FLORIDA | Board of Pharmacy
Rules Subcommittee Meeting
Class III Institutional Pharmacy Permit Discussion

DRAFT
April 19, 2018 – 9:00 a.m.

Best Western Gateway Grand Hotel and Conference Center
*4200 NW 97th Boulevard * Gainesville, FL 32606*
(352) 331-3336

Richard Montgomery, BPharm, MBA
Chair, Class III Institutional Pharmacy Permit Rules Subcommittee

C. Erica White, MBA, JD
Executive Director

Thursday, April 19, 2018

Those present for all or part of the Class III Institutional Pharmacy Permit Rules Subcommittee Discussion included the following:

BOARD MEMBERS PRESENT:

- Richard Montgomery, BPharm, MBA, Chair

COMMITTEE MEMBERS PRESENT:

- Dominic Bracero, MBA – Pharmacy Director, Florida Hospital, Central Fill Facility
- Heather Fuller, MBA, PharmD, MPharm, – Division Director of Pharmacy Services, North Florida - HCA
- Michael Magee, MS, RPh, FASHP – Vice-President of Pharmacy, BayCare Health System
- Thomas Johns, PharmD – Director of Pharmacy Services – University of Florida Health/Gainesville Campus

BOARD COUNSEL:

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

STAFF PRESENT:

- C. Erica White, MBA, JD, Executive Director
- Robert DiFiore, RPh, Pharmaceutical Program Manager – Department of Health, Division of Medical Quality Assurance - Bureau of Enforcement

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

The Subcommittee Discussion convened at approximately 9:01 a.m.

Introductions

Mr. Montgomery thanked everyone for being part of this brainstorming session, and facilitated the introductions of subcommittee members.

Overview of Rule Drafting

(*Facilitator – Lawrence Harris*)

Mr. Harris provided an overview of the rule drafting and rulemaking process. To the extent that rulemaking is required to implement or interpret the statute as changed by HB 675, this is what the subcommittee is going to focus on. This working group will come up with draft rules to bring back to the Full Board for voting.

The goal is to present to the Board the proposed rules from the subcommittee at the June 2018 meeting of the Board of Pharmacy, and after following the necessary publishing and public comments timeframes, Mr. Harris is hopeful that the rules implementing HB 675, would be published around the send of September 2018.

Review of Legislation/ Drafting of Permit Application
(*Facilitator – Richard Montgomery*)

Mr. Montgomery provided a review of the HB 675 legislation. The authority that Institutional Pharmacies were given in HB 675, in addition to the normal duties of dispensing, distributing, compounding, and filling prescriptions, includes the ability to prepackage of drug products instead of just repackaging the drug products. Also conducting other pharmaceutical services for entities under common control, and the term "common control" is defined in the legislation. Provide medications and pharmaceutical services to an entity which holds a health care clinic establishment permit. This legislation helps align Florida with the federal government requirements. Also, it creates a permit for a central distribution facility, so under a Class III you can provide all pharmaceuticals to affiliated Class III institutions. Also, additional changes were made to Chapter 499, F.S., the Florida Drug and Cosmetic Act, which is administered by the Florida Department of Business and Professional Regulation. The effective date is July 1, 2018.

Dr. Johns stated that the legislation extends what each pharmacy facility is able to do, to include distribution. Mr. Flynn stated that this legislation allows a Class III to do everything a Class II Institutional Pharmacy can do, but now add distribution to those existing duties. Mr. Montgomery stated that there are no changes to FDA for FTC rules, this legislation just allows licensees to move product without permitting. The Trace and Trace stops at the front door of the pharmacy.

Mr. Magee stated this legislation extends the walls of the hospital. In the prepackage /repackage world, the hospital practice has been done under the guidance of USP for years. This is not changing, it is just going to be done in a health system instead of just a hospital – under a Class III. It is not reselling, but just being done under the common practices – repackage is not for resell, but for further distribution within the same entity. Dr. Johns said that in pharmacies under the Class II Institutional Pharmacies, perform these activities on a regular basis, and have been doing so under the context of existing regulations.

Mr. Magee explained the difference between Class II and Class III Institutional Pharmacies – the new developments in this legislation is the component related to central fill. Most common license associated with health systems are Modified Class 2B Institutional Pharmacies. Mr. DiFiore stated that Modified Class 2C Institutional Pharmacies are occasional, and Modified Class 2A Institutional Pharmacies are rare – from a permitting perspective. Mr. Montgomery stated that we have to figure out how to "marry up" these common entities under a Class III Permit.

