

AD HOC COMMITTEE ON COMPOUNDING
Virginia Board of Medicine

Thursday, June 9, 2005

Department of Health Professions

Richmond, VA

CALL TO ORDER: The meeting convened at 9:35 a.m.

MEMBERS PRESENT: John Armstrong, M.D., Chair
Thomas Leecost, D.P.M, Board President
James Bowles, Jr., M.D.
Hugh Bryan, III, M.D.
Lee Ann Hansen
Richard Ingram, M.D.
James May, III, M.D.
Burton Sundin, M.D.

MEMBERS ABSENT: David Newton, M.D.

STAFF PRESENT: William L. Harp, M.D., Executive Director
Scotti Russell, Executive Director, Bd of Pharmacy
Ola Powers, Deputy Executive Director, Licensure
Karen Perrine, Deputy Executive Director, Discipline
Elaine Yeatts, DHP Senior Policy Analyst

OTHERS PRESENT: Terri Beirne, McCandlish Holton
Mike Jurgensen, Medical Society of Virginia
Becky Snead, Virginia Pharmacies Association
Mark Vaughan, Virginia Pharmacies Association

INTRODUCTIONS

The committee members each introduced themselves.

ADOPTION OF THE AGENDA

Dr. Richard Ingram moved to adopt the agenda. The motion was seconded and carried.

PUBLIC COMMENT

No public comment.

NEW BUSINESS

Review of legislation and mandate for adoption of regulations by the Board of Medicine

Ms. Yeatts explained House Bill 2524 of the 2005 General Assembly. She advised that the task of the Committee is to develop and propose regulations to the Board of Medicine that establish the standards for the mixing, diluting, or reconstituting of a manufacturer's product drug for administration to a patient by an MD or DO. Ms. Yeatts explained that the enactment clause of HB2524 requires that these regulations be promulgated within 280 days of enactment. Therefore, they will be promulgated as emergency regulations and be effective for one year after adoption. During that year, the regulations will be promulgated in the normal course, with a NOIRA, a 30 and 60 day comment period, public hearing, etc.

Ms. Yeatts explained that the regulations would address standards for the following:

- mixing, diluting, or reconstituting of a manufacturer's product drug for administration to a patient by an MD or DO
- supervision of persons other than the MD or DO who would be mixing, diluting or reconstituting
- transportation of the drugs
- facilities in the which mixing, diluting, or reconstituting of a manufacturer's product drug occurs
- inspection program for the facilities

Ms. Yeatts also provided a copy of HB2857 as a handout for the Committee's information.

Overview of USP and compounding

Ms. Russell briefly explained the history and applicability of the USP (United States Pharmacopoeia), which is recognized as the official compendia of drug standards by the FDA. Chapter <797> of the USP provides procedures and requirement for compounding sterile products. Ms. Russell explained that even though the preparation of sterile products by physicians for the purpose of administration to patients has been carved out of the definition of compounding in the Virginia Drug Control Act, such preparation is still considered compounding under federal law. Therefore, physicians would be required to comply with the USP requirements, which is the standard in federal law.

Several committee members expressed concerns regarding the requirements of the USP as it would apply to physicians' offices. Ms. Russell noted that currently amendments are being proposed to the USP which should address these concerns.

Review of USP requirements for compounding

Ms. Hansen provided the Committee a memo dated June 9, 2005 containing a content review of USP Chapter <797> and related articles. Ms. Hansen reviewed this document for the Committee, beginning with the article entitled "The ASHP Discussion Guide on USP Chapter <797> - Compounding Sterile Preparations" by Eric S. Kastango, MBA, RPh, FASHP. Ms. Hansen noted that as to the responsibility of compounding

personnel, it is very important to have written policies and procedures, documentation of compounding activities, training and documentation of training. She also noted that most activity in a physician's office would be considered low risk, except drugs that are administered over a prolonged period, which would be medium risk. The section of Chapter <797> that is probably the most controversial due to the economic cost is Environmental Quality and Control.

Issues to be addressed

Dr. Armstrong reiterated that the standards must address several areas, as noted on the agenda. He asked for comments from each Committee member, and for each member to indicate what area he or she preferred to work on.

Each member then provided a brief comment as to his or her viewpoint, with several expressing concerns that the regulations not be overbroad or burdensome. All members and staff expressed a willingness to assist in anyway needed.

The Committee briefly discussed the inspection process and recognized a need for physician offices who mix, dilute or reconstitute to register with the Board.

The Committee received a handout with the proposed revisions to USP Chapter <797> and briefly discussed the proposed revisions.

Summary

Dr. Armstrong stated that the sentiment of the Committee seemed to be to use USP Chapter <797> with the proposed exemptions for physicians' offices as a template for the regulations. Ms. Yeatts stated that she would draft a proposed regulation, based on the discussion today and Dr. Armstrong's summary, for the Committee's consideration.

ANNOUNCEMENTS

The next meeting will be held sometime after the July 14, 2005 Board meeting, in the evening. Staff will coordinate a date and time with the Committee members.

ADJOURNMENT

With no other business, the meeting adjourned at 11:30 a.m.

John Armstrong, M.D.
Chair

William L. Harp, M.D.
Executive Director

Karen W. Perrine
Recording Secretary