

KENTUCKY BOARD OF PHARMACY

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Agenda for Regulation Committee

June 21, 2021

9:00 a.m.

- I. Call to Order
- II. Minutes – March 19, 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. **KitCheck/RFID**
‘Jill Rhodes moved to send this item to the Regulation Committee for evaluation and amendment of technology terminology. Craig Martin seconded, and the motion passed unanimously.’ Excerpt from November 5, 2020 minutes – “Ralph Bouvette requested clarification on the issue of RFID tagging sent to the committee. Current regulation allows for barcode scanning. Mr. Poole stated the Board’s intent was to modernize language in regulations to include advanced technology. Craig Martin suggested the language include future advances in technology.”
 - Language from Jennifer Symon
 - 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.”
 - 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.”
 - F. **201 KAR 2:030, License Transfer**
- IV. Next meeting date
- V. Adjournment

**KENTUCKY BOARD OF PHARMACY
REGULATION COMMITTEE**

via teleconference

June 21, 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, Elisha Bischoff; Cathy Hanna, Joel Thornbury, Chris Killmeier, Kimberly Croley and Mike Burleson. Absent: Jennifer Grove and Chris Palutis. Staff: Larry Hadley, Executive Director; Eden Davis, General Counsel and Darla Sayre, Executive Staff Advisor.

Mike Burleson moved to accept the minutes of the March 19, 2021 meeting. Joel Thornbury seconded, and the motion passed unanimously.

201 KAR 2:074, Decentralized Pharmacies. Chairperson Bouvette gave a brief overview of previous discussions for the two new members. The committee resumed discussion on offsite locations utilizing an automated dispensing system under the main pharmacy permit. Questions raised during the discussion included:

- Who owns the product at the offsite location?
- How is this transfer to the offsite location documented?
- Who is responsible for the security of the product?
- In case of theft/loss, who does the DEA hold accountable for the product?

KitCheck/RFID The committee reviewed the following proposed language to amend 201 KAR 2:074, "Machine readable identifier that meets established industry standards to ensure quality, performance and safety." The language was proposed by Jennifer Symon at the request of the committee during discussion on the issue in a previous meeting. Kim Croley proposed adding a definition to the regulation for 'machine readable identifier [MRI]. Mike Burleson moved to direct Eden Davis to draft an amended regulation for presentation to the Board replacing references to 'barcode' with "machine readable identifier that meets established industry standards as approved by the Kentucky Board of Pharmacy to ensure quality, performance and safety." Joel Thornbury seconded, and the motion passed unanimously.

201 KAR 2:030, License Transfer Chairperson Bouvette advised the committee that this regulation is due to sunset this year. The options for the committee are to recommend keep as is, revise or allow to expire. Eden Davis informed the committee that the recommendation must be filed to LRC by October 1st. Due to a need to update the articles incorporated by reference, Joel Thornbury moved to revise this regulation and direct Eden Davis to prepare an amended draft for the next meeting. Cathy Hanna seconded, and the motion passed unanimously.

Repository Regulation Larry Hadley advised the committee that the draft for their review was provided by Faith Pharmacy. He suggested amending this draft to remove the exchange of money and limit donations to only those from permitted facilities to ensure the quality of the medications. Mike Burleson agreed with removing individual donations but suggested inserting donations of refrigerated stock. Kim Croley stated that

many sections of the draft could be removed by limited donations to only permitted facilities. Mike Burleson moved to direct Eden Davis to amend the proposed draft with the following:

- eliminate fee language,
- eliminate donations from individuals,
- remove 'charitable' to allow participation from all pharmacies; and
- review for compliance with current statutes.

Elisha Bischoff seconded, and the motion passed unanimously.

KRS 315.0351, Non-resident pharmacies Chairperson Bouvette proposed tabling this item until the next meeting to allow new members the opportunity to review. A proposed regulation will be drafted by Board staff for review at the next meeting.

201 KAR 2:230, Central Fill The Board has directed the committee to evaluate the regulation for a broader scope of practice allowing for modern business models. Eden Davis gave an overview of current business models practiced in other states that are not allowed by the regulation. Chairperson Bouvette proposed tabling this item to allow committee members an opportunity to review the materials submitted just prior to the meeting. Joel Thornbury moved to table this item until the next meeting. Cathy Hanna seconded, and the motion passed unanimously.

On motion by Chris Killmeier, seconded by Mike Burleson and passed unanimously, Chairperson Ralph Bouvette adjourned the meeting at 11:25 p.m.