

VIRGINIA BOARD OF MEDICINE

Mixing, Diluting, and Reconstituting (MDR) Regulations Review Meeting

Friday, May 15, 2015

Department of Health Professions

Henrico, VA

CALL TO ORDER: The meeting convened at 1:13 p.m.

MEMBERS PRESENT: Syed Ali, MD, Chair
Lori Conklin, MD
Caroline Juran, RPh
Maxine Lee, MD
David Newton, PhD

MEMBERS ABSENT: None

STAFF PRESENT: William L. Harp, MD, Executive Director
Jennifer Deschenes, JD, Deputy Director, Discipline
Colanthia Morton Opher, Operations Manager
Elaine Yeatts, DHP Senior Policy Analyst
Erin Barrett, JD, Assistant Attorney General

OTHERS PRESENT: Cal Whitehead, VA Society of Eye Physicians & Surgeons
Holly Sobczak, MSV
Joel Andrus, US Oncology
Michael Jurgensen, MSV

ROLL CALL

EMERGENCY EGRESS INSTRUCTIONS

Dr. Harp provided the emergency egress instructions.

ADOPTION OF AGENDA

Dr. Conklin moved to adopt the agenda as presented. The motion was seconded and carried unanimously.

SUMMARY OF MEETING

Dr. Harp stated that the charge of the Committee was to review the MDR regulations and recommend any changes thought necessary to bring them into compliance with USP standards.

Dr. Harp noted that the central issue is the definition of “immediate-use”. He pointed out that the Board’s regulations allow 10 hours between preparation of a compounded drug and the beginning of its administration. USP’s guideline for immediate-use is 1 hour for all compounded preparations.

Dr. Newton provided the Committee with a very informative account about the history of this issue.

The Committee discussed in detail: 1) what constitutes low-risk and medium-risk levels of compounding, 2) sterile manipulations within ISO classified areas, 3) qualifications as to what can be designated immediate-use, 4) 503 (A) anticipatory compounding, and 5) pharmacy bulk packages.

During the discussion, Dr. Ali stated that, for the purposes of our regulations, USP will not include the drugs in our office-based anesthesia regulations. Dr. Newton remarked, to the contrary, there are several drugs used by anesthesiologists that contain propofol. He also pointed out that E.coli is one of the more rapidly growing bacteria that could create a bioburden within an hour.

Dr. Newton then stated that if administration of the compounded drug begins with 1 hour, then it has met the requirement of immediate-use. However, there is no requirement or written parameter on how long compounded drugs can be stored.

Dr. Lee stated that it would not be good to set standards that cannot be practically upheld in practice, and that continuously discarding and compounding on an hourly basis is impractical and enhances the margin of error.

Ms. Juran said that Pharmacy is not trying to persuade the Board of Medicine to adopt the USP regulations, but to inform it on what is in place for compounding oversight, and that the adoption of USP is the minimum threshold. Mr. Juran stated that by not complying with USP the Board of Medicine may be put in a defensive posture.

In response to the question of why the Board of Medicine is regulating this at all, Ms. Yeatts advised that in other states, compounding is compounding and under the Boards of Pharmacy. However, in Virginia by virtue of a lobbying effort, MDR was taken out of the law and placed under the Board of Medicine. She stated that if this regulation did not exist, we would be out of compliance. However, if the law was changed to eliminate the MDR carve-out, the requirement would fall back under the Drug Control Act and the Board of Pharmacy.

The Committee identified oncology, anesthesiology and ophthalmology as specialties that would be most affected by any changes.

Dr. Everhart, an ophthalmologist in attendance, reported that she has had an opportunity to speak to colleagues in the retina community and address their drug concerns. She asked the Committee to consider delaying any decision about the regulations until the FDA has made a declaration regarding immediate-use of ophthalmologic drugs.

Dr. Conklin moved to retain the current MDR regulations until additional information or comments can be obtained from other specialties that are affected by any changes. There was no second.

Ms. Juran suggested that the language be reviewed by counsel since USP is not federal law, but it does affect our licensees and their practice.

Dr. Conklin then moved to adopt a Notice of Intended Regulatory Action for consideration of amending the regulations. The motion was seconded and carried unanimously. The Committee agreed that the Notice should identify the issues as being: 1) the definition of immediate-use, 2) the public safety issue of compounding oncology drugs in a non-sterile environment, 3) and the selection of appropriate USP chapters and language applicable to Medicine's MDR regulations.

With no other business, the meeting adjourned at 3:30 p.m.

Syed Ali, MD
Chair

William L. Harp, MD
Executive Director

Colanthia M. Opher
Recording Secretary