

MEETING MINUTES  
DEPARTMENT OF HEALTH  
BOARD OF PHARMACY  
COMPOUNDING RULES COMMITTEE

DECEMBER 2, 2013

Hilton Hotel University of Florida  
1714 SW 34<sup>th</sup> Avenue  
Gainesville, FL 32607  
(352) 371-3600

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Committee Members:

Michele Weizer, PharmD, Boca Raton, Chair  
Debra Glass, BPharm, Tallahassee

Board Staff:

Tammy Collins, Acting Executive Director  
Christy Robinson, Program Operations Administrator  
Jay Cumbie, Regulatory Specialist II

Board Counsel:

David Flynn, Assistant Attorney General

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

Monday, December 2, 2013 – 1:00p.m.

Dr. Michele Weizer called the meeting to order at 1:07p.m.

Dr. Weizer welcomed the audience to the December 2, 2013 Compounding Rules Committee. Dr. Weizer acknowledged non-Committee members Dr. Mark Mikhael and Mr. Jeenu Philip and thanked them for their attendance.

Dr. Weizer introduced the changes to Rule 64B16-27.797 and requested members of the audience come forward with any comments or requested changes.

Mike Glazer approached the committee to discuss concerns and possible changes to the language regarding glove boxes and negative pressure rooms.

George Malone approached the committee to express concern regarding negative pressure rooms and also expressed concern on Chapter 71 regarding sterility testing and beyond use dating.

David Flynn spoke about the Federal Legislation "HR 3204" and how the Federal Government has the economic impact and not the Board of Pharmacy.

Mr. Flynn then went on to request the committee members make a decision regarding whether or not to bring the recommendation to adopt USP797 as our standard of practice to the full Board for a vote.

**Motion:** by Dr. Weizer, seconded by Mrs. Glass, to bring recommendation to adopt USP797 as Florida's standard of practice to the full Board. Motion carried.

Mr. Flynn presented the issue of reverse prescriptions for discussion amongst the committee and audience members.

Mrs. Glass expressed her concern with the tracking aspect of reverse prescriptions.

Dr. Mikhael expressed his concern with the liability aspect of reverse prescriptions.

The committee discussed, in regards to office-use compounding, that tracking of the prescription should be on the doctor.

Bob Parrado approached the committee to reiterate the fact that office-use compounding is intended to be used for doctors to administer not dispense.

Mike McQuone approached the committee to discuss language conflicts in Rule 64B16-27.700 regarding the definition of "dispensing" in office-use compounding.

Dr. Weizer recommended we clean up our current rule regarding "quantities" in office-use compounding.

Mark Schneider approached the committee to express his concern that doctors are "dispensing" compounded drugs that should be "administered". Mr. Schneider questioned how were these drugs that aren't patient specific nor dispensed being paid for.

Mr. Philip suggested that stipulations be added to the "written agreement" section with doctor's office that prohibit doctors from allowing patients to take prescriptions home.

Mr. Flynn responded to Mr. Philip by stating that quantity is what led to the bigger issue regarding office-compounding. Mr. Flynn then reminded the committee they have the authority to open up Rule 64B16-27.700 for further development.

Mrs. Glass suggested tightening the parameter regarding "logs" and stated that non-sterile compounded products make up the bulk of the problem.

George Malone approached the committee to speak against strengthening the log rules. Mr. Malone stated he had been the consultant pharmacist of record for a company that had 16 community health centers and that each month, none of the 16 community health centers had their logs filled out correctly.

Dr. Mikhael asked Dr. Weizer if she would consider opening up Rule 64B16-27.700 for further development.

Richard Montgomery approached the Board to state that we need to be careful in limiting quantities, as it will affect our institutional use.

**Motion:** by Dr. Weizer, seconded by Mrs. Glass, to open Rule 64B16-27.700 for development. Motion carried.

**Motion:** by Dr. Weizer, seconded by Mrs. Glass, to adjourn the meeting at 2:33p.m. Motion carried.