

KENTUCKY BOARD OF PHARMACY

**Justice and Public Safety Building
125 Holmes Street, 1st Floor Conference Room
Frankfort, KY 40601**

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November 29, 2023

10:00 a.m.

Board Meeting Agenda

- I. CALL TO ORDER
- II. MINUTES
- III. INTERAGENCY/PROFESSIONAL ASSOCIATIONS
- IV. BOARD REPORTS
 - A. Executive Director
 - a. eMars
 - b. Pharmacy Technician Background Check Questionnaire
 - c. Offsite Storage
 - d. Licensing Software
 - e. Delegation of Authority Guidance Document
 - B. General Counsel
 - a. Travel Request, FARB Forum on Professional Regulation
 - b. Change of Ownership Regulation
 - c. Regulation Status Update
 - C. Deputy Executive Director/Inspection Staff
 - a. PIC Checklist Tool
- V. COMMITTEE REPORTS
 - a. KYPRN
 - b. Regulation Committee

- c. Advisory Council
- d. Protocol Review Committee

VI. APPLICATIONS

- a. Pharmacists
 - i. Parmar, Smitaben Surendrabhai (MPJE Request)
- b. Pharmacy Technicians
 - i. Greer, Alexis
 - ii. Sullivan, Heather
- c. Non-Resident Pharmacy
 - i. Express Med Pharmaceuticals, INC DBA SelectRX

VII. CORRESPONDENCE

- a. Dual PIC Requests
 - i. AZ2831 and AZ284 – Stephen Persons (KY License 018674)
 - ii. P01578 and P07448 – Jim Cherry (KY license 008814)
- b. Offsite Storage Requests
 - 1. Commons Corner Apothecary (P08278)
 - 2. Medicine Shoppe Inez (P01894)
 - 3. Amerimed, INC (P07532)
 - 4. ARH Paintsville Pharmacy (P08067)
 - 5. UKHC Retail Pharmacies (P07556, P07636, P07686, P07583, P08184, P08211, P08210, P01621)

VIII. OLD BUSINESS

- a. 201 KAR 2:210 proposed amendment

IX. NEW BUSINESS

- a. Pharmacy Closures and Pharmacist Strikes
- b. 201 KAR 2:370 Clarification Request
- c. Proposed 2024 Board Meeting Dates and January Case Review Panel
- d. Election of 2024 Officers and Case Review Panel Members

X. CLOSED SESSION

ATTENTION: A portion of the meeting may be held in closed/executive session for the purpose of discussing and deliberating upon open investigations or the review of information required to be conducted in private according to federal and state law. The specific statutory sections authorizing closed session 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)(k). Following discussion and deliberation, any and all action will be taken in open/public session.

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
November 29, 2023
10:00 a.m.

CALL TO ORDER: President John Fuller called the meeting to order at 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; Amanda Harding, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector; Rhonda Hamilton, Pharmacy and Drug Inspector; Hannah Rodgers, Staff Attorney; and Nikki Holiday, Executive Assistant.

MINUTES: Anthony Tagavi motioned to approve the September 20, 2023 meeting minutes. Jonathan Van Lahr seconded, and the motion passed unanimously.

(Skipped to agenda item: KYPRN Committee Report)

KYPRN Committee: Brian Fingerson gave the PRN Committee report. The Committee met on November 14, 2023. There are 20 clients, 4 are not known to the Board as they are self-reports. The next meeting is on January 9, 2024, and the remaining meetings for 2024 will be scheduled at that time. Mr. Fingerson made a request to the Board for funding for Committee members to attend the CAPTASA conference in Lexington in February. Executive Director Harlow informed the Board that this expense was not included in the Budget for this year. He also expressed that Board staff would have to research paying non-employees and if that is allowed by Finance, and if so if it could be processed in time for this year's conference.

Action: Jonathan Van Lahr motioned to approve paying for no more than 4 Committee members if Board staff can get the appropriate approvals from Finance, and the only cost potentially covered would be the registration fee. Peter Cohron seconded, and the motion passed unanimously.

INTERAGENCY/PROFESSIONAL ASSOCIATIONS

KPhA: Taylor Williams, Executive Fellow at KPhA, talked about CE opportunities including the opioid requirement. KPhA will be launching their new vetting process for Board of Pharmacy nominations next year. More information about that will be available after the first of the year as they are finalized by the Professional Affairs Committee. Pharmacy Day at the Capitol will be February 22, 2024 for anyone interested in attending.

