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

DRAFT
May 24, 2018 – 4:00 p.m.

Telephonic Conference Call
Conference Call Number: (888) 670-3525
Conference Code Number: 5134896685

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

C. Erica White, MBA, JD
Executive Director

Thursday, May 24, 2018

Those present for all or part of the Class III Institutional Pharmacy Permit Rules Subcommittee Teleconference Meeting 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
- Trina Richardson, Regulatory Specialist III

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

The Subcommittee Discussion convened at approximately 4:00 p.m.

Call to Order:
(*Facilitator – Richard Montgomery)*
Mr. Montgomery called the meeting to order, and Ms. White took a roll call. All Subcommittee members were present along with Board Staff, Ms. White and Ms. Richardson.

Review of April 19, 2018 minutes:
(*Facilitator – Richard Montgomery)*
Dr. Michelle Weizer (public call member) had a correction on page 3 of the April 19th minutes. On page 2, paragraph 3, the words should be "track and trace" and not "trace and trace". Motion to accept the minutes as corrected made by Mr. Magee, and seconded by Mr. Bracero, and Motion carried with no objection.

Overview of Draft Rule 64B16-28.750, F.A.C. - Class III Institutional Pharmacies:
(*Facilitator – Lawrence Harris*)
Mr. Harris stated that he believes the first draft of rule language included in the materials captured the discussion of the Subcommittee at their April 19th meeting. Mr. Harris got some comments back from Enforcement staff, and from other parties, which were incorporated in the rule draft provided to the Subcommittee.

Mr. Harris highlighted some of the areas in the proposed rule where the comments he received were incorporated as follows, revised version on May 15, 2018:

- One of the points which was made, it was pointed out that a new pharmacy which meets the requirements for a Class II, could apply for an Institutional Class III, instead of just existing Class II pharmacies or Central Distribution facilities.
- Enforcement staff brought up the issue of increasing the notice to the permitholders that drug records have to be maintained. The suggestion was to make it very clear that those requirements under state and federal law (i.e. – drug records, controlled substance inventory, anti-diversion, labeling requirements) are still in place. This information would be included in the policy and procedures as reviewed by the Board to ensure that they are appropriate.
- The changes in the application form as stated above by Mr. Harris were also made in the proposed Institutional Class III application forms.

Mr. Montgomery stated that he felt that Mr. Harris did a great job on his draft language. Mr. Harris also acknowledged Mr. DiFiore and the Enforcement Staff who pointed out that their comments really assisted in this area. Mr. Harris also brought up the fact that Institutional Class III permitholder would still be able to engage in compounding activities, and that this was not something that changes as a result of this legislation or the proposed rule/application.

Mr. Harris stated as far as the transportation aspect goes, it is also governed by state and federal law, in addition to labeling activities. To the extent that there is going to be movement of medicinal drugs (i.e. – "hub and spoke" model, as it relates to labeling or re-labeling – it would be very specific to the individual permit holders. Mr. Harris stated that as a hospital or business entity, there would be some type of internal tracing of these materials, they are not just going to fall into a "black hole" where no one knows where the medicinal drugs are going. The Committee members collectively agreed that these tracking activities are already taking place, and agreed with Mr. Harris that there is no need to go into this area with the proposed rules.

Mr. Harris asked if these facilities would need different levels of inspections based on the type of facility, will the types of inspections be significantly different for the Institutional Class III permit? Mr. Montgomery stated that there may be a little bit more scrutiny relating to record-keeping and tracing from one facility to the next, to make sure that there is a "clean-record" of movement.

Mr. Johns echoed Mr. Montgomery's response to this. He said that there may be an added task of looking at the records for transfer, but the essence of the pharmacy operation is no different than what it is today, and he believes that the same level of inspection which is currently occurring for existing Institutional Class II permits would still occur for the Institutional Class III permits. Ms. Fuller stated that she agreed with Mr. Johns and that we may have some variance for inspections relating to the Central Distribution centers, because not all centers may be doing the same functions. Mr. Magee stated that if you take a look at the inspection sheets, that there might be an answer of "n/a" regarding some of the requirements on the inspection sheets.

Mr. Harris stated that the inspector's big concerns are record-keeping and ensuring compliance. How are the inspectors going to verify "track and trace" – how will they know where controlled substances are? Also ensuring that anti-diversion activities methods are in place, and because this is a new model, there is some uncertainty regarding how these activities are going to take place. Mr. Harris' understanding of the inspector's concerns, is whether or not the labeling on the drugs needs to change based on the

transportation from each facility (within a common owner) to accurately track the process/progress of how that drug is transferred for the purpose of inspecting the facility.

Mr. Montgomery stated that he believes that the origin of the repackaging should be on the label. Ms. Fuller agrees with Mr. Montgomery's comment, and stated that this process is closely monitored and tracked. Mr. Montgomery also stated that there are financials tied to this, because it affects on-site dollars regarding the moving of product. Mr. Harris asked if the inspectors would be able to see the labels when they come out for the inspection, so that they can determine the origin of the drugs. Mr. Magee said that the process is no different than what is done with multiple facilities which are part of a current institutional setting. Mr. Magee stated that we certainly should know if the drugs are transferred from one place to another. Mr. Bracero stated that the current repackaging documentation and the track that occurs currently, could be expanded to include other facilities. Mr. Johns stated that the Subcommittee does not need to make things more complicated that what it actually is – there is a tendency to overcomplicate things just because they are new.

