KENTUCKY BOARD OF PHARMACY

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

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September 20, 2023 10:00 a.m.

Board Meeting Agenda

- I. CALL TO ORDER
- II. MINUTES a. July 26, 2023 & July 27, 2023

III. APPEARANCES

- a. Tabor, Brenda- Pharmacy Technician Reinstatement Request
- b. Perpich, John Pharmacist License Reinstatement Request

IV. INTERAGENCY/PROFESSIONAL ASSOCIATIONS

V. BOARD REPORTS

- A. Executive Director
 - a. eMars
 - b. Budget Update and ABR Request
 - c. NABP District 3 Updates
- B. General Counsel
 - a. Expungement Request Case 17-0486
- C. Deputy Executive Director/Inspection Staff
 - a. DEA 106 trends
- **VI.** COMMITTEE REPORTS
 - a. KYPRN

- b. Regulation
 - i. 201 KAR 2:210 Proposed Amendments
 - ii. Inspection Staff Review 201 KAR 2:210 and 201 KAR 2:074
- c. Advisory Council
- d. Protocol Review

VII. APPLICATIONS

- a. Pharmacy Technicians
 - i. Simpson, Jennifer
 - ii. Webb, Amanda
- b. Non-Resident Wholesaler
 - i. Biopeptek Pharmaceuticals, LLC

VIII. CORRESPONDENCE

- a. Dual PIC Requests
 - i. Fischbeck, Tabithia (019425) P08298 & P08258
- b. Offsite Storage Request
 - i. Sterling Health Pharmacy (P07940)
 - ii. Ely Drugs of Bowling Green (P07516)
 - iii. West Knox Pharmacy (P07704)
 - iv. University of KY Healthcare (multiple permits)
- c. UofL Health UofL Hospital Infusion Center at Shelbyville Hospital (P08285)
 - i. Water source external to permitted pharmacy request

IX. OLD BUSINESS

a. 201 KAR 2:480 Telework for Remote Prescription Processing

X. NEW BUSINESS

a. DEA Final Rule, Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances between Pharmacies for Initial Filling, effective August 28, 2023

XI. CLOSED SESSION

- a. 23-0012
- b. 22-0075

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 September 20, 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 (via zoom), and Jason Belcher.

Staff present: Christopher Harlow, Executive Director; Eden Davis, General Counsel; Juliana Swiney, Deputy Executive Director; Amanda Harding, Pharmacy and Drug Inspector; Rhonda Hamilton, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector; John Romines, Pharmacy and Drug Inspector; Paul Daniels, Pharmacy and Drug Inspector; Hannah Rodgers, Staff Attorney; Nikki Holiday, Executive Assistant; Grace Martini, Pharmacy Intern; and Elizabeth (Izzy) Royalty, Pharmacy Intern.

MINUTES: Meredith Figg had asked that on the minutes from July 26, page 2, all the background information be put together in the same section.

Jonathan Van Lahr motioned to approve the July 26, 2023 (retreat) and July 27, 2023 (meeting) meeting minutes with Meredith Figg's revision. Peter Cohron seconded, and the motion passed unanimously.

APPEARANCES

Brenda Tabor had technical difficulties, so we moved to the next agenda item while she addressed her technology issues.

John Perpich came before the Board to request reinstatement of his pharmacist license. Dr. Perpich appeared before the PRN Committee at their September 12, 2023 meeting. After Dr. Perpich gave his statement of the circumstances that led to the suspension of his pharmacist license, Brian Fingerson gave the Board a summary of Dr. Perpich's appearance at the most recent PRN Committee meeting. The Committee voted 8-0 to recommend to the Board that he sit for examination so long as he continues KYPRN monitoring. Once he obtains passing grades on his exams he will then come back before the PRN Committee and the Board to discuss terms for any ongoing monitoring that may be required after licensure.

Next, General Counsel Eden Davis gave a brief timeline of Dr. Perpich's situation. In 2013 Dr. Perpich petitioned the Board for reinstatement, but the request was denied. There was a positive test for diphenhydramine in August 2013. On May 14, 2014, his license was suspended for 5 years and 1 day. In 2017, a case was opened against Dr. Perpich for failure to call in the PRN program. He was fined \$600, and the required monitoring time started over for his PRN program requirement. In 2021 Dr. Perpich had a positive PET test. There has been no positive test since.

