During the presentation, it came to light that in the will-call area of the pharmacy, prescriptions that had been final product verified (PV2) as well as those without PV2 occurring yet were co-mingled. Board members raised concerns about this and said it is prime for unverified prescriptions to be sold. CVS clarified that these comingled prescriptions are already present in the will-call area of CVS stores in KY because of the use of virtual verification. The Board thanked CVS for their presentation and said they would address areas of concern later in the agenda with the discussion of the amendment of 201 KAR 2:210.

INTERAGENCY/PROFESSIONAL ASSOCIATIONS

KPhA: Cathy Hanna gave the KPhA update to the Board. Applications for the 2025 appointments to the Board of Pharmacy are due by March 31, 2024.

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 bill (HB6). Board staff continue to work on the contract with Thoughtspan for the new technology platform, and they will be onsite April 11th and 12th to meet with staff. The goal is to have at least the first version of the technology rolled out by October 1, 2024. We are waiting for the Budget Bill to be signed to move forward with the contract. Executive Director Harlow then gave the Board staff update. He introduced Ms. Taylor Rostova, Pharmacy and Drug Inspector for the greater Jefferson County area. He also informed the Board we have extended an offer to Ms. Taren Robin for the Administrative Assistant – Front Desk position with a start date of April 1st.

Dr. Harlow then gave a Legislative update. SB188, PBM reform – this does have language in it relating to the Board of Pharmacy. In this bill the Board's role will be with data collection. If this passes, the Board will be required to promulgate regulation relating to data collection. It will go through the normal process. The data collection will not start until January 2026, and we will provide that to the Department of Insurance. HB 274 did pass and has been delivered to the Governor for signature. This bill allows pharmacists to immunize patients down to age 5. Implementation will be sometime in July. He noted HB 386 which amends the limits for pseudoephedrine. HB 829, medical cannabis has passed the House and is now in the Senate waiting to be put on the agenda for a Committee. If this passes, patients will be required to have a consultation with a pharmacist, and the Board will be required to promulgate regulation by August 1, 2024. HB 438, prescribing glucagon to a school. It will allow pharmacists to dispense glucagon in the name of a school.

General Counsel Report: General Counsel Eden Davis gave a review of "Walking Quorums" to the Board.

Deputy Executive Director/Inspection Staff: Deputy Executive Director Juliana Swiney reintroduced Taylor Rostova, the new Pharmacy and Drug Inspector for the greater Jefferson County area. She also thanked the Inspection Staff for their help in training Ms. Rostova.

COMMITTEE REPORTS

KYPRN Committee: Emily Caporal gave the KYPRN Committee report. The Committee met on March 12, 2024, and they had one appearance, Leann Henderson. There are 2 new committee members who the Board chose at their January meeting. Stuart Lemarr was elected chairperson and Lisa Bradley was elected vice chairperson. The Committee voted 8 – 0 in support of recommending to the Board that she be allowed to take the NAPLEX and MPJE. If she passes the exams, then she would need to come back before the Board to determine any terms on her licensure. There are currently 24 individuals being monitored, 20 of which are known to the Board. The next meeting is May 9, 2024 at 2:00 p.m.

Regulation Committee: Cathy Hanna gave the Regulation Committee report. The Committee met on March 15, 2024. The Committee reviewed the Change of Ownership proposed regulation and has asked for more information about business law to assist with their review of the regulation. Next on this committee's agenda is the Pharmacy Technician regulation.

Protocol Review Committee: Deputy Executive Director Juliana Swiney gave the Protocol Review Committee report. She presented the new signature page for Board approval. This page will apply to all the Board approved protocols.

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

FACILITY APPLICATIONS

Non-resident pharmacy application, Express Med Pharmaceuticals, d/b/a SelectRx PA - Revisit: Kyle Decker (in person) and Janelle Martens (via Zoom) attended to answer any questions. They had provided the requested documentation for the Board's review which included the script that they use when contacting people via telephone to see if they want to enroll in their services, and the number of patients served out of their currently permitted facility in Indianapolis facility. Board members expressed concern with their script and their target audience. They also expressed concern with how a patient can opt-out of the program, and how their prescriptions will be transferred. Ultimately, it was determined that there is no violation of pharmacy law, so there is no reason to deny the permit.

Action: John Fuller motioned to approve the non-resident pharmacy application and Anthony Tagavi seconded. Meredith Figg asked the representatives if they would be willing to clean up the language in their phone script, so it is very clear to the patient what they are agreeing to. The representatives agreed that they would. The motion passed unanimously.

