

MINUTES
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
COMPOUNDING RULES COMMITTEE

October 6, 2014

Embassy Suites South - LBV
4955 Kyngs Heath Road
Kissimmee, FL 34746
(407) 597-4000

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, October 6, 2014 – 2:00p.m.

Dr. Weizer called the meeting to order at 2:05p.m.

Dr. Weizer stated Rule 64B16-27.820 is the first item on the agenda and turned it over to David Flynn for explanation.

Mr. Flynn gave a brief overview of the proposed addition to Rule 64B16-27.820(3)(i) that states "In conformity with existing and past practices and notwithstanding 3(a) above, there is no minimum hour requirement for the pharmacist to be present and on duty at the facility and no requirement that a pharmacist be present and on duty whenever the facility is operational and open to the public through support staff and pharmacy technicians. However, a pharmacist must be present and on duty (a) whenever drugs are being prepared, compounded, or dispensed, (b) when the part of the facility in which drugs are stored, prepared, compounded or dispensed is not locked or secured or is accessible to the facility staff, or (c) when those acts in which a pharmacist must be present pursuant to applicable Florida Statutes and regulations are performed."

Dr. Mikhael elaborated on the petitioners request and stated that CMS currently sees this particular practice setting as closed even though prescriptions are still being processed.

Rich Montgomery (Florida Hospital) stated if you don't need a registered pharmacy technician, you aren't practicing pharmacy.

Dr. Weizer made the comment that if there is not a pharmacist on the premises, the pharmacy is closed.

Dr. Weizer then stated that Rule 64B16-28.100 is the next item on the agenda regarding the new nonresident sterile compounding permit application.

Mr. Flynn gave a brief overview of the formal rule language for the nonresident sterile compounding permit application and suggested changing the language regarding an applicant being contacted within 7-14 days be changed to 30 due to the provisions of Chapter 120.

Mrs. Glass questioned whether or not we will have to change our other applications formats to match this new permit.

Mr. Flynn pointed out some legal issues with page 6 of the application.

Motion: by Mrs. Glass, seconded by Dr. Fallon, to remove page 6 from the application. Motion carried.

Dr. Mikhael wanted to clearly state for the record that all nonresident pharmacies must have this permit in order to ship, mail, deliver, or dispense any compounding products into the state of Florida in any manner.

Motion: by Dr. Fallon, seconded by Dr. Mikhael, to approve the rule language as well as the updated nonresident sterile compounding permit application. Motion carried.

Motion: by Dr. Mikhael, seconded by Mrs. Glass, to open Rule 64B16-28.100 for rule development. Motion carried.

Motion: by Dr. Fallon, seconded by Dr. Mikhael, that the changes will not exceed \$200,000 based on the 2012 survey results and that a SERC is not required. Motion carried.

Dr. Weizer introduced House Bill 7077 as the next topic of discussion.

Mr. Flynn spoke about a “pattern of compliance”.

Mark Whitten (Chief of Enforcement) approached the committee to discuss 3rd party inspections for nonresident pharmacies including the NABP. Mr. Whitten also expressed his desire to keep Florida inspectors in Florida.

Mr. Flynn gave a brief overview of the different rules that will need to be discussed at the next workshop.

David Joseph approached the committee to state his concern that there is not any flexibility with the 6 month prior inspection requirement.

Mr. Flynn stated that the Board isn't required to deviate from the requirement but reserve the right to do so if they choose. Mr. Flynn stated that it must be included in the rule if they do decide to deviate.

Dr. Mikhael stated that adding all the “ifs and buts” makes the process more convoluted than it needs to be. He then went on to state that he believes the 6 month requirement should not have deviations.

Mr. Whitten suggested a review committee that has the sole purpose of reviewing the inspection forms and making a determination.

Mr. Flynn stated that the committee would have the ability to recommend to the full board but will not have the ability to outright deny.

Dr. Mikhael suggested that the questioned applications come before the Compounding Rules Committee.

Mr. Flynn stated that can't be done statutorily.

Dr. Weizer requested any input from the members regarding criteria for third party inspections.

Mr. Flynn requested the committee open the rules involved with this issue for development and setting up a workshop at the next board meeting in December.

Dr. Weizer stated PCAB had been bought out by AHC.

Motion: by Dr. Mikhael, seconded by Dr. Fallon, to open the rule involved with the third party inspection process for development. Motion carried.

Motion: by Dr. Fallon, seconded by Dr. Mikhael, to adjourn the meeting at 4:09p.m. Motion carried.