Action: Jonathan Van Lahr motioned to accept the recommendation of the PRN Committee and allow him to take the exams. Meredith Figg seconded, and the motion passed unanimously.

INTERAGENCY/PROFESSIONAL ASSOCIATIONS

KPhA: Heather Williams, Executive Fellow at KPhA informed the Board that the KPhA fall conference was going to be held in Lexington on October 20-21.

BOARD REPORTS

Executive Director Report: Dr. Harlow gave the eMars financial report as well as an update on the budget process. The biannual budget is due October 1, and he has been working with the budget office to get this completed. Once it goes through the budget office it then goes to the Governor's Office and then to the legislature for appropriation during this legislative cycle. Dr. Harlow is asking the Board to approve an additional inspector position if we are appropriated the funds.

Action: Peter Cohron motioned to approve the additional inspector in the existing open position. Jonathan Van Lahr seconded, and the motion passed unanimously.

Dr. Harlow informed the Board that he has been in discussions with a new software vendor to help continue to modernize processes in the office. He is looking at one particular software vendor who currently works with Alabama and North Carolina. This software encompasses everything from initial licensure to case management, includes our database, and has functions for Board members and inspection staff. Executive Director Harlow and Board member Anthony Tagavi attended NABP District 3, which is a combined meeting of the Board of Pharmacy as well as the Colleges of Pharmacy in the region. It gave them an opportunity to discuss challenges that the Colleges are facing with enrollment. There was an MPJE task force from NABP that was looking into a potential national MPJE exam instead of it being state-specific. They will have recommendations within the next 12 months.

Kentucky will be hosting the NABP District 3 meeting in 2025. Dr. Harlow is going to look into the Galt House unless there is opposition. (No opposition.)

Dr. Harlow gave an update on the background check information that the Board had requested. He is still gathering information and will have it at the November meeting.

Brenda Tabor: Ms. Tabor was able to join the meeting via speaker phone with the help of Pharmacy and Drug Inspector Amanda Harding. Ms. Tabor was before the Board for have her pharmacy technician registration reinstated. She shared her background, including a DUI charge and possession of pills in her vehicle. She is currently in recovery and has a sponsor.

Action: Jonathan Van Lahr motioned to allow Brenda Tabor to register as a pharmacy technician. Anthony Tagavi seconded the motion. Meredith Figg would like to add that any employer must be made aware of her history through an agreed order of reinstatement. The motion passed. Agreed order will be sent to the applicant.

General Counsel Report: Eden Davis had one expungement request – case #17-0486. Board member Peter Cohron recused himself at the beginning of the conversation.

Action: Anthony Tagavi motioned to expunge case 17-0486. Jonathan Van Lahr seconded, Peter Cohron recused, and the motion passed.

Deputy Executive Director/Inspection Staff: Pharmacy Intern Grace Martini gave a presentation on DEA 106 trends/reported controlled substance losses.

COMMITTEE REPORTS

KYPRN: Brian Fingerson gave the PRN Committee report. The Committee met on Sept 12, 2023, and Dr. John Perpich appeared at that meeting. The Board previously heard the Committee's recommendation. Currently there are 27 clients being monitored by KYPRN, 23 are required to participate via an agreed order, and 4 are self-reports. The next meeting is November 14, 2023 at 3:00 p.m.

Regulation Committee: Mike Burleson gave the Regulation Committee report. The Committee met on September 1, 2023, and completed amendments to 201 KAR 2:210 which was provided to the Board in their meeting materials. Jonathan Van Lahr had a question regarding it stating in one place that patient records be kept for 180 days, and in another it states they must be kept for 12 months. General Counsel determined that was pre-existing language that the Committee did not change. Pharmacy and Drug Inspector Amanda Harding clarified that the historic interpretation of it has been 180 days refers to active patient records that includes things like demographic information, and 12 months refers to actual prescriptions and dispensing records. Both Mr. Burleson and Executive Director Harlow expressed thanks to the Regulation Committee for all their hard work on these regulations. Staff recommends reviewing the rules from Missouri (3) and see how they can fit with what is already being allowed in Kentucky. Meredith Figg requested that Executive Director Harlow send the Missouri rules out to the Board members separately for review. Jonathan Van Lahr commented that this regulation is so closely tied to the central fill regulation that they both need to be worked on together.

