FLORIDA | Board of Pharmacy

Compounding Committee

Meeting Minutes

April 3, 2018
Residence Inn Tallahassee Universities at the Capitol
600 West Gaines Street
Tallahassee, Florida 32304
850-329-9080

Mark Mikhael, PharmD, JD
Committee Chair

C. Erica White, MBA, JD
Executive Director

Tuesday, April 3, 2018

Those present for all or part of the Florida Board of Pharmacy Compounding Committee Meeting included the following:

COMMITTEE MEMBERS PRESENT:

- Mark Mikhael PharmD – Chair
- Richard Montgomery, BPharm, MBA
- Blanca Rivera, BPharm, MBA
- David Wright, BPharm

BOARD MEMBERS PRESENT:

- Jonathan Hickman, PharmD
- Jeenu Philip BPharm
- Jeffrey Mesaros, PharmD, JD
- David Bisaillon

BOARD COUNSEL:

- David Flynn, Assistant Attorney General

STAFF PRESENT:

- C. Erica White, MBA, JD, Executive Director
- Savada Knight, Regulatory Supervisor

AUDIO from this meeting may can be found online: http://floridaspharmacy.gov/

The Committee Meeting convened at approximately 11:45 a.m.

Chair Mikhael opened the meeting by providing greetings and having introductions by staff, Committee members and non-voting Board members.

1. **Rule 64B16-27.797 - Standards of Practice for Compounding Sterile Products and**
3. **Stability and chemo attached devices - discussion**

Chair Mikhael mentioned that there was a Variance and Waiver received regarding a chemotherapy transfer device during the February 2018 meeting. The question came to the Committee whether or not this was something that the Board wanted to include in the rule. There was some FDA Evidence and published studies from 2012-2013 which showed with the specific product, they were able to get longer stability on single-dose vials for chemotherapy agencies that were in short supply. The Board did grant that Variance and Waiver, and allowed the applicant (with certain guardrails) to use the device.

The question before the Committee if it is good for one hospital system within the State of Florida, is this something that the Committee wants to recommend that we include in the rule. From a regulatory standpoint, some of the inspectors are seeing these types of requests, and are looking to the Board of Pharmacy for some guidance. Mrs. Rivera commented that she actually sends out a question to all of her fellow cancer centers nationally, and most, if not all of them, are not doing this. Her concern is the liability piece of the Board of Pharmacy doing something that is not "standard of care" nationally.

Mr. Montgomery commented that the Joint Commission issued a statement that these closed system devices were not approved, under FDA guidance, for this indication, and that they would consider this an act of omission on their standards. Dr. Mikhael said that based on the comments of the other Committee members, that we will keep the rule closed, and take any changes on a case-by-case basis.

Mrs. Rivera said that it was her understanding that the applicant would be coming back with a study and indicate what the results would be from this study, and she thinks that this information would be significant. Dr. Mikhael said that based on the Variance and Waiver on this issue (from the February 2018 meeting), that there were very specific "guardrails", as far as testing, and showing that sterility was still intact with the use of the containment device.

Mr. Montgomery asked if there was a specific time when the applicant for the Variance or Waiver would be coming back before the Board, and Mr. Flynn said that it would be 120 days from the effective date of the Order. Mr. Montgomery offered a Motion to table this discussion until this issue comes forward again, and just leave it as a specific Variance or Waiver to Rule 64B16-27.797, F.A.C., with somebody showing a financial hardship to this rule and asking for an exception. Mrs. Rivera seconded the Motion, and there was no opposition, so Motion carried.

2. **Sterile Compounding Pharmacy Permit applications – discussion and review**
   - **Special Pharmacy Permit – DH MQA 1220**
   - **Special Sterile Compounding Pharmacy Permit – DH MQA 1270**

Chair Mikhael provided a background on the application review process for DH MQA 1220 and DH MQA 1270, to see if the questions currently contained within these applications needed to be updated.

<u>Special Pharmacy Permit – DH MQA 1220</u>
Mr. Montgomery had a question regarding the similarity between these questions and the questions on the Special Sterile Compounding Pharmacy Permit – DH MQA 1270. Why are both applications necessary – the public has confusion regarding the difference between the two? Mr. Flynn said that it depends on the relevance of the Special Parenteral and Enteral Pharmacy Permits (Special P/E) and the Special-Parenteral/Enteral Extended Scope Pharmacy Permits (SPE Extended), in light of today's Special Sterile Compounding Pharmacy Permit (SSCP).

