

KENTUCKY BOARD OF PHARMACY

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

ZOOM (Maximum 100 Participants)

<https://us02web.zoom.us/j/82789480321?pwd=WURwUEowM1dkK25GdkNidUhURWhZQT0>

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Meeting ID: 827 8948 0321

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Dial by your location

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May 24, 2023

10:00 a.m.

Board Meeting Agenda

- I. CALL TO ORDER
- II. MINUTES
 - a. March 22, 2023
- III. APPEARANCES
 - a. Robert Cruse, License 8011, 22-0135 Agreed Order Modification Request
 - b. Justin Anderson, License 022321 Reinstatement Request
- IV. INTERAGENCY/PROFESSIONAL ASSOCIATIONS
- V. BOARD REPORTS
 - A. Executive Director
 - a. eMars
 - b. Travel Report and NABP Task Force Reports
 - c. Non-Resident Pharmacist Licensure Stakeholder Meeting
 - d. Date for Special Called August Meeting
 - e. Board meeting location update
 - B. General Counsel
 - a. Student Loan Default Legal Update
 - b. Travel Request, Quarles Symposium
 - c. End of Public Health Emergency
 - C. Deputy Executive Director/Inspection Staff

- a. RX Summit

VI. COMMITTEE REPORTS

- a. Diversity & Inclusion
- b. KYPRN
- c. Pharmacy Technician
- d. Regulation

VII. REGULATIONS

- a. 201 KAR 2:076 Compounding
 - i. Federal Law Requirements
 - ii. Review of Comments Received
 - iii. Draft Amendment Consideration
- b. 201 KAR 2:050
 - i. Proposed fee increases on pharmacies, manufacturers, wholesale distributors, and third-party logistic providers
 - ii. Pharmacy (non-resident and resident) applications update
- c. Fee proposal (from 201 KAR 2:050) update in applications incorporated by reference:
 - i. 201 KAR 2:390
 - ii. 201 KAR 2:205
 - i. 201 KAR 2:225
 - ii. 201 KAR 2:240
 - iii. 201 KAR 2:320
 - iv. 201 KAR 2:340
 - v. 201 KAR 2:105

VIII. APPLICATIONS

- a. Pharmacy Technicians
 - i. Eric Tomelin
 - ii. Bobbie Slucher
 - iii. Gabrielle Campfield
- b. MPJE Request/License Transfer
 - i. David Wilkey
- c. Non-Resident Pharmacy
 - i. CPRX MSO, LLC (CarePathRx Pharmacy Services)
- d. Non-Resident Outsourcing Facility
 - i. RxQ Compounding, LLC

IX. CORRESPONDENCE

- a. Dual PIC Requests
 - i. Amy Spears, P08108 and P08082
 - ii. Rachel Connors, P06368 and P06923
 - iii. Richard Slone, P07140 and P06091
- b. University of Louisville Pharmacy Intern Application Inquiry

X. OLD BUSINESS

XI. NEW BUSINESS

- a. Central Fill Pharmacy and Automation
 - i. Robert Dixon, iARx- Central Fill Automation
 - ii. Jeff Scott, Kroger Central Pharmacy Services
 - iii. Charlie Mollien, Meijer Pharmacy
 - iv. Michael Gorski, Costco Pharmacy
 - v. Nichole Cover, Walgreens Pharmacy
- b. DSCSA Update

XII. CLOSED SESSION

- a. 22-0195 Consideration of Recommended Order of Default

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 Building
125 Holmes Street, 1st Floor Conference Room
Frankfort KY 40601
and via Zoom

BOARD MEETING
May 24, 2023
10:00 a.m.

CALL TO ORDER A regularly scheduled hybrid meeting was held at the Kentucky Justice and Public Safety Building, 1st Floor Conference Room in Frankfort, KY. 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; John Romines, Pharmacy and Drug Inspector; Rhonda Hamilton, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector; Nikki Holiday, Executive Assistant.

MINUTES: Peter Cohron motioned to approve the minutes March 22, 2023 meeting. Jonathan Van Lahr seconded, and the motion passed unanimously.

