

FLORIDA | BOARD OF PHARMACY

Controlled Substance Standards Committee

Meeting Minutes

April 02, 2018

Residence Inn Tallahassee Universities at the Capitol

600 West Gaines Street

Tallahassee, FL 32304

Contact Hotel: 850-329-9080



Gavin Meshad
Committee Chair

C. Erica White, MBA, JD
Executive Director

Monday, April 02, 2018 at 3:00 PM

Call to Order - The meeting was called to order by the Committee Chair, Mr. Meshad, at 3:00 p.m.

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

Board Members

Gavin Meshad, Chair
David Bisailon
Jeenu Philip, BPharm
Jeffrey Mesaros, PharmD
Richard Montgomery, BPharm, MBA

Attorneys

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

Board Staff:

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

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

Mr. Meshad welcomed new Board members.

1. 64B16-27.831 – Standard of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education (pg. 4)

Discussion:

Mr. Flynn states the current proposed rule reflects the changes the Board made at the last meeting regarding to the continuing education requirements. At the last meeting, there was discussion about giving credit to all pharmacist who have already taken the current validation continuing education course. The Board is giving credit for courses taken from October 17, 2017 through May 1, 2018. Mr. Flynn suggested extending the date to July 1, 2018, to give the course providers time to submit their course information for approval. Mr. Philip asked Michael Jackson, Florida Pharmacy Association, if the July 1, 2018 deadline will provide the Board with enough time to revise the content of the control substance rules? Mr. Jackson affirms that the deadline will not pose any issues. Mr. Jackson voiced his concerns about the emergency treatment of opioid overdose and the state's Surgeon General standing order regarding Naloxone. He questions if the order will be impacted when the Governor leaves office. Mr. Flynn states that the Board has the option to adopt the current rule and later change the language based on the Surgeon General standing order. The Committee discussed the impact the Surgeon General's order and the Governor's order will have on the Board and the profession including possible changes to the language of the rule.

Mr. Montgomery asked about the standards for disposing unused controlled substances. Mr. Bisailon commented that the continuing education provider should provide information of what the proper disposal standard would be. Mr. Rivera thinks the biggest problem is that OASHA standards and the DEA standards differ which results in the pharmacist not know what standard to follow. Mr. Flynn commented that when drafting the rule his aim was to make sure there was

education on disposing controlled substances. He states the goal here was to provide education as opposed to creating rules. The Committee discussed the importance in ensuring the patient disposes of their unused controlled substances. The Committee discussed possible changes in the language. Motion to approve the rule as amended by Dr. Mesaros. Motion seconded by Mr. Phillips. Motion pass unanimously.

2. 64B16-27.831 – Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education (pg. 10)

Discussion:

Mr. Flynn- At the last meeting, the Committee brought forth mandatory counseling when there is a prescription for an opioid naïve patient. Mr. Flynn made changes to subsection 3. Mr. Meshad open the floor for discussion. Mr. Jackson commented on the process in which a pharmacist would take to counsel a opioid naïve patient. Mr. Flynn commented that a pharmacist should follow the process outlined in HB 21 to ensure compliance. The process would require a query in the PMP. Dr. Mikhael commented on the work flow issues within the pharmacy. He is concerned with the unintended consequences it creates from a workflow aspect. His suggestion is to engage the technicians to alleviate the burden on the pharmacist. Mr. Rivera commented that the pharmacist is the best option to relay the information to the patient. She suggest that the information can be provided in other methods that would not require the pharmacist to have a lengthy conversation with every patient. Mr. Philip comments on the changes that are happening with prescribers around HB 21, which include the continuing education and the mandatory PDMP checks. He suggest the Committee may be moving too fast on certain actions without fully seeing the impact of the current changes happening with HB 21. The Committee discussed how the Committee should approach the issue. Mr. Flynn reminds the Committee the rule mandates patient counseling and questions the approximate number of patients the Committee believes actually refuses counseling. Mr. Meshad suggest the Committee be proactive on the issue. Mrs. Rivera suggest adding language which only requires the pharmacist to offer counseling. The Committee discussed issues that may arise if the patient refuses counseling including language barriers, liability issues, and alternative methods to provide counseling. Need to figure out how to give the pharmacist the tools to execute the task required while keeping in mind the pharmacist is not being compensated for counseling each patient. Mr. Meshad suggest not using language that makes the counseling mandatory. The Committee decided to continue to get feedback from the members and continue the discussion at an upcoming meeting. The Committee decided to focus on the following issues: What is a naïve patient?; How long will the Board give the pharmacists to implement counseling?; How many patient will be impacted by the mandatory counseling? Mr. Meshad asked Dr. Mikhael and Mr. Flynn will work collectively on researching the issues.

