

KENTUCKY BOARD OF PHARMACY
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

Notice and Agenda for Special Meeting of Regulation Committee

September 4, 2018
9:00 a.m.

- I. Call to Order
- II. Selection of Chair and Vice-Chair
- III. Discussion pertaining to regulations expiring in 2019
- IV. Next meeting date
- V. Adjournment

**KENTUCKY BOARD OF PHARMACY
STATE OFFICE BUILDING ANNEX, SUITE 300
125 HOLMES STREET
FRANKFORT, KY 40601**

**REGULATION COMMITTEE
September 4, 2018**

MINUTES

Executive Director Larry Hadley called the meeting to order at 10:02 a.m. Members present: Ralph Bouvette, Larry Hadley, Chris Killmeier, Katie Busroe, Craig Martin, Trish Freeman and Chris Palutis. Staff: Cheryl Lalonde, Board Counsel and Darla Sayre, Executive Staff Advisor.

Mr. Hadley accepted nominations for chairperson. Dr. Martin moved to nominate Trish Freeman for chairperson. Mr. Palutis seconded, and the motion passed unanimously. Dr. Freeman moved to nominate Dr. Bouvette for vice chair. Dr. Martin seconded, and the motion passed unanimously.

Ms. Lalonde gave an overview regarding the regulation scheduled to sunset in 2019. Regulations dated prior to July 2012 will need to be reviewed to determine if they should be allowed to expire, repeal, keep but amend or keep as is.

Dr. Freeman suggested the committee work through the list of regulations to provide a list of recommendations at the September 12, 2018 Board meeting.

201 KAR 2:010 – KEEP BUT AMEND – Section 3 update references to most current versions, discuss Canadian references, update address.

Dr. Bouvette recommended that in all remaining regulations references and physical address of the Board be amended without future discussion.

201 KAR 2:070 – KEEP AS IS – Ms. Busroe questioned if this regulation pertained to patient assistance programs. After much discussion, it was determined not to be the case. Dr. Bouvette stated that the Board only has jurisdiction over the pharmacist not the intermediary service. Ms. Lalonde advised that the term intermediary is not defined in our laws.

201 KAR 2:080 – EXPIRE – After much discussion, it was determined that this regulation was no longer needed. The intent of this regulation is addressed elsewhere.

201 KAR 2:090 – KEEP BUT AMEND – Remove Sections 1, 2, 4 and 5, amend Section 3 to be non-specific.

201 KAR 2:095 – KEEP BUT AMEND – Remove Sections 1 and 2, change title to better reflect the intended purpose. Dr. Freeman suggested moving the remaining section to another regulation and allowing this regulation to expire.

201 KAR 2:100 – KEEP BUT AMEND – Discuss barriers in Section 1, delete or move Sections 4 and 5.

201 KAR 2:105 – KEEP BUT AMEND – Amend to align with DSCSA.

201 KAR 2:106 – KEEP BUT AMEND – Strike Section 2[g], amend to be consistent with other regulations. Ms. Busroe advised that this regulation does not address licenses newly instituted by the Board [Third Party Logistics Provider and Outsourcer Facility Provider].

201 KAR 2:115 – EXPIRE – Allow to expire or repeal once incorporated into 201 KAR 2:116.

201 KAR 2:116 – KEEP BUT AMEND – Amend to include electronic versions of orange book and purple book, incorporate 2:115 title.

201 KAR 2:160 – KEEP AS IS

201 KAR 2:165 – KEEP BUT AMEND – Amend to include both new prescriptions and refills, discuss allowing transfers by pharmacy technicians and interns and transfers to/from Canada.

201 KAR 2:170 – KEEP AS IS

201 KAR 2:175 – KEEP BUT AMEND – Amend to include unit of use product, physician death and to allow professional judgement in determining length of emergency fill[>72 hours].

201 KAR 2:180 – KEEP AS IS

201 KAR 2:185 – KEEP AS IS

201 KAR 2:190 – KEEP AS IS

201 KAR 2:210 – KEEP AS IS

201 KAR 2:215 – KEEP AS IS

201 KAR 2:225 – KEEP BUT AMEND – Amend to incorporate 201 KAR 2:230, 201 KAR 2:240 and 201 KAR 2:340.

201 KAR 2:230 – EXPIRE – Allow to expire/repeal once incorporated into 201 KAR 2:225.

201 KAR 2:240 – EXPIRE – Allow to expire/repeal once incorporated into 201 KAR 2:225.

201 KAR 2:340 – EXPIRE – Allow to expire/repeal once incorporated into 201 KAR 2:225.

201 KAR 2:250 – KEEP AS IS

201 KAR 2:260 – KEEP AS IS

201 KAR 2:270 – KEEP BUT AMEND – Strike Section 2[1][c], amend Section 2[1][a] to read practicing after failure to renew license or technician registration and discuss addition of other minor violations.

Dr. Freeman adjourned the meeting for lunch at 12:05 p.m. Dr. Freeman called the meeting to order at 12:36 p.m.

201 KAR 2:280 – KEEP AS IS

201 KAR 2:300 – KEEP AS IS

201 KAR 2:310 – KEEP BUT AMEND – Amend title and wording to indicate veterinary use not human use.

201 KAR 2:320 – KEEP BUT AMEND – Amend to align with DSCSA.

201 KAR 2:330 – KEEP BUT AMEND – Change to ‘Keep but Amend’ if Section 2[3][a] and [b] need changing if 201 KAR2:090 is amended.

Mr. Killmeier moved to approve these recommendations and present them to the Board requesting approval and to empower the committee to move forward with these changes and if necessary make other changes based on these recommendations. Dr. Martin seconded, and the motion passed unanimously.

Mr. Hadley proposed monthly meetings to address this issue. Dr. Freeman will poll the members of their availability and will inform the committee of the next meeting date.

On motion by Mr. Palutis, seconded by Dr. Martin and passed unanimously, Chairperson Freeman adjourned the meeting at 1:36 p.m.