

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

**Agenda for Regulation Committee**

January 28, 2019  
3:00 p.m.

- I. Call to Order
- II. Minutes – November 6, 2018
- III. Approval of amended regulations:
  - A. 201 KAR 2:100
  - B. 201 KAR 2:116
  - C. 201 KAR 2:165
  - D. 201 KAR 2:225
  - E. 201 KAR 2:240
  - F. 201 KAR 2:340
- IV. Discussion:
  - A. 201 KAR 2:170
  - B. 201 KAR 2:230
  - C. 201 KAR 2:270
  - D. 201 KAR 2:310
  - E. 201 KAR 2:330
  - F. 201 KAR 2:105
  - G. 201 KAR 2:106
- V. Next meeting date
- VI. Adjournment

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

**REGULATION COMMITTEE**

**January 28, 2019**

**3:00 pm**

**MINUTES**

Chairperson Trish Freeman called the meeting to order at 3:00 p.m. Members present: Ralph Bouvette, Chris Killmeier, Katie Busroe, Craig Martin and Chris Palutis. Staff: Darla Sayre, Executive Staff Advisor. Larry Hadley arrived at 4:00 p.m.

Chris Palutis moved to accept the minutes of the November 6, 2018 meeting. Craig Martin seconded, and the motion passed unanimously.

On motion by Chris Killmeier, seconded by Chris Palutis and passed unanimously, 201 KAR 2:100 with amendments was approved for submission to the Board. Insert 'and' at the end of Line 14, page 1.

**201 KAR 2:116**

Proposed changes in addition to previously approved changes:

Page 1, Line 7 – change to read 'This administrative regulation references drug products with active ingredients or dosage forms that are deemed interchangeable. All other products not listed as interchangeable are deemed non-interchangeable.'

Section 1, Line 15 – change to read 'Drug Products with Therapeutic Equivalence Evaluations" (Orange Book).'

Section 1, Line 19 – change to read 'Exclusivity and Biosimilarity or Interchangeability Evaluations" (Purple Book).'

Section 2. "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book)", 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.

On motion by Craig Martin, seconded by Chris Killmeier and passed unanimously, 201 KAR 2:165 with amendments was approved for submission to the Board.

On motion by Chris Palutis, seconded by Craig Martin and passed unanimously, 201 KAR 2:225 with amendments was approved for submission to the Board.

On motion by Craig Martin, seconded by Chris Killmeier and passed unanimously, 201 KAR 2:240 with amendments was approved for submission to the Board.

On motion by Chris Killmeier, seconded by Craig Martin and passed unanimously, 201 KAR 2:340 with amendments was approved for submission to the Board.

**201 KAR 2:170** – Chris Killmeier proposed a wording change to Section 1(3). After much discussion, this regulation was tabled until the next meeting.

**201 KAR 2:230** – Katie Busroe stated that there have been multiple requests to expand this regulation to include initial fills as well as refills. After much discussion, this regulation was tabled until the next meeting.

**201 KAR 2:270** – After much discussion on Section 2 (a), Katie Busroe moved to keep disciplinary action due to unlicensed practice expungable. Craig Martin seconded provided a time frame is included. The motion passed unanimously.

Proposed changes:

Section 2:

(1) (a) Any unlicensed, unregistered or unpermitted practice occurring up to seven (7) days after the expiration of the license, registration or permit due to failure to timely renew a license, registration or permit;

(c) (c) Failure to comply with any provisions of 201 KAR 2:106 for pharmacy, manufacturer, or distributor closures.

(2) A licensee, registrant or permit holder seeking expungement of a record of a disciplinary action resulting from a violation designated in subsection (1) of this section shall, in accordance with KRS 315.121(6):

(3) The board shall consider each request and shall, if the conditions of subsection (2) of this section are satisfied, expunge every record under its custody relating to the subject disciplinary order.

Chris Killmeier moved to adopt all proposed changes. Craig Martin seconded and the motion passed unanimously.

Dr. Freeman proposed the next meeting to be held February 20, 2019, 2:30 pm – 4:30 pm to be held at the Board Office.

On motion by Craig Martin, seconded by Chris Killmeier and passed unanimously, Chairperson Freeman adjourned the meeting at 5:03 p.m.