Non-resident pharmacy application, Almac Clinical Services LLC – Revisit: Frances Smith with Almac attended the meeting virtually. They are a clinical trial pharmacy, and there are currently no rules addressing decentralized clinical trials in Kentucky. It was agreed that the Board would promulgate a regulation for pharmacies servicing decentralized clinical trials, and once that occurs Almac shall follow the rules promulgated and the waivers granted today will be void. The following waivers were granted via the action below:

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: John Fuller motioned to approve the non-resident pharmacy permit application with the waivers until such rules can be promulgated. Anthony Tagavi seconded, and the motion passed unanimously.

CORRESPONDENCE

Ohio County Healthcare Waiver Request: 201 KAR 2:074(7)(2)(a)(2): Due to staffing shortages they are looking for alternatives until qualified pharmacy technician candidates can be found. They are requesting consideration for a waiver to be allowed to designate and train specific RNs who will be assigned to work in the pharmacy department during specific times to restock the ADCs until the appropriate certified pharmacy technicians can be hired and trained to complete the task.

Action: John Fuller motioned to approve temporary waiver through August 15, 2024 to authorize registered nurses (RNs) also registered as pharmacy technicians to load automated dispensing systems. Should the pharmacy be able to hire certified pharmacy technicians prior to August 15, 2024, the pharmacy should utilize

those certified pharmacy technicians in lieu of RNs registered as pharmacy technicians. Anthony Tagavi seconded, Meredith Figg abstained, and the motion passed.

Offsite Storage Requests

P06279, South Creek Drug

Action: John Fuller motioned to approve the offsite storage request for P06279. Meredith Figg seconded, and the motion passed unanimously.

P06700, Clinic Pharmacy, Cynthiana

Action: John fuller motioned to approve the offsite storage request for P06700. Anthony Tagavi seconded, and the motion passed unanimously.

Dual (multiple) PIC request, Harry Mattingly (010934), P05146, P07677, and pending application:

Breckinridge Memorial Hospital is going to establish a trailer outside of the currently permitted space with the plan of expanding the pharmacy space inside the hospital in approximately the next 3 years. Board members asked if there were other pharmacists currently working there who could be the PIC for the additional permit. Inspector Rhonda Hamilton had already spoken with the pharmacy staff and they did say there was someone else who could take on the role if the request was denied.

Action: Meredith Figg motioned to approve the dual PIC request for 3 months. There was no second, and the motion died. Therefore, the request was denied.

Taylor, Mackynzie – NAPLEX and MPJE eligibility extension request: Due to health and family issues, Ms. Taylor requested an extension of her eligibility to take the exams.

Action: Meredith Figg motioned to approve the request. John Fuller seconded. Executive Director Harlow asked for clarification on how long the extension is valid. Board members and Ms. Taylor agreed that 6 months will be sufficient. The motion passed unanimously.

OLD BUSINESS

201 KAR 2:370 Clarification Request: Representatives (John Long, Joe Lavino, and Mark Kemper) from CVS gave a presentation about automatic dispensing machines in long term care facilities. (*An Overview of Emergency Dispensing Automation in LTC*) Some Board members were interested in visiting a long-term care facility to see how this process works, but scheduling was difficult so CVS made this presentation to explain the process. Cathy Hanna, past Board member, explained the intent of this regulation when it was written because she was on the Board at the time. Board members had questions including, but not limited to, 1) Who is responsible for med errors? 2) Is this system tamper resistant? 3) What is the definition of “tamper resistant”? 4) How would inspection staff inspect and enforce? General Counsel Eden Davis and Member Anthony Tagavi stated that the Board needs to define “tamper resistant.”

Action: Anthony Tagavi motioned that the CVS Omnicell process is compliant with 201 KAR 2:370. John Fuller seconded, and the motion passed 4 – 1.

Action: Anthony Tagavi motioned to direct Board staff to define “tamper resistant.” John Fuller seconded, and the motion passed unanimously.

201 KAR 2:465, Non-Resident Pharmacy Applications and Waivers – New Regulation; 201 KAR 2:030, License Transfer and Non-Resident Pharmacist License – Amendment; 201 KAR 2:050, Licenses and Permits, fees – Amendment: All three of these regulations are ready to be filed upon the approval of the Board.

Action: Meredith Figg motioned to file these regulations. John Fuller seconded, and the motion passed unanimously.

