

FINAL/APPROVED

**VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE ON COMPOUNDING**

Monday, May 13, 2013
Commonwealth Conference Center
Second Floor
Board Room 3

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: A meeting of an Ad Hoc Committee on Compounding of the Board of Pharmacy was called to order at 1:15P.M.

PRESIDING: Jody H. Allen, Committee Chairman

MEMBERS PRESENT: David C. Kozera – Board Chairman
R. Crady Adams- Board Member
Empsy Munden- Board Member
Ellen Shinaberry – Board Member
Chris Currin representing VPhA
James Dice representing VSHP
Dr. Alan Wagner representing MSV
Dr. Jeff Newman representing VVMA

MEMBERS PARTICIPATING VIA TELEPHONE: Eric Kastango, Principal-CEO, Clinical IQ, LLC

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Howard Casway, Sr. Asst. AG, Board Counsel
Elaine Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

APPROVAL OF AGENDA: With no changes made, the agenda was approved as presented.

OVERVIEW OF COMPOUNDING REQUIREMENTS: Ms. Allen stated that the committee objective was to identify common areas of confusion and non-compliance with compounding requirements and recommend consensus language to the board for its consideration when adopting guidance to address the identified areas. Ms. Juran briefly identified the law and regulation within the agenda packet which requires compounding to be performed in compliance with USP-NF standards. Mr. Kastango then provided a brief overview of USP-NF requirements for sterile compounding by reviewing with everyone the slides included in the agenda packet.

DEVELOPMENT OF CONSENSUS
LANGUAGE:

Ms. Allen led discussion for each of the 13 identified areas of confusion/non-compliance which was found on page 15 of the agenda packet. Various comments and input were provided by the committee participants for each of the subjects. Staff was tasked with drafting “frequently asked questions” on each subject for the committee to present to the full board for its consideration at the June 18, 2013 full board meeting. The FAQs are intended to clarify areas of confusion with sterile compounding requirements and improve compliance.

Dr. Wagner expressed concern that many pharmacies, following board inspection, were no longer willing to provide repackaged Avastin for office administration. Dr. Wagner indicated the Avastin is frequently administered for off-label uses to treat various retinal conditions, other drug treatments were cost-prohibitive, and that patients would go blind without access to the Avastin. Ms. Juran explained that pharmacists may only repackage Avastin pursuant to a patient-specific prescription. The act of repackaging Avastin for office use does not comport with the definition of “compounding” as it does not involve the “combining of two or more ingredients”, but rather with “manufacture” as it involves repackaging (Va Code §54.1-3401). Because federal law also prohibits pharmacies from providing repackaged Avastin for office administration and Congress is currently reviewing proposed bills to address compounding issues, Dr. Wagner was encouraged to first address this issue on a federal level.

Dr. Newman stated that veterinarians frequently rely on compounded drugs to treat animals for which a commercial drug is not available. In treating emergent conditions, he indicated it is important for the veterinarian to have the compounded drug on-hand. Ms. Juran confirmed that §54.1-3410.2 does allow a pharmacy to provide a compounded drug to a veterinarian for office administration. Dr. Newman expressed concern that he cannot directly dispense a compounded drug to the client as §54.1-3410.2 does not allow a pharmacy to compound a drug for further distribution. While a prescription may be provided to the client to have dispensed by a pharmacy, Dr. Newman stated that often the compounded drug is needed in a timelier manner. Dr. Newman was also

encouraged to address this issue federally during current Congressional discussions of proposed bills since federal legislation would likely dictate the direction of state laws.

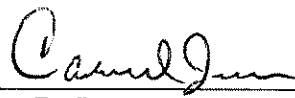
As time did not permit the review of the 17 draft FAQs on pages 16-18 of the agenda packet, staff volunteered to review the FAQs for completeness and accuracy prior to the June board meeting. No other areas of concern/non-compliance were identified or discussed during the meeting.

ADJOURN:

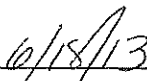
With all business concluded, the meeting adjourned at 5:05P.M.




Jody H. Allen, Committee Chairman



Caroline D. Juran
Executive Director



Date



Date