

KENTUCKY BOARD OF PHARMACY

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

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July 24, 2024
9:00 a.m.

Board Meeting Agenda

- I. CALL TO ORDER
- II. MINUTES
 - A. May 22, 2024 Minutes
 - B. June 25, 2024 Special Called Meeting Minutes
- III. BOARD RETREAT TOPICS CONTINUED IF NECESSARY, FROM JULY 23, 2024
- IV. APPEARANCES
 - A. DSCSA Update- Josh Bolin, NABP
- V. INTERAGENCY/PROFESSIONAL ASSOCIATIONS
 - A. KPhA Summary of Feedback on Proposed Amendment 201 KAR 2:070
- VI. BOARD REPORTS
 - A. Executive Director
 - a. eMARs
 - b. Increment Request- Hannah Rodgers
 - c. ACE Award Request- Paul Daniels
 - d. Letter for Novo Nordisk on Compounding of Semaglutide
 - B. General Counsel
 - a. Report from the Q&B Pharmacy Law Symposium

VII. COMMITTEE REPORTS

- A. KYPRN
- B. Diversity & Inclusion Task Force
- C. Protocol Review Committee
 - i. Acute Influenza Infection Chemoprophylaxis Protocol
 - ii. Self-Care Conditions: Over-the-Counter Dietary Supplement Protocol
 - iii. Self-Care Conditions: Over-the-Counter Probiotics Protocol
 - iv. Self-Care Conditions: Diabetes Testing and Injection Supplies Protocol

VIII. CORRESPONDENCE

- A. CoverMyMeds Pharmacy (P08325), Shared Services Pilot Program Request
- B. Deem, Daniel (017694), Dual PIC Request (TX1958 & TX1615)
- C. St. Matthews Pharmacy (P07869), Sink Waiver Request
- D. St. Matthews Pharmacy (P08335), Equipment Waiver Request
- E. Lexington Compounding Pharmacy (P06932), Offsite Storage Request
- F. Kentuckycare Pharmacy 62 (P07590), Offsite Storage Request
- G. Care More Pharmacy (P06601), Offsite Storage Request
- H. Baptist Health Hardin Pharmacy (P08136), Offsite Storage Request
- I. Walmart Pharmacies, One-Way Return Box

IX. OLD BUSINESS

- A. 201 KAR 2:015 Review of comments received since public hearing
- B. 201 KAR 2:030 Review of comments received since public hearing
- C. 201 KAR 2:050 Review of comments received since public hearing
- D. 201 KAR 2:465 Review of comments received since public hearing

X. NEW BUSINESS

- A. Regulation Committee Appointment (One Appointment)
 - i. Adams, Nathaniel
 - ii. Davis, Gary
 - iii. Eiler, Joseph "Max"
 - iv. Goetz, Ross
 - v. Hankinson, William
 - vi. Moore, Daniel
 - vii. Reams, Jonathon "Scotty"
 - viii. Stacy, Andrew
 - ix. Ward, Amanda

- B. Advisory Council Confirmation (Roll Call Vote)
 - i. Richardson, Katie (Pharmacist Appointment by the Kentucky Pharmacists Association)

XI. CLOSED SESSION

- A. 22-0056/23-0514A Final Order
- B. 23-0558 REVISIT (2024 CRP)

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

July 24, 2024

9:00 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; Paul Daniels, Pharmacy and Drug Inspector; 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 9:00 a.m.

MINUTES: Minutes from the May 22, 2024 and June 25, 2024 (Special Called) meetings.

Action: John Fuller motioned to accept the minutes as written from the May 22, 2024 meeting. Kimberly Croley seconded, and the motion passed unanimously.

Action: Kimberly Croley motioned to accept the minutes as written from the June 25, 2024 special called meeting. Jason Belcher seconded, and the motion passed unanimously.

APPEARANCES

Josh Bolin, NABP: Mr. Bolin gave a presentation on DSCSA updates.

Cover My Meds, Maricela Lara-Nevarez and Nick Mesa: Ms. Lara-Nevarez and Mr. Mesa appeared before the board on behalf of their employer, Cover My Meds, to ask for the Board's consideration of a proposed shared services pilot program and a waiver of applicable rules to engage in such. Cover My Meds is also offering to provide any data obtained through this pilot program to the Board to assist in the rulemaking process.

Action: Anthony Tagavi motioned to grant Cover My Meds a waiver for one (1) year in hopes that the shared services regulation will be completed. Cover My Meds will only work with one (1) pharmacy, all pharmacists involved with be licensed in Kentucky prior to the start of the program, the patients will be required to "opt-in" and deliver monthly data reports to the Board and come back to the Board in 6 months to give an update. Data provided to the Board will include temperature excursion information. All other rules not specified in the waiver apply. Kimberly Croley seconded, and the motion passed unanimously.

There was discussion about the waiver process and past requests for "pilot programs" and/or waivers. General Counsel Eden Davis stated she would provide guidance on waivers for the Board and Stakeholders at the next meeting.

INTERAGENCY/PROFESSIONAL ASSOCIATIONS

KPhA: Ben Mudd gave a summary of feedback from members on the proposed amendment to 201 KAR 2:070. Specifically, the delivery of prescriptions by UK to local health departments for dispensing to patients.

Action: Anthony Tagavi motioned to send 201 KAR 2:070 to the Advisory Council. John Fuller seconded, and the motion passed unanimously.

BOARD REPORTS

Executive Director Report: Executive Director Chris Harlow gave the financial (eMARS) report that was included in the Board meeting materials.

Executive Director Harlow asked the Board to approve a salary increment for Staff Attorney Hannah Rodgers.

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

Executive Director Harlow asked the Board to approve an ACE Award for Pharmacy and Drug Inspector Paul Daniels for his outstanding work going above and beyond in training our newest inspection staff member, Taylor Rostova.

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

Novo Nordisk on Compounding of Semaglutide update – Executive Director Harlow gave the Board an update that the Boards of Medical Licensure, Nursing, and Pharmacy are working on a joint statement regarding not only the compounding of semaglutide, but the compounding of IV hydration therapies as well by non-licensed people.

General Counsel Report: General Counsel Eden Davis gave the Board an update on the Quarles and Brady forum she attended.

Ms. Davis took this time to address questions/issues from the temperature tracking discussion from the prior day's retreat. Topics she covered included wholesalers and the DSCSA, the Chevron case that was recently overturned, interstate commerce law, and the importance of when making rules that we have the appropriate data to back up our rule making. Regarding the issue of temperature tracking, Ms. Davis recommends working together with stakeholders who do this to help us gather the appropriate data needed.

Kimberly Croley suggested making two separate motions regarding gathering data on temperature tracking of shipped prescription medications.

Action: Kimberly Croley motioned to direct Board staff reach out to all KY-permitted pharmacies that ship medications in the state and into the state and ask if they do not already include the Board's contact information, would they be willing to do so? Jason Belcher seconded, and the motion passed unanimously.

Action: Kimberly Croley motioned to make a second ask to the same parties requesting information about what their temperature tracking processes they already have in place. Do they capture data from consumers about issues/complaints, do they use temperature trackers and if so, do they use them in all prescription shipments or just refrigerated prescriptions? Jason Belcher seconded, and the motion passed unanimously.

COMMITTEE REPORTS

KYPRN Committee: Brian Fingerson gave the PRN Committee report. The Committee met on July 9, 2024. There are 3 people who have completed the KYPRN program and are now removed from the report. There is one new client on the report. There are 22 individuals under monitoring that are under a Board order and 3 that are self-reports and anonymous to the Board.

Diversity & Inclusion Task Force: Executive Director Harlow gave the report and told the Board that there is an issue with them regularly having a quorum. The Task Force has requested that the Board make the student members non-voting members. Due to the turnover of the students, it is often preventing them from conducting business. They are continuing to work on their podcasts.

Action: John Fuller motioned to make the student members non-voting members. Anthony Tagavi seconded, and the motion passed unanimously.

Protocol Review Committee: Juliana Swiney gave the Protocol Review Committee report. The Committee met on June 4, 2024. The Committee had a presentation by pharmacist Dustin Miracle on OTC hormonal contraceptives. The Committee voted to review it at their August meeting.

Executive Director had one correction to the Diabetes and injection supplies protocol. The Committee recommended the removal of "primary care provider." The Regulation does state "primary care provider" so that term cannot be removed.

Action: Kimberly Croley motioned to approve the Acute Influenza Infection Chemoprophylaxis Protocol. John Fuller seconded, and the motion passed unanimously.

Action: Anthony Tagavi motioned to approve the Self-Care Conditions: Over-the-Counter Dietary Supplement Protocol. Kimberly Croley seconded, and the motion passed unanimously.

Action: Kimberly Croley motioned to approve the Self-Care Conditions: Over-the-Counter Probiotics Protocol. Anthony Tagavi seconded, and the motion passed unanimously.

Action: Kimberly Croley motioned to approve (with the edits including "primary care provider" and additional providers language) the Self-Care Conditions: Diabetes Testing and Injection Supplies Protocol. Anthony Tagavi seconded, and the motion passed unanimously.

CORRESPONDENCE

Dual PIC Request: Deem, Daniel (017694) for TX1958 and TX1615

Action: Anthony Tagavi motioned to approve this dual PIC request for 120 days. Meredith Figg seconded, and the motion passed unanimously.

Sink Waiver Request: St. Matthews Pharmacy (P07869)

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

Equipment Waiver Request: St. Matthews Pharmacy (P08335)

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

Offsite Storage Request: Lexington Compounding Pharmacy (P06932)

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

Offsite Storage Request: Kentuckycare Pharmacy 62 (P07590)

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

Offsite Storage Request: Care More Pharmacy (P06601)

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

Offsite Storage Request: Baptist Health Hardin Pharmacy (P08136)

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

The Board moved to the voting of the Regulation Committee member so Executive Director Harlow could begin tallying the votes. The following people applied for the vacancy:

- Adams, Nathaniel
- Davis, Gary
- Eiler, Joseph “Max”
- Goetz, Ross
- Hankinson, William
- Moore, Daniel
- Reams, Jonathon “Scotty”
- Stacy, Andrew
- Ward, Amanda

The Board then moved back to OLD BUSINESS on the agenda.

OLD BUSINESS

Review of Public Comments – 201 KAR 2:015, 201 KAR 2:030, 201 KAR 2:050, and 201 KAR 2:465

The Board reviewed all comments on the above referenced draft regulations. The Board voted on all the comments collectively in one action apart from comments submitted by Kroger. (Board member John Fuller will recuse.) General Counsel Eden Davis went through each comment in the table provided to the Board members and documented each response for the Statement of Consideration.

Action: John Fuller motioned to accept all responses documented by the Board members on each comment. Kimberly Croley seconded, and the motion passed unanimously.

Action: Kimberly Croley motioned to accept the Board’s response to the public comment from Kroger. Jason Belcher seconded, John Fuller abstained, and the motion passed.

NEW BUSINESS

Regulation Committee Appointment (One Appointment): The Board voted by ballots to elect Jonathon “Scotty” Reams to the Regulation Committee. (The following were the three people who received votes in the order of the amount of votes they received: Jonathon “Scotty” Reams, Amanda Ward, Gary Davis)

Action: Kimberly Croley motioned to accept the Board's vote of Mr. Reams to the Regulation Committee. Anthony Tagavi seconded, and the motion passed unanimously.

Advisory Council Confirmation (Roll Call Vote): The Board confirmed the appointment of Katie Richardson by the Kentucky Pharmacist Association by a roll call vote as follows:

Jonathan Van Lahr – Yes

Anthony Tagavi – Yes

John Fuller – Yes

Meredith Figg – Yes

Kimberly Croley – Yes

Jason Belcher – Yes

CLOSED SESSION

Action: Anthony Tagavi motioned to go into closed session. Meredith Figg seconded, and the motion passed unanimously.

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

Case 22-0056/23-0514A:

Action: Jonathan Van Lahr motioned to accept the recommendation of the hearing officer. Jason Belcher seconded, John Fuller, Anthony Tagavi, and Meredith Figg abstained, and the motion passed. (Mr. Fuller, Mr. Tagavi, and Ms. Figg recused from the discussion.)

Case 23-0558 Revisit:

Action: Meredith Figg motioned for the following settlement: The respondent will enter into an agreed order of probation for a term of 3 years, a \$25,000 fine, with a trigger clause that the fine must be paid by the deadline stated or the respondent must pay an additional \$25,000 as originally ordered by the Case Review Panel, and add an additional 2 years of probation for a total fine of \$50,000 and 5 years' probation, should they violate the amended terms. Jason Belcher seconded, Kimberly Croley, Anthony Tagavi, and John Fuller abstained, and the motion passed. (Ms. Croley, Mr. Tagavi, and Mr. Fuller all recused from the discussion.)

NEXT MEETING: September 25, 2024

ADJOURNMENT – 3:32 p.m.

Action: Meredith Figg motioned to adjourn the meeting. Jason Belcher seconded, and the motion passed unanimously.