

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 20, 2024

10:00 a.m.

Members present: Board President Jonathan Van Lahr, Vice President Anthony Tagavi, John Fuller, Meredith Figg, Jason Belcher, and Kimberly Croley.

Staff present: Christopher Harlow, Executive Director; Eden Davis, General Counsel; Jessica Williams, Pharmacy and Drug Inspector; John Romines, Pharmacy and Drug Inspector; Rhonda Hamilton, Pharmacy and Drug Inspector; Taylor Rostova, Pharmacy and Drug Inspector; Hannah Rodgers, Staff Attorney; Juliana Swiney, Deputy Executive Director; and Nikki Holiday, Executive Assistant.

CALL TO ORDER: President Jonathan Van Lahr called the meeting to order at 10:00 a.m.

MINUTES: September 25, 2024

Action: Kimberly Croley motioned to approve the September 25, 2024 minutes. Anthony Tagavi seconded, and the motion passed unanimously.

APPEARANCES

Cruse, Robert; Agreed Order Modification Request: General Counsel provided background information on Mr. Cruse's case and Agreed Order. President Van Lahr asked the Board to defer this decision until after the discussion on Agreed Order modification later in the meeting.

Silver, Brad; MPJE Request

Action: John Fuller motioned to approve this MPJE request. Kimberly Croley seconded, and the motion passed unanimously.

Leach, Crystal; Pharmacy Technician Reinstatement

Action: Anthony Tagavi motioned to approve the technician registration. Kimberly Croley seconded, John Fuller abstained, and the motion passed.

Precision Compounding Pharmacy & Wellness:

Action: Kimberly Croley motioned to table this until the January meeting. John Fuller seconded, and the motion passed unanimously.

INTERAGENCY/PROFESSIONAL ASSOCIATIONS

KPhA: There were no updates from the KPhA.

BOARD REPORTS

Executive Director Report: Executive Director Harlow gave the Financial/eMARS report. He then reviewed the Board Delegation Authority document for the annual ratification.

Action: Kimberly Croley motioned to approve the document. Meredith Figg seconded, and the motion passed unanimously.

Executive Director Harlow gave an update on the new technology platform, including the fact that there will be a one-week delay in the pharmacist renewal period.

2025 meeting dates – January 22, March 26, May 28, July 22 (retreat), July 23, September 24, and November 19, 2025. After some discussion, the dates were approved noting that there could be a change in the May date if necessary.

Action: John Fuller motioned to approve the 2025 meeting dates. Anthony Tagavi seconded, and the motion passed unanimously.

General Counsel Report: General Counsel Eden Davis had one expungement request, (17-495B, Christy Green). This request was denied, as the Board did not feel it was a minor offense.

Action: John Fuller motioned to deny the request. Meredith Figg seconded, and the motion passed unanimously.

Ms. Davis reviewed 201 KAR 2:416E and 201 KAR 2:416 relating the SB188 and the collection of the cost of dispensing data from pharmacies for the Department of Insurance and requested approval of the draft regulations.

Action: Kimberly Croley motioned to approve the regulations. John Fuller seconded, and the motion passed unanimously.

General Counsel then requested guidance on how the Board would like to handle the modification of past Agreed Orders.

Action: John Fuller motioned for the Board to entertain agreed order modification petitions when the Agreed Order was executed at least five years ago, and the Order does not contain specific terms regarding how reinstatement shall be sought. Anthony Tagavi seconded, and the motion passed unanimously.

The Board went back to the agenda item Robert Cruse (22-0135) regarding the request for modification of his Agreed Order.

Action: John Fuller motioned to lift all restriction on Mr. Cruse's current Agreed Order. Anthony Tagavi seconded, and the motion passed unanimously.

General Counsel reviewed the regulation status spreadsheet and the status of the Board's current regulations.

201 KAR 2:400, Outsourcing Facility: Ms. Davis requested approval from the Board to file a Certification of Amendment for this regulation.

Action: Kimberly Croley motioned to leave the regulation as is and file a Certification of Amendment. Anthony Tagavi seconded, and the motion passed unanimously.

AG Opinion, Non-resident Licensure: Derek Lewis, the co-chair of the ARRS Subcommittee, requested this opinion through the Speaker of the House. We were given one week to respond, and we were to limit our response to statutory authority and statutory construction. In the General Counsel's response, she laid out the long-standing board interpretation of our statutory authority. The AG responded six days after the Board's response was provided to the attorney general.

The opinion is publicly available on the Attorney General's website. It is Opinion 24-11. The opinion of the AG is binding on public agencies, and there is not an appeals process. The opinion can be cited in all courts of the Commonwealth.

