

KENTUCKY BOARD OF PHARMACY RETREAT

**Louisville Marriott Downtown – Bluegrass I and II
280 West Jefferson Street
Louisville KY 40202**

**July 26, 2022
9:00 a.m. – 5:00 p.m.**

AGENDA

TOPICS IN ORDER OF PRIORITY:

- 1) Workplace Conditions**
- 2) White, Clear, and Brown Bagging**
- 3) Remote Work/Common Database/Central Fill**
- 4) Pharmacy Technician Advancement**
- 5) Out of State Pharmacy Permit Regulation**
- 6) Compliance Packaging**

MINUTES

KENTUCKY BOARD OF PHARMACY

held at

Louisville Marriott Downtown

Louisville, KY

BOARD RETREAT

July 26, 2022

WELCOME President Cohron gave welcome.

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

Staff: Christopher Harlow Executive Director; Eden Davis, General Counsel; Amanda Harding, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector, Nikki Holiday, Executive Assistant, Amanda Montgomery, Law Clerk and Ryan Montgomery KBOP Intern.

TOPIC #1 – WORKPLACE CONDITIONS

Executive Director Harlow gave a presentation on workplace conditions. Topics discussed among the Board members and the attendees included: limitations on continuous hours of work; schedule and staffing; metrics, goals, quotas; roles of pharmacy/permit holder v. PIC; and proposed language for a new regulation. Language discussed, “Failure to provide appropriately requested rest and meal periods as permitted by state and federal law.” “Pharmacies under common ownership and control,” was removed.

ACTION Anthony Tagavi made a motion to adopt the proposed regulation with language as revised under part (1)(c). Jonathan Van Lahr seconded the motion and it passed unanimously.

TOPIC #2 – WHITE, CLEAR, AND BROWN BAGGING

Executive Director Harlow gave a presentation on white, clear, and brown bagging. Following the presentation there was policy discussions and considerations among the Board members, Board inspection staff, and several guests.

ACTION John Fuller motioned to move this topic to the Advisory Committee for further review and discussion. The motion was seconded by Jonathan Van Lahr and passed unanimously.

TOPIC #3 – REMOTE WORK

Executive Director Harlow gave a presentation on Centralized and Remote Processing & Telework. Representatives from PipelineRx spoke in support of the proposed rule and explained their business model. Pipeline Rx is a remote processing company that does order entry, review, and verification. John Long, CVS, spoke to the fact that this issue ties into the prior discussion about workplace conditions. A lot of state and pharmacies are moving towards remote processing to reduce workload for pharmacies and improve workload for pharmacists. Other issues discussed included: central processing and central fill, labeling issue, licensing of the pharmacist and/or technician doing the remote work, compared to mail order. Executive Director Harlow suggested collecting written comments related to proposed draft regulations from people who have spoken on this topic.

ACTION President Cohron made a motion to accept written comments about the proposed rules and submit them to the Board office for inclusion at the August 31 Board meeting. Jonathan Van Lahr seconded the

motion, and the motion passed unanimously. **Eden Davis clarified comments must be received by August 15.

TOPIC #4 – PHARMACY TECHNICIAN ADVANCEMENT

Executive Director Harlow gave a presentation on pharmacy technician advancement. David Figg, Chairman of the Pharmacy Technician Committee, presented the committee's findings on advancing the role of pharmacy technicians. The Board had discussion about how pharmacy technician's roles would be defined, how would they be trained and registered.

ACTION Jonathan Van Lahr motioned that the Board promulgate a regulation that would create the classification of advanced registered pharmacy technicians to perform tasks delegated to them by a pharmacist. John Fuller seconded the motion, and the motion passed unanimously.

TOPIC #5 – OUT OF STATE PHARMACY PERMIT

Executive Director Harlow stated the draft regulation came from the Regulation Committee, and we did receive some comments on the proposed regulation. There was discussion among the Board members and guests about the proposed regulation. Issues/topics discussed included: jurisdiction over anyone who is involved in a prescription for a Ky resident, NABP Verify program, and what other states are doing.