201 KAR 2:210, Patient records, drug regimen review, patient counseling, and final product verification: Kim Croley, Chairperson of the Advisory Council, gave the Board a report on what the Advisory Council discussed and their edits on this regulation. Executive Director Harlow gave the Board some background and explained that the regulations first went to the Regulation Committee, then to the Advisory Council, and now back to the Board. There was no specific language changes suggested by the Council, but they recommended that the quality control percentage be reduced to 1%. They decided that 1% was a large enough sample size to capture any errors. This was the only change/recommendation on this regulation from the Council.

Board President Jonathan Van Lahr expressed that he would like to see all of the changes effectuated and see the final version before voting on the regulation.

Action: Anthony Tagavi motioned to table the vote on this regulation until the May meeting and post the draft regulation on the website. John Fuller seconded, and the motion passed unanimously.

201 KAR 2:480, Telework – New regulation: Kim Croley then gave the Board the Advisory Council's recommendations on this regulation. They included the following: update the definition of telework; add the definition of electronic supervision; in section 3, requirements, make inspection 6 to 12 months; add more technology language to the policy and procedures section; cyber security is going to have to be addressed at some point; do not move section 6 to policy and procedures.

Action: Anthony Tagavi motioned to table the vote on this regulation until the May meeting and post the draft regulation on the website. John Fuller seconded, and the motion passed unanimously.

Central Fill/Shared Services Proposed Regulation: This is going to be a retreat topic.

Action: Anthony Tagavi motioned to defer the discussion on this regulation to the retreat. Meredith Figg seconded, and the motion passed unanimously.

NEW BUSINESS

CE Deferral Requests Pursuant to 201 KAR 2:015(5)(2):

Action (007168): John Fuller motioned to approve this deferral for one (1) year. Pharmacist must complete 30 hours of CE for 2024. Anthony Tagavi seconded, and the motion passed unanimously.

Action (010211): Anthony Tagavi motioned to approve this deferral for one (1) year. Pharmacist must complete 30 hours of CE for 2024. John Fuller seconded, and the motion passed unanimously.

Action (013117): Anthony Tagavi motioned to approve this deferral for the opioid requirement. Pharmacist has already completed the requirement. John Fuller seconded, and the motion passed unanimously.

Action (017066): Anthony Tagavi motioned to approve the deferral of this opioid requirement. Pharmacist must complete this requirement within 30 days. John Fuller seconded, and the motion passed unanimously.

Action (021938): Anthony Tagavi motioned to approve the deferral. Pharmacist must complete CE by 2/28/2024. John Fuller seconded, and the motion passed unanimously.

Board member Anthony Tagavi directed Board staff that when a pharmacist is identified who has not completed the opioid CE requirement, they are to be immediately contacted and told they have 30 days to complete this requirement.

201 KAR 2:015 Proposed Amendment: This amendment would change the CE period to align with the pharmacist renewal period (Mar 1 – Feb 28) instead of the period being a calendar year (Jan 1 – Dec 31) annually. Board members discussed implementing a grace period or enforcement discretion. Executive Director Harlow told the Board that Board staff would work on language clarifying this.

Action: Anthony Tagavi motioned to approve the language which moves the current CE period from calendar year (Jan 1 – Dec 31) to mirror the pharmacist renewal period year (March 1 – Feb 28). Meredith Figg seconded, and the motion passed unanimously.

Closure of W04422 due to nonuse: A representative (Cesar Rodriguez's secretary, Liz) from Value Wholesale Solutions (W04422) appeared before the Board. This entity has a pending non-resident wholesaler license application with the Tennessee Board of Pharmacy. Liz stated that Tennessee is awaiting Kentucky's decision before they approve or deny their application. Inspector Jessica Williams explained to the Board that she has been unable to conduct any successful inspections since the permit was issued on Aug. 6, 2020. There is simply nothing to inspect. Mr. Tagavi told Liz they could reapply in the future.

Action: Anthony Tagavi motioned to close W04422 due to nonuse. John Fuller seconded, and the motion passed unanimously.

BOARD RETREAT TOPICS DISCUSSION

Executive Director Harlow asked the Board if they were still interested in having CE at the retreat or do they want to eliminate the potential CE and only have discussion topics. Topics will include the following and will be prioritized at the May meeting:

- Shared services
- Temperature tracking
- Pharmacy Technicians
- DSCSA – update on the dispensing side
- USP
- Intermediary services

NEXT MEETING: May 22, 2024

ADJOURNMENT

Action: Meredith Figg motioned to adjourn the meeting. John Fuller seconded, and the meeting adjourned at 5:11 p.m.