This area of the law has been gray, and attorneys disagree on interpretation. The AG opinion interprets the Board's statutory authority to rulemake as much more limited than previously interpreted by the Board.

The opinion laid out three primary arguments. (1) Kentucky statutes are presumed to apply only within the state unless a clear intent for extraterritorial application is shown in statute. (2) The principle of expression unius est exclusion alterius suggests that the specific licensure requirement for the pharmacist in charge implies the exclusion of such requirements for other non-resident pharmacists. Because in KRS 315.0351 the non-resident pharmacy must have a Kentucky licensed pharmacist in charge, that statement implies the exclusion of licensure for other pharmacists. (3) Executive agencies, like the Board, can only exercise authority explicitly granted by the legislature. Any ambiguous or unclear authority is resolved against the agency. Agency authority is not to be implied. It should be express.

Moving forward, when the board feels the need to amend or author new rules, the first step will be to evaluate if we have the statutory authority to do so.

Action: Anthony Tagavi motioned to remove non-resident licensure language in 201 KAR 2:030, 050, and 465. Kimberly Croley seconded, and the motion passed unanimously.

COMMITTEE REPORTS

KYPRN Committee: Brian Fingerson gave the KYPRN Committee report. The committee met on November 12, 2024. The committee reviewed the report which includes 23 clients, 20 are under agreed order with the Board and 3 are self-reports. The next committee meeting is January 14, 2025.

Protocol Review Committee: Deputy Executive Director Juliana Swiney reported there are no updates for the Board.

Advisory Council: The Advisory Council reviewed 201 KAR 2:045, Pharmacy Technicians. Executive Director Harlow told the Board the Advisory Council recommended moving forward with the enumerated tasks, not the delegated model. Dr. Harlow gave a summary of what the Advisory Council discussed regarding the technician regulation. The draft of the version of the regulation they approved is attached.

OLD BUSINESS (Board moved to the first item in this section and will return to Old Business after Correspondence.)

201 KAR 2:210 Amendment Request – CVS: Representatives from CVS were John Long and Joe Lavino, and Quarles & Brady attorney Brenda Schafer. They asked the Board to remove Section 5 (7) of 201 KAR 2:210. They agreed to share data to support their ask, but only in closed session.

Action: Kimberly Croley motioned to go into closed session. Jason Belcher seconded, and the motion passed unanimously.

Action: Anthony Tagavi motioned to return to open session. Kimberly Croley seconded, and the motion passed unanimously.

After discussion, the Board made a language change to Section 5 (7) of 201 KAR 2:210.

Action: Anthony Tagavi motioned to approve the language change (attached) in 201 KAR 2:210 per the request of CVS. Kimberly Croley seconded, and motion passed with 5 yes votes and 1 no vote (Jason Belcher).

Action: Kimberly Croley motioned to grant CVS' request that section 7 of 201 KAR 2:210 be changed (attached) pending approval by the ARRS Committee. John Fuller seconded, and the motion passed with 5 yes votes and 1 no vote (Jason Belcher).

CORRESPONDENCE

Dual PIC Requests

P07834 and P06482, Whistead, Whitney (013378):

Action: Anthony Tagavi motioned to approve the dual PIC request until the March 2025 meeting. Meredith Figg seconded, and the motion passed unanimously.

P08207 and P08066, Jervis, Larry (011559):

Action: Anthony Tagavi motioned to approve the dual PIC request. Kimberly Croley seconded, and the motion passed unanimously.

Off-site Storage Requests

P08036:

Action: Kimberly Croley motioned to approve the off-site storage request. John Fuller seconded, and the motion passed unanimously.

P07214 and P07242:

Action: Meredith Figg motioned to approve the off-site storage request. Kimberly Croley seconded, and the motion passed with Anthony Tagavi abstaining.

Letter to Board from KIPA: The Board was provided a letter from the Kentucky Independent Pharmacy Alliance (KIPA) regarding their opposition to pharmacy kiosks.

OLD BUSINESS (Board went back to this section after Correspondence.)

Compounding Survey and Compliance Update: Executive Director Harlow provided the Board with the complete results of the compounding survey that was sent to all resident pharmacies.

Survey on Shipping of Prescription Drugs by a Common Carrier: Executive Director Harlow provided the Board with the complete results of the shipping of prescription drugs survey that was sent to all resident pharmacies.

