DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF COMPOUNDING WORKGROUP

August 26, 2014
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER:	The meeting was called to order at 9:02 A.M.
PRESIDING:	Jody H. Allen, PharmD, Board of Pharmacy member
MEMBERS PRESENT:	R. Crady Adams, RPh, Board of Pharmacy member Syed Salman Ali, MD, Board of Medicine member Sarah Colgan, RPh, Representing Virginia Society of Health System Pharmacists Mark Johnson, DVM, Board of Veterinary Medicine president Jamin Engel, PharmD, Participated at the request of Board of Pharmacy chairman David W. Newton, PhD, 2010-2015 USP Compounding Expert Committee member (serving in lieu of Eric Kastango) Claudia True, DVM, Representing Virginia Veterinary Medicine Association (serving in lieu of Steve Escobar, DVM) Alexander Pytlarz, PharmD, Representing Virginia Pharmacists Association Dan Berinstein, MD, Representing Virginia Society of Eye Physicians and Surgeons (serving in lieu of Gary Cook, MD and Alan Wagner, MD)
MEMBERS NOT PRESENT:	Brian Mitchell, MD, Representing Medical Society of Virginia Ellen Shinaberry, PharmD, Board of Pharmacy chairman
STAFF PRESENT:	Caroline D. Juran, RPh, Executive Director J. Samuel Johnson, Jr., RPh, Deputy Executive Director Beth O'Halloran, RPh, Individual Licensing Manager Elaine J. Yeatts, Senior Policy Analyst, DHP James Rutkowski, Assistant Attorney General David Brown, DC, Director, DHP Jaime Hoyle, Esq., Chief Deputy Director, DHP
PUBLIC COMMENT:	There were no public comments offered.
APPROVAL OF MINUTES:	Two edits were offered for the draft minutes: change "PharmD" for Sarah Colgan to "RPh" and change "sinus cavity" on page 4 to "lungs".
MOTION:	**The working group approved the minutes from the July 31, 2014 meeting, as amended.**
RESPONSE FROM COUNSEL REGARDING PHARMACISTS COMPOUNDING IN PHYSICIAN'S OFFICE:	Board counsel advised of the following: • A pharmacist must comply with laws and regulations overseeing

pharmacists, regardless of the environment in which he practices and therefore, must always compound in compliance with USP-NF standards as required in §54.1-3410.2;

- The exception in the definition of "compounding", §54.1-3401, for mixing, diluting, and reconstituting when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or A 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 does not apply to pharmacists;
- A physician may supervise a pharmacist as an employer, but the pharmacist must compound independently and not under the physician's supervision;
- A pharmacist would not be advised to perform verification of a drug that was mixed, diluted, or reconstituted as referenced in the definition of "compounding", §54.1-3401; and,
- A pharmacist performing compounding at a physician's practice location may do so pursuant to a pharmacy permit and may not perform compounding under the supervision of a physician maintaining a physician selling permit.

DISCUSS AND APPROVE DRAFT REPORT:

Several edits were offered by the workgroup on the draft report. Additionally, Dr. Berinstein shared highlights of the written comments provided as a handout which were authored by Gary R. Cook, MD, F.A.C.S. on behalf of the Virginia Society of Eye Physicians and Surgeons. After discussion, the workgroup concluded that there appears to be a legitimate need for pharmacists to provide a reasonable amount of compounded human drugs to a physician's office for administration to a patient if there is a critical need to treat an emergency condition. Therefore, it was the workgroup's opinion that the Board of Pharmacy legislative proposal addressing outsourcing facilities should restrict compounding human drugs for office use, but not prohibit the activity.

RECOMMENDATION:

There was consensus for staff to circulate electronically the amended version of the draft report and if no additional substantive changes submitted, the third meeting of the workgroup would be cancelled. Additionally, it was recommended that the workgroup provide written comment to the FDA regarding its prohibition for compounding human drugs for office use. Specifically, the workgroup will advise the FDA of the need for pharmacists to provide a reasonable amount of compounded human drugs to a physician's office for administration to a patient if there is a critical need to treat an emergency condition and that any conflict between state and federal law on this subject is concerning as it places health care providers in the difficult situation of meeting patient needs as authorized under state law versus complying with federal law.

ADJOURNMENT:

With all business concluded, the meeting adjourned at approximately 1PM.

JODY H. ALLEN, WORKGROUP CHAIRMAN	CAROLINE D. JURAN, EXECUTIVE DIRECTOR
DATE	DATE