

VIRGINIA BOARD OF MEDICINE

Ad Hoc Committee on Review of Mixing, Diluting, or Reconstituting Regulations

Wednesday, September 30, 2015 Department of Health Professions Henrico, VA

CALL TO ORDER: The meeting convened at 10:04 a.m.

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

MEMBERS ABSENT: Maxine Lee, MD

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

OTHERS PRESENT: Gary R. Cook, MD, VSEPS
Michael Jurgensen, MSV
Gabrielle Cosel, The Pew Charitable Trusts
Aimee Perran Siebel, VAAAP
Joel Andrus, Virginia Oncology Associates
James Pickrel, VPLA
Lindsay Walton, MacBur
Stephanie Kriston, American Society for Clinical Oncology
Cal Whitehead, VA Society of Eye Physicians & Surgeons
Jody Agena, Virginia Cancer Specialists – US Oncology

ROLL CALL

EMERGENCY EGRESS INSTRUCTIONS

Dr. Harp provided the emergency egress instructions.

APPROVAL OF THE MINUTES FROM MAY 15, 2015

Dr. Conklin moved to approve the minutes as presented. The motion was seconded and carried unanimously.

ADOPTION OF AGENDA

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

PUBLIC COMMENT

After the members of the public introduced themselves, the Work Group heard comment from the following individuals:

Gabielle Cosel - representing The Pew Charitable Trusts, referenced her previously submitted letter in which the Committee was encouraged to revisit the current regulations on preparation of immediate use drugs, specifically the timeframe within which these drugs must be used. Ms. Cosel expressed her concerns that the timeframe currently allowed by the Board is significantly longer than USP Chapter <797> which, in addition, allows for microbial growth, contamination and human error.

Gary Cook, MD – on behalf of the Virginia Society of Eye Physicians and Surgeons voiced concern about the proposed compounding changes and stated that they are premature and unwarranted and asked the Committee to reject the proposal to issue a NOIRA on the subject of physician in-office use of MDR drugs, given the uncertainty of the FDA position on the subject.

SUMMARY OF MEETING

Dr. Conklin began the discussion by stating that her struggle was why would we change a regulation knowing that the changes can cause harm – based on something that “might” happen but has not been proven. Error is more likely to occur if mixing takes place emergently and she doesn’t think we should put these restrictions into place knowing that physicians will break the regulations.

Dr. Harp reviewed the regulations and stated that these have been in place for some time. He also noted that in response to his EXECNET inquiry, the oversight of compounding in physicians’ practices fell under the jurisdiction of the Boards of Pharmacy with the exception of Oklahoma.

Dr. Newton, who for the record was not there as a representative for the USP, provided some background history as to the birth of the immediate use section of USP in 2008, advising that it was more for the purpose of use than the timeframe. He went on to provide additional insight to some of the changes made since its inception. He said that there is a proposed revision to the immediate use section; public comment will be received November 1, 2015 until January 1, 2016. Dr. Newton said that the earliest any new revisions to this section of USP would become effective 2017-2018.

Dr. Ali addressed the three fields of medicine that would be impacted by any changes to the regulations, e.g. ophthalmology, oncology and anesthesiology; the Committee discussed how each would be affected. The Committee discussed the dangers of establishing a standard and then providing a carve-out for certain designations and also the challenge of how to balance safety and access.

Ms. Juran, Executive Director for the Board of Pharmacy, agreed that while it is difficult to apply the same policies to all practitioners, there are other avenues for achieving the result of having needed medication accessible like using a compounding pharmacy or adding a hood to an operating suite. Using a hood to mix drugs would extend the time until administration up to 12 hours.

Dr. Newton pointed out that the USP is about compounding, packaging, storage and transporting, NOT about the practice of medicine. He further stated that MDR should be done strictly according to the manufacturer's insert.

The Committee also discussed what the impact on patient care would be if these regulations did not exist.

After discussion, Dr. Conklin moved to allow the MDR regulations to remain as written with no revisions. The motion was seconded and after further discussion, the motion failed 2-2.

Ms. Juran moved that the Committee recommend to the Board of Medicine revisions to the regulations that establish the definition of immediate-use at 1 hour as in USP. The motion was seconded and then failed 2-2.

Dr. Ali announced that without a passing motion, the current regulations remain in place and the topic is tabled.

Ms. Juran informed the Committee that Board Counsel had opined that a pharmacist was not allowed to perform MDR, only compounding. In addition, a pharmacist should not be recognized or authorized to do a second check.

Dr. Conklin moved to recommend to the Full Board the following revision:

18VAC85-20-400. Requirements for immediate-use sterile mixing, diluting or reconstituting.

3. Establish and implement procedures for verification of the accuracy of the product that has been mixed, diluted, or reconstituted to include a second check performed by a doctor of medicine or osteopathic medicine or ~~a pharmacist~~, or by a physician assistant or a registered nurse who has been specifically trained pursuant to subdivision 2 of this subsection in immediate-use mixing, diluting or reconstituting. Mixing, diluting or reconstituting that is performed by a doctor of medicine or osteopathic medicine, ~~a pharmacist~~, or by a specifically trained physician assistant or registered nurse or mixing, diluting or reconstituting of vaccines does not require a second check;

--- DRAFT UNAPPROVED ---

The motion was seconded and carried.

With no other business, the meeting adjourned at 12:27 p.m.

Syed Ali, MD
Chair

William L. Harp, MD
Executive Director

Colanthia M. Opher
Recording Secretary