NEW BUSINESS

Pharmacist Recovery Network Applicants (4 appointments): The following Ky-licensed pharmacists submitted their application for the Pharmacist Recovery Network Committee:

- Adams, Phillip
- Colurn, Kacee
- Divers, Cari
- Eastman, Emily
- Janson, Erin
- Jarrell, Lauren
- Lewis, Sarah
- McKinley, Alexandria
- McMahan, Laura
- Winters, Amelia

The Board members voted by secret ballot and the following 4 individuals received the most votes:

- Adams, Phillip
- Eastman, Emily
- Jarrell, Lauren
- McMahan, Laura

Action: Kimberly Croley motioned to accept these individuals as the new appointments to the KYPRN Committee. John Fuller seconded, and the motion passed unanimously.

Regulation Committee Applicants (3 appointments): The following Ky-licensed pharmacists submitted their application for the Regulation Committee:

- Adams, Nathaniel
- Burleson, Michael
- Burton, Carly
- Crawford, Lacy
- Davis, Gary
- Goetz, Ross
- Grove, Jennifer
- Jarrell, Lauren
- Jones, Joshua
- Jung, Vicki
- Kramer, Andrea
- Moore, Daniel
- Palutis, Christopher
- Stacy, Andrew
- Ward, Amanda
- Wills, Rheagan

The Board members voted by secret ballot and the following 3 individuals received the most votes:

- Burleson, Michael
- Grove, Jennifer
- Palutis, Christopher

Election of 2025 Case Review Panel:

Action: Meredith Figg motioned to elect Jason Belcher, Kimberly Croley, and Anthony Tagavi to the 2025 Case Review Panel. John Fuller seconded, and the motion passed unanimously.

Election of 2025 Board Officers:

Action: John Fuller motioned to elect Anthony Tagavi as President of the 2025 Board of Pharmacy. Meredith Figg seconded, and the motion passed unanimously.

Action: Anthony Tagavi motioned to elect Meredith Figg as Vice President of the 2025 Board of Pharmacy. John Fuller seconded, and the motion passed unanimously.

The Board went back to the discussion of the technician regulation. The regulation is attached and will be brought back to the January meeting along with the transfer regulation.

Staff Update: John Fuller has accepted the vacant Pharmacy and Drug Inspector position with the Board office.

Vice President Anthony Tagavi expressed his thanks from him and on behalf of the Board to 2024 Board President Jonathan Van Lahr.

Board member John Fuller resigned from the Board of Pharmacy. A new member will be appointed by the Governor's Office.

NEXT MEETING: January 22, 2025

ADJOURNMENT – 3:41 p.m.

Action: Meredith Figg motioned to adjourn the meeting at 3:41 p.m. Kimberly Croley seconded, and the meeting adjourned at 3:41 p.m.

AUDIO/VIDEO TRANSCRIPT AVAILABLE UPON REQUEST

201 KAR 2:045. Technicians.
(Amended Regulation)

RELATES TO: KRS 315.010(12), (20), (26), 315.020(4)(b), (5)(b), 315.191(1)(a), (g), (l)
STATUTORY AUTHORITY: KRS 315.010(~~21~~)(20), 315.020(4)(b), 315.191(1)(a), (g), (l)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the Board to promulgate administrative regulations governing pharmacy technicians. KRS 315.020(4)(b) authorizes the board to establish the scope of practice for pharmacy technicians. KRS 315.010(20) and 315.191(1)(l) authorize the board to promulgate administrative regulations establishing when a pharmacy technician ~~may can~~ be under the general supervision of a pharmacist, and establishes the scope of practice for a pharmacy technician.

Section 1. A person shall be recognized by the board as a certified pharmacy technician, if:

(1)

(a) The person has successfully completed the Pharmacy Technician Certification Exam (PTCE) administered by the Pharmacy Technician Certification Board (PTCB) or the Examination for the Certification of Pharmacy Technicians (ExCPT) by the National Healthcareer Association (NHA); and

(b) The certificate issued by the PTCB or NHA is current; or

(2) The person has successfully completed the Nuclear Pharmacy Technician Training Program at the University of Tennessee.

Section 2. Registered Technician.

(1) A registered pharmacy technician may, under the immediate supervision of a pharmacist, engage in the following activities at a permitted location to the extent that the activities do not require the exercise of professional judgment:

(a) Initiate or receive telephonic or electronic communication from a practitioner or practitioner's agent concerning refill authorization. If the practitioner or practitioner's agent communicates information that does not relate to the refill authorization:

1. The technician shall immediately inform the pharmacist; and

2. The pharmacist shall receive the communication;

(b) Enter information into and retrieve information from a database or patient profile, including order entry;

(c) Prepare and affix labels;

(d) Stock and retrieve, or return product to or from the pharmacy inventory including the stocking and loading of an automated filling or dispensing system with the use of barcode technology;