Mr. Flynn stated that it would be ideal to eliminate the Special P/E and SPE Extended permits in favor of migrating to only utilizing the SSCP permit, if the facility is performing the same function. Mr. Flynn also said that the Special P/E and SPE Extended permits sometimes serve Institutional Pharmacy in a stand-alone capacity; however, he also stated that the problem is that the SSCP permit cannot stand alone, unlike the Special P/E and SPE Extended. Mr. Flynn stated that the Board needs to determine what the consequences are of just having the SSCP, instead of the Special P/E and SPE Extended.

Dr. Mikhael said that the Special P/E and SPE Extended are not community based, they really just basically serve institutions/hospitals. Mr. Montgomery stated that a recommendation was made by a Board inspector for one of the facilities in his company to move from a SSCP to a Special P/E permit, and could lead to some confusion regarding what type of permit is necessary.

<u>Special Sterile Compounding Pharmacy Permit – DH MQA 1270</u>
Dr. Mikhael stated that he thought that most of the questions contained within the application were adequate. Mr. Montgomery stated that he had some concerns about the Special P/E (Question #12) talks about layout and accepted techniques, but when you go to the SSCP, the questions are about whether the

hood is certified, which doesn't exist in the Special P/E application.

Dr. Mikhael stated that the SSCP application, Question #18, asks about hood certification and the frequency of certification, but it doesn't ask when the hood was certified. Mr. Montgomery stated that the application doesn't ask about the room, it just talks about the hood, but there are other things in Chapter 797, which could be brought it. Mr. Flynn suggested that Mr. Montgomery "redline" the application to bring his comments back for consideration by the Committee. Mr. Flynn stated that he recognizes that some of the comments made by members of the Committee for amendments to DH MQA 1270 and DH MQA 1220 did not make it into the version being considered at the current April meeting.

Dr. Mikhael asked the Committee members to review the questions in applications DH MQA 1270 and DH MQA 1220, and bring them back for discussion at the next meeting (June 2018). Mrs. Rivera stated that we needed to understand the rationale for these questions, and whether or not there is any value to these questions. Mr. Flynn stated that when the emergency rule was created related to sterile compounding (a few years ago), that the questions in the current application migrated from what was contained within the emergency rule.

Mr. Montgomery stated that some of the suggested changes to questions are contained within the SSCP application, but not within the Special P/E application. Dr. Mikhael stated that if the questions attached to the applications are reviewed or verified by the inspectors, then there is nothing that the Board needs to consider.

Mr. Montgomery stated that because this is an application, that there is a certain level of information the application needs to submit for review and consideration. There is a certain level of expectation of information to be received. Mr. Wright stated that he thinks that the question contained within the application should represent all questions which applicants need to answer.

Robert DiFiore stated that the questions contained within the application, are not really helpful to the inspector. He said that the inspection report is really what is needed for the pharmacy permit inspection. What is helpful to the inspector are also the Policy and Procedures. Dr. Mikhael said that he is not sure how the questions are getting utilized in the application process.

Mr. Flynn asked Ms. White about the Board process for review of Policy and Procedures, and confirmed that the Board Office has an OPS Senior Pharmacist on staff to review Policy and Procedures for SSCP and Special P/E and SPE Extended permits. Mr. Wright asked Mr. DiFiore if the Committee was discussing something (i.e. – questions on the application), which are really not a problem? Mr. DiFiore stated that the Enforcement Unit really goes on site where the pharmacy permit applicant is located, and actually has a more in-depth knowledge regarding the substance of the Policy and Procedures.

Mr. Flynn stated that he would like comments submitted from Board members within the next two (2) weeks.

4. **Old Business –** Marty Dix made a comment about the Special P/E and SPE Extended permits. He was around within the initial rule was drafted. He suggested to keep these permits around for those facilities who have been around for a while (i.e – small hospitals and emergency rooms)

5. **New Business** - Dr. Mikhael encouraged Committee members to look at the new FDA Guidance regarding bulk compounding.

6. **Public Comment**

Motion to adjourn made by Mr. Montgomery, with a second made by Mr. Wright. No opposition, Motion carried.

The Committee Discussion concluded at approximately 12:15 p.m.