BOARD REPORTS

Executive Director Report: Executive Director Harlow addressed the opioid CE requirement. In conversations with NABP, the original plan was to code these courses in their CE monitor as 08 and it would then show that this requirement had been met, however that has not yet been done as of this morning. Since it is such a broad category, there are many out there that are not coded 08 but clearly meet the requirement. He is requesting that for the 2024 CE audit, that Board staff do not audit for this requirement. We do a 100% audit, and there is no way logistically to audit for this requirement since there are more than just the ones coded 08. The expectation is that this requirement is to be met, but it will be based on pharmacists' professional judgement if the course meets the requirement or not. The question is asked on the renewal application.

Board Guidance: Pharmacists should use professional judgement to ensure that they have met the opioid CE requirement.

Executive Director Harlow then discussed the upcoming pharmacist renewal period which will open on January 2, 2024. Board staff is in the testing environment now, and the KASPER upload last year was just a one-time requirement as we are now requiring this for all new licensees. We have had technology issues with our software/database. The vendor moved to a cloud-based system over the summer which is what has seemed to cause these problems, and it does not seem like they have the capacity to fix it. The wholesaler renewal period was quite frankly a nightmare, and we continue to have issues today with pharmacy technician registrations. That said, we have been looking at moving to more of a paperless system and streamlined process including the database, inspection software, case management, etc. Dr. Harlow has been in contact with a vendor who can provide these services, and the information is in the Board packet. The Commonwealth Office of Technology (COT) is aware of the issues and the potential change to a new vendor and is in support of it. They have informed us we are not the only agency experiencing technical issues with the current vendor, Tyler Technologies. If we get the appropriation from the Legislature for the new technology, then we can move forward.

The eMars report was provided to the Board members and there were no questions.

The pharmacy technician background check survey results were discussed next. Executive Director Harlow went over the results of the survey. There are gaps in background checks being performed. This survey is for informational purposes only. To require a background check for pharmacy technicians, we would have to have a statutory change to authorize it. Jonathan Van Lahr suggested addressing background checks in our newsletter and encourage employers to conduct them.

Every three (3) years the Board gets audited by the FBI and KSP on our process and how we manage the results of the background checks that are performed on new pharmacist applicants. The Board just completed these audits and received full compliance from both agencies.

Offsite storage – At the last meeting there was discussion about offsite storage and the requirements, etc. Board staff recommends at some point in the future amending 201 KAR 2:100 to make the timelines more clear regarding offsite storage and a waiver provision. There was further discussion about things that should be considered to include in the regulation when it is drafted.

Action: Anthony Tagavi motioned to make the following the Board's guidance on this issue while a regulation is being written by the Regulation Committee: Allow records of one (1) year or greater to be moved offsite with the approval of the Board, notwithstanding any other laws. Meredith Figg seconded, and the motion passed unanimously.

Delegation of authority document – Board staff have created a "Delegation of Authority" document which establishes a specific policy for our Board stating what things are delegated to the Board or specific Board members, and what has been delegated by the Board to the Executive Director in one centralized document, to be reviewed annually. Anthony Tagavi asked if we can add the date the item was delegated. President Fuller stated that the document should be reviewed annually when the Board does annual training.

Action: Jonathan Van Lahr motioned to approve the delegation of authority document with the addition of adding the dates and reviewing it annually. Anthony Tagavi seconded, and the motion passed unanimously.

General Counsel Report: General Counsel Eden Davis requested to attend the Federation of Association of Regulatory Boards (FARB) Forum on Professional Regulation in Fort Worth, Texas January 25 – 27, 2024.

Action: Anthony Tagavi motioned to approve the out-of-state travel request. Peter Cohron seconded, and the motion passed unanimously.

Potential change of ownership regulation – General Counsel requested authority from the Board to draft framework for a change of ownership regulation. Once drafted, this would go to the Regulation Committee and then to the Board for final approval. Items to be considered in the potential regulation included the following: if a complaint has been filed against someone or they are involved in an active investigation a change of ownership would not be approved until the discipline has been resolved, and being mindful of when a change in the permit number is required. Board staff fields questions daily about what defines a change of ownership, and what is required when there is a change of ownership. This regulation would provide clarity to permit holders as to when a change of ownership application is required.