ACTION Jonathan Van Lahr motioned to accept the draft regulation. Anthony Tagavi seconded it, and the motion passed unanimously.

TOPIC #6 – COMPLIANCE PACKAGING

KBOP Intern Ryan Montgomery gave a presentation on compliance packaging.

ACTION Jonathan Van Lahr motioned to send this topic to the Advisory Council to evaluate and send back policy statements to the Board. John Fuller seconded the motion, and it passed unanimously.

ADJOURN Anthony Tagavi made a motion to adjourn. Meredith Figg seconded the motion, and the motion passed with no opposition. Meeting adjourned at 5:12pm.

KENTUCKY BOARD OF PHARMACY

Louisville Marriott Downtown – Bluegrass I and II

280 West Jefferson Street

Louisville KY 40202

July 27, 2022

9:00 a.m.

AGENDA

- I. CALL TO ORDER**
- II. MINUTES**
 - A. June 1, 2022
- III. APPEARANCES**
 - A. Cordant Health Solutions
 - B. Brian Yarberry, Norton Healthcare- Waiver request for 201 KAR 2:074 section 7(2)(3)(4)
 - C. Connect Med, 360
- IV. INTERAGENCY**
- V. BOARD REPORTS**
 - A. Executive Director
 - 1. ED Report
 - 2. eMars
 - B. General Counsel
 - 1. Regulatory Use of Waivers- Memo
 - 2. Expungement Requests
 - a. 16-0292
 - b. 19-0047
 - c. 17-0547
 - d. 17-0289
- VI. COMMITTEE REPORTS**
 - A. Advisory Council
 - B. Pharmacist Recovery Network (PRNC)
 - C. Continuous Professional Development
- VII. LEGISLATION/REGULATION**
 - A. Legislative Priority – Facility Fee Limitations
 - B. 201 KAR 2:440, Legend Drug Repository
 - C. 201 KAR 2:413E, Ordering and administering vaccinations

- D. Senate Bill 11 - 201 KAR 2:370, Pharmacy services in long-term care facility (LTCF)
- E. 201 KAR 2:015, Review of Comments Received
- F. 201 KAR 2:380, Proposed Amendments

VIII. CORRESPONDENCE

- A. Lisa Patton, P05150 and P08239- Dual PIC Request
- B. Leila Moore/Eric Christian, P07877 and P07915- Dual PIC Request
- C. Patti Pitcock, P07516 and P07674- Dual PIC Request
- D. NABP- Late Score Transfer Inquiry, Applicant Chrystelle Kevine Nokam Noumsi
- E. Non-Resident Pharmacy Application, Raven Holdings LLC DBA Raven Pharmacy
- F. Nephron Pharmacy Application and Dual PIC Request, Michael DeLuca
- G. Trish Freeman- Stocking Naloxone Emergency Departments

IX. OLD BUSINESS

- A. Workplace Conditions
 - a. NABP District 3 Report
- B. Retreat topics
- C. NABP Verify Program

X. NEW BUSINESS

- A. PrEP Protocol
- B. Advisory Council Appointment (*1 vacancy*)
 - a. Jillianne Harrelson-Hiller
 - b. Mandy Jones
 - c. Melissa Fain
 - d. Ross Goetz
 - e. Stephen Creasy
 - f. Steve Cummings
- C. Pharmacy Technician Applications
 - 1. DC9015
 - 2. JP2189
 - 3. CA4448

XII. CLOSED SESSION

- A. Leann Henderson
- B. Final Orders
 - 1. 21-0200C
 - 2. 19-0283C

3. 20-0100

B. Proposed Litigation

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

Louisville Marriott Downtown

Louisville, KY

BOARD MEETING

July 27, 2022

CALL TO ORDER A regularly scheduled meeting was held at the Louisville Marriott Downtown in Louisville, KY. President Cohron called the meeting to order 9:01 a.m.