APPEARANCES

Robert Cruse, license #008011, appeared before the Board to request a modification to his Agreed Order from case #22-0135. He is prohibited from being a PIC in the AO and he requested that he be allowed to become a PIC.

Action: Peter Cohron made a motion to deny the request at this time, but Mr. Cruse may return in one year to make the request again. Anthony Tagavi seconded, Jonathan Van Lahr abstained, and the motion passed.

Justin Anderson, license #022321, appeared before the Board to request reinstatement of his license with the following restrictions:

(1) Respondent's pharmacist license shall be placed on probation upon completion of the following:

- a. Paying the requisite fees;
- b. Tendering proof of completion of the required fifteen (15) hours of continuing education;
- c. Submitting a completed renewal application to the Board.

(2) Respondent's shall comply with the following conditions during the period of probation, ending on August 1, 2027:

- a. Utilize an evidence based psychobehavioral therapy program such as NA, AA, MARA or any other evidence based psychobehavioral program approved by the KYPRN;
- b. Authorize semi-annual inspections at Respondent's place of employment for the first year of probation and annual inspections at the place of employment for the remaining period of probation. Respondent will be invoiced, no more than \$500 per inspection. The invoice is to be paid within 30 days. Costs will be determined by time, travel cost, and mileage charges of the inspector(s);
- c. Work no more than 45 hours per week or 90 hours every two weeks, with a maximum of 50 hours in any seven consecutive days.

- d. Provide a copy of this Agreed Order to all employers and the pharmacist-in-charge of all places of employment.
- e. Comply with your KYPRN aftercare contract. Any violation of the contract shall be reported to the Board within twenty-four hours.
- f. Notify the Board of change of home address, telephone number, and/or email within 7 days of change.
- g. Provide observed urine, other body fluid, or hair samples for drug/alcohol screens at the discretion of PRN, the Board, or any other monitoring body. Provide copies of any results of any screens ordered by anyone to the PRN Chair or Board. Provide notification to PRN Chair, Board, and testing company of anything that may affect pharmacist's availability for screens (vacations, travel, family obligations, etc) prior to the event. a missed screen shall be cause for reporting such to the Board. Any positive screen that is a violation of the AO or PRN contract shall be communicated to the Board by the PRN Chair within 24 hours;
- h. Shall not utilize any prescription medication without a healthcare provider's drug order for a current condition. Shall report any use to KYPRN. Shall provide a copy of the pharmacy printout that contains prescriber, patient, drug, quantity, and date filled if requested by KYPRN;
- i. Advise the Board at all times of place of employment and shall only practice at a location with a work schedule that has received prior approval of the Board or its President;
- j. Provide monthly written self-performance evaluation to the PRN Chair and the Board and shall make all appearances before the PRN Committee as requested, including an appearance at the PRN meeting closest to the anniversary date of reinstatement; and
- k. Provide same-day written notice to KYPRN of any medication, including over-the-counter medications or supplements, ingested.

Action: Anthony Tagavi made a motion to reinstate Mr. Anderson's license with an Agreed Order and the terms listed on the worksheet and as discussed above. Jonathan Van Lahr seconded, and the motion passed unanimously.

INTERAGENCY/PROFESSIONAL ASSOCIATIONS

KPhA – Emily Wilkerson gave the KPhA update. She informed the Board that Jordan Wilson was working as an intern with KPhA. She also announced the KPhA Annual Meeting will be June 9-11 in Bowling Green, and on June 8 the Annual KPhA Foundation golf outing will be held. She told the Board that the self-nomination period is open for KPhA's spots on the Advisory Council and the deadline is July 10, 2023.

BOARD REPORTS

Executive Director: Dr. Harlow gave a report on eMars. He reported that the Board is at 92% of expenditures of the allocated budget. He reminded the Board that Hannah Rodgers will move from a part-time attorney to a full-time attorney for the Board. Dr. Harlow stated that work has begun on the biennial budget, and it will be presented to the Board at the November meeting. This budget begins July 1, 2024 and will run through June 30, 2026. He also reminded the Board that there is a 6% raise in salaries for all state employees.

Dr. Harlow provided the Board with NABP Task Force Committees report in their packet for informational purposes.