Action: Jonathan Van Lahr motioned to give General Counsel the authority to draft the framework for a change of ownership regulation. Jason Belcher seconded, and the motion passed unanimously.

Regulation updates – There are at least 10 regulations going to the Joint Committee on Health Services on December 13, 2023. General Counsel provided the regulation spreadsheet to the Board members in their packet. 201 KAR 2:070 will sunset in April 2024. The Board can request certification from LRC to get 18 additional months if needed.

Action: Anthony Tagavi motioned to move 201 KAR 2:070 to the Regulation Committee for review due to it sunseting in April 2024. Peter Cohron seconded, and the motion passed unanimously.

Deputy Executive Director/Inspection Staff: Inspection staff have created a document that is a tool for Pharmacists In Charge (PIC) which outlines the responsibilities of a PIC. This checklist can be used as a guide for any new PIC. Meredith Figg suggested emailing this document out whenever someone submits a PIC change form.

Meredith Figg had one suggested change to the document. She suggested in the section “Process for notifying Board of Pharmacy in writing within 14 calendar days of: -Pharmacy staff changes; and -Change in the employment of the PIC” to change “Pharmacy staff” to say only “Pharmacists.”

Action: Jonathan Van Lahr motioned to approve the PIC Checklist document with Meredith Figg’s change. Meredith Figg seconded, and the motion passed unanimously.

COMMITTEE REPORTS

Regulation Committee: Mike Burlison gave the Regulation Committee report. The Committee met on November 17, 2023. The main focus was Centralized Prescription Processing, which the Committee finished and has moved on to the Board for approval. The Committee tabled 201 KAR 2:220, Collaborative Care Agreements until the January meeting. The next meeting is January 12, 2024. The Committee has scheduled their 2024 meetings for two Fridays prior to the Board meeting. This ensures that materials will be ready for the Board packet each month.

Action: Jonathan Van Lahr motioned to send the Centralized Prescription Processing and Telework Regulations to the Advisory Council for review. Anthony Tagavi seconded, and the motion passed unanimously.

Advisory Council: Executive Director Harlow gave the Advisory Council report. The non-resident licensure draft regulation passed the Advisory Council by a vote of 7 – 2. The Council voted to move forward with the draft regulation that was filed and then pulled last year, with the caveat that we reduce the fees for a license transfer utilizing NABP Verify. Executive Director Harlow recommended bringing the draft regulation we had before back to the Board for review in January.

Protocol Review Committee: Executive Director Harlow gave the Protocol Review Committee report. The Committee is still reviewing the flue and strep protocols and will bring them back to the Board for approval when they are completed. The next Protocol Review Committee meeting is December 19, 2023.

APPLICATIONS

Pharmacist: Parmar, Smitaben Surendrabhai (MPJE Request)

Action: Jonathan Van Lahr motioned to approve this MPJE Request. Anthony Tagavi seconded, and the motion passed unanimously.

Pharmacy Technician: Greer, Alexis

Action: Anthony Tagavi motioned to approve this pharmacy technician registration via an Agreed Order that would state that she cannot work in a pharmacy where there are drugs physically present. Peter Cohron seconded, and the motion passed unanimously.

Pharmacy Technician: Sullivan, Heather

Action: No action was taken. Ms. Sullivan must first see if her employer has a DEA waiver allowing her to work there due to her felony conviction, or the employer must first obtain one. Once that occurs, she may bring her request back to the Board.

Non-resident Pharmacy: Express Med Pharmaceuticals, Inc. d/b/a SelectRX

Action: No representative from this facility attended the meeting, therefore no action was taken. The Board requested to revisit the application at the January meeting so long as a representative from the applicant attends the meeting.

CORRESPONDENCE

Dual PIC Request: Stephen Persons (018674) for AZ2831 and AZ284.

Action: No action was taken. The Board would like to speak to the applicant and has requested that he attend the January meeting.

Dual PIC Request: Jim Cherry (008814) for P01578 and P07448.

Action: Jonathan Van Lahr motioned to approve this dual PIC request for 3 months. Meredith Figg seconded, and the motion passed unanimously.

Offsite Storage Request: Commons Corner Apothecary (P08278). Jonathan Van Lahr recused himself from this discussion.

Action: Peter Cohron motioned to approve this request. Meredith Figg seconded, Jonathan Van Lahr abstained, and the motion passed.

