FLORIDA | Board of Pharmacy

Legislative Committee

Draft Meeting Minutes

April 02, 2018

Residence Inn Tallahassee Universities at the Capitol

600 West Gaines Street

Tallahassee, FL 32304

Contact Hotel: 850-329-9080

Jeenu Philip, BPharm

Committee Chair

Monday, April 02, 2018 at 1:00 PM

Call to Order - The meeting was called to order by the Committee Chair, Mr. Philip, at 1:00 p.m.

Roll Call - Those present during the meeting included the following:

Committee Members

Jeenu Philip, BPharm, Chair

John Hickman,PhamD

Mark Mikhael, PharmD

Blanca Rivera, MPharm

Montgomery

Attorneys

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

Board Staff:

C. Erica White, Executive Director
Savada Knight, Regulatory Supervisor

Note: Participants in this public meeting should be aware that these proceedings are being recorded.

1. Review of Bills from the 2018 Legislative Session.

HB 21

Discussion:

Dr. Phillip gave an overview of HB 21 and the impact it will have on Floridians. The bill defines acute pain and creates a controlled substance continuing education for prescribers. The bill defines the Department of Health to adopted rules on the standards for treating acute pain and requires each of the established prescribing boards to write rules establishing guidelines for prescribing controlled substance for acute pain. The bill includes requirements for prescribing opioid drugs and the use of the Florida Prescription Drug Monitoring Program in the implementation of the bill.

Mr. Philip opened the floor for discussion on the impact HB 21 will have in Florida.

Dr. Hickman commented on issues the Committee may face in implementing HB 21. He commented on the requirements of the day supply enforcement of controlled substances and the impact it may have on the patients. Dr. Hickman also commented

on the enforcement of the Florida Prescription Drug Monitoring Program search query and whether the Board or the pharmacist will have a role in the recordkeeping. He continued with the issues that may arise in determining what drugs are prescribed for chronic and acute pain by definition and the role the pharmacist will play in making such determinations.

Mr. Flynn continued the discussion on process to determine whether a prescription is written for chronic or acute pain. He continued with the standards outlined in HB21 which require the prescriber to indicate on the prescription whether the medication is being proscribed for acute or chronic pain. The verification process will be the responsibility of the pharmacist to check each proscription to verify that all required information is present before filling the prescription.

Dr. Jeffrey Mesaros, Board Member, asked about the process the Committee plans to use when a prescription is presented without the proper prescribing indicators for pain. He commented on the identification requirements in HB 21 and what alternative methods may be used to properly verify identification. Mr. Flynn commented on the identification process based on the previous standards used by the Board. He informed the Committee that identification requirements are the same as the requirements in Chapter 893.005 Florida Statutes. Mr. Flynn does not foresee a significant impact to in the implementation of the identification process by pharmacists since the same identification requirements are already outlined Chapter 893.005 Florida Statutes.

Mr. Flynn continued to discuss the possibility of initiating rulemaking around the citation rules and the disciplinary guidelines based on the requirements outlined by HB 21 for violations in the enforcement of the Florida Prescription Drug Monitoring Program. He discussed the possibility of opening the rules to set the citation fines and any required continuing education based on the expected violations. Also, he explains the bill requires the Board to initiate the disciplinary process for multiple citations for failure to check the Florida Prescription Drug Monitoring Program. Mr. Flynn recommends the Committee open the disciplinary guidelines first, based on the bill's mandate to enter the disciplinary process for multiple violations for failure to check the Florida Prescription Drug Monitoring Program. He continues to explain that by law, there must be disciplinary guidelines in place prior to taking any disciplinary actions against a respondent. He recommends the Committee finalize the rulemaking process before the July 1, 2018 implementation of the bill.

Mr. Harris, discussed the catchall provision in the disciplinary guidelines for violating any provision of Chapter 456, Florida Statutes, which will allow for the prosecution of offenses not specifically outlined in the disciplinary guidelines.

Mr. Phillip asked what process will the Board use in disciplining a pharmacist for failure to check the Florida Prescription Drug Monitoring Program when there is not a requirement to keep any records in the statute. Dr. Mikheal commented that the Florida Prescription Drug Monitoring Program has stated the system would be able to provide records of any queries made in the system should a discrepancy arise.

Mrs. Rivera commented on the PMP process. She asked what kind of impact will the Prescription Drug Monitoring Program have statewide as it relates to the Board of Medicine and Dentistry? She recommends the Committee contact for the Florida Prescription Drug Monitoring Program to discuss what options are available to track the use of the system and the specific reports that are available to the Board.

Ms. White responded to Mrs. Rivera's question by informing the Committee of an upcoming conference call with the Board of Medicine, Dentistry, Podiatry and Nursing on April 18,2018 to discuss the implementation of HB 21. She informed the Committee that Mr. Philip previously requested a representative from the Board of Pharmacy to be present at the meeting.

Dr. Hickman, Mr. Philip, Mr. Flynn and Dr. Mersaros discussed the possible issues that may arise when a patient presents a prescription for a controlled substance accompanied by the required opioid antagonist and the patient refuses to use the opioid antagonist or does not return retrieve the medication. The thought is to give the Board the option to look at each case and allow the Board to proceed based on the facts of that case keeping in mind the standards of practice and the statutory requirements. Dr. Hickman asked for clarification on whether the required indictor was only required for new opioids or all controlled substance prescription. Mr. Philip commented that the required indictor applies to all prescription for controlled substance including refill prescriptions that are in the Prescription Drug Monitoring Program.

