

KENTUCKY BOARD OF PHARMACY

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Agenda for Regulation Committee

August 13, 2020

1:00 p.m.

- I. Call to Order
- II. Minutes – June 10, 2020
- III. Discussion:
 - A. **Repository Program**

“Jill Rhodes moved to send the draft versions to the Regulation Committee. Peter Cohron seconded, and the motion passed unanimously. *The charge to the committee is to review and consider the establishment of repository regulation.*”
 - B. **201 KAR 2:205, Pharmacist-in-charge.**
 - C. **RX Adaptation**

“The Advisory Council submitted language for RX adaptation. *Craig Martin moved to send this proposed language to the Regulation Committee for insertion in an existing or creation of a new regulation.* Peter Cohron seconded, and the motion passed unanimously.”
 - D. **201 KAR 2:061, Procedures followed by the Kentucky Board of Pharmacy in the investigation and hearing of complaints.**

“Ron Poole informed the Board of the results from a survey sent to all state boards of pharmacy requesting information regarding disciplinary case review specifically in regards to voting members for case recommendations. Katie Busroe stated that the disciplinary regulation is under review by the Regulation Committee. The inspection staff has requested the regulation be amended to eliminate the inspector’s vote. *Jill Rhodes moved to direct the Regulation Committee to review the data results from the survey and other formats to remove the required vote from the inspector.* Peter Cohron seconded, and the motion passed unanimously.”
 - E. **201 KAR 2:270, Expungement.**

“Larry Hadley informed the Board that comments received regarding this regulation amendment had not previously been presented to the Board. *Peter Cohron moved to direct the Regulation Committee to review the comments and insert them into the regulation.* Craig Martin seconded, and the motion passed unanimously.”
 - F. **KRS 315.0351 Non-resident Pharmacy Permit Questions**

“*After discussion, Jill Rhodes moved to direct the Regulation Committee to review these issues and provide recommendations to the Board for regulation amendments or implementing Board policy.*”
 - G. **201 KAR 2:074 Decentralized Pharmacies**

“*After discussion, Jill Rhodes moved to direct the Regulation Committee to review these issues and provide recommendations to the Board for regulation amendments or implementing Board policy.*”
- IV. Next meeting date
- V. Adjournment

**KENTUCKY BOARD OF PHARMACY
REGULATION COMMITTEE**

via teleconference

August 13, 2020

1:00 p.m.

MINUTES

Chairperson Ralph Bouvette called the meeting to order at 1:00 p.m. Members present via teleconference: Larry Hadley, Ralph Bouvette, Katie Busroe, Chris Palutis, Cathy Hanna, Jennifer Grove and Mike Burleson. Staff: Anthony Gray, Board Counsel. Absent: Elisha Bischoff and Joel Thornbury.

Mike Burleson moved to accept the minutes of the June 10, 2020 meeting. Cathy Hanna seconded, and the motion passed unanimously.

Repository Regulation Larry Hadley gave a brief overview of the repository program and proposed regulation. He suggested the committee look at the Faith Community Pharmacy version as it is based on Kentucky statutes. Katie Busroe informed the committee that she was invited to participate in a NABP Task Force meeting on unused medications in October. The information obtained at that meeting may provide insight in how other states handle this issue. Ms. Busroe advised the committee that Kentucky has 8 charitable pharmacies. She requested the committee look at expanding the regulation and statute to include other healthcare facilities who dispense to the uninsured or underinsured public. Katie Busroe moved to expand the scope of the statute to include other healthcare facilities. Mike Burleson seconded, and the motion passed unanimously.

201 KAR 2:205 Chris Palutis moved to Keep but Amend this regulation. Cathy Hanna seconded, and the motion passed unanimously. Katie Busroe requested the committee look at the regulation to better align with current practices. She presented the following concerns from the inspection staff:

- PIC is held responsible for pharmacy policies when it is beyond their control. The pharmacy owner is the entity implementing the pharmacy policies.
- Minimum requirement of working 10 hours a week in the pharmacy.
- Allow dual PIC under certain circumstances without obtaining a waiver from the Board.
- Require PIC to sign an agreement specifying their responsibilities or obtain continuing education on being a pharmacist in charge.
- Establish a more defined quality assurance program.

Katie Busroe moved to discuss increasing the minimum of 10 hours per week. After discussion, Chris Palutis moved to keep the wording as is. Jennifer Grove seconded, and the motion passed with Katie Busroe and Mike Burleson voting no. Cathy Hanna moved to add employment changes of pharmacy technicians to the required notification to the Board by the PIC. Mike Burleson seconded, and the motion passed unanimously. Katie Busroe moved to have Anthony Gray draft a pharmacist in charge agreement or continuing education. The motion died from lack of a second. Chris Palutis moved to keep the regulation as is. Cathy Hanna seconded, and the motion passed with Katie Busroe voting no.

RX Adaptation Larry Hadley gave an overview of the history of this proposed regulation change. The committee reviewed the proposed wording drafted by the Advisory Counsel. Chris Palutis moved to remove

(1)(d). Cathy Hanna seconded, and the motion passed unanimously. Jennifer Grove moved to include 'for maintenance drugs pursuant to KRS 15.202' in (1)(c). Cathy Hanna seconded, and the motion passed unanimously. Jennifer Grove moved to change the wording of (1)(b) to read 'The change in quantity is related to therapeutic interchange.' Chris Palutis seconded. The motion died for lack of a vote. After further discussion, Katie Busroe moved to send this language back to the Board for clarification of their intention and to receive research from other states on the implementation of RX adaptation. Mike Burleson seconded, and the motion passed unanimously.

201 KAR 2:061 Anthony Gray advised that this regulation was up for sunset. The Board staff reviewed the regulation and presented an amended draft. Mike Burleson moved to Keep but Amend. Jennifer Grove seconded, and the motion passed unanimously. The committee reviewed the amended draft. Katie Busroe stated that 'Kentucky Pharmacy Law' in Page 1, Line 21/22 should read 'Kentucky Pharmacy Practice Act'. Board staff will rewrite the language regarding a contracted investigator to either remove entirely or include the wording 'in case of a conflict of interest.' Katie Busroe moved to remove the amended language identifying the Board member on the panel as the Board President. This wording will remain as is. This will continue throughout the regulation. Cathy Hanna seconded, and the motion passed unanimously.

The committee discussed removing the investigating inspector from the Case Review Panel. This would leave only two voting members, the Executive Director and the assigned Board member. After discussion, Anthony Gray will research Attorney General Opinions on resolving the issue of a tie vote and the issue of establishing a quorum for case recommendation votes if multiple Board members are included on the panel.

The next meeting will be determined by a poll of the members. On motion by Katie Busroe, seconded by Cathy Hanna and passed unanimously, Chairperson Ralph Bouvette adjourned the meeting at 4:51 p.m.