

KENTUCKY BOARD OF PHARMACY

Kentucky Department of Transportation Auditorium

200 Mero Street, Frankfort KY

August 31, 2022

9:00 a.m.

AGENDA

via Zoom (maximum 100 participants)

<https://us02web.zoom.us/j/88345516406?pwd=R2tmOUFRWUFYRnVMUnhBbXlEYm1DUT09>

Meeting ID: 883 4551 6406 Passcode: rf4kAQ

Dial by your location

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Meeting ID: 883 4551 6406 Passcode: 950471

- I. CALL TO ORDER
- II. MINUTES
 - a. July 26 & 27, 2022
 - b. Special Called Meeting August 10, 2022
- III. APPEARANCES
 - a. Verlon Pierce- License application for reinstatement request
 - b. Chris Clifton- St. Elizabeth Healthcare waiver request
 - c. Superior Post Op-Nephron Pharmacy pending permit
- IV. INTERAGENCY
- V. BOARD REPORTS
 - a. Executive Director
 - i. Emars Report
 - ii. Declaratory Order- Screening Out of State Disciplinary Notifications
 - iii. Deputy Executive Director- hiring update
 - iv. DSCSA Rulemaking Proposed Comments
 - b. General Counsel
 - i. ASPL travel request
 - ii. Proposal-change in employment status of law clerk
 - iii. Expungement Requests
 - 1. Michael DeLuca; 08-0029
 - 2. Joseph Abell; 00-0043
 - 3. Brian Keith Yarde; 19-0248

- c. Anthony Tagavi
 - i. NABP District 3 meeting update

VI. COMMITTEE REPORTS

- a. Pharmacist Recovery Network Committee
- b. Diversity & Inclusion
- c. Regulation Committee
 - i. 201 KAR 2:220

VII. LEGISLATION/REGULATION

- a. Regulation Status Update Spreadsheet
- b. 201 KAR 2:380E and 201 KAR 2:380
- c. 201 KAR 2:450
- d. Proposed Amendment to 201 KAR 2:360
- e. Out of State Pharmacy Regulation (Proposed 201 KAR 2:460) and Stakeholder Feedback

VIII. CORRESPONDENCE

- a. Pharmacist Applications
 - i. Jennifer Chang; License transfer application request
 - ii. Alexander Clapsaddle; License transfer application request
 - iii. Mehar Dhillon; Initial pharmacist application
 - iv. Aryn Pinson; Initial pharmacist application
 - v. Adam Roorda; License transfer application request
- b. Dual PIC request
 - i. Benjamin Wesley Huff; Dual PIC Request
- c. 3PL Application
 - i. Sharp Packaging Services, LLC; 3PL license application
- d. General Correspondence
 - i. University of Kentucky- North Fork Valley Community Health Center Pharmacy
 - ii. KPhA Request for Workplace Environment Committee; Misty Stutz

IX. OLD BUSINESS

- a. Workplace Conditions
 - i. NABP District 3 report
- b. Centralized and Remote Processing & Telework Draft Regulations

X. New Business

- a. Pharmacy Technician applications

- i. JP2189
- ii. CA4448
- iii. CB7063
- iv. DW2404
- v. CL2409
- vi. MI7213

ATTENTION: A portion of the meeting may be held in closed/executive session for the purpose of (1) deliberating as a judicial or quasi-judicial body regarding the final adjudication of the Board's pending cases; (2) discussing and deliberating upon open investigations, which are preliminary matters that may result in litigation being filed on behalf of the Board and include the review of information required to be conducted in privacy according to federal and state law; and (3) Discussions or hearings which might lead to the appointment, discipline, or dismissal of an individual employee, member, or student without restricting that employee's, member's, or student's right to a public hearing if requested. The specific statutory sections providing exemptions 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)(f)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

200 Mero Street
Frankfort KY 40601

BOARD MEETING

August 31, 2022

CALL TO ORDER A regularly scheduled hybrid meeting was held at the Kentucky Transportation Building, Frankfort, Kentucky. President Cohron called the meeting to order 9:00 a.m.

Members present: Peter Cohron, John Fuller, Jonathan Van Lahr, Meredith Figg, Jason Belcher, and Anthony Tagavi (via Zoom).

Staff: Christopher Harlow Executive Director; Eden Davis General Counsel; Paul Daniels, Pharmacy and Drug Inspector; John Romines, Pharmacy and Drug Inspector; Rhonda Hamilton, Pharmacy and Drug Inspector; Amanda Harding, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector, Nikki Holiday Executive Assistant.

Guests:

MINUTES: Jonathan Van Lahr moved to accept the minutes from the July 27, 2022, meeting. John Fuller seconded, and the motion passed unanimously.