Advisory Council: Kim Crowley gave the Advisory Council report. There was not a lot to report yet. The Council had their introductory meeting on August 24 and elected Ms. Crowley as the chairperson for the Advisory Council. Their second meeting was on September 19. The Council determined that their standing meetings would be on the second Tuesday of every month. The first topic to be discussed is non-resident pharmacist licensure, and the second one is white, clear, brown bagging. The Council is still working on the first topic, non-resident pharmacist licensure. The next scheduled meeting is October 10 at 9:00 a.m.

Protocol Review Committee: Cassie Hobbs gave the Protocol Review Committee report. Their first meeting was August 29, and the Committee elected Cassie to be the chairperson of the Committee. The Committee is starting with the flu and strep protocols and they plan to meet monthly. The Committee must meet at least quarterly as stated in regulation. Their next meeting is September 26, 2023.

APPLICATIONS

Pharmacy Technician: Jennifer Simpson appeared before the Board to request a pharmacy technician registration. She has multiple charges that are meth related, including felony charges. The DEA would require her to have a waiver from them if she was to be employed in a pharmacy that has a DEA registration (deals with controlled substances).

Action: Peter Cohron motioned to approve Jennifer Simpson's pharmacy technician registration. Jonathan Van Lahr seconded, and the motion passed unanimously.

CORRESPONDENCE

Dual PIC Request: Tabithia Fischbeck (019425) for P08298 and P08258 – Peter Cohron recused himself from this discussion and vote.

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

Offsite Storage Request: Sterling Health Pharmacy (P07940)

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

Offsite Storage Request: Ely Drugs of Bowling Green (P07516)

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

Offsite Storage Request: West Knox Pharmacy (P07704)

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

Offsite Storage Request: University of KY Healthcare – Anthony Tagavi recused himself from the discussion and vote of this request. UK requested that the following permitted locations (P08184, P08211, P08210) be added to the offsite storage request approval for 531 Wellington Way from 2020 (permits approved in 2020 request - P01621, P07583, P07556, P07636, P07686). Additionally, UK wanted to add verbiage to the approval to include any new pharmacies they may open in the future.

Action: Peter Cohron made a motion for the current request made by UK, but they need to come back to the Board to request offsite storage for each new pharmacy. Jonathan Van Lahr seconded, Anthony Tagavi recused, and the motion passed.

UK had an additional request about records that are less than 2 years old being stored in the basement of Kentucky Clinic. The Board asked them to provide more information about this request and bring back to the Board at the November meeting.

OLD BUSINESS

201 KAR 2:480 Telework for Remote Prescription Processing: The Board worked on this regulation at the July retreat, and it was posted on our website for public comment. We received no comments. Executive Director Harlow recommended sending this regulation to the Advisory Council because the Council is made up of stakeholders from several different practice settings and experiences. The Board recommended putting this item after the white, brown, and clear bagging item on the Council's list.

Action: Meredith Figg motioned to send this regulation (201 KAR 2:480) to the Advisory Council for their review and input as topic #3. Jonathan Van Lahr seconded, and the motion passed unanimously.

Action: Peter Cohron motioned to accept the changes made to 201 KAR 2:480 by the Regulation Committee. Jonathan Van Lahr seconded, and the motion passed unanimously.

NEW BUSINESS

DEA Final Rule, Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances between Pharmacies for Initial Filling, effective August 28, 2023. Executive Director Harlow presented the proposed amendments to 201 KAR 2:165 to the Board. These amendments clean up language and align with DEA language.

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. Jason Belcher seconded, and the motion passed unanimously.

NON-RESIDENT WHOLESALER APPLICATION

Action: Peter Cohron motioned to deny Biopeptek's non-resident wholesaler license application. Jonathan Van Lahr seconded, and the motion passed unanimously.

CLOSED SESSION

Action: Meredith Figg motioned to go into closed session. Jonathan Van Lahr 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: Peter Cohron motioned to adopt the court's order of default as the final order for case #23-0012. Jonathan Van Lahr seconded, Anthony Tagavi, John Fuller and Meredith Figg recused, and the motion passed.

Action: Peter Cohron motioned for the issuance of a Letter of Concern (LOC) in case #22-0075 B and C. Jonathan Van Lahr seconded, John Fuller, Meredith Figg and Jason Belcher recused, and the motion passed.

ADJOURNMENT

Action: Peter Cohron motioned to adjourn and the meeting adjourned at 1:35 p.m.