MINUTES
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
FULL BOARD MEETING
CONFERENCE CALL
July 29, 2016
12:00 pm

Call-in number: 888-670-3525
Code: 5134896685

Board Members
Debra B. Glass, BPharm, Chair, Tallahassee
Mark Mikhael, PharmD, Vice-Chair, Orlando
Goar Alvarez, PharmD, Cooper City
Michele Weizer, PharmD, Boca Raton
Leo "Lee" Fallon, BPharm, PhD, The Villages
Gavin Meshad, Consumer Member, Sarasota
Jeenu Philip, BPharm, Jacksonville
Jeffrey J. Mesaros, PharmD, JD, Orlando
David Bisaillon, Consumer Member, Bradenton

Board Staff
Allison Dudley, Executive Director
Amber Wilkins, Regulatory Specialist III

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

Meeting called to order at 12 noon by Debra Glass, Chair.

Gavin Meshad was not present.

1. Rule 64B16-32.001, F.A.C. Nonresident Pharmacy Permit

Board Counsel David Flynn explained Rule 64B16-32.001, F.A.C. Nonresident Pharmacy Permit. As pointed out by the Joint Administrative Procedure Committee, on page 2 of the application, questions 12-18 are currently based off an older version of statute 456.0635(2). He proposed to change the questions to directly reflect the most recent statutory correct provision.

Motion: by Dr. Mikhael, to accept the changes based off updating current wording to be more congruent with what is most currently being used. Motion carried.

Motion: by Dr. Fallon that there will be no adverse impact on small business or create an aggregate of $200,000 or greater. Motion carried.

2. Rule 64B16-32.007, F.A.C. Nonresident Sterile Compounding Permit for Nonresident Pharmacies

Board Counsel David Flynn explained Rule 64B16-32.007, F.A.C. Nonresident Sterile Compounding Permit for Nonresident Pharmacies. Based off the previously discussed updates to 456.0635(2) on page 2 of 5 of the application questions have been updated. Mr. Flynn expressed the need to eliminate verbiage on page 7 of 7, the Attestation page "…under penalties of perjury I declare I've read the foregoing attestation and facts stated are true." The sentence is unnecessary and the Board may not have the authority to include.

Dr. Weizer had a question regarding the signatures required on the attestation page. Out of state locations can potentially have someone other than the PIC or PDM overseeing the sterile compounding area, is it possible to add a third signature to include these people.

Mr. Flynn points out that the statute requires PDM or PIC however in the actual form it asks "or equivalent of thereof". They are unable to add a third signature but are able to modify to say "(PDM/PIC/or Equivalent over Sterile Compounding)"

Amended motion: by Dr. Fallon to accept all changes including amended changes to include additional signature options. Motion carried

Motion: by Dr. Fallon that there will be no adverse impact on small business or create an aggregate of $200,000 or greater. Motion carried.

3. Rule 64B16-32.009, F.A.C. Nonresident Sterile Compounding Permit for an Outsourcing Facility

Board Counsel David Flynn explained the Rule 64B16-32.009, F.A.C. Nonresident Sterile Compounding Permit for an Outsourcing Facility. Based off the previously discussed updates of 456.0635(2) on page 2 of 7 of the application questions have been updated as well as the attestation page to include proper verbiage. On page 2 of 7 of the application, question 11 requests that those engaged in patient specific sterile compounding to please provide a telephone number that is available 6 days a week, for 40 hours a week. Mr. Flynn stated that statutorily the authority for the amount of days and time are only found in the Non Residential 465.0156 and also in the internet pharmacy 465.0158. Outsourcing facilities don't mandate date and time requirements and cannot mandate terms of telephone number. Each label out of an outsourcing facility is federally required to include a telephone number and any container from which drugs are moved must have the website for the FDA and med-watch number. Also the jurisdiction from where they reside may have their own telephone requirements.

Dr. Weizer had questions regarding the compliance with good manufacturing practices. She presented issues with inspections not occurring frequently, after initial registration inspections not happening until a year or more later, as well as the difficulties in assessing compliance from the 483 and not the actual inspection form.

Mr. Flynn addressed Dr. Weizer's concerns by proposing a Sterile Compounding Committee meeting separate from the Board meeting scheduled for August 9th in order to approve different entities to perform CGMP inspections. Mr. Flynn similarly recommended at the separate meeting the discussion of properly enumerated inspection reports.

Mark Whitten, Chief Enforcement Officer, informed the Board that in house inspection forms are in development and will be available within 60 days. Also the Bureau of Enforcement have created a list of facilities still requiring inspections. Mr. Whitten, Ms. Dudley and Mr. Flynn will be discussing and formulating a plan if these remaining facilities choose to use the Department for their inspections.

Mr. Flynn also suggested a change on page 2 of the instruction form to remove the second sentence that suggests going to the Board of Pharmacy's website for a list of provided Board approved entities, as these entities can no longer be found on the website. But suggested keeping the first sentence that requests that applicants submit current and satisfactory report from an approved entity.

Motion: by Dr. Fallon to accept the recommendations put forward. Motion carried.

Motion: by Dr. Fallon that there will be no adverse impact on small business or create an aggregate of $200,000 or greater. Motion carried.

Closing remarks: Ms. Dudley expressed gratitude to the Board for being available.

Motion: by Dr. Fallon, to adjourn at 12:22pm. Motion carried.