APPEARANCES

Verlon Pierce – License application for reinstatement request.

Action: John Fuller moved to approve Mr. Pierce's application for reinstatement. Jonathan Van Lahr seconded, and the motion passed unanimously.

Chris Clifton/St. Elizabeth Healthcare: Waiver request regarding a kiosk 2-year pilot program. It was noted that the DEA and the OIG have not been consulted on this model to date. Ben Mudd, KPhRA, spoke against the model, stating that the Board should not give preferential treatment and they are fearful it could have the opposite effect on the five (5) pharmacies in that area.

Action: Anthony Tagavi made a motion directing Executive Director Harlow and General Counsel Eden Davis to perform research on making a regulatory change to allow this model. Jason Belcher seconded the motion, and the motion passed.

Superior Post Op-Nephron Pharmacy pending permit: Superior Post-Op (Nephron) appeared with their attorneys, Vickie Yates Glisson and Sheldon Bradshaw. Mr. Bradshaw appeared remotely. Mr. Bradshaw addressed the Board's concern with an outsourcing facility operating as a wholesaler. Mr. Bradshaw asserted the exceptions on the prohibition on wholesaling included when an outsourcing facility provides compounded drugs to healthcare practitioners and pharmacies that in turn dispense directly to patients. Ms. Glisson asserted that if the FDA issues guidance to the contrary that Superior Post-Op would cease operations immediately.

Action: Anthony Tagavi made a motion to approve the Dual PIC request on a temporary basis for 6 months. Jonathan Van Lahr seconded, and the motion passed unanimously. The Board said they could move forward with the permitting process.

INTERAGENCY

KPhA: Ben Mudd gave the KPhA updated which included the following: annual meeting; flooding update (all but 1 pharmacy has reopened); opioid forum webinars; the foundation extended the application for grants to advance the profession; they are still taking donations for flooding victims on the website. Executive Director Harlow expressed his thanks to KPhA for helping with the flood efforts.

BOARD REPORTS

Executive Director: Dr. Harlow addressed out-of-state grievances and if they should or should not accept these as cases if there is not a direct effect on a Kentucky patient. He requested guidance from the Board as to if he should or should not accept these as cases. President Cohron agreed that where there is no Kentucky nexus, the grievance should not be accepted as a case.

Action: John Fuller made a motion to not accept as cases any out-of-state grievances that do not involve a Kentucky patient. Jonathan Van Lahr seconded the motion, and it passed unanimously.

Deputy Executive Director update-Dr. Harlow requested Board members to participate in the interviewing process, with an expected start date of October 1st or 17th.

DSCSA rule making proposed comments for the FDA proposed licensing standards for wholesalers and 3PLs. All comments were reviewed by Executive Director Harlow and General Counsel Davis.

Action: Jonathan Van Lahr made a motion to accept the comments and submit them. Meredith Figg seconded the motion, and the motion passed unanimously.

General Counsel: President Cohron addressed the ASPL travel request from Eden Davis and encouraged the Board to fund the trip for Eden Davis.

Action: John Fuller made a motion to approve this travel request. Jonathan Van Lahr seconded the motion, and the motion passed unanimously.

Ms. Davis proposed a change in employment status of our law clerk from interim employee to a part time employee.

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

Actions Expungement Requests:

- 1) Michael DeLuca, 08-0029 – John Fuller made a motion to expunge. Meredith Figg seconded, and the motion passed.
- 2) Joseph Abell, 00-0043 – Meredith Figg made a motion to expunge. Jonathan Van Lahr seconded, and the motion passed.
- 3) Brian Keith Yarde, 19-0248 – Jonathan Van Lahr made a motion to expunge. John Fuller seconded, and the motion passed.

Anthony Tagavi gave an update from his trip to the NABP district III meeting. He spoke about Oklahoma's website where pharmacists and technicians can report unsafe working conditions online directly to the Board. He also said major topics discussed were DSCSA, telepharmacy/future of pharmacy, the Verify program, and workplace conditions.

COMMITTEE REPORTS

PRNC: Brian Fingerson gave the report for the committee which met on August 17th. KYPRN reported 28 clients, 23 have a board order, and 5 do not. KYPRN has been working with the committee to update the language in the contract to be compliant with the ADA and the work on that continues.

Diversity & Inclusion Task Force: Executive Director Harlow met with the co-chairs of the task force to do an update as to their charge and membership. After discussion, they came up with some recommendations to the Board. One is to update the membership to 6 pharmacist and 2 student (one from each college) members, with terms to begin in October and run for 3 years, (students for 1 year). The second is to update the charge to be a more targeted effort with the biggest impact. Develop a cultural competency plan and training for pharmacists and pharmacy technicians to address diversity, equity, and inclusion in pharmacy practice. Determine policies the Board needs to address for implementation to ensure the success of the competency plan and training. Develop methods to engage women and minorities in pharmacy activities.

