

**FLORIDA** | Board of Pharmacy

**Controlled Substance Standards Committee**

# Draft Meeting Minutes

**October 3, 2017**

Rosen Plaza Hotel

9700 International Drive

Orlando, FL 32819

Contact Hotel: 407-996-9700



**Gavin Meshad**  
Committee Chair

**C. Erica White**  
Executive Director

Tuesday, October 3, 2017 at 9:00 AM

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**Call to Order** - The meeting was called to order by the Committee Chair, Mr. Meshad, at 8:02 a.m.

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

**Board Members**

Gavin Meshad, Chair  
Debra Glass, BPharm  
Jeenu Philip, BPharm  
Michele Weizer, PharmD

**Attorneys**

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

**Board Staff:**

C. Erica White, Executive Director  
Irene Lake, Program Operations Administrator  
Jessica Hollingsworth, Government Analyst II

Mr. Meshad began the committee with a moment of silence in recognition of the Las Vegas shooting.

**1. Assignment Updates from August 2017 Committee Meeting**

Discussion:

Mr. Meshad informed the committee that CVS Pharmacy modified their protocol in relation to controlled substances and the Governor's office proposed legislation similar to what has been discussed in the Controlled Substance Committee, which he finds encouraging. The committee continued with discussing research found for the multi-board meeting in November.

**Physician Asks:**

Ms. Glass informed the committee that many of the state rules urge Physicians to follow the CDC guidelines on limiting dosing, but there is no requirement nor guidelines on how this is monitored. Ms. Glass observed that most of the information was related to emergency room prescriptions and fills. Ms. Glass also discussed how Kentucky mandated Physicians to complete certain CE categories and offered free CEs on subjects related to CDC and PDMP in addition to CEs required for renewal. She also noticed that many CE requirements applied to PAs, since they can prescribe. Information regarding limiting initial fills indicated a three-day maximum.

Mr. Meshad added that he believed the Board of Medicine should establish parameters to hold

Physicians accountable in following the CDC guidelines. He further stated that not all physicians should be able to prescribe the same things, since specific drugs can be dangerous. Dr. Weizer agreed with Mr. Meshad.

Dr. Mikhael asked Ms. White if Mr. Meshad may attend the multi-board meeting with Dr. Mikhael, to which she answered that he may attend as a member of the public but not as a committee member.

### **Manufacturer:**

Dr. Mesaros stated that he didn't have a strategic recommendation to provide at this point.

Dr. Bisailon's research showed many parties involved with manufacturing, adding to its complexity. He found that legal suits are widespread and increasing such as the Ohio lawsuit, which filed for a jury instead of a judge trial. He also discussed a case with an insurance firm in the northeast, which found that when asked to cover costs of less addictive but just as effective drugs, companies were less likely to do so if the expense was higher. Dr. Bisailon feels that Big Pharma is heading in a direction that will eventually force the federal government to deal with them like they had to deal with the tobacco industry. He thinks the outcome of his research will be based on the proven facts for the cases he is following. Dr. Bisailon recommends continuing to follow updates from other government organizations and continuing to support legislation that expands actions to address the opioid crisis.

Mr. Meshad stated that until manufacturers have incentive to do better for the public, he feels this will be an ongoing issue. He expressed his frustration in lethal drugs being easily available to the public and suggested focusing on alternative drug therapy as a recommendation. Dr. Mikhael informed Mr. Meshad that this was a discussion at the first multi-board meeting and agreed that it should be a continued discussion.

Mr. Philip stated that depending on the type of pain, Physicians tend to choose opioids because other medications may require pre-authorization through insurance companies and Physicians do not want to jump through those hoops due to the time involved, to which Mr. Meshad agreed also needs to be addressed.

### **Better Use of PDMP:**

Dr. Mikhael recalled hearing at the August meeting that there is funding for the PDMP. Rebecca Poston, Program Director for the Prescription Drug Monitoring Program, confirmed this and clarified where the PDMP receives its funding, which was primarily through grants and donations but is now through the legislator, where they receive recurring funds of \$500,000. Ms. Poston added that they would like to undergo system enhancements so they are requesting 1.5 million (an addition of 1 million to what they already receive) to cover scope and labor. Mr. Meshad stated that he felt it is very important to integrate to electronic medical records and thanked Ms. Poston for their hard work.

Mr. Meshad concluded that the recommendation should be to emphasize the importance of using the PDMP at a prescribing and dispensing level. Mr. Meshad asked about using money from the board trust funds towards the PDMP, to which Mr. Flynn pointed out that a legislative opportunity could allow use of \$1 from every licensing fee. Mr. Meshad agreed with that recommendation and assumed the request would need to come from the Governor's office or the Department of Health.

## **Mandatory Counseling:**

Dr. Alvarez reviewed language from all 50 states regarding mandatory counseling for opioids. Though no states required this, he reported the number of states that require counseling and the type of counseling used.

Dr. Mikhael expressed that he felt this topic could have the biggest impact at the multi-board meeting due to the importance of ensuring patients know how their prescriptions should be handled. He further stated that he did not feel this would be effective unless mandated.

Dr. Alvarez informed Mr. Flynn that he sent proposed language regarding counseling to Ms. Lake, to which Mr. Flynn agreed to review in comparison to the current dispensing requirements within rule. Dr. Mesaros pointed out that different settings should be considered when updating this section of the rule.

