KENTUCKY BOARD OF PHARMACY

via Zoom

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Meeting ID: 848 6165 5827 Passcode: eq9cS6 Dial by your location +1 312 626 6799 US (Chicago) +1 646 558 8656 US (New York) Meeting ID: 848 6165 5827 Passcode: 558139 Kentucky Department of Transportation Auditorium 200 Mero Street, Frankfort KY June 1, 2022 10:00 a.m. AGENDA

I. CALL TO ORDER

- II. MINUTES
 - A. March 30, 2022

III. APPEARANCES

A. NABP – William Cover, NABP Verify program

IV. INTERAGENCY

V. BOARD REPORTS

- A. Executive Director
 - 1. eMars, March and April
 - 2. 2022 Board Retreat
 - 3. FDA National License Standards KY Board of Pharmacy comments
 - 4. Expungement Requests
 - a) 19-0023
 - b) 11-0078B
 - c) 17-0313
 - 5. NABP District III Meeting

VI. COMMITTEE REPORTS

- A. Kentucky Professional Recovery Committee, Brian Fingerson
- B. Diversity and Inclusion Task Force, Shannon Borden and Crystal Isaacs
- C. Continuous Professional Development Committee, Adrienne Matson

VII. LEGISLATION/REGULATION

- A. Legislative Update
- B. 201 KAR 2:440, Legend Drug Repository

- C. 201 KAR 2:412E, Ordering and administering vaccinations
- D. Senate Bill 11 201 KAR 2:370, Pharmacy services in long-term care facility (LTCF)

VIII. CORRESPONDENCE

- A. Andrea McAlpin, P05156 and P07852 Dual PIC Request
- B. Whitney Crabtree, P08059 and P07503 Dual PIC Request
- C. Kayla Prewitt, P08098 and CP00132 Dual PIC Request
- D. Fred Nowak, P07258 and P07208 Dual PIC Request
- E. Shawn Tankersley, P07856 and CP00129 Dual PIC Request
- F. Kelli Todd, CP00134 and P08236 Dual PIC Request

IX. OLD BUSINESS

- A. Workplace Conditions
 - 1. Survey Results, Maddie Urbanek
 - 2. Workplace Conditions Meeting, NABP Annual Meeting

X. NEW BUSINESS

- A. Exela Pharma Sciences LLC, OSF00134 and W03412
- B. Reciprocal Application Exam Requests
 - 1. Amanda Whitman
 - 2. Arthur DeLashmet
 - 3. Jennifer Chang
- C. Pharmacy Technician Applications
 - 1. MW5708
 - 2. NB5920

XII. CLOSED SESSION

- A. Final Orders
 - 1. 20-0100
 - 2. 21-0130C

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

BOARD MEETING June 1, 2022

CALL TO ORDER A regularly scheduled hybrid meeting was held at the Kentucky Board of Transportation, Frankfort, Kentucky. President Cohron called the meeting to order 10:00 a.m.

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

Staff: Christopher Harlow Executive Director; Martin K. Poynter, serving as 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 Katie Busroe, Pharmacy Inspections and Investigations Supervisor; Nikki Holiday, Executive Assistant and Darla Sayre, Executive Staff Advisor.

Guests: Bill Cover, NABP; Cathy Hanna, APSC; Kerri Johnson, Chewy; Cheryl Lalonde and Julie Anderson, RX Crossroads by McKesson.

MINUTES Anthony Tagavi moved to accept the minutes from the March 30, 2022 meeting. Jonathan Van Lahr seconded, and the motion passed unanimously.

APPEARANCE

NABP Verify Program Bill Cover gave a presentation on the NABP Verify program that enables the issuance of a state credential based on continued evidence of ongoing licensure in good standing, as determined via the NABP monitoring service.

Action: Peter Cohron requested NABP provide a copy of the memorandum of understanding that specifies the responsibilities of NABP and the Board.

INTERAGENCY

Cathy Hanna, KPhA The KPhA Annual Meeting will be held at the Campbell House in Lexington, KY on June 2-5, 2022.

BOARD REPORTS – EXECUTIVE DIRECTOR

eMars Christopher Harlow presented the March and April financial reports to the Board.

FDA MOU Dr. Harlow reported the FDA has extended the MOU comment period. He stated that the Board must align the wholesaler and third-party logistics regulations with the FDA guidelines.

Action: Jonathan Van Lahr moved to table this discussion until the July meeting. Meredith Figg seconded, and the motion passed unanimously.

Board Retreat Dr. Harlow provided the topics to be discussed at the retreat. Topics will be discussed as time allows. 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

NABP District III Dr. Harlow informed the Board that the NABP District III meeting will be held in Flowood, MS on August 7-10, 2022.

Action: Jonathan Van Lahr moved to allow two Board members to attend in addition to the Executive Director. Anthony Tagavi seconded, and the motion passed unanimously.

Expungement Requests Dr. Harlow presented Case 19-0023 for expungement.

Action: Anthony Tagavi moved to approve the expungement of Case 19-0023. Jonathan Van Lahr seconded, and the motion passed unanimously.

Dr. Harlow presented Case 11-0078 B for expungement.

Action: Anthony Tagavi moved to approve the expungement of Case 11-0078 B. Jonathan Van Lahr seconded, and the motion passed unanimously.

Dr. Harlow presented Case 17-0313 for expungement.