Action: Jonathan Van Lahr made a motion to approve the updated membership and charge of the task force. John Fuller seconded, and the motion passed unanimously.

Regulation Committee: Mike Bureson gave the Regulation Committee update. The committee met on August 3rd. At that meeting, Mike Bureson was elected chairman of the committee. Sterile water and sterile saline draft regulation was discussed, and more information was needed. The committee will be reaching out to some other states to see how they have addressed the issue. 201 KAR 220 collaborative care agreements, which will sunset. After discussion the committee decided to put definitions in the regulation and made one change in terminology in changing “gender” to “sex.”

Action: Jonathan Van Lahr made a motion to direct Eden to send a letter to LRC to inform them we will be making changes to the collaborative care regulation, and that letter will extend the deadline for 18 months. Meredith Figg seconded, and the motion passed unanimously.

LEGISLATION/REGULATIONS

Eden Davis reviewed the regulation spreadsheet with the Board, as well as 201 KAR 2:380E, 201 KAR 2:380, and 201 KAR 2:450. Ms. Davis presented the Board with proposed amendment to 201 KAR 2:360 (Naloxone).

Action: Jonathan Van Lahr motioned to approve the proposed amendment to 201 KAR 2:360 and to file the regulation. John Fuller seconded, and the motion passed unanimously.

Ms. Davis reviewed the out-of-state pharmacy regulation update and the stakeholder feedback the Board received and well as the Verify MOU with NABP. (Proposed 201 KAR 2:460) Discussion and an amendment were made to the proposed regulation.

Action: John Fuller made a motion to approve the regulation with the amendment, attestation, and the MOU. Jonathan Van Lahr seconded, and the motion passed unanimously.

CORRESPONDENCE

Pharmacist Applications:

- 1) Jennifer Chang, license transfer application request – Jonathan Van Lahr made a motion to approve. John Fuller seconded, and the motion passed unanimously.
- 2) Alexander Clapsaddle, license transfer application request – John Fuller made a motion to approve. Meredith Figg seconded, and the motion passed unanimously.
- 3) Mehar Dhillon, initial pharmacist application – Meredith Figg made a motion to approve. Jonathan Van Lahr seconded, and the motion passed.
- 4) Aryn Pinson, initial pharmacist application – John Fuller made a motion to approve. Jonathan Van Lahr seconded, and the motion passed unanimously.
- 5) Adam Roorda, license transfer application request – John Fuller made a motion to approve. Jonathan Van Lahr seconded, and the motion passed.

Dual PIC request:

- 1) Benjamin Wesley Huff – John Fuller made a motion to approve the request for 6 months. Jonathan Van Lahr seconded, and the motion passed.

3PL Application:

- 1) Sharp Packaging Services, LLC – Meredith Figg made a motion to deny until they can produce a recent inspection report. Jonathan Van Lahr seconded, and the motion passed.

General:

- 1) UK – North Fork Valley Community Health Center Pharmacy. Paper records were destroyed in the flood. They requested a letter from the Board stating that they have acknowledged that they do not have paper records, but they do have electronic records that will be kept for 5 years.

Action: Jonathan Van Lahr made a motion to provide this letter of acknowledgement to them. Meredith Figg seconded, Anthony Tagavi abstained, and the motion passed.

- 2) KPhA request for Workplace Environment Committee – no action taken

NEW BUSINESS

Pharmacy Technician applications:

- 1) JP2189 – John Fuller made a motion to approve. Meredith Figg seconded, and the motion passed.
- 2) CA4448 – John Fuller made a motion to approve. Jonathan Van Lahr seconded, and the motion passed.
- 3) CB7063 – Jonathan Van Lahr made a motion that applicant must appear at the October meeting. John Fuller seconded, and the motion passed.
- 4) DW2404 – Jonathan Van Lahr made a motion that applicant must appear at the October meeting. Jason Belcher seconded, and the motion passed.
- 5) CL2409 – John Fuller made a motion to approve. Jonathan Van Lahr seconded, and the motion passed.
- 6) MI7213 – Jonathan Van Lahr made a motion that the applicant must appear at the October meeting. John Fuller seconded, and the motion passed.

OLD BUSINESS

Centralized and Remote Processing & Telework Draft Regulations: Discussion about amended language in the regulations including direct-to-patient central fill models, definition of electronic supervision, refill requests, labeling requirements, etc.

ADJOURNMENT

Action: Jonathon Van Lahr made a motion to adjourn. John Fuller seconded and the motion passed unanimously. Meeting adjourned at 2:16 pm.