Mr. Bracero asked how he would know if another facility has another Class III Institutional Pharmacy permit, and whether a facility should verify that another facility actually has a Class III permit as well. Mr. Harris stated that the way that he thought it would work, is that each individual facility would maintain documents (i.e. – recordkeeping) regarding which facilities hold the Class III permits. This documentation would then be provided to the inspector upon request or to review. Mr. Harris said that his thought would be to keep the documentation on site at the facility level, instead of at the Department level. Mr. Magee stated that the documentation would be more dynamic if it is at the local level, instead of at the Department level.

Overview of Draft Class III Institutional Pharmacy Permit application:
(*Facilitator – Lawrence Harris*)
Mr. Montgomery stated that the major changes were on pages 2 -3, but that most of the discussion was had during the previous discussion on the rule.

Overview of Change of Permit Association Form (proposed):
(*Facilitator – C. Erica White*)
Ms. White stated that she provided a form for consideration by the Subcommittee which would allow a current pharmacy permit licensee to "translate" their current Institutional Class II license to an Institutional Class III license. Ms. Fuller asked if the Health Clinic Establishments (HCE) would be included on this form; however, Ms. White stated that this form would only be used for entities currently licensed by the Board. Ms. White also stated by utilizing this form, the review process would be streamlined.

Mr. Magee asked why we would need to review the Policy and Procedures again, if the licensee would already be licensed. Mr. Montgomery suggested to reduce the questions relating to Policy and Procedures down to just the transportation component, and movement of the product. Mr. Montgomery suggested to only include questions: 5, 6, 7 and 8. By streamlining these questions, it will allow for an easier review process for Board staff. Ms. White stated that she would revised the form, and send it out to the committee for final review and approval.

Mr. Harris asked for clarification regarding what this Change of Permit Association Form would be used for. Ms. White stated the Change of Permit Association Form would allow for a current licensed

Institutional Class II pharmacy to change to a Institutional Class III pharmacy without having to complete an entirely new application. Ms. White stated that what she did was model the Change of Permit Association Form after the current Change of Ownership application, but that it would not require a new license because the Federal Employer Identification Number would not change. Mr. Harris stated that he would update the proposed rule to include a reference to the Change of Permit Association Form.

Old Business/ New Business:
(*Facilitator – Richard Montgomery)*
No old business was discussed. Mr. Montgomery stated that he would be presenting the recommendations of the Subcommittee to the full Board of Pharmacy during the June 2018 meeting.

Mr. Harris asked to discuss the timing of having the documentation for the association of all of the Class III Institutional permits located within a health system. Mr. Magee stated that to initiate the transfer of a medicinal product from one Institutional Class III Pharmacy to another, there has to be some sort of validation that the receiving facility of the medicinal product is an actual licensed Class III Pharmacy. He further stated that common ownership may be known, but the status of licensure needs to be known. Mr. Bracero stated that he thinks that inspectors would appreciate having this information up front. Mr. Johns stated that the Institutional Class III facility would need to maintain this information, because the facility could be a sender or receiver of any medicinal products at any point. Mr. Montgomery stated that the onus would be institutional "universe" to make sure that everybody was currently permitted before everything was started moving.

Mr. Montgomery asked Mr. Harris to walk the Subcommittee to "walk" everyone through the timeline of the rule adoption in this matter. The Board will be meeting on June 12, 2018, assuming that the Board votes to approve the form, this will start Board Counsel with initiating the rulemaking process. The rule will be sent to the Governor's Office for review during a seven (7) day waiting period, to see if they have any concerns. After the Governor's Office reviews the proposed rule, Board Counsel will publish a Notice of Rule Development. This is the first point of entry for parties – it is notification that the Board is considering doing with a rule, and we have to explain what the Board is considering doing. This triggers the ability for interested persons to request workshops or provide comments on what the Board is planning to do, and this is a fourteen (14) day period. At the end of the fourteen (14) day period, assuming that there is no request for a workshop, the Board Counsel publishes the proposed language. When the language is published, that is a second point of entry, which triggers a twenty-one (21) day clock. Within that twenty-one (21) days, the Joint Administrative Procedures Committee (JAPC) has an opportunity to provide comments and concerns that have to be resolved by the Board before the rule can be adopted. It also gives interested parties the opportunity to request a different workshop or a hearing on the rule. Assuming that no hearings or workshops are requested, if there are JAPC comments or workshop requests, the rule would come back to the Board at the August 2018 meeting. If there are no comments, the rule could theoretically be adopted or effective by the end of August 2018, or in the alternative, if there are comments or JAPC comments, the rule could be adopted or effective by the end of September 2018.

Public Comment
No public comment was provided. Mr. Magee made a motion to adjourn the meeting, and said motion was seconded my Ms. Fuller, without objection.

The Subcommittee Discussion convened at approximately 5:00 p.m.