

KENTUCKY BOARD OF PHARMACY

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Meeting ID: 840 1251 9982	Passcode: 8itayA
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Agenda for Regulation Committee October 23, 2020 9:00 a.m.

- I. Call to Order
- II. Minutes – August 13, 2020
- III. Discussion:
 - A. **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.”
 - B. **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.*”
 - C. **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.*”
 - D. **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.*’
- IV. Next meeting date
- V. Adjournment

**KENTUCKY BOARD OF PHARMACY
REGULATION COMMITTEE**

via teleconference

October 23, 2020

9:00 a.m.

MINUTES

Chairperson Ralph Bouvette called the meeting to order at 9:03 a.m. Members present via teleconference: Larry Hadley, Ralph Bouvette, Katie Busroe, Chris Palutis, Cathy Hanna, Jennifer Grove, Elisha Bischoff, Joel Thornbury and Mike Bureson. Staff: Eden Davis, General Counsel; Paul Daniels, Pharmacy and Drug Inspector; Amanda Harding, Pharmacy and Drug Inspector; Jessica Williams, Pharmacy and Drug Inspector and Darla Sayre, Executive Staff Advisor.

Joel Thornbury moved to accept the minutes of the August 13, 2020 meeting. Cathy Hanna seconded, and the motion passed unanimously.

RFID Tagging Under direction from the Board, the Regulation Committee discussed RFID tagging technology for evaluation and amendment of technology terminology in appropriate regulations. Jennifer Symon, KitCheck appeared to address any questions. Christina Hatfield from Baptist Health Louisville Pharmacy was available to provide insight into the process they are currently utilizing. Concerns from the committee were the durability of the tag itself and the lack of a final check by a licensed pharmacist. Chris Palutis moved to have a more specific request of how the Board would like the regulation to be amended and review information from other states on their language and implementation. Joel Thornbury seconded, and the motion passed unanimously.

201 KAR 2:270, Expungement Under direction from the Board, the Regulation Committee reviewed comments received on 201 KAR 2:270. The comments under consideration are:

Section 2. ~~Minor Violations and~~ Expungement Procedure. (1) The following violations are to be considered ~~minor in nature~~:

- (a) Any unlicensed, unregistered, or unpermitted practice occurring no more than seven (7) days after the expiration of the license, registration, or permit due to failure to timely renew a license, registration, or permit;
- (b) Failure to timely obtain required continuing education; and
- (c) Failure to comply with any provisions of 201 KAR 2:106 for pharmacy, manufacturer, or distributor closures;
- (d) Letters of reprimand;
- (e) Any Agreed Order that included no harm to a patient and the fine was less than \$2500.00; and
- (f) Any pharmacist, intern, or technician whose probation from a PRN agreement has ended with no substantial deficiencies in meeting the conditions of that agreement.

Elisha Bischoff moved to amend the regulation with the addition of (d) and (e). Jennifer Grove seconded. The motion failed with a vote of 3-4. Elisha Bischoff moved to request disciplinary action information from Board staff. Information should include the number of cases, fine amounts and the violations. Cathy Hanna

seconded, and the motion passed unanimously. Eden Davis will provide expungement language from other states for the committee to review at the next meeting. Joel Thornbury moved to remove (f) from consideration due to statutory interpretation excluding this violation from expungement. Chris Palutis seconded, and the motion passed unanimously.

KRS 315.0351, Non-resident pharmacy application questions At the request of the Board, the committee reviewed questions from the inspection staff regarding the approval of non-resident pharmacy applications. The primary concern is the accuracy of the resident state's inspection process. Additional questions include: the number of days pharmacy must be open in a week, toll-free number directed to the PIC and shipment of prescriptions on a limited/temporary basis. After discussion, Michael Burleson moved that the committee is interested in receiving information about out of state pharmacy and how it is treated for the purpose of reviewing a regulation. Cathy Hanna seconded, and the motion passed unanimously.

201 KAR 2:074, Decentralized pharmacy questions At the request of the Board, the committee reviewed questions from the inspection staff regarding satellite pharmacies. There is currently no definition of a satellite pharmacy. Katie Busroe stated that in some cases multiple specialty pharmacies located within the same institution are utilizing one pharmacy permit. Ralph Bouvette stated that it appears the definition of 'institution' is being interpreted as "an enterprise." Jennifer Grove suggested starting the discussion with a definition of 'institution'. Ralph Bouvette asked staff to review activities from other states and be prepared to provide input on what they would like to see in a regulation. Several members of the committee suggested the committee reach out to KSHP for input. Larry Hadley agreed he would reach out to KSHP leadership to see if they would like to provide input to the committee.

The next meeting will be determined by a poll of the members. On motion by Joel Thornbury, seconded by Michael Burleson and passed unanimously, Chairperson Ralph Bouvette adjourned the meeting at 11:45 a.m.