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

Staff: Christopher Harlow Executive Director; Eden Davis, General Counsel; Amanda Harding, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector, Nikki Holiday, Executive Assistant, Amanda Montgomery, Law Clerk and Ryan Montgomery KBOP Intern.

MINUTES Jonathan Van Lahr moved to accept the minutes from the June 1, 2022, meeting. John Fuller seconded, and the motion passed unanimously.

APPEARANCES

Cordant Health Solutions Bob Mann presented the business model of Cordant Health Solutions. After much discussion about this unique delivery model, it was determined that Cordant Health Solutions is operating within the parameters of the law and no action was taken by the Board.

Brian Yarberry, Norton Healthcare-Waiver request for 201 KAR 2:074 Section 7(2),(3), and (4) discussion about the challenges in recruiting and retaining pharmacy technicians. The request was to revise regulation from “certified pharmacy technician” to “pharmacy technician” or request for a waiver. There was concern that this request would decrease the standard. Since pharmacy technician rules were discussed earlier, it was mentioned that the Board may want to look at all the rules in one sweep.

Action: Jonathan Van Lahr motioned to allow Executive Director and General Counsel to look at the technician language in its entirety by the October Board meeting. Meredith Figg seconded, and the motion passed unanimously.

Connect Med, 360 President Cohron directed Executive Director Harlow and General Counsel to review legislation to potentially change in conjunction with changes discussed at the retreat.

INTERAGENCY Ben Mudd, KPhA reported that they had their annual meeting and John Fuller was recognized/awarded at that meeting. He gave updates on the Naloxone co-pay program (excluding Medicaid at this point) which allows patients to receive Naloxone free of charge. Dr. Jagers is the lead on this initiative. Dr. Martin has put together opioid forums across the state. Aug 13-EKU, Aug 20-WKU, Aug 27-NKU.

BOARD REPORTS

Executive Director Report Executive Director Harlow gave an update on HB 3. He confirmed that 315.315 has been amended (presumption of validity of prescriptions). He briefed the Board on the budget cycle starting July 1, gave updates on staff roles/responsibilities and announced the upcoming retirement of Katie Busroe.

Upon the recommendation of the Personnel Cabinet, the Board will be posting a Deputy Executive Director position. He would like to involve Eden Davis, Nikki Holiday, inspection staff and any Board member who would like to in the interviewing/hiring process.

Action Anthony Tagavi motioned to approve the posting for the new Deputy Executive Director position. Jason Belcher seconded it, and the motion passed unanimously.

General Counsel Report Eden Davis reviewed the use of regulatory waivers, how waivers should be utilized (sparingly), and only in unforeseen circumstances. She suggested to formulate criteria for waivers in the future, and if we are seeing a need for changes the best course of action is regulatory changes. Jonathan Van Lahr agreed that waivers can be problematic.

Expungement Requests

- 16-0292; CE violation
- 19-0047; CE violation
- 17-0547; Self-prescribed medication for self and family use.
- 17-0289; CE violation

Action Jonathan Van Lahr motioned that the three CE violations be expunged. Meredith Figg seconded the motion, and it passed unanimously.

Action John Fuller made a motion to deny the request for expungement of case 17-0547 because the violation was not a minor violation. Meredith Figg seconded the motion, and it unanimously.

COMMITTEE REPORTS

Advisory Council Chris Clifton gave the report. The Advisory Council met July 7, 2022. They nominated and elected a chair and vice chair. Mark Taylor was elected chairman and Chris Clifton was elected vice chairman.

Pharmacist Recovery Network (PRNC) Brian Fingerson gave the report. The Committee worked on the amendment of the contract. There are currently 29 people under monitoring, 24 have a Board agreed order and 5 are voluntary.

Continuous Professional Development Committee The Committee has discussed the CPD model vs. the CE model. ACPE is working on a program and the Committee decided to wait 6 months and monitor their program and reevaluate.

