

KENTUCKY BOARD OF PHARMACY

<https://us02web.zoom.us/j/86098589916?pwd=Z0V1RW94RVBhVEdsMHQwYUNZVDRNUT09>

Meeting ID: 860 9858 9916 Passcode: 7NsP6b

Dial by your location

+1 312 626 6799 US (Chicago) +1 646 558 8656 US (New York)

Meeting ID: 860 9858 9916 Passcode: 770883

Agenda for Regulation Committee

February 18, 2021

9:00 a.m.

- I. Call to Order
- II. Minutes – January 22, 2021
- III. Old Business:
 - A. **201 KAR 2:061, Procedures followed by the Kentucky Board of Pharmacy in the investigation and hearing of complaints.**
'The Board requested the Regulation Committee provided amended language to remove the inspector from the voting process and add the Vice President of the Board as a voting member.'
- IV. Next meeting date
- V. Adjournment

KENTUCKY BOARD OF PHARMACY

REGULATION COMMITTEE

via teleconference

February 18, 2021

9:00 a.m.

MINUTES

Chairperson Ralph Bouvette called the meeting to order at 9:00 a.m. Members present via teleconference: Larry Hadley, Ralph Bouvette, Katie Busroe, Chris Palutis, Elisha Bischoff; Cathy Hanna, Joel Thornbury, Jennifer Grove and Mike Burleson. Staff: Eden Davis, General Counsel; Paul Daniels, Pharmacy and Drug Inspector; Amanda Harding, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector; Rhonda Hamilton, Pharmacy and Drug Inspector; John Romines, Pharmacy and Drug Inspector and Darla Sayre, Executive Staff Advisor.

Joel Thornbury moved to accept the minutes of the January 22, 2021 meeting. Mike Burleson seconded, and the motion passed unanimously.

201 KAR 2:061, Procedures followed by the Kentucky Board of Pharmacy in the investigation and hearing of complaints. Ralph Bouvette gave a brief overview of 201 KAR 2:061 and what was required of the committee. This regulation will sunset and action must be taken by the Board prior to June 12, 2021. The committee was charged by the Board to review and consider suggested amendments for recommendation to the Board. The committee discussed the proposed amendments addressing questions and concerns. Joel Thornbury moved to change the proposed makeup of the Case Review Panel to comprise the Board President, an assigned Board member and the Executive Director. Cathy Hanna seconded and the motion passed with Katie Busroe voting no. After further discussion, the committee reviewed the proposed draft.

Section 1. Ralph Bouvette questioned the meaning of 'Kentucky Pharmacy Law'. Eden Davis stated that this would need to be changed to more specific language citing the referenced statutes and regulations.

Section 2. Cathy Hanna questioned the use of a contracted investigator. She would prefer the use of inspection staff. Cathy Hanna moved to include language to limit the use of a contracted investigator unless there is a conflict of interest. Mike Burleson seconded. Katie Busroe requested that 'contracted investigator' be replaced with 'special investigator' as this term is found in statute. Cathy Hanna amended her motion to include this request with Mike Burleson amending his second. The motion passed unanimously. Several members addressed concerns with requiring the notice to the licensee at the initiation of the investigation. Concerns were raised that this would jeopardize an investigation involving other state or federal agencies. Mike Burleson questioned if Section 2 conflicts with Section 1. Eden Davis will provide additional research on this for the next meeting. Jennifer Grove questioned who would decide if an extension was needed. What is the process for obtaining an extension?

Section 3. Katie Busroe moved to strike the language requiring the Panel to meet a minimum of five times per calendar year. Cathy Hanna seconded, and the motion passed unanimously. Joel Thornbury moved to strike the language requiring the investigative findings and evidence be provided to the Case Review Panel at least seven days prior to the meeting. He suggested this be addressed by policy rather than regulation. Katie Busroe

seconded, and the motion passed with Jennifer Grove, Cathy Hanna and Chris Palutis voting no. Eden Davis stated that concerns have been raised regarding the inclusion of the inspection staff. Joel Thornbury stated that during his term he found the inspection staff to be informative and advantageous during the discussion of the cases. He moved to strike this language restricting the participants of the case discussion to the Case Review Panel, General Counsel and the inspector on file. Mike Burleson seconded. With a vote of 3 [Joel Thornbury, Mike Burleson and Katie Busroe] voting yes and 5 [Jennifer Grove, Chris Palutis, Cathy Hanna, Elisha Bischoff and Larry Hadley] voting no, the motion did not pass. Eden Davis was directed to provide more insight into the use of prior Board members as alternative members in case of Board member recusal.

Section 4. Cathy Hanna moved to strike the language regarding administrative conferences and add language to the proposed Section 4 to address due process. Mike Burleson seconded, and the motion passed unanimously.

Section 6. Chris Palutis suggested changing the language to read 'a vote of all Board members excluding those that participated in the Case Review Panel.' Cathy Hanna moved to amend the composition of the Case Review Panel to the Board President and two assigned Board members. After further discussion, Cathy Hanna amended her motion to include the restriction of participation in the case discussion to be the Case Review Panel, the General Counsel, the Executive Director and the inspector of the case. Chris Palutis seconded, and the motion passed with Katie Busroe and Joel Thornbury voting no.

Chairperson Bouvette directed Eden Davis provide an updated version for the next meeting.

On motion by Joel Thornbury, seconded by Cathy Hanna and passed unanimously, Chairperson Ralph Bouvette adjourned the meeting at 12:14 p.m.