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

Agenda for Regulation Committee
August 22, 2019

I. Call to Order

II. Minutes – May 20, 2019

III. Discussion:

A. 201 KAR 2:105, Licensing and drug distribution requirements for wholesale distributors.
B. 201 KAR 2:106, Pharmacy, manufacturer, or distributor closures.
C. 201 KAR 2:320, Permit requirements for manufacturers.
D. 201 KAR 2:280, Prescription dispensing for formulary compliance.
E. Repository regulation
F. Unused Permits
G. 201 KAR 2:095, Pharmacist Interns
H. KRS 217.177 Sale and disposal of hypodermic syringes or needles.

IV. Next meeting date

v. Adjournment

KENTUCKY BOARD OF PHARMACY
125 HOLMES STREET
FRANKFORT, KY 40601

REGULATION COMMITTEE
August 22, 2019
9:00 a.m.

MINUTES

Chairperson Trish Freeman called the meeting to order at 9:06 a.m. Members present: Larry Hadley, Ralph Bouvette, Chris Palutis, Craig Martin and Chris Killmeier. Staff: Darla Sayre, Executive Staff Advisor and Anthony Gray, Board Counsel. Absent: Katie Busroe. Guests: Kelli Myers, Pharmacist Intern and Cathy Hanna.

Craig Martin moved to accept the minutes of the February 20, 2019 meeting. Larry Hadley seconded, and the motion passed unanimously.

201 KAR 2:105 – After discussion, the committee directed staff to present a draft at the next meeting addressing any concerns or defects observed by the inspection staff and language from the NABP Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers and Wholesale Distributors, Section 7, 8 and 9 [removing repackagers and adding Outsourcers]. The language from the NABP Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers and Wholesale Distributors, Section 7, 8 and 9 should also be inserted into the following regulations: 201 KAR 2:320, 201 KAR 2:390 and 201 KAR 2:400 to be presented at the next meeting for review and approval.

201 KAR 2:320 – After discussion, the committee directed staff to present a draft at the next meeting addressing any concerns or defects observed by the inspection staff and the following changes:

1. Remove 'within the Commonwealth' from Section 1, (2);
2. Insert the first sentence of the NABP Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers and Wholesale Distributors, Section 1 include both resident and non-resident facilities.

201 KAR 2:280 - Chairperson Freeman presented a draft with language to include electronic prescriptions to this regulation. After discussion, Chris Palutis moved to accept the following amendment for Board approval at the next meeting.

Section 1. Dispensing. (1) A pharmacist may dispense a therapeutic equivalent drug product under the following conditions:
(a) The ordering practitioner has indicated ~~"~~formulary compliance approval~~"~~ on the prescription, in one of the following ways:
1. By adding a notation on a written prescription indicating that formulary compliance approval is authorized ~~in the practitioner's own handwriting~~; or
2. By checking a "formulary compliance approval" box on a preprinted form; or
3. By adding a notation to an electronic prescription indicating that formulary compliance approval is authorized.

(b) The pharmacist receives a formulary change as a consequence of the patient's third-party plan; and
(c) The product designated as "preferred" by the third-party formulary is in the same therapeutic class as the prescribed drug.
(2) The pharmacist, within twenty-four (24) hours of the formulary compliance substitution, shall notify the ordering practitioner~~, in an original writing, by facsimile or electronically or by facsimile~~:
(a) That the pharmacist engaged in formulary compliance; and
(b) The therapeutic equivalent drug product that was dispensed.
Section 2. The pharmacist ~~may~~ shall make adjustments ~~in the quantity and directions~~ to provide for an equivalent dose of the preferred formulary therapeutic alternative.

Chris Killmeier seconded, and the motion passed unanimously. Chairperson Freeman suggested tabling the discussion on repository regulation until the next meeting due to time constraints.

201 KAR 2:095 – The Board at the July 31, 2019 directed the committee to review the suggestions received from LRC regarding the duties of a pharmacist intern. Larry Hadley proposed inserting the reference to KRS 315.010 (22), the definition of the practice of pharmacy. During the discussion, Chairperson Freeman left the meeting. Vice Chairperson Bouvette chaired for the remainder of the meeting. After discussion, Craig Martin proposed inserting the following language after the KRS 315.010 (22) reference:

> 'with the exception of prior to dispensing, the pharmacist must verify the accuracy and appropriateness to include DUR and final product verification of the prescription or product dispensed.'

The committee directed staff to draft this amendment for presentation and review at the next meeting.

KRS 217.177 - Larry Hadley and Anthony Gray provided a summary of discussions with the Kentucky Cabinet for Health and Family Services concerning the sale of hypodermic syringes and needles in retail pharmacies. The Board's goals are to remove unnecessary barriers for access to needles and syringes at the retail level and better align opportunities for pharmacists to partner with local health departments to participate in needle exchange programs. As part of the discussion, the Cabinet advised that its legislative agenda already has been finalized for the 2020 Regular Session of the Kentucky General Assembly.

The Committee noted the Cabinet for Health and Family Services currently has jurisdiction over the sale and disposal of syringes or needles as well as needle exchange programs pursuant to KRS 217.177 and KRS 218A.500, respectively, and, as such, the Board and, by extension, the Regulations Committee had no authority to write or revise regulations for either statute. By consensus, the Committee felt the most expedient way to implement the Board's goals was for the Board to advocate for statutory changes to KRS 218A.500 that would authorize pharmacies to participate with local health departments in needle exchange programs and, further, authorize the Board to promulgate administrate regulations for the sale of syringes or needles in a manner more consistent with the objectives of a needle exchange program, notwithstanding the current KRS 217.177.

On motion by Craig Martin, seconded by Chris Palutis and passed unanimously, Vice Chairperson Bouvette adjourned the meeting at 12:12 p.m.