

MINUTES
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
COMPOUNDING RULES COMMITTEE

FEBRUARY 10, 2014

The Florida Hotel & Conference Center
1500 Sand Lake Road
Orlando, FL 32809
(407) 859-1500

Committee Members:

Michele Weizer, PharmD, Boca Raton, Chair
Debra Glass, BPharm, Tallahassee
Mark Mikhael, PharmD, Orlando

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, February 10, 2014 - 2:00p.m.

Dr. Weizer opened the meeting at 2:05 and had the committee members as well as the additional panel members introduce themselves.

All committee members were present along with Mrs. Patricia Kienle, Mr. Joel Parnes, and Mr. Robert Hoye.

David Flynn introduced the Federal legislation and gave a brief overview of 503A and 503B.

Mr. Flynn stated that if a compounder meets all conditions of 503A, they are exempt from needing a new drug application or amended drug application, adequate directions or use, or having to comply with good manufacturing practices.

Dr. Weizer introduced the proposed rule adoption of USP 797 as the next item for discussion.

Dr. Weizer started a discussion regarding using detergent as a substitute for the use of sterile water in regards to cleaning a workstation.

David Joseph approached the Board to speak about possible discrepancies between USP797 and the public perception of a good standard of practice.

Ms. Kienle expressed her concerns with the exemptions and stated the importance and necessity of using the sterile water when cleaning the workstation.

Dr. Weizer asked the committee and audience if anyone had anything they wanted to discuss from paragraph 1, to which nobody came forward.

Dr. Weizer asked the committee and audience if anyone had anything they wanted to discuss from Chapter 797.

Michael Glazer approached the committee to suggest an exemption that allows a pharmacy to use a properly vented negative pressure glove box outside instead of a negative pressure room. Mr. Glazer stated that the addition of a negative pressure room could be extremely expensive and possibly cost prohibitive.

Mr. Flynn stated legislation from 1997 already mandated a lot of these USP797 requirements but that nobody was complying. Mr. Flynn then went on to state that "low-volume" in regards to sterile compounding needs to be defined.

Ms. Kienle suggested defining low-volume as zero.

Mr. Flynn and Dr. Weizer explained the overall issue with the lack of a negative pressure room being the liability of the box falling and exposing employees to hazardous drugs.

Martin Dix approached the committee to explain how the negative pressure glove box exemption would benefit hospitals by providing more flexibility.

Mike Glazer stated the provision in 797 that requires air to enter from the ceiling should include an exception that states that as long as a business meets the standard, the state shouldn't regulate how it got to that point.

Dr. Weizer requested comments from the committee and audience regarding Chapter(s): 1160, 71, 85, 731, and 1231. There were no comments from the audience or committee members.

Dr. Weizer introduced minimum standards as the next point and stated that a practitioner will not be punished for practicing above the minimum standards.

Dr. Weizer brought up some exceptions including the reference to sterile water being struck in section 4B though stated the language in 4A regarding the donning of sterile gloves will remain.

Dr. Mikhael questioned whether 1 patient a day or 1 patient a week is considered low-volume.

Dr. Mikhael recommended low-volume compounding be defined as no more than 60 doses a month.

Dr. Weizer and Ms. Kienle expressed their concern that 60 doses a month is too high.

Motion: by Dr. Mikhael, seconded by Mrs. Glass, to define low volume compounding as no more than 40 doses per month. Motion carried.

Motion: by Dr. Mikhael, seconded by Mrs. Glass, to approve Rule 64B16-27.797 with the recent amendment regarding low-volume compounding. Motion carried.

Motion: by Dr. Mikhael, seconded by Dr. Weizer, that there is no adverse economic impact. Motion carried.

Dan Fucarino approached the committee to speak in opposition to the adoption of USP 797.

Mr. Flynn reminded the committee and audience that Florida's rule does not automatically adopt the new versions of USP797. If the Board would want to adopt a new version, the whole process would start over again.

Robert Hoyer expressed his concern over non-residents not having to comply with USP797 Standards and still having the ability to ship drugs into Florida.

The Committee came to the conclusion that the adoption date for USP797 will be October 1, 2014.

David Flynn brought up Rule 64B16-28.820 F.A.C. and requested the Board clarify the due to confusion by striking subsection 6.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to strike subsection 6 from Rule 64B16-28.820 F.A.C. Motion carried.

Dr. Weizer introduced the House Bill on non-resident pharmacies and gave a brief overview of the language. Dr. Weizer then went on to state that the language requires all non-resident pharmacies that ship sterile compounded products into Florida to acquire a Sterile Compounding Permit. Dr. Weizer also stated that the language allows our agency to inspect the non-resident pharmacies.

Motion: by Dr. Mikhael, seconded by Mrs. Glass, to adjourn the meeting at 4:55p.m. Motion carried.