COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor
Henrico, Virginia 23233

(804) 367-4456 (Tel)
(804) 527-4472(Fax)

Amended Tentative Agenda of Meeting

February 1, 2013

9:00AM- 5PM

TOPIC	PAGE(S)
Call to Order: Ellen Shinaberry, Chairman	
• Welcome & Introductions	
• Reading of Emergency Evacuation Script	
• Approval of Agenda	
• Review requests for information sent to nonregistered pharmacies	1-4
• Review confidential information submitted in response to requests	confidential handouts
• Adjournment	

The Board will have a working lunch at approximately 12pm.

COMMONWEALTH of VIRGINIA

Dianne L. Reynolds-Cane, M.D.
Director

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TEL (804) 367- 4400
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November 26, 2012

Dear Pharmacist-in-Charge:

[name of pharmacy] currently maintains registration number [registration number] with the Virginia Board of Pharmacy as a nonresident pharmacy and pursuant to §54.1-3434.1 must comply with the Va. Drug Control Act, §§54.1-3400 *et seq.* Specifically, Va. Code §54.1-3410.2(E) requires compliance with USP-NF standards for both sterile and non-sterile compounding. To assist the Board in determining if the pharmacy is currently shipping compounded sterile products (CSP) into Virginia compliant with USP-NF standards in accordance with Va. Code §54.1-3434.1, please reply to the following questions and provide the applicable documentation no later than **December 28, 2012**. Failure to provide a complete response may constitute grounds for possible disciplinary action against this nonresident pharmacy registration.

Check all that apply:

1. ☐ The pharmacy does not compound sterile products.
2. ☐ The pharmacy maintains a continuous quality improvement program pursuant to § 54.1-3434.1.
3. The pharmacy compounds ☐ low, ☐ medium, or ☐ high-risk CSP?
4. ☐ The pharmacy distributed CSP into Virginia during the calendar year of 2012.
   If checked, approximately how many CSP units were distributed into Virginia during 2012?
   _____
5. The pharmacy distributed CSP into Virginia:
   ☐ pursuant to patient-specific prescriptions
   ☐ not pursuant to patient-specific prescriptions, but intended for office administration by a prescriber
6. ☐ The pharmacy intends to distribute CSP into Virginia in the future.

If items 3 or 5 are checked, reply to all of the following questions and submit copies of documentation demonstrating compliance with items 1 through 6 (*) for the past 2 years:

1. (*) Are Compounded Sterile Products (CSP) compounded entirely under ISO Class 5 conditions?
2. (*) Are low, medium, or high-risk CSP prepared in an ISO Class 5 hood in an ISO Class 7 buffer area with ISO Class 7 or 8 ante area?
3. (*) Are hazardous CSP prepared in an ISO Class 5 in ISO Class 7 buffer area that is physically separated with ISO Class 7 or better ante area? If not, please explain.
4. (*)In the absence of passing a sterility test, what storage periods are assigned to products compounded for low, medium, and high risk levels.

5. (*) For all individuals preparing CSP, is documentation maintained of initial and annual (at least every 12 months) media-fill tests for low and medium risk compounding and semiannual (every 6 months) media-fill tests for high-risk level compounding.
6. (*)Is documentation maintained of a passing media-fill test for any individual preparing a CSP after a failed media-fill test?
7. Does a demarcation line or barrier identify separation of the buffer area from the anteroom area?
8. Is documentation available that controlled temperature areas within the pharmacy are monitored at least daily and recorded on a temperature log: Refrigerators 2° to 8°; Freezers -20° to -10°; Incubators 30° to 35°?
9. Is documentation maintained for the life of equipment indicating that written procedures are followed regarding required equipment calibration; annual maintenance and routine maintenance; monitoring of proper function; and controlled procedures for use of equipment?
10. Is a record maintained of daily accuracy assessment of automated compounding devices?
11. Is documentation maintained of a formal Quality Assurance Program that provides a mechanism for monitoring, evaluating, correcting, and improving activities and processes?
12. Are specific handling and exposure instructions included on the exteriors of containers packed with CSPs?
13. Do labels and accessory labeling include clearly readable beyond-use dates and storage instructions?
14. Is documentation maintained of a formal training program for home care responsibilities expected of the patient or caregiver, to include storage, handling and administration?

Questions regarding this letter may be directed to Sammy Johnson, Deputy Executive Director, at (804) 367-4456 or by email to pharmbd@dhp.virginia.gov .

Sincerely,

Caroline D. Juran, Executive Director
Virginia Board of Pharmacy

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November 26, 2012

Dear Virginia-licensed pharmacist in charge:

As the designated pharmacist in charge for [name of pharmacy] which currently maintains registration number [registration number] with the Virginia Board of Pharmacy as a nonresident pharmacy and pursuant to §54.1-3434.1, you are responsible for the pharmacy's compliance with the Va. Drug Control Act, §§54.1-3400 *et seq*. Specifically, Va. Code §54.1-3410.2(E) requires compliance with USP-NF standards for both sterile and non-sterile compounding. To assist the Board in determining if the pharmacy is currently shipping compounded sterile products (CSP) into Virginia compliant with USP-NF standards in accordance with Va. Code §54.1-3434.1, please reply to the following questions and provide the applicable documentation no later than **December 28, 2012**. Failure to provide a complete response may constitute grounds for possible disciplinary action against this nonresident pharmacy registration.

Check all that apply:

1. ☐ The pharmacy does not compound sterile products.
2. ☐ The pharmacy maintains a continuous quality improvement program pursuant to § 54.1-3434.1.
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4. (*)In the absence of passing a sterility test, what storage periods are assigned to products compounded for low, medium, and high risk levels.
5. (*) For all individuals preparing CSP, is documentation maintained of initial and annual (at least every 12 months) media-fill tests for low and medium risk compounding and semiannual (every 6 months) media-fill tests for high-risk level compounding.
6. (*)Is documentation maintained of a passing media-fill test for any individual preparing a CSP after a failed media-fill test?
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9. Is documentation maintained for the life of equipment indicating that written procedures are followed regarding required equipment calibration; annual maintenance and routine maintenance; monitoring of proper function; and controlled procedures for use of equipment?
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12. Are specific handling and exposure instructions included on the exteriors of containers packed with CSPs?
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Sincerely,

Caroline D. Juran, Executive Director
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