LEGISLATION/REGULATION

Legislative Priority-Facility Fee Limitations Currently, there are regulations which limit raising application fees for facilities. Executive Director Harlow pointed out that Kentucky's fees are significantly lower than other states, and he would like to remove the caps in the statute. He also added that the pharmacist licensing fees would not be affected. Meredith Figg reminded the Board that inflation is affecting pharmacies too.

Action Jonathan Van Lahr motioned to support legislative priority and to include amendments to outsourcing facilities and third-party logistic provider regulations. John Fuller seconded the motion. The motion passed unanimously.

Legend Drug Repository; 201 KAR 2:440 President Cohron recognized Dr. Jill Rhodes for her work on this regulation.

Ordering and Administering Vaccinations; 201 KAR 2:413E This was reviewed at the June Board meeting. Regulation is in effect until March 24, 2023.

SB 11; 201 KAR 2:370 Eden Davis amended language based on the June Board meeting. To match our definition, we need to exclude assisted living facilities (Board approved). Executive Director Harlow pointed out that this regulation includes language about technicians. He asked that the Board not vote on this until this language is amended.

201 KAR 2:015; review of comments received The KPhA opposes the requirement of one hour of CE pertaining to Opioid Use Disorder. They believe that pharmacists should be able to choose their CE based on their specific pharmacy environment. Ben Mudd stated that the KPhA has a policy that they do not support specific CE requirements and that is why they issued the comment. He stated that if this is passed KPhA will assist in helping provide this type of CE. Board members expressed that this is a relevant topic, and that other professional Boards require specific subject matter for their CE requirements.

Action Jonathan Van Lahr motioned to accept the proposed amendment. Anthony Tagavi seconded the motion, and the motion passed unanimously.

201 KAR 2:380 proposed amendments Trish Freeman commented that protocol-driven care is improving. Protocols always come to the Board for approval and then they are listed in the regulation. Amendments were made.

Action Anthony Tagavi motioned to accept the amendments to the regulation and Meredith Figg seconded it. The motion passed unanimously.

CORRESPONDENCE

Dual PIC request, Lisa Patton, P05150 and P08239 Anthony Tagavi made a motion to approve the request. Jonathan Van Lahr seconded, and the motion passed unanimously.

Dual PIC request, Patti Pitcock, P07516 and P07674 Anthony Tagavi motioned to approve the request. Meredith Figg seconded, and the motion passed unanimously.

NABP Late Score Transfer, Chrystelle Kevine Nokam Noumsi John Fuller motioned to grant the request, Jonathan Van Lahr seconded, and the motion passed unanimously.

Non-Resident Pharmacy Application, Raven Holdings LLC Carla Simpson appeared representing Raven and she is new to the company. She noticed that 34 prescriptions had been sent into Kentucky without a permit. She is wanting to correct the issue. The last shipment was in April and no controlled substances have been shipped. She wants to be transparent in requesting this permit. They have a consent order with Arizona. Blue Sky Specialty, based in Charleston, SC, owns both pharmacies. They are licensed in 49 states with CA pending right now. They have a specialty model on one side and a retail model on the other side of the premises. After discussion among the Board about the best way to move forward, a motion was made to grant this permit.

Action Anthony Tagavi motioned to approve the request for a permit with no restrictions. Jonathan Van Lahr seconded the motion and it passed unanimously.

Dual PIC request, Eric Christian, P07877 and P07915 John Fuller made a motion to approve the amended 10 hours and the temporary dual PIC request to last until the October 26, 2022, Board meeting. Anthony Tagavi seconded the motion and it passed unanimously.

Stocking Naloxone in Emergency Departments; Trish Freeman Non-fatal overdose is a great predictor of future, fatal overdose. Therefore, when someone enters the emergency department with a non-fatal overdose they need to leave with naloxone. There is some legal concern because doses would be stored in the emergency department, not in the hospital pharmacy. The Legislature's intent through recent actions has been to increase access to and remove barriers for patients to this life saving medication.

