

**Kentucky Board of Pharmacy**  
**October 24, 2015**  
**Seelbach Hotel**  
**Louisville, KY**  
**Retreat Agenda**

- I. Breakfast (8:00 am to 8:45 am)**
  
- II. Welcome (8:45 am to 9:00 am)**
  
- III. Topics (9:00 am to finish)**
  - 1. Inspectors presentation and discussion on compounding inspections USP 797 and 795 (9 am to 11 am)**
  - 2. USP 800**
  - 3. Non-Resident Pharmacy Inspections**
  - 4. Outsourcers**
  - 5. Third party logistics**
  - 6. Specialty Drugs**
  - 7. Emergency Preparedness**
  - 8. Pharmacist Delegation of Duties**
  - 9. Professional Development**
  - 10. Pharmacist Care Services**
  - 11. Naloxone Regulation providing for an agency**

**MINUTES**  
**KENTUCKY BOARD OF PHARMACY**  
**The Seelbach Hilton Hotel**  
**500 South Fourth Street**  
**Louisville, Kentucky 40202**

**BOARD RETREAT – October 24, 2015 Began at 8:45 a.m.**

Members present: Joel Thornbury, Brian DeWire, Larry Hadley, and Cathy Hanna. Staff: Steve Hart, Executive Director; Shannon Allen, Christina Amburgey, Caleb Benningfield, Katie Busroe, and Amanda Harding, Pharmacy and Drug Inspectors; Cheryl Lalonde, Assistant Attorney General and Board Counsel; and Lisa Atha, Executive Secretary. Guests: Robert McFalls, Chris Palutis, and Chad Corum, KPhA; Anne Policastri and Michael Herald, KSHP; Trenika Mitchell, Ashlee Klevens, Philip Schwieterman, and Kimberly Hite, University of Kentucky Health Care; Michelle Deluca Fraley and Ashley Cambron, Ephraim McDowell Health; Hilary Pohn and Erik Mayes, Louisville Pharmacy; Lindsay Miller and Lindy Ashby, Kings Daughters Medical Center; John Giordullo, David Roth and Amanda Rapson McCoy, St. Elizabeth Healthcare; Leon Claywell, Medica Pharmacy; Ron Poole, Poole's Pharmacy Care; Ralph Bouvette, APSC; Mike Bursleson; Jan Gould and Shannon Stiglitz, Kentucky Retail Federation; Cathy Hance and Anne Marie Megibben, Compound Care Pharmacy; Barbara Jolly, Sullivan University College of Pharmacy; Willis Triplett, HQAA/QCCP; Chris Killmeier, Walgreens; and Taryn Howell, Walmart.

**Sterile Compounding USP 797 Compliance.** The Pharmacy and Drug Inspectors presented a summary of compliance with USP 797 found during 2015 inspections. The Pharmacy and Drug Inspectors requested clarification from the Board on certain issues not defined in USP 797. After discussion, Dr. DeWire moved to form a Task Force to work with the inspectors for clarification on the issues presented and to formulate a grading scale to present the facilities after the sterile compounding inspection. The Board of Pharmacy is to educate pharmacists of the Task Force clarifications. The Board of Pharmacy is to send out a letter to all pharmacists stating compliance with USP 797 is expected. Dr. Hanna seconded, and the motion passed unanimously.

**Non-Resident Pharmacy Inspections.** There was a brief discussion of requiring non-resident pharmacy inspections but it would require a change to KRS 315.0351.

**USP 800 Hazardous Drugs.** There was discussion regarding USP 800 and Kentucky statute KRS 217.015 requiring complete compliance with USP 800.

**Outsourcers (503B Facilities).** Outsourcers (503B facilities) are permitted as wholesale distributors in Kentucky. A statute and regulation change would be required to create a permit for outsourcer (503B facilities).

**Third Party Logistics (3PLs).** Third Party Logistics (3PL) cannot be permitted as wholesale distributors per Federal law. A statute change would be required to create a permit for Third Party Logistics (3PL).

**Specialty Drugs.** There was discussion of defining specialty drugs in the Kentucky Pharmacy Law.

**Emergency Preparedness.** Robert McFalls, KPhA, informed attendees that KPhA has a volunteer pool of pharmacists for emergencies.

**Pharmacist Delegation of Duties.** There was discussion regarding technician duties versus pharmacist professional acts. The discussion revolved around allowing technicians to transfer prescriptions and take new verbal orders from prescribers and/or prescribers' agents.

**Professional Development.** There was discussion regarding the appropriateness of 15 hours of continuing education and moving to professional development instead of continuing education.

**Pharmacist Care Services.** There was discussion regarding moving the profession of pharmacy forward from collaborative care agreements to independent practice.

**Naloxone Regulation.** There needs to be some changes to 201 KAR 2:360, Naloxone Dispensing regarding the dispensing of naloxone to agencies, which is allowed in the statute but not in the regulation.

**ADJOURNMENT:** On motion by Mr. Hadley, seconded by Dr. Hanna and passed unanimously, President Thornbury adjourned the Board Meeting and Retreat at 4:10 p.m. The next regularly scheduled Board Meeting is scheduled to begin at 9:00 a.m. on December 16, 2015 at the Board Office, Frankfort, Kentucky.

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Steve Hart, R.Ph.