

MINUTES
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
COMPOUNDING RULES COMMITTEE

SEPTEMBER 20, 2013

The Peabody Hotel
9801 International Drive
Orlando, FL 32819
(407) 352-4000

Committee Members:

Michele Weizer, PharmD, Chair
Debra Glass, BPharm,
DeAnn Mullins, BPharm

Advisors:

Robert Hoye, CRPH., FIACP, FACA
Steve Hughes, R.Ph.
Patricia Kienle, R.Ph., MPA, FASHP
Joel Parnes, PharmD, MHA

Board Staff:

Mark Whitten, Executive Director
Tammy Collins, Program Operations Administrator

Board Counsel:

David Flynn, Assistant Attorney General

Participants in this public meeting should be aware that these proceedings are being recorded.

Dr. Michele Weizer called the meeting to order at 9:00am and welcomed the audience to the September 20, 2013 Compounding Rules Committee.

Dr. Weizer then introduced Scotti Russell of the National Association of Boards of Pharmacy (NABP).

Ms. Russell gave a brief overview of Senate Bill 959. Ms. Russell then discussed the NABP's position on the federal legislation and gave an explanation on the factors that helped form that position.

The Committee discussed the financial and training aspects involved with the investigative side of adopting USP 797.

Mark Whitten informed the committee that several inspectors have been trained and will be provided refresher training. Mr. Whitten acknowledged there will be a transition period in regards to pharmacies becoming compliant.

The Committee discussed whether or not USP 797 is a guideline or a federal standard.

The Committee discussed the importance of educating not only the inspectors but also anyone who practices compounding.

Dr. Weizer and the rest of the Committee thanked Ms. Russell for attending and participating in the meeting.

Dr. Weizer then introduced Rule 64B16-27.700, F.A.C., as the next item on the agenda and introduced office-use compounding as the topic of discussion.

The Committee and members of the audience discussed the benefits and dangers of office use compounding.

Dr. Weizer announced that the Committee was not prepared to make a recommendation to the Board at this time and that the topic would be continued for further discussion at the Full Board meeting.

Dr. Weizer then introduced USP on compounding as the next agenda item and encouraged Committee members and audience members to provide input on the aspects of USP 797 that they believe should be left out in regards to adoption of USP 797.

Committee and audience members discussed sections regarding frequency of sterility testing.

Committee and audience members then discussed sections regarding beyond use dating.

Wayne Boudreaux approached the Committee to state that (as a nuclear pharmacist) the general consensus among the nuclear pharmacists who were present is that they are in support of the Board adopting USP 797.

George Malone (Chair of the Legal and Regulatory Affairs Counsel for the Florida Society of Health System Pharmacists) approached the Committee to inform them that his membership doesn't have any issues with the adoption of USP 797.

Dr. Weizer called for any additional comments and then explained that the next step of this committee is to provide a report to the full Board on the discussion that took place during the meeting.

Motion: by Dr. Weizer, seconded by Mrs. Mullins, to adjourn meeting at 1:11pm. Motion passed.