Offsite Storage Request: Medicine Shoppe Inez (P01894)

Action: Peter Cohron motioned to approve this request. Jonathan Van Lahr seconded, and the motion passed unanimously.

Offsite Storage Request: Amerimed, Inc. (P07532)

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

Offsite Storage Request: ARH Paintsville Pharmacy (P08067)

Action: Anthony Tagavi motioned to approve this request. Jonathan Van Lahr seconded, and the motion passed unanimously.

Offsite Storage Request: University of KY Healthcare (P07556, P07636, P07686, P07583, P08184, P08211, P08210, P01621). Anthony Tagavi recused himself from this discussion. The request will be amended to state records greater than 1 year old instead of records greater than 6 months old. Inspector Jessica Williams provided the Board members with a summary and had no issues with the request.

Action: Peter Cohron motioned to approve this request with the amendment to records greater than 1 year old. Meredith Figg seconded, Anthony Tagavi abstained, and the motion passed.

OLD BUSINESS

201 KAR 2:210 proposed amendment: General Counsel Eden Davis and Executive Director Harlow both gave background information on the proposed amendment and feedback from the Regulation Committee. The Board discussed the proposed amendments.

Action: Jonathan Van Lahr motioned to forward this regulation to the Advisory Council for review and request their input by the March Board meeting. Peter Cohron seconded, and the motion passed unanimously.

NEW BUSINESS

Pharmacy Closures and Pharmacist Strikes: For informational purposes only. There have been some questions about how any pharmacy closures caused by pharmacist strikes should be handled. The closure regulation, 201 KAR 2:106, should be referenced and followed in this situation.

201 KAR 2:370 Clarification Request: Pharmacy and Drug Inspector Amanda Harding explained why this clarification is necessary and went through the scenario of how a certified pharmacy technician loads automated, prefilled medication machines in long-term care facilities. Inspection staff needs clarification if they are complaint with law in this filling process. Cathy Hanna explained the intent behind the regulation, as she was a Board member at the time this regulation was authored. Ms. Hanna explained that the intent was that there would be no further manipulation after the pharmacist checked the medication drawers at the pharmacy prior to delivery and insertion into the machine. Board members Jonathan Van Lahr and Anthony Tagavi expressed an interest in visiting a long-term care facility that uses pre-loaded medication machines. General Counsel will prepare a legal briefing on this issue and the Board tabled this topic until the January meeting.

Proposed 2024 Board Meeting Dates and January Case Review Panel: The following are the proposed 2024 Board of Pharmacy meeting dates. They will all begin at 10:00 a.m.:

January 24, 2024

March 27, 2024

May 22, 2024

July 24, 2024

September 25, 2024

November 20, 2024

Action: Peter Cohron motioned to approve these dates for the 2024 Board meetings. Jonathan Van Lahr seconded, and the motion passed unanimously.

The Case Review Panel members decided to have a planning meeting on December 14, 2023, at 10:00 a.m.

Election of 2024 Officers and Case Review Panel Members:

Action: Anthony Tagavi motioned to nominate Jonathan Van Lahr as Board President for 2024. Peter Cohron seconded, and the motion passed unanimously.

Action: Peter Cohron motioned to nominate Anthony Tagavi as Board Vice President for 2024. Jonathan Van Lahr seconded, and the motion passed unanimously.

Action: Anthony Tagavi motioned to elect Meredith Figg to the 2024 Case Review Panel as the Chairperson. Jonathan Van Lahr seconded, and the motion passed unanimously.

Action: Peter Cohron motioned to elect Jason Belcher to the 2024 Case Review Panel. Anthony Tagavi seconded, and the motion passed unanimously.

Action: Peter Cohron motioned to elect Jonathan Van Lahr to the 2024 Case Review Panel. Anthony Tagavi seconded, and the motion passed unanimously.

CLOSED SESSION

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

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

Action: Anthony Tagavi motioned that permit P07711 constitutes an imminent danger to public health and welfare, therefore the Board will be seizing the drugs and pharmacy records from the permitted space. Jonathan Van Lahr seconded, and the motion passed unanimously.

NEXT MEETING: The next meeting of the Kentucky Board of Pharmacy will be January 24, 2024 at 10:00 a.m.

ADJOURNMENT

Action: Meredith Figg motioned to adjourn. Peter Cohron seconded, and the meeting adjourned at 2:15 p.m.