

KENTUCKY BOARD OF PHARMACY
125 Holmes Street, Ste 300
Frankfort KY 40601

Agenda for Regulation Committee

November 6, 2018
1:00 p.m.

- I. Call to Order
- II. Minutes – October 15, 2018
- III. Approval of amended regulations:
 - A. 201 KAR 2:010
 - B. 201 KAR 2:090
 - C. 201 KAR 2:095
- IV. Discussion:
 - A. 201 KAR 2:100
 - B. 201 KAR 2:115 and 201 KAR 2:116
 - C. 201 KAR 2:165
 - D. 201 KAR 2:175
 - E. 201 KAR 2:225 include 2:230, 2:240 and 2:340
 - F. 201 KAR 2:270
 - G. 201 KAR 2:310
 - H. 201 KAR 2:330
- V. Next meeting date
- VI. Adjournment

**KENTUCKY BOARD OF PHARMACY
125 HOLMES STREET
FRANKFORT, KY 40601**

REGULATION COMMITTEE

November 6, 2018

1:00 p.m.

MINUTES

Vice-Chairperson Ralph Bouvette called the meeting to order at 1:04 p.m. Members present: Ralph Bouvette, Larry Hadley, Chris Killmeier, Katie Busroe, Craig Martin and Chris Palutis. Staff: Cheryl Lalonde, General Counsel and Darla Sayre, Executive Staff Advisor. Guest: Katie Goodlett, APSC APPE student.

Chris Killmeier moved to accept the minutes of the October 15, 2018 meeting with one correction. Craig Martin seconded, and the motion passed unanimously.

On motion by Craig Martin, seconded by Chris Palutis and passed unanimously, 201 KAR 2:010 with amendments was approved for submission to the Board.

On motion by Chris Killmeier, seconded by Craig Martin and passed unanimously, 201 KAR 2:090 with amendments was approved for submission to the Board.

On motion by Chris Killmeier, seconded by Craig Martin and passed unanimously, 201 KAR 2:095 with amendments was approved for submission to the Board.

Trish Freeman joined the meeting at 1:21 p.m.

201 KAR 2:100 – Craig Martin moved to make the following changes;

Change Section 1 to read as follows:

Section 1 (1) A pharmacy shall:

(a) provide adequate security and control of its controlled substances and prescription legend drugs, and

(b) be closed in the absence of a pharmacist.

(2) If a pharmacy is located within a larger establishment which is open to the public for business at times when a pharmacist is not present then the pharmacy shall be fully enclosed by partitions which may be either solid, solid transparent, or chain linked secured by a lock from other departments of the store. In the absence of a pharmacist such pharmacies shall be locked and secured. No person shall be authorized to enter the closed pharmacy during those hours when a pharmacist is not present.

Katie Busroe seconded, and the motion passed unanimously.

Chris Killmeier moved to allow staff to change must/may to shall for the remaining regulations under review. Craig Martin seconded, and the motion passed unanimously.

Cheryl Lalonde presented a new proposed regulation regarding unprofessional conduct. This regulation may be expanded at the committee's discretion while reviewing the remaining regulations.

201 KAR 2:115 and 201 KAR 2:116 – These two regulations will be merged into 201 KAR 2:116. 201 KAR 2:115 will be repealed at that time.

Proposed changes:

Title – Substitution of drugs, biologics and biosimilar products.

Section 1. The following have been determined by the board to be interchangeable:

- (1) drugs, drug products, or dosage formulations considered by the United States Food and Drug Administration to be therapeutically equivalent as published in the "Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)".
- (2) biologics drugs, biologics drug products, or biologics dosage formulations considered by the United States Food and Drug Administration to be therapeutically equivalent as published in the "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book)".

Section 2. "Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)", 38th Edition, United States Food and Drug Administration and "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book)", United States Food and Drug Administration are incorporated by reference.

201 KAR 2:165

Proposed changes:

Section 1. (1) The transfer of prescription information for any noncontrolled substance prescription for the purpose of new or refill dispensing may occur if: ...

(3)(d) The date of original dispensing, if applicable;

(e) The refill authorization remaining and the date of the last refill, if applicable; ...

Section 3. Violation of a provision of this administrative regulation may constitute unethical or unprofessional conduct in accordance with KRS 315.121(2)(d), (f), and (g).

201 KAR 2:175 – Trish Freeman proposed tabling this regulation until resolution of proposed statute changes introduced by Senator Bentley.

201 KAR 2:225

Proposed changes:

Title – Special Limited Pharmacy Permit – Medical Gas

Change all references of medicinal gasses to medical gases.

Change all references of special pharmacy permit to special limited pharmacy permit.

Change all references of special pharmacy permit for medical gasses to special limited pharmacy permit – medical gas.

Section 1. (2) “Medical gasses” means gases (including liquefied gases) classified by FDA as drugs or devices that are used for medical applications and which may be stored and administered through the use of Medical Gas Related Equipment, which may or may not be required under Federal or State law for the immediate container to bear the label, “Rx only” or “Caution: Federal or State law prohibits dispensing without a prescription.”

Section 2. (1)(a)An applicant...shall comply with the requirements of 201 KAR 2:180, except Section 5 and 201 KAR 2:205...

(b) The pharmacist-in-charge shall review records and do an onsite visit of the special limited pharmacy permit – medical gas not less than once each quarter.

Update both initial and renewal application and change references in Section 4.

201 KAR 2:230 Trish Freeman proposed tabling this regulation until the next meeting for further discussion on central fill/central refill.

201 KAR 2:240

Proposed changes:

Title – Special Limited Pharmacy Permit – Charitable Pharmacy

Add to definitions. (4) "Special limited pharmacy permits" means a permit issued to a pharmacy that provides miscellaneous specialized pharmacy service and functions.

Direct staff to create initial and renewal applications for the Special Limited Pharmacy Permit – Charitable Pharmacy and incorporate by reference in Section 3.

Direct staff to initial a unique credential number identifying the special limited pharmacy permit – charitable pharmacy. This unique number will be used from this point forward. Those

facilities currently identified as a charitable pharmacy may continue to use their previously issued pharmacy permit.

201 KAR 2:340

Title – Special Limited Pharmacy Permit – Clinical Practice

Change all references of special pharmacy permit for clinical practice to special limited pharmacy permit – clinical practice.

Section 1. Definition. (1) "Special limited pharmacy permits" means a permit issued to a pharmacy that provides miscellaneous specialized pharmacy service and functions.

(2) "Special limited pharmacy permit – clinical practice" means...

Section 3. Pharmacy Closure. The permit holder shall provide notifications to the board fifteen (15) days prior to permanent pharmacy closure.

Update both initial and renewal application and change references in Section 4.

Ralph Bouvette moved to adopt all proposed changes. Chris Killmeier seconded and the motion passed unanimously.

Trish Freeman proposed the next meeting to be held December 6, 2018 at 1:00 p.m to 4:00 p.m. to be held at the Board Office. Chris Killmeier proposed revisiting 201 KAR 2:270 at the next meeting.

On motion by Chris Killmeier, seconded by Craig Martin and passed unanimously, Chairperson Freeman adjourned the meeting at 4:04 p.m.