Action Anthony Tagavi moved to formalize in a regulation that non-24-hour outpatient pharmacies are not prohibited from supplying naloxone to emergency departments for dispensing and to allow enforcement discretion until the regulation is approved on the impacted areas of security and control, DUR, and recordkeeping. Jonathan Van Lahr seconded the motion and it passed unanimously.

Nephron Pharmacy Application and Dual PIC Request; Michael DeLuca Representatives from Nephron explained their business. Nephron dispenses preparations compounded by an outsourcing facility to an ambulatory surgery center up to 48 hours prior to a surgery and to be dosed at the time of surgery by an anesthesiologist.

Action Anthony Tagavi motioned to approve the dual PIC temporarily until October 26, 2022. John Fuller seconded the motion, and the motion passed unanimously.

Action Anthony Tagavi motioned to approve the permit. Motion died for lack of a second. Motion denied.

Action John Fuller motioned to repeal the motion to grant dual PIC. Meredith Figg seconded the motion, and the motion passed unanimously.

The Board asked Nephron representatives to return for the August 31, 2022, Board meeting.

OLD BUSINESS

Pharmacy Technician Committee The committee chair asked for clarification on how the Board would like the committee to move forward. The Board charged Executive Director Harlow and Eden Davis with reviewing the technician rules and bring findings back to the Board for review.

NABP Verify Program Eden Davis gave an overview of legal concerns with the Verify program including no jurisdiction and possible 5th Amendment due process violations.

Action Jonathan Van Lahr made a motion for the Board to NOT take part in the NABP Verify program at this time. John Fuller seconded the motion, and it passed unanimously.

NEW BUSINESS

Advisory Council Appointment The Board voted on the six applicants. Mandy Jones was elected as the new Advisory Council member.

Action Jonathan Van Lahr made a motion that Jones be appointed to the Advisory Council and to extend her term until 2024. Anthony Tagavi seconded the motion, and it passed unanimously.

Pharmacy Technician Applications

- DC9015-Anthony Tagavi motioned to deny the application. John Fuller seconded the motion, and it passed unanimously.
- JP2189-Jonathan motioned to approve the application and amended his motion to request the appearance of the applicant at the next Board meeting. Anthony Tagavi seconded the motion, and it passed with no opposition.

- CA4448-Anthony Tagavi motioned to request the appearance of applicant at the next Board meeting. Meredith Figg seconded, and it passed with no opposition.

CLOSED SESSION Anthony Tagavi entered the Board into closed session to include Christopher Harlow, Eden Davis, and Nikki Holiday for the purpose of reviewing, discussing, and deliberating upon open investigations, all of which are matters that may result in litigation being filed on behalf of the Board and/or require the review of information deemed confidential in accordance with state and federal law. The deliberations require the panel members to review and discuss information compiled in the course of the Board's work to detect and investigate statutory and regulatory violations (the premature release of which may harm the Board's ability to carry out its administrative adjudication or prospective law enforcement functions, if an investigation remains open and final action is not taken in this meeting) and to determine whether to initiate litigation on behalf of the Board against individual licensees, permit holders or registrants. The statutory sections providing authorizing executive session are KRS 61.810(c)(j) and (k) and KRS 61.878(1)(a) and (1)(h). Anthony Tagavi motioned to go back into open session, Jonathan Van Lahr seconded it, and the motion passed unanimously.

Proposed Litigation

Action Jonathan Van Lahr motioned to issue a final order in 21-0200C. XXXXXX seconded the motion and it passed unanimously.

Action John Fuller motioned to dismiss 19-0283C and 20-0100. Jonathan Van Lahr seconded, and the motion passed unanimously.

Action John fuller motioned to have General Counsel, or a contract attorney pursue two civil cases. Jonathan Van Lahr seconded, and the motion passed unanimously.

ADJOURNMENT

Action Anthony Tagavi motioned to adjourn the meeting, Meredith Figg seconded, and the motion passed unanimously.

Meeting adjourned at 3:38pm.