

KENTUCKY BOARD OF PHARMACY
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort, KY 40601
Sterile Compounding Task Force
November 19, 2015
11 am – 1 pm EST
AGENDA

- I. Call to order
- II. Introductions
- III. Charge of Task Force
 - A. Clarify Issues
 - 1. Compound Record
 - 2. Out of Compliance Testing Timeline for Compliance
 - 3. Process for Correcting Facility Compliance
 - 4. Requirements to Compound: Education/Competency/Gap Analysis
 - 5. Supervision
 - B. Grading Scale
- IV. Discussion of Issues to Clarify
 - A. Compound Record – Information included
 - B. Out of Compliance Testing Timeline for Compliance – Information included
 - 1. Nonviable Air Sampling/ISO Classification
 - 2. Viable Air Sampling
 - 3. Surface Sampling
 - C. Process for Correcting Facility Compliance
 - D. Requirements to Compound: Education/Competency/Gap Analysis – Information included
 - E. Supervision – Information included
- V. Next Meeting – December 3, 2015, Place TBD, 11 am – 1 pm EST.
- VI. Next Meeting Agenda
 - A. Issues not discussed November 17, 2015
 - B. Grading Scale
- VII. Adjournment

MINUTES
STERILE COMPOUNDING TASK FORCE
KENTUCKY BOARD OF PHARMACY
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Chair Katie Busroe called the meeting to order at 11 a.m. Members present: Michelle Deluca Fraley, Ephraim McDowell Regional Medical Center; John Giordullo, St. Elizabeth Health System; Larry Hadley, Board Member; Amanda Harding, Pharmacy and Drug Inspector; Tiffany Herald, ARH; Barbara Jolly, Sullivan University College of Pharmacy; Tammy McDowell, NutriShare; Trenika Mitchell, University of Kentucky College of Pharmacy; Laura Riley, HDM Veterinary Pharmacy; Kent Shelton, Lexington Compounding Pharmacy; Laura Stiles, Owensboro Health Muhlenberg Hospital; Robin Walters, Pikeville Medical Center Oncology Center; and ex-officio members Robert McFalls, Executive Director, KPhA; and Anne Policastri, Executive Vice President, KSHP. Staff present: Steve Hart, Executive Director, Shannon Allen, Christina Amburgey, and Caleb Benningfield, Pharmacy and Drug Inspectors; and Cheryl Lalonde, Board Counsel. Guests: Marla Whitaker, Eric Miller and Russ Judd, Saint Joseph Hospital; Walter Miller and Jeff Davis, Cardinal Health; Anne Gresham and Mike Gresham, Doc Lane's Veterinary Pharmacy; Ronnie Brooks, Brooks Quality Assurance Consulting; Tod Adams, Lexington Compounding Pharmacy; Matt Martin, PCCA; Daren White and Gary Harris, Pasadena Pharmacy; Wendell Short, Hospice of the Bluegrass; Josh Bowling, Baptist Health Corbin; Alex Bessler, Medicare Pharmacy; Robert Mayne, LifePoint Health; Elizabeth Lovell, Bourbon Community Hospital; and Joseph Tucker, Gabrielle Spencer and Blake McLeod, College of Pharmacy interns.

Katie Busroe gave background on the reason and charge of the Sterile Compounding Task Force. The Task Force meetings are scheduled for December 3, 2015, December 17, 2015, January 7, 2016, and January 21, 2016 from 11 a.m. to 1 p.m. at 125 Holmes Street, Frankfort, Kentucky.

The Task Force began discussion on issues from USP 797 of which the Pharmacy and Drug Inspectors were requesting clarification. Amanda Harding moved to adopt the compound record outlined in the proposed revision of USP 797 as a required minimum for a compound record. Laura Riley seconded. During discussion, Cheryl Lalonde, Board Counsel, explained the motion would not be enforceable by the Board of Pharmacy because it is not a regulation or statute. This would only be a best practice document. Amanda Harding amended the motion to move the Board of Pharmacy issue a policy statement outlining best practice for information to include on a compound record and inform pharmacists this is the compound record requirements published

in the proposed revision of USP 797. Laura Riley seconded, and the motion passed unanimously.

There was further discussion centering on compliance with USP 797 requirements for non-viable air sampling, pressure differentials, air changes per hour, viable air sampling, surface sampling and facility non-compliance. Non-compliance of these items results in the facility being regarded as having a segregated compounding area with only low risk, non-hazardous sterile preparations with a 12 hour beyond use date allowed to be compounded. The 2015 sterile compounding inspections were educational but full compliance with USP 797 is expected and any non-compliance found during the 2016 sterile compounding inspections may result in disciplinary action.

Supervision was mentioned with further discussion at the next meeting. KRS 315.020(1) requires compounding to be performed under immediate supervision as defined by KRS 315.010(11), meaning the physical and visual supervision of a pharmacist.

Additional issues to be discussed at the next meeting include the appointment by each facility of a responsible pharmacist for sterile compounding, continuing education, gap analysis and the grading scale.

On motion by Amanda Harding, seconded by Robin Walters and passed unanimously, the Sterile Compounding Task Force meeting was adjourned at 1 p.m.

The next scheduled Sterile Compounding Task Force meeting is scheduled to begin at 11 a.m. at the conference room on the first floor of State Office Building Annex, 125 Holmes Street, Frankfort, Kentucky, 40601.

Submitted by Katie Busroe, RPh, Chair of Sterile Compounding Task Force