

AGENDA  
DEPARTMENT OF HEALTH  
BOARD OF PHARMACY  
COMPOUNDING RULES COMMITTEE

AUGUST 12, 2013

Rosen Plaza Hotel  
9700 International Drive  
Orlando, FL 32819  
(407) 996-9700

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Committee Members:

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

Board Staff:

Mark Whitten, Executive Director  
Tammy Collins, Program Operations Administrator  
Jay Cumbie, Regulatory Specialist II

Board Counsel:

David Flynn, Assistant Attorney General

Monday, August 12, 2013 – 2:00p.m.

Dr. Weizer called meeting to order at 2:00p.m.

Dr. Weizer provided an update regarding a non-resident permitted pharmacy residing in Texas having recalled sterile compounded products. Dr. Weizer informed the audience this event is not the first negative occurrence since the NECC situation.

Dr. Weizer introduced Rule 64B16-27.700 as the first agenda item.

David Flynn introduced a letter from the Joint Administrative Procedures Committee written in response to the letter he crafted regarding Rule 64B16-27.700.

Ed Bayo approached the committee and stated that the version of the draft language on the agenda is not the most current language. Mr. Bayo stated his support for Mr. Flynn's letter.

Mr. Whitten requested the audience members take this opportunity to approach the committee and add comments regarding 64B16-27.700.

Fritz Hayes stated that he believes the rule being worked on is not a new rule and that Committee has only been strengthening the rule. Mr. Hayes then stated his support for the response letter to JAPC written by Mr. Flynn.

Ms. Mullins requested more discussion regarding the rule and its effect on patient care.

Mr. Bayo approached the Board to comment on batching. Mr. Bayo stated that, according to USP797, when a certain threshold is reached, sterility testing is required.

David Joseph approached the committee to argue against the perceived dangers of batching.

Dr. Weizer made the recommendation to bring up to the Board on August 13, 2013, that the committee is in support of Mr. Flynn's letter.

Dr. Weizer introduced Rule 64B16-27.797 and stated that the information will be available online after the meeting. Dr. Weizer also stated a full version of USP797 will be available for review at the Board office in Tallahassee, FL.

John Ford (Barnes Health Care) approached the Board to discuss potential issues with adoption of USP797 and stated that adoption would help protect the pharmacist but hurt the patient.

Ms. Mullins stated that the Board will have to work very closely with the inspectors to make sure the Board's actions aren't hurting the profession of pharmacy.

Mark Whitten stated that Investigative Services has reached out and specifically asked for Dr. Weizer to attend their training sessions.

Shannon Wedekind (Chair for Government Affairs Committee for FPA) stated his committee is not in support of full adoption of USP797 though he stated there are parts of it that his committee supports.

Michael Jackson (Florida Pharmacy Association) asked the Committee if the Board's plan is to have Rule 64B16-27.799 replace Rule 64B16-27.797, to which Dr. Weizer confirmed. Mr. Jackson then stated his concern of whether or not the non-resident pharmacies will have to comply with updates as resident pharmacies will.

Mr. Flynn stated that once the rule is adopted, the Board will not automatically adopt the updated versions of USP797. Mr. Flynn then stated that the Board will have the ability to choose whether or not to adopt the updated versions.

Michael Glazer approached the Committee and stated his opposition to adoption of USP797 due to the negative economic impact.

Mr. Flynn stated that failure to comply with the 2008 version of the rule should not be considered a negative economic impact.

Mr. Whitten stated committee's intention of bringing USP797 to the full Board for a vote and also commented on the lack of public feedback received at the May rules workshop that was created with the sole purpose of discussing the adoption of USP797.

Ms. Mullins stated she would like more dialogue on the matter before a vote.

Sam Prath approached the Committee to discuss his opposition to the adoption of USP797. Mr. Prath stated that no pharmacy could be compliant with USP797, meet the needs of the patients, and stay in business. Mr. Prath then stated that USP797 only makes sense for high volume manufacturing practices.

Larry Gonzalez approached the Committee to thank them for their efforts in protecting the public.

Mr. Flynn introduced the proposed non-resident legislative draft and discussed the modifications made to various sections.

Dr. Weizer stated that the proposed legislation can be taken to the full Board for discussion.

**Motion:** by Dr. Weizer, seconded by Ms. Mullins, to adjourn the meeting at 4:00p.m.