

KENTUCKY BOARD OF PHARMACY  
State Office Building Annex, First Floor Conference Room  
125 Holmes Street  
Frankfort, KY 40601  
STERILE COMPOUNDING TASK FORCE  
December 3, 2015  
11 a.m. – 1 p.m.  
AGENDA

I. Call to order

II. Introductions

III. Minutes – November 19, 2015

IV. Discussion of supervision - information included

IV. Discussion for proposed regulatory changes

- A. Appointment of responsible pharmacist for sterile compounding
- B. Required gap analysis - information from other states included
- C. Required continuing education - information from other states included

V. Discussion of grading scale – sterile compounding inspections summary sheet included

VI. Suggestions for any other items to discuss at future meetings

VII. Next Meeting – December 17, 2015, Board Office Conference Room, 11 am – 1 pm EST

VIII. Adjournment

**MINUTES**  
**STERILE COMPOUNDING TASK FORCE**  
**KENTUCKY BOARD OF PHARMACY**  
**State Office Building Annex**  
**125 Holmes Street**  
**Frankfort, KY 40601**

**December 3, 2015**

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: Shannon Allen, Christina Amburgey, and Caleb Benningfield, Pharmacy and Drug Inspectors; and Cheryl Lalonde, Board Counsel. Guests: Cindy Cummings, Baptist Health Louisville; Ronnie Brooks, Brooks Quality Assurance Consulting; Mike Herald, KSHP/ARH; Kevin Poe and Marla Whitaker, Saint Joseph Hospital; Wendell Short and Debra Kelley, Hospice of the Bluegrass; Michael Wyant and Walter Miller, Cardinal Health; Jason Guy, Unified Healthcare; Jeff Davis, Cumberland Isotopes; Daren White and Gary Harris, Pasadena Pharmacy; Josh Bowling, Baptist Health Corbin; and Gabrielle Spencer, College of Pharmacy intern.

On motion by Amanda Harding, seconded by Michelle Deluca Fraley and passed unanimously, the Minutes of the Sterile Compounding Task Force meeting of November 19, 2015, were approved.

The Task Force began discussion on supervision and the meaning of “immediate supervision” being under the physical and visual supervision of a pharmacist. The ability of the pharmacist to immediately supervise technician compounding may be difficult in certain situations. Facility changes such as adding windows to the compounding area and camera systems as an alternative were discussed. There was discussion of changing the statute regarding supervision of compounding. More information from other states’ definitions of supervision will be brought to the December 17, 2015 Sterile Compounding Task Force meeting.

201 KAR 2:076, Section 3, states the pharmacist-in-charge (PIC) shall be knowledgeable in the specialized functions of preparing and dispensing compounded, sterile pharmaceuticals. The

PIC may be assisted by additional personnel adequately trained in this area of practice. Because this is in the current regulation, it was determined an additional appointment of a responsible pharmacist for sterile compounding was not needed. Further discussion centered on not requiring continuing education or a gap analysis but using these tools as part of disciplinary action for violations. KSHP and KPhA will publicize various available tools including continuing education and gap analysis. Barbara Jolly moved to have Board staff update 201 KAR 2:076 to be reflective of current language and practice for sterile and nonsterile compounding and present the revised regulation at the December 17, 2015 Sterile Compounding Task Force meeting for review. Michelle Deluca Fraley seconded, and the motion passed unanimously.

A Summary of Sterile Compounding Inspection form was presented to the Task Force to be considered in place of a grading scale. There was concern a grading scale would take the focus away from the noncompliant issues and that the grading scale would not provide beneficial information to pharmacists. The Summary of Sterile Compounding Inspection form was amended so that the headings are Compliant/Partially Compliant/Noncompliant/NA. Robin Walters moved to present the Kentucky Board of Pharmacy with the revised Summary of Sterile Compounding Inspection form instead of a grading scale. Trenika Mitchell seconded, and the motion passed unanimously.

Barbara Jolly had an intern who suggested a universal auxiliary label with information regarding a 12 hour beyond use date (BUD) be developed that pharmacists would have the option of using should the BUD need to change due to facility issues or the preparation being compounded in a segregated compounding area. This auxiliary label would draw attention to the new, non-standard BUD. It would be voluntary for facilities to use the label but would be available. Dr. Jolly is to bring a prototype to the December 17, 2015 Sterile Compounding Task Force meeting.

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. on December 17, 2015 in 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