Non-resident licensure stakeholder meeting – Dr. Harlow gave a review of the timeline of the conversations, which began in August 2022. The meeting notes were provided to the Board as well as the follow-up communication which included a proposal from the group to create a task force. After discussion from Keri Johnson (Chewy), Kelley Abell (Rotunda Group), Ben Mudd (KPhA), and the Board it was decided to move this

topic to the newly formed Advisory Council instead of creating a new group. The stakeholder group can then work with the Advisory Council on this topic.

Action: Anthony Tagavi made a motion to move the topic of non-resident licensure to the newly formed Advisory Council and make it priority one. Meredith Figg seconded, and the motion passed unanimously.

Board meeting location updates – The July Retreat will be held at Sullivan University in Louisville July 26 and 27. The University of Kentucky College of Pharmacy has offered to host the September meeting. There will be a special called meeting scheduled for August 30th for public comment if regulations are passed during this meeting. This meeting can be fully virtual.

General Counsel: Eden Davis informed the Board that in the past there has been a question for all licensees and registrants about if you are in default of your student loans and if so, we were obligated under state law not to issue a license/registration to that individual. In 2019 the law was repealed, so we need to remove the language from our application(s).

Action: Peter Cohron made a motion to remove the student loan default language from our application(s). Jonathan Van Lahr seconded, and the motion passed unanimously.

Ms. Davis requested to attend the Quarles and Brady Pharmacy Law Symposium in Chicago July 19 – 20, 2023.

Action: Jonathan Van Lahr made a motion to approve the travel request. Meredith Figg seconded, and the motion passed unanimously.

Ms. Davis reviewed the end of the public health emergency. HSS issued the 11th amendment to the PREP Act on May 12 that will maintain the authority of pharmacists to order and give the flu and COVID vaccines down to 3 years of age according to the PREP Act which will expire on December 31, 2024. This pre-empts the stricter state law.

Deputy Executive Director: Juliana Swiney gave a report on her work on the Protocol Registry. She also reported on her attendance at the Rx and Illicit Drug Summit in Atlanta, GA. Jonathan Van Lahr requested that Ms. Swiney distribute the slide deck from the meeting to all Board members.

COMMITTEE REPORTS

Diversity & Inclusion Task Force, Chris Harlow: This group did meet and is continuing to work on their updated charges.

Pharmacist Recovery Network Committee, Emily Caporal: The Committee met on May 9 and there were 2 appearances: Abby Stone – anniversary appearance and the reinstatement appearance for Justin Anderson. The vote was 9 – 0 for him to appear before the Board for reinstatement. There are currently 26 clients being monitored, and 5 of those are unknown to the Board. There is 1 new client. The Committee also finalized the language in the KYPRN contract and MOU to be compliant with the ADA.

Pharmacy Technician Committee, Chris Harlow: The Committee continues to work on the updated regulation and will be presenting the updated regulation at the July retreat.

Regulation Committee, Mike Burlison: The Committee met on April 21 and continues work on the proposed telework draft regulation (201 KAR 2:480). The Committee got through about half of the regulation and will meet again and have information to present at the July retreat. The next meeting is scheduled for July 14 but Mike will work with Nikki and the Committee to move that meeting to July 7.

LEGISLATION/REGULATIONS

201 KAR 2:076, Compounding: Dr. Harlow stated that there will be a 60-day comment period following the approval of the regulation. General Counsel stated that the Federal floor requires the adoption of 795 and 797, or compounders must submit an NDA for the compound to the FDA. Enforcement discretion may be utilized. Eden Davis recommended moving all the waiver language to one section. Based on the comments submitted, the concern from most is having time to adapt. Based on the comments, Dr. Harlow said the main things that need to be addressed are education and time to implement. Bill cover with NABP informed the Board that NABP has been working closely with USP to update their inspection forms. There was also discussion to revise the PIC language to read the PIC or designated representative.