Fritz Hayes, a former board member, informed the committee that in regards to counseling, some states have established repositories of information such as websites that patients can visit to learn more about medication, misuse, and addiction. Ms. Poston handed out pamphlets to the committee to show another example of a medium that can be used.

Bob Parrado, a former board member, informed the committee that Rule 64B16-27.810, FAC already refers to mandatory counseling.

Mr. Philip informed the committee that Mandatory Escribe for controlled substances is something that will require legislative change, in which 6 states already do through statute and 5 states have legislation introduced. Mr. Philip stated that based on data from states that already use this, mandatory escribe would create a positive impact for everyone in saving time. Mr. Meshad agreed that this recommendation should be made at the multi-board meeting.

Discussion ensued regarding the feasibility of making all prescriptions electronic with Dr. Weizer and Ms. Rivera explaining the difficulty of this due to how electronic prescriptions are set up and the amount of data that would need to be converted.

## **Better Access to Rehab:**

Ms. Rebecca Poston provided the committee with a pamphlet that Dr. Weizer referred to, in which she discussed the last item listed. Dr. Weizer informed the committee that the federal government has one state agency in every state cover substance abuse and mental health, which is the Department of Children and Families for Florida. She suggested adding a link of the DOH Substance Abuse webpage to the board website, which provides additional links to information through DCF and the federal government. A link can be found on the board website in the "Resources" tab, under "Controlled Substances / Opioid Information" and below:

<http://www.floridahealth.gov/programs-and-services/prevention/substance-abuse/index.html>

Mr. Meshad thanked Mr. Weizer and suggested eventually adding this information into continuing education so Pharmacists can easily provide resources to patients who may need help. Dr. Weizer and Mr. Meshad agreed that the link could also benefit prescribers if it were posted to the Board of Medicine and Osteopathic Medicine websites.

## **Pharmacy CS Mandatory CE:**

Mr. Flynn informed the committee that language to make the education mandatory was added in his proposed amendments for Rule 64B16-27.831, FAC. but believes the length of time and substance of the education should be a discussion for the multi-board meeting. Mr. Meshad suggested having the board review the proposed amendments for discussion during full board. Dr. Mesaros asked if it would be beneficial to table this rule until the December meeting, after possible legislative changes and discussion at the multi-board meeting. Mr. Meshad tabled the discussion.

## **499 Disposals of Medication:**

Mr. Philip recognized Drew Winters, the Director for the Division of Drugs, Devices, and Cosmetics with DBPR, for assisting him with this subject. Mr. Philip informed the board that Florida does not have specific statutes related to drug take-back programs, but the DEA has rules to help reduce the risk of diversion or harm. He listed the take-back methods and who may participate.

Mr. Meshad asked how many collectors were in the state, which Mr. Philip did not have an answer to, though he stated his organization collected 72-tons of disposed medication over the last 12 months.

Mr. Philip informed the committee that there are Florida statutes and rules that cover reverse distributors, but they only refer to drugs not suitable for dispensing and not take-back programs. Mr. Philip did, however, point out that there is language deferring to DEA rules in the event of a conflict. Mr. Winters confirmed this and further explained that section 499.0121, FS, has certain record-keeping requirements, but since the DEA designates collectors and applicable license types, DBPR follows those recommendations.

Mr. Philip recommended stating at the multi-board meeting that Florida doesn't have obstacles in regards to collecting waste so anyone can participate as long as they are complying with the DEA rules.

Dr. Alvarez pointed out potential barriers with HIPAA, regarding the DEA's silence on pharmacists' responsibility when patients who throw their whole vial in the take-back container, and with costs, regarding who should pay for the destruction of the drugs. Mr. Philip stated that many local governments are mandating take-back programs but if Florida continues to see enough volunteers, they should not have to. He further suggested reaching out to manufacturers for funding to mitigate the cost-barrier.

Dr. Weizer pointed out that the DEA website provides education to patients on how they can destroy left-over prescriptions themselves and suggested this could be discussed during Pharmacist-Patient counseling.

Mr. Meshad suggested that if less drugs were prescribed in the first place; this could be less of an issue. Dr. Alvarez stated that education on this would be easier if all pharmacies participated in drug take-back, making the process more accessible. Dr. Weizer agreed with Dr. Alvarez, providing the example that there are only 20 take-back pharmacies between Palm Springs and South Ft. Lauderdale.

## **DEA Changes:**

Dr. Mesaros recommended that communication needs to improve between the DEA, the Board of Pharmacy, stakeholders of the multi-board meeting, and stakeholders of respective professions. He further suggested that the DEA needs to be more consistent with their answers across the country and their laws need updating to make it easier for the right patients to get their medication.

Mr. Meshad stated that a finalized list of recommendations for the multi-board meeting will be reviewed in full board.

## **2. Presentations / Remarks/ Comments:**

### **a. Gary White, MPH, CPH - Associate Director, Hillsborough County Anti-Drug Alliance**

#### **Discussion:**

Mr. White thanked the committee for allowing him to attend and provided a brief PowerPoint presentation on Medication Assisted Treatment (MAT) in the Opiate Epidemic. Mr. Meshad thanked Mr. White for his time.

## **Break: 10:22 a.m. – 10:38 a.m.**

### **b. Drew Winters, Esq. - Director, Division of Drugs, Devices and Cosmetics / Department of Business & Professional Regulation**

Before the next presentation, Mr. Meshad welcomed Blanca Rivera, the newest board member, to her first meeting.

#### **Discