

KENTUCKY BOARD OF PHARMACY

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Agenda for Regulation Committee

August 25, 2021

9:00 a.m.

- I. Call to Order
- II. Minutes – June 21, 2021
- III. Old Business:
 - A. **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.”
 - B. **201 KAR 2:030, License Transfer**
 - Draft of amended regulation
 - C. **Repository Regulation**
“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.”
 - Draft of proposed regulation
 - D. **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.”
 - Draft of proposed regulation
 - E. **201 KAR 2:230, Central Fill**
“Jonathan Van Lahr moved to direct the Regulation Committee to evaluate 201 KAR 2:230 for a broader scope of practice allowing for modern business models. Chris Harlow seconded, and the motion passed unanimously.”
- IV. Next meeting date
- V. Adjournment

**KENTUCKY BOARD OF PHARMACY
REGULATION COMMITTEE**

via teleconference

August 25, 2021

9:00 a.m.

MINUTES

Chairperson Ralph Bouvette called the meeting to order at 9:01 a.m. Members present via teleconference: Ralph Bouvette, Cathy Hanna, Joel Thornbury, Chris Killmeier, Kimberly Croley Jennifer Grove, Chris Palutis and Mike Burlison. Absent: Elisha Bischoff. Staff: Larry Hadley, Executive Director; Eden Davis, General Counsel and Darla Sayre, Executive Staff Advisor.

Chris Killmeier moved to accept the minutes of the June 21, 2021 meeting. Cathy Hanna seconded, and the motion passed unanimously.

201 KAR 2:074, Pharmacy services in hospitals and other healthcare facilities. The committee resumed discussion on amending this regulation to address the issue of decentralized pharmacies. Eden Davis provided a draft of the proposed amendments. Chris Killmeier moved to approve the draft [attached] as amended and submit to the Board at the August 31, 2021 Board meeting. Cathy Hanna seconded, and the motion passed unanimously. The committee agreed that once this regulation amendment becomes effective, education will need to be provided to those pharmacies impacted. Suggestions included: a webinar posted on the Board's website and continued education from the inspection staff.

The committee tabled the discussion on correctional facility pharmacies after determining that they did not fall under this regulation.

201 KAR 2:030, License Transfer The committee reviewed a draft of the regulation as provided by Eden Davis. Cathy Hanna moved to approve the draft [attached] as amended and submit to the Board at the August 31, 2021 Board meeting. Joel Thornbury seconded, and the motion passed unanimously.

Mike Burlison left the meeting.

Repository Regulation Eden Davis provided a draft of the regulation. This draft was written from the previous draft with modifications taken from other states. After review, the committee made the following revisions. Chris Palutis moved to add 'visually' in Section 3 (1)(d). Cathy Hanna seconded, and the motion passed unanimously. Chris Palutis moved to change 'six months' to 'ninety days' in Section 3 (1)(f). Chris Killmeier seconded, and the motion passed unanimously. Cathy Hanna moved to strike the waiver language in Section 6. Kim Croley seconded, and the motion passed unanimously.

There was much discussion on the definition of 'dispenser' and the need for it to be included in the regulation. The committee requested this draft be edited to reflect the above changes and returned to the committee for further discussion at the next meeting.

Out of State pharmacy permits. Eden Davis provided a working draft of a proposed new regulation. In preparing the working draft, Ms. Davis advised Kentucky's current statute has a high degree of detail for a statute. Accordingly, this draft was written to provide clarification of the requirements stated in KRS 315.0351 based on the review of what other states are doing and earlier comments and concerns provided by the inspection team. The committee began reviewing the draft. After much discussion, Cathy Hanna moved to accept the language in Section 2 as written. Joel Thornbury seconded. The motion passed with Joel Thornbury, Cathy Hanna and Kim Croley voting aye and Chris Palutis, Chris Killmeier and Jennifer Grove voting nay. Chairperson Bouvette broke the tie voting in favor of the motion. The committee discussed Section 3, Exemptions and Section 4, Waivers. This item was tabled until the next meeting.

On motion by Joel Thornbury, seconded by Chris Killmeier and passed unanimously, Chairperson Ralph Bouvette adjourned the meeting at 11:50 a.m.