(e) Count and pour prescription drugs into patient storage containers;

(f) Obtain, record or maintain information for a patient record;

(g) Make an offer to counsel;

(h) Sell and record the sale of an over-the-counter ephedrine, pseudoephedrine, or phenylpropanolamine product;

(i) Certify for delivery unit dose mobile transport systems that have been refilled by another technician in an institutional pharmacy;

- (j) Receive diagnostic orders within a nuclear pharmacy;
and
- (k) Non-sterile and sterile drug compounding.
- (2) A registered pharmacy technician may, under electronic supervision, perform order entry from a location outside of the permitted pharmacy pursuant to KRS 315.020(5)(b) and (c).
- (3) A registered pharmacy technician may, under general supervision:
 - (a) Administer a vaccine to an individual if the technician:
 - 1. Completes a minimum of two (2) hours of immunization-related continuing education accredited by the Accreditation Council for Pharmacy Education (ACPE) per each state registration period;
 - 2. Completes, or has completed, a practical training program accredited by ACPE that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines; and
 - 3. Possesses a current certificate in basic cardiopulmonary resuscitation.
 - (b) Stock an automated dispensing system in a residential hospice facility if a pharmacist is on-site; and
 - (c) Administer point of care tests.

Section 3. Certified Pharmacy Technician.

- (1) A certified pharmacy technician, under the general supervision of a pharmacist, may be delegated by the supervising pharmacist to perform any function within the practice of pharmacy except the following:
 - (a) Patient counseling, including clinical advisement necessary to all areas of a patient's health;
 - (b) Drug evaluation, utilization, and regimen review;
 - (c) Interpretation of medical orders and prescriptions;
 - (d) Final prescription verification;
 - (e) Receipt of new verbal prescription drug or medical orders; and
 - (f) Other acts, services, or decisions that require professional judgement. perform the following functions under the general supervision of a pharmacist:
 - ~~(1) Certify for delivery unit dose mobile transport systems that have been refilled by another technician;~~
 - ~~(2) Within a nuclear pharmacy, receive diagnostic orders; and~~
 - ~~(3)~~
 - ~~(a) Initiate or receive a telephonic communication from a practitioner or practitioner's agent concerning refill authorization, after the certified pharmacy technician clearly identified himself or herself as a certified pharmacy technician; and~~
 - ~~(b) If a practitioner or practitioner's agent communicates information that does not relate to the refill authorization:~~
 - ~~1. A technician shall immediately inform the pharmacist; and~~
 - ~~2. The pharmacist shall receive the communication.~~

Section 4. Directing pharmacist responsibility.

~~(1) A technician who has not been certified by PTCB or NHA may perform the functions specified by Section 2 of this administrative regulation under the immediate supervision of a pharmacist.~~

~~(2) A function performed by a certified pharmacy technician or pharmacy technician shall be performed subject to review of the pharmacist who directed the technician to perform the function.~~

~~(2) (3) A pharmacist who directs a certified pharmacy technician or pharmacy technician to perform a function shall be responsible for the technician and the performance of the function.~~

(3) A pharmacy technician shall only perform tasks for which they have been specifically trained. The pharmacist in charge shall ensure documentation of training is readily retrievable at the permitted location and shall be provided to delegating pharmacists and board of pharmacy staff, upon request.

Section 5. Application.

1. An applicant shall provide the following information as part of their technician registration application:

(a) Name, maiden, and other names used currently or previously;

(b) telephone number;

(c) address;

(d) social security number;

(e) NABP eprofile number;

(f) email address;

(g) place of employment;

(h) Record of convictions of any felony or misdemeanor offense, other than traffic offenses, and whether or not a sentence was imposed or suspended;

(i) Record of any technician registration revocation, suspension, restriction, termination, or other disciplinary action by any board of pharmacy or other state authority;

(j) Record of any condition of impairment, such as substance or alcohol abuse or dependency that in any way impacts the technician's ability to assist in the practice of pharmacy in a safe and competent manner;

(k) Record of licensure, certification or registration as a pharmacy technician in any other state, if applicable; and

(l) Record of certification as a pharmacy technician with a national organization, if applicable.

Section 6. Material Incorporated by Reference.

1. The following material is incorporated by reference:

(a) "Application for Registration as a Pharmacy Technician", 07/2024

(b) "Application for Pharmacy Technician Renewal", 07/2024

(c) "Charitable Pharmacy Technician Application" 07/2024

(d) "Charitable Pharmacy Technician Renewal Application", 07/2024

2. This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

This material is also available on the Board's website at:

<https://pharmacy.ky.gov/professionals/Pages/Pharmacy-Technicians.aspx>.