Mr. Philip asked Mr. Flynn and Mr. Harris, if there any steps the Board would be required to take presently regarding HB 21? Mr. Flynn suggested having the Controlled Substance Committee vote to open certain rules related to the citations and discipline under HB 21. If the rules are opened by the Controlled Substance Committee, Mr. Flynn suggested asking the Controlled Substance Committee to refer action to the Rules Committee. At this time there is no further action needed from the Legislative Committee.

Mr. Phillip open the floor for any public comments on HB21. No comments were made.

Mr. Philip continued giving an brief overview of the bills which either passed or failed during this session.

HB351
Discussion:
The bill is geared around prescription drug pricing transparency. There is creation of statutes in Chapters 624,627,and 641 of the Florida Statutes that related to pharmacy benefit manager contracts. The bill also eliminated Chapter 465.1862 in the pharmacy statutes. There is a requirement for registration through the Office of Insurance Regulation and requirement for the commission to write rules to administer the guidelines under the statute. Mr. Philip continues with an overview of the statutory

requirements for the Prescription Department Manger and the limitations on maximum level cost for prescriptions. The effective date for HB 351 is July 1,2018.

Mr. Philip open the floor for any public comments on HB21. No comments were made.

HB 431

Discussion

The bill died in Health Policy Committee on March 10, 2018. Dr. Mesaros requested more information on the process of the bill or any concerns discussed. Dr. Hickman responded the bill was never heard in the House committee.

HB 513

Discussion

Distributing Pharmaceuticals Drug and Devices passed. Effective July 1, 2018

HB 675

Discussion

Creation of Class III Pharmacies takes place under this bill. Mr. Montgomery gives a overview of the bill. The bill creates a Class III permit which allow for the dispensing, distribution, compounding, and filing prescription of municipal drugs. The bill allows for preparation of prepackaged drug products. It allows for the distribution of drugs to hospital and entities under common control, the bill defines common control. It provides medication and services to healthcare clinics which are connected under common ownership. The bill creates a central distribution centers. Lastly, the bill revises the membership for the Board of Pharmacy to include Class III permits holders.

Mrs. Rivera asked if the 340B entities with a contract pharmacy arrangement will not need the limited distributor permits? Mr. Montgomery responded, the limited distributor permit will not be needed.

Mr. Philip asked Mr. Flynn if there were any rules tied to the statute? Mr. Flynn responded in the affirmative and deferred the discussion to the Rules Committee.

HB679

Discussion

The bill covered remote dispensing of drugs. The bill died on March 10, 2018.

HB689

Discussion

The bill ties to the practice of pharmacy. The bill died in Health Policy Committee.

HB 1047

Discussion

The Department of Health bill. There were a few revision ties to pharmacy and sterile compounding. Mr. Philips asked Mr. Harris if the bill not passing had an impact on the practice of pharmacy? Mr. Harris responded that the bill does not have an impact. The bill died.

HB1099

Discussion

This bill was tied to advanced birth centers. The bill died in committee. It would have established a birth center as sub-class of an institutional pharmacy type.

Dr. Hickman commented on HB 689, he suggests the profession to keep an eye on this issue because there is an explosion of specialty pharmacies. He believes that the profession would be able to help tremendously in the future.

Dr. Mesaros asked if we have an accounting of the different bills that went through the different committees? Is there any way to find out why certain bills died? His concern is to have a resource to expedite the bills through the system to avoid bills dying due to lack of time. Mr. Philip commented that there is a push pull element tied into the process. He believes there must be an assertive effort to work together to see progress happen with the proposed bills. Mrs. Rivera asked if the bills need to be signed by the Governor? Mr. Philips affirmed the bills have been signed. Dr. Mikhael commented that the Board should handle more issues as opposed to the legislative. He believes the Board will get more issue solved this way.

2. Advance Practice Technician Discussion

Discuss

Mr. Philip gave a brief overview of the previous discussions on the advance practice technician. There have been previous discussion of whether there needs to be rules written for advance practice technician or if the rules need to be referred back to the Legislative Committee for discussion around what pieces will go into statute. He recommends referring the discussion around advance practice technician to the Rules Committee. Mr. Philip open the floor for any comment before referring the discussion to the Rules Committee. Dr. Mesaros commented that he has received additional information based on the articles. He will continue to gather information and forward it to Mr. Flynn and Mr. Harris to review and distribute the relevant information to the Board before the upcoming Board meetings. Mr. Philip would like to see the a provision added to statute to allow the Board to approve or deny pilot programs. Dr. Mesaros thinks the idea of the pilot programs would be beneficial to the Board's review process, especially the ability to collaborate with other boards of different issues. Mr. Philip and Mr. Flynn discuss the option of granting a waiver or variance to allow for a pilot program. Mr. Flynn states it would be a very complex process based on the limitation presented in Chapter 120. He will research the issue to avoid any unconstitutional activity by the Board. Dr. Mesaros suggest finding any language created by another state that allows there board to approve pilot programs. Dr. Hickman

agrees that there should be research done to try and accomplish getting pilot programs. Dr. Mikhael commented on the advance practice technician, he wants to know at what point will the Board move forward with the rest of the world with advance practice technician. Mr. Philip directs the discussion to the Rules Committee where all the appropriate board members will be present.

No further discussion.

3. **Old Business/New Business**
   None

4. **Public Comment**
   5. No further discussion.

6. **Adjournment**
   Motion made by Dr. Hickman to adjourn. Motion Seconded by Dr. Mikael. Meeting adjourned at 6:06 p.m.