Mr. Montgomery stated that this legislation only allows a Class II Institutional Pharmacy to receive product, but nothing else will change. The legislation will just allow a central fill or central hub hospital to able to move the necessary drugs, and also repackage those drugs centrally and move them without having a restrictive wholesale distribution license. Mr. Bracero stated that currently a Modified Class 2B Institutional Pharmacy cannot currently move product under the current legislation, and the rules should be written to allow this type of facility to be able to obtain the Class III license. Ms. White suggested that perhaps one way to facilitate the transition under the new legislation is to write the rules to allow a Modified Class 2B Institutional Pharmacy to relinquish their license and then be issued a new Class III license.

Dr. Johns described the current state of permitting in Florida. It is quite a complicated process, and the ultimate goal is to simplify the process of regulating this area. Dr. Johns is the Consultant of Record (COR) for a large Class 2 Institutional Pharmacy Permit – Shands Teaching Hospital and Clinics, Inc. There are several permits under this permit:

- SSCP (Special Sterile Compounding Permit - does not anticipate this permit will change under this legislation)
- SLC (Special Limited Community Permit - does not anticipate this permit will change under this legislation)
- Four (4) COMM (Community Pharmacy Permits - does not anticipate these permits will change under this legislation)
- SPE (Special P/E Permit - does not anticipate this permit will change under this legislation)
- Series of Ten (10) Modified Class 2B Institutional Pharmacies (does not anticipate these permits will change under this legislation)
    - 2 Free Standing Emergency Departments;
    - Ambulatory Wound Care Center;
    - Surgery Centers;
    - Endoscopy Centers; and
    - Dialysis Centers

Dr. Johns' vision for this legislation would be to "convert" the Modified Class 2B Institutional Pharmacies to Class III Pharmacies. Also to "convert" the main Class II Institutional Pharmacy to a Class III Pharmacy, and by doing so it allows distribution between all of the entities which are in the Class III network under common control. In additional to what Dr. Johns described above, the central fill pharmacy would also be classified as a Class III to allow for distribution to all other Class III Pharmacies in the network.

Dr. Johns also mentioned that since this legislation is a modernization of the Institutional Pharmacy permits, what types of places in the future will want a Class II Institutional Pharmacy license? It may be some small critical access hospitals or some smaller rural hospitals that are not part of a network, but the majority of the Institutional permits going forward will be Class III's.

Lunch

The lunch break was skipped in order for participants to continue with completing the agenda.

Drafting of Rules (Break included)
(*Facilitator – Richard Montgomery*)

Mr. Harris asked for clarification for what "Other Pharmaceutical Services" language (looking at page 3 of 15, new Section 21, line 67) meant in the legislation. Mr. Magee responded and said that what the industry was perceiving (i.e. – BayCare) was that there might be other activities being conducted in the central distribution warehouse, which are not related to distribution. For example, BayCare has a transition of care program where pharmacist contact patients after discharge to make that they know how to take their medications properly. These pharmacists are housed at the central distribution facility. Also, there is a community benefit program, where anyone can call the central distribution facility to obtain help if they are having difficulty with access to medications. Also centralized contracting is being performed at the BayCare central hub facility as well.

Mr. Harris also recommended that there be some kind of standard for the prepackaged drugs – whatever the current standard about the minimum requirements for the preparation for prepackaged drug products. Mr. Harris also discussed other rules within the Florida Administrative Code which required conforming changes as a result of this legislation (Chapter 64B16-28.501, F.A.C., 64B16-28.502, 64B16-28.602, F.A.C., 64B16-28.6021, F.A.C., 64B16-28.603,F.A.C., 64B16-28.604,F.A.C., 64B16-28.605,F.A.C., 64B16-28.606,F.A.C., and 64B16-28.810,F.A.C.)

7. **Summary –** Mr. Harris will get a draft Institutional Pharmacy permit form out to the committee, and Mr. Montgomery asked all committee members to review it and get back to Mr. Harris with their comments. Mr. Montgomery also asked all committee members to look through their policy and procedure manuals identify standards which could be used for benchmark purposes.

The Board Office will coordinate the next conference call of the committee around mid-May 2018. The committee members thanked Mr. Montgomery for coordinating the discussion on this topic, and he thanked the committee members for participating in the meeting.

8. **Public Comment**

Public comment was provided and taken by the committee throughout the discussion.

The Subcommittee Discussion convened at approximately 1:15 p.m.