3. 64B16-27.810 - Prospective Drug Use Review (pg. 12)

Discussion:

Based on the discussion from the last meeting, there has been added language to subsection (g) which require a determination of where there is a physical dependence, addiction, misuse, or abuse. If present, counseling may occur at the discretion of the pharmacist, it is not mandatory. Mr. Flynn suggest the Committee look at whether there should be a mandate for counseling after the prospective drug utilization review is completed by the pharmacist. Dr. Philip asked, how can a pharmacist who is looking at the patient profile determine physical dependence, addiction, misuse, or abuse? He does not think the language discussed is appropriate for this rule. Mr. Flynn asked for clarification on when the review of the patient profile actually takes place. The Committee confirms that the review could take place while the patient is present or after the patient has received the medication. Mrs. Rivera commented on

the issues that may arise in determining whether the patient has physical dependence, addiction, misuse, or abuse based solely on a review of their profile or a patient interview. She suggest the task must be completed by a psychiatrist, especially when dealing with detecting an addiction. The Committee discussed the process in which the pharmacist should use to determine physical dependence, addiction, misuse, or abuse in the PDMP. The Committee discussed the obligation of the pharmacist under the rule. There is a mandate for the pharmacist to check the PDMP. Mr. Bryan Kahn, pharmacist and attorney, commented on the importance of the Committee understanding the process of how administrative laws help establish disciplinary standard for the profession. He continued to discuss creating a community standard and how the community standard helps establish a negligence case under civil law. He discussed the legal impact of a pharmacist not fulfilling their obligation to check the PDMP. Mr. Flynn clarifies that a pharmacist should never pass a prescription that they have knowledge of or have reason to believe is not related to a legitimate medical relationship for a legitimate medical purpose. The PDMP is a tool to help the pharmacist fulfill their obligation. Mrs. Rivera proposed a change in the language of the rule. The Committee discussed removing addiction, misuse, and abuse language from the rule and the impact it would have on the profession. Motion to withdraw subsection (g) and the mandatory patient counseling by Mr. Montgomery. Motion seconded by Mr. Meshad. Motion passes unanimously.

4. **64B16-27.820 - Patient Counseling (pg. 14)**

Discussion:

There is recommended language changes to the patient counseling. Based on the previous discussions by the Committee, Mr. Flynn recommended the Committee not review subsection (4) or (5) because it deals with language regarding naïve patients and patient counseling. In subsection (1) the interactive digital image format language has been changed to interactive digital audio format, which will allow for the use of method such as skype, facetime, etc. The Committee discussed removing subsection (3) from the rule based on the extra care and mandatory counseling language in the rule. The Committee discussed using the following language: The licensee shall use their professional judgement in determining whether patient counseling and education is warranted. Mr. Flynn does not recommend repeating the language in statute in a rule. Mr. Philip does not agree that the language should be in the patient counseling rule because there is controlled substance rule that goes into the aspects of what a pharmacist should and should not do when filling a prescription for a controlled substance. He continues with clarifying the origin of the opioid crisis and the impact HB 21 will have to controlled the crisis. He recommends letting the statute take effect then the Committee can assess what additional rules would be needed for the profession. Motion to accept changes to subsection (1) and strike subsections (3),(4), and (5) made by Mr. Basaillon . Motion seconded by Mr. Meshad. Motion passes unanimously.

5. **Policy and Procedures Related to Dispensing of Opioid Prescriptions**

Discussion:

No discussion.

6. **2018 Legislation Impacting or Relating to Controlled Substances**

Discussion:

Dr. Mikheal commented on the 3 day supply change and the impact it may have on the profession. Mrs. Rivera clarifies the requirement is only for acute pain and there is an option to increase the prescription to seven day supply. The Committee discussed the different exceptions that can be made to increase the daily supply on prescriptions based on chronic or acute pain. The Committee also discussed how pharmacies and patients may be impacted by

the new changes in the rule.

7. Old Business / New Business

Mr. Flynn requested to have the citation rules refer to the Rule Committee for Dr. Mesaros and Mr. Harris to work on in conjunction with the disciplinary guidelines.

8. Public Comment

Mr. Jackson commented on the requirement in HB 21 for a prescriber to provide patients with a pain severity level 9 or higher with an narcotic antagonist and the possible impacts the requirement would on pharmacists.

9. Adjournment

The meeting adjourned at 6.00 p.m.

DRAFT