

MINUTES
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
COMPOUNDING RULES COMMITTEE

August 11, 2014

DoubleTree by Hilton
100 Fairway Drive
Deerfield Beach, FL 33441
(800) 624-3606

Committee Members:

Michele Weizer, PharmD, Boca Raton, Chair
Leo "Lee" Fallon, BPharm, PhD The Villages
Debra Glass, BPharm, Tallahassee
Mark Mikhael, PharmD, Orlando

Board Staff:

Patrick Kennedy, Executive Director
Tammy Collins, Program Operations Administrator
Jay Cumbie, Regulatory Specialist II

Board Counsel:

David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

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

Monday, August 11, 2014 - 3:00p.m.

Dr. Weizer called the meeting to order at 3:00p.m.

Dr. Weizer stated the first order of business would be to discuss recommended changes to Rule 64B16-27.797. Dr. Weizer stated that Chapters 1160 and 1231 need to be stricken from the rule.

Dr. Mikhael requested a clarification regarding the ability of certain chapters to be federally regulated.

Motion: by Dr. Fallon, seconded by Mrs. Glass, to strike Chapters 1160 and 1231 from Rule 64B16-27.797. Motion carried.

David Flynn then stated that a technical change regarding the reference year is the next item to be voted on by the committee.

Motion: by Dr. Mikhael, seconded by Dr. Fallon, to accept the changing of the reference year in Rule 64B16-27.797 to 2013. Motion carried.

Motion: by Dr. Mikhael, seconded by Mrs. Glass, that there is no negative economic impact on the profession resulting from the proposed rules changes. Motion carried.

Dr. Weizer then stated that the next topic up for discussion would be House Bill 7077.

David Flynn gave an overview of the various rules that are going to be affected by the bill.

Mark Whitten (Chief of Enforcement) approached the committee to recommend using a national inspection agency for the non-resident pharmacies rather than using our in-state inspectors for cost purposes.

Dr. Mikhael spoke about the timeframes between inspections and differences between state and Federal level inspections.

David Flynn, Mark Whitten, and members of the committee discussed the details of the actual inspection process.

Mark Whitten stated that his unit would enjoy the ability to utilize a citation system to avoid having to open cases.

David Flynn then introduced Lawrence "Larry" Harris as Lynette Norr's replacement and requested Mr. Harris work on a rule that will allow Enforcement with some level of citation authority.

Dr. Weizer stated Rule 64B16-27.700 is the next topic for discussion.

David Flynn stated that JAPC believes the entire rule should be repealed. Mr. Flynn believes the committee will be facing potential objections and to be prepared to continue to working on the rule.

Michael Oney approached the Committee and stated he wrote the original draft of 64B16-27.700 in 1992. Mr. Oney went on to speak about nuclear pharmacists.

Richard Green (Cardinal Health Care) approached the committee to discuss nuclear pharmacies as well. Mr. Green stated there could be some unintended consequences with the rule as it is.

The Committee took a break from 4:20p.m. – 4:39p.m.

Dr. Weizer stated that determining whether outsourcing facilities within the geographical area of Florida need a permit would be the next order of business.

Mr. Whitten stated that his team will train on inspecting outsourcing facilities regardless of whether Board deems it necessary.

Dr. Mikhael stated his concern over adding yet another new permit and requested discussion on potentially altered the existing permit.

Mr. Whitten suggested inviting the outsourcing facility owners to the next meeting for their input on the matter.

Motion: by Dr. Mikhael, seconded by Mrs. Glass, to open rule development on a new permit for outsourcing facilities in state. Motion carried.

Michael Jackson (Florida Pharmacy Association) approached the Committee to discuss the fact that non-resident pharmacies don't require prescription department managers to be Florida registered pharmacists. Mr. Jackson stated the Board can't hold them responsible for the CE requirements.

Mark Whitten informed the Board that the Bureau of Enforcement will be holding a workshop September 17, 2014 to discuss the sterile compounding inspection forms. Mr. Whitten said the meeting will be held in Orlando, FL at a hotel to be determined.

Motion: by Dr. Fallon, seconded by Mrs. Glass, to adjourn the meeting at 5:35p.m. Motion carried.