Action: Anthony Tagavi motioned to approve the amendment of 201 KAR 2:076 to include the 2022 revisions for USP 795 and 797 but the Board will exercise enforcement discretion regarding the USP 795 and 797 2022 revisions until January of 2026. During the period of enforcement discretion, the 2008 and 2009 USP revisions will be enforced. If a permit holder opts to move forward with compliance prior to 2026, the Board will inspect to the 2022 revision standards. The Board will permanently exercise enforcement discretion regarding the addition of flavoring to a drug and will not consider that non-sterile compounding. The draft regulation will also remove the PIC from responsibility for compounding, and instead require a designated person to be appointed. Federal Food, Drug and Cosmetic Act section 503A allowances and exemptions shall be placed into the language of the regulation. Jonathan Van Lahr seconded, Peter Cohron opposed, and the motion passed.

201 KAR 2:050, Proposed fee increases on pharmacies, manufacturers, wholesale distributors, and third-party logistic providers:

Action: Jonathan Van Lahr motioned to accept the changes to the fee structure and the associated forms/applications. Anthony Tagavi seconded, and the motion passed unanimously.

APPLICATIONS

Technician: Eric Tomelin came before the Board for permission to register as a pharmacy technician.

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

Technician: Bobbie Slucher withdrew her request.

Technician: Gabrielle Campfield came before the Board for permission to register as a pharmacy technician.

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

MPJE Request: David Wilkey came before the Board to request permission to sit for the MPJE.

Action: Anthony Tagavi motioned to grant Mr. Wilkey permission to sit for the MPJE. Meredith Figg seconded, and the motion passed.

Non-resident Pharmacy: CPRX MSO, LLC (CarePathRx Pharmacy Services) – Their application does not fit into a current non-resident pharmacy type.

Action: Anthony Tagavi motioned to approve the application with the exclusions that mimic a clinical pharmacy permit in Kentucky. Peter Cohron seconded, and the motion passed unanimously.

Action: Anthony Tagavi motioned to make non-resident pharmacy applications for all types of resident pharmacy applications that we currently have. Meredith Figg seconded, and the motion passed unanimously.

Non-resident Outsourcing Facility: RxQ Compounding, LLC – This application was tabled until they send in newer inspection reports.

CORRESPONDENCE

Dual PIC Requests:

Amy Spears (013513), P08108 and P08082

Action: Meredith Figg motioned to approve the request to cover the maternity leave. Jonathan Van Lahr seconded, and the motion passed.

Rachel Connors (017947), P06368 and P06923

Action: Peter Cohron motioned to approve the request for 3 months. Meredith Figg seconded, and the motion passed.

Richard Slone (008306), P07140 and P06091

Action: Peter Cohron motioned to approve the request for 3 months. Jonathan Van Lahr seconded, and the motion passed.

University of Louisville Intern Application Inquiry: U of L asked the Board to allow out-of-state graduated pharmacists who are now PGY1 or 2 and waiting for reciprocity to be registered as interns.

Action: Peter Cohron motioned to allow Board Staff to fix the process and amend the necessary regulation to match the statute that allows for “intern” registration for graduated out-of-state pharmacists who are now PGY1 or 2 and waiting on reciprocity. Jonathan Van Lahr seconded, and the motion passed. Ms. Davis to bring the amended regulation to the July meeting.

OLD BUSINESS

NEW BUSINESS

Central Fill Pharmacy and Automation: The following people/companies came before the Board to discuss how they are utilizing central fill and automation in their business models and describe their workflow and internal processes:

Robert Dixon, iARx-Central Fill Automation

Jeff Scott, Kroger Central Pharmacy Services

Charlie Mollien, Meijer Pharmacy

Michael Gorski, Costco Pharmacy

Nichole Cover, Walgreens Pharmacy

Board member Anthony Tagavi

Walgreens is seeking approval of their central fill facility in Memphis, TN.

Action: Anthony Tagavi made a motion to approve the Walgreen’s application and any other central fill applications going forward based on the industry standards. Peter Cohron seconded, with the comment that up until today he had no idea companies were doing this, and the motion passed.

Dr. Tagavi also directed Board staff to research language on dispensing/quality assurance/final product verification for potential rulemaking to be presented at the next board meeting.

CLOSED SESSION

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

--Closed Session--

Action: Jason Belcher motioned to go back into open session. Jonathan Van Lahr seconded, and the motion passed.

ADJOURNMENT

Action: Peter Cohron motioned to adjourn. Meredith Figg seconded, and the motion passed unanimously. Meeting adjourned at 4:15 p.m.