

AD HOC COMMITTEE ON COMPOUNDING
Tuesday, July 19, 2005
Richmond, Virginia

The Ad Hoc Committee of the Board Medicine on Compounding met on July 19, 2005, at 4 p.m., at the Department of Health Professions, 6603 West Broad Street, Richmond, Virginia. The meeting was called to order by John Armstrong, MD, Chair.

MEMBERS PRESENT: John Armstrong, MD, Chair
Thomas Leecost, DPM, Board President
James Bowles, Jr., MD
Hugh Bryan, III, MD
Lea Ann Hansen, Pham.D
Richard Ingram, MD
James May, III, MD
Burton Sundin, MD
David Newton, PhD

STAFF PRESENT: William L. Harp, M.D., Executive Director
Elaine Yeatts, Senior Policy Analyst
Emily Wingfield, Assistant Attorney General
Ola Powers, Deputy Executive Director for Licensing

OTHERS PRESENT: James Pickral, VPHA
John Garrett Kemper, US Oncology
Terri Beirne, McCandlish Holton

Approval of Minutes of June 9, 2005

Dr. Hansen moved to approve the minutes with corrections. The motion was seconded and carried.

Adoption of the Agenda

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

Public Comment on Agenda Items

There was no public comment.

NEW BUSINESS

Dr. Newton, Ph.D. Chairman of the USP Committee on Sterile Compounding provided the committee with a presentation and literature pertaining to the compounding of sterile drugs and nutrients and responded to questions regarding USP standards.

1. Review of charge of the committee

Ms. Yeatts 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.

2. Review of draft regulations prepared by staff

The initial draft of regulations prepared by staff was distributed.

3. Revision of draft regulations

The committee reviewed and discussed each item of the draft regulations.

The committee asked that the word "compounding" be deleted from the draft, as it was deemed confusing.

The committee chose to define immediate use, low-risk mixing, diluting and reconstituting as that in which no more than four sterile manufactured drug products are mixed and administration begins in one hour. The completion time for administration of twelve hours was deleted.

Training required was deemed to be practices and principles of aseptic manipulations and solution compatibility.

The second checking of a product can be made by an MD, DO, Pharmacist, PA or a Licensed Nurse. This is required unless the product is prepared by an MD or DO.

The committee did not want a requirement for separate documentation for immediate use low-risk mixing, diluting, and reconstituting.

The committee did not want media fill testing required for immediate use, low-risk mixing, diluting and reconstituting.

The committee decided to use NIOSH (Appendix A) to identify hazardous drug products.

Storage and transportation were not deemed to be issues as long as the one hour limit on administration was met.

Labeling would not be required for immediate use, low-risk compounding.

The committee did not want to require the absence of adverse reactions to drugs, but rather affirmatively record any adverse reaction.

The inspection process received general discussion, with further definition of the process delegated to staff.

4. Next step in process

Dr. Harp explained that another draft with changes will be prepared and provided to all present and that the committee could meet again before the Full Board meeting in September if necessary.

Adjournment

With no further business to discuss, the meeting of the Ad Hoc Committee was adjourned.

John Armstrong, MD
Chair

William L. Harp, M.D.
Executive Director

Ola Powers
Recording Secretary