Meeting Notice
Missouri Board of Pharmacy
Sterile Compounding Sub-Committee
Conference Call
February 23, 2018 3:00 p.m.

Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

Notice is hereby given that designated members of the Board will be meeting to review proposed changes to the sterile compounding rule via conference call on February 23, 2018. The full Board will not be meeting. However, public notice of the meeting is being provided as detailed herein to ensure compliance with Chapter 610, RSMo.

If any member of the public wishes to attend the meeting, s/he should be present at the Division of Professional Registration, Executive Conference Room, 3605 Missouri Boulevard, Jefferson City, Missouri, at approximately 3:00 p.m. on February 23, 2018.

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the Missouri Board of Pharmacy, P O Box 625, 3605 Missouri Blvd., Jefferson City, Missouri 65102, or by calling (573) 751-0091 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966. Please see the attached tentative agenda for this meeting.
1. Review of 20 CSR 2220-2.200(20)/Discussion of Required Remedial Actions When a Highly Pathogenic Microorganism is Detected

2. Future Meeting Topics
   a. Sterile Compounding Questionnaire
   b. Sterile Compounding Survey

3. Future Meeting Dates/Times

4. Adjourn
(20) Remedial Investigations: A remedial investigation shall be required if: 1) any sampling or testing required by this rule demonstrates a colony forming unit (CFU) count that exceeds USP Chapter 797 recommended action levels for the type of sampling/testing and/or 2) if a highly pathogenic microorganism is detected in any preparation or ISO classified area (e.g., Gram-negative rods, coagulase positive staphylococcus, molds, fungus, or yeasts).

(A) CSPs and any ingredients used within the compounding process that are part of the remedial investigation shall be quarantined until the results of the investigation are known. All affected areas shall be resampled to ensure a suitable state of microbial control as part of the remedial investigation. If a highly pathogenic microorganism is detected, or if the CFU count exceeds USP 797 action levels in any ISO-5 or ISO-7 classified area, no further compounding shall be performed until resampling shows a suitable state of microbial control. The pharmacy shall ensure that no misbranded, contaminated, or adulterated CSP is administered or dispensed for patient use.

(B) For ISO-5 classified areas: If a highly pathogenic microorganism is detected, or if the CFU count exceeds USP 797 action levels in any ISO-5 classified area, no further sterile compounding shall be performed in that specific ISO-5 classified area until resampling shows a suitable state of microbial control.

(C) For ISO-7 classified areas: If a highly pathogenic microorganism is detected, or if the CFU count exceeds USP 797 action levels sterile compounding may continue while the pharmacy conducts the remedial investigation and resampling. However, if the resampling fails to show a suitable state of microbial control, the pharmacy must cease sterile compounding activity until further resampling shows such state has been achieved.

(D) For ISO-8 classified areas: If a highly pathogenic microorganism is detected sterile compounding may continue while the pharmacy conducts the remedial investigation and resampling.

(E) The pharmacy shall notify the board in writing within seven (7) days if any preparation or environmental monitoring/testing detects a highly pathogenic microorganism, regardless of CFU count.
Kim and Christian,

Thank you for considering emergency rule revisions to 20 CSR 2220-2.200 Sterile Compounding. We appreciate the opportunity to provide feedback and comments. Delays and interruptions in the provision of timely and life sustaining compounded sterile preparation (CSPs) to patients in Missouri are happening right now because of this rule. More than once a pharmacy we know or are affiliated with has ceased compounding due to a viable sample above action limit. In many cases the above action results have been in ISO-7 ante rooms.

Our strong desire to see this rule amended stems from our personal experiences of delays to patient access to life sustaining chemotherapy treatment. Communicating this delay to patients fighting for their lives is a reality that we have faced. We are committed to doing everything we can to ensure that chemotherapy patients are not faced with this same situation again.

We don’t suggest allowing continued compounding in exchange for unacceptable patient risk. A properly functioning primary engineering control will maintain an ISO-5 environment that allows the patient access to safe medications while remediation occurs. We believe that the changes we have proposed are in line with the current rule which allows Risk Level 1 compounding in a segregated compounding area that does not require surface or air sampling to be performed.

In response to the Board’s suggestion to provide guidance for review at the April meeting, we propose the following language for consideration:

“If a highly pathogenic microorganism is detected, or if the CFU count exceeds USP 797 action levels on a surface sample performed in any ISO-5 or ISO-7 classified area, the sampled area and all equipment and supplies within the area must be cleaned 3 times with a disinfectant that demonstrates activity against the identified CFUs. Cleaning must be documented and the area must be subsequently re-sampled to show a suitable state of microbial control. Until a suitable state of microbial control is achieved, the beyond use date for all compounded sterile products shall not exceed the beyond use date for Risk Level 1 products.

If a highly pathogenic microorganism is detected, or if the CFU count exceeds USP 797 action levels on an active air sample performed in any ISO-5 classified area, no further compounding shall be performed in that area until resampling shows a suitable state of microbial control.

If a highly pathogenic microorganism is detected, or if the CFU count exceeds USP 797 actions levels on an active air sample performed in any ISO-7 classified area, the sampled area must be evaluated for engineering control deficiencies including but not limited to: unfiltered air leaks, inadequate pressure differentials, and changes in HVAC air supply to the ISO-7 area. Identified issues must be corrected and the area must be subsequently re-sampled to show a suitable state of
microbial control. Until a suitable state of microbial control is achieved, the beyond use date for all compounded sterile products shall not exceed the beyond use date for Risk Level 1 products.”

Thank you for considering this language and diligently working to improve the safety of the Missouri public.

Alison Smith, PharmD  
BCPS  
Pharmacy Operations Manager  
The University of Kansas Cancer Center  
asmith17@kumc.edu  
nathan.hanson@tmcmed.org  
(913) 574-2309

NATHAN HANSON, PHARMD, MS,  
Director of Pharmacy  
Truman Medical Centers  
(816) 404-9319