Action: Meredith Figg moved to approve the expungement of Case 17-0313. Jonathan Van Lahr seconded, and the motion passed unanimously.

NABP Committee Involvement Request Dr. Harlow requested any Board members wishing to serve on NABP committees to email him for further information. This information is due June 3, 2022.

COMMITTEE REPORTS

Kentucky Professional Recovery Network Brian Fingerson informed the Board that there are currently 25 known individuals being monitored and 5 unknown individuals. The next scheduled meeting is July 13, 2022.

Continuous Professional Development Committee Chairperson Adrienne Matson reported the committee is exploring the ACPE/NABP programs for continuous professional development to create a template for possible use with disciplinary actions replacing required additional continuing education.

LEGISLATION/REGULATION

Legislative Update Christopher Harlow provided an update from the current legislative session listing all proposed legislation that has potential to impact pharmacy practice. He requests the Board develop regulations on remote work in response to House Bill 240. Due to Senate Bill 11, the Board needs to amend 201 KAR 2:370, Pharmacy Services in long-term care facility [LTCF].

Action: Anthony Tagavi moved to allow the General Counsel to amend 201 KAR 2:370 to exclude assisted living facilities from the definition of LTCF. The amended regulation will be presented at the July Board meeting for review. Jonathan Van Lahr seconded, and the motion passed unanimously.

201 KAR 2:412E Dr. Harlow presented an amendment to 201 KAR 2:412E. This emergency regulation must be amended before it's expiration.

Action: Jonathan Van Lahr moved to approve the amended regulation as drafted for submission to LRC. Meredith Figg seconded, and the motion passed unanimously.

CORRESPONDENCE

Actions:

Andrea McAlpin, P05156 and P07852 - Dual PIC Request Anthony Tagavi moved to approve this permanent request. Meredith Figg seconded, and the motion passed unanimously.

Whitney Crabtree, P08059 and P07503 - Dual PIC Request Jonathan Van Lahr moved to approve this permanent request. Anthony Tagavi seconded, and the motion passed unanimously.

Kayla Prewitt, P08098 and CP00132 - Dual PIC Request Anthony Tagavi moved to approve this permanent request. Jonathan Van Lahr seconded, and the motion passed unanimously.

Fred Nowak, P07258 and P07208 - Dual PIC Request Meredith Figg moved to approve this request for up to six months. Anthony Tagavi seconded, and the motion passed unanimously.

Shawn Tankersley, P07856 and CP00129 - Dual PIC Request Jonathan Van Lahr moved to approve this permanent request. Anthony Tagavi seconded, and the motion passed unanimously.

Kelli Todd, CP00134 and P08236 - Dual PIC Request Jonathan Van Lahr moved to approve this request for three months from application approval. Meredith Figg seconded, and the motion passed unanimously.

OLD BUSINESS

Workplace Conditions Maddie Urbanek presented the survey results from the Kentucky Board of Pharmacy workplace conditions survey. Workplace conditions is on the list of topics to be discussed at the retreat. Jonathan Van Lahr requested these results be available at the retreat.

NEW BUSINESS

Exela Pharma Sciences LLC Bridget Archer requested the Board approve for multiple locations be listed under one permit/license. North Carolina and the FDA both allow this.

Action: Anthony Tagavi moved to approve one outsourcer facility license to correlate with the FDA with the understanding that the geographical locations must be located to allow for one day inspection of both locations. Meredith Figg seconded, and the motion passed unanimously.

Amanda Whitman, Reciprocal Application Anthony Tagavi moved to allow examination. Jonathan Van Lahr seconded, and the motion passed unanimously.

Arthur DeLashmet, Reciprocal Application Meredith Figg moved to allow examination. Jonathan Van Lahr seconded, and the motion passed unanimously.

Jennifer Chang, Reciprocal Application Jonathan Van Lahr moved to defer this request until the July Board meeting and requested the applicant to be in attendance. The Board requests clarification on how this licensure will be utilized. Jason Belcher seconded, and the motion passed unanimously.

Pharmacy Technician Applications Dr. Harlow presented two pharmacy technician applications for approval.

Actions: Anthony Tagavi moved to defer the application [MW] to the July Board meeting and requested the applicant to be in attendance. Jonathan Van Lahr seconded, and the motion passed unanimously. Jonathan Van Lahr moved to approve the application [NB]. Anthony Tagavi seconded, and the motion passed unanimously.

CLOSED SESSION Anthony Tagavi moved to go into closed session to include Christopher Harlow, Keith Poynter, Nikki Holiday, Amanda Harding and Darla Sayre for the purpose of reviewing, discussing and deliberating upon open investigations [termination of KYPRN agreement] 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). Jonathan Van Lahr seconded, and the motion passed unanimously. Anthony Tagavi moved to come out of closed session after a discussion regarding Final Orders. Jonathan Van Lahr seconded, and the motion passed unanimously.

Action: Anthony Tagavi moved to accept the recommended Final Order for case 20-0100. Jonathan Van Lahr seconded, and the motion passed unanimously. Anthony Tagavi moved to accept the recommended Final Order for case 21-0130 C. Jonathan Van Lahr seconded, and the motion passed unanimously.

Peter Cohron thanked Keith Poynter for providing legal services in the absence of Eden Davis.

ADJOURNMENT Meredith Figg moved to adjourn. Jonathan Van Lahr seconded, and the motion passed unanimously. President Cohron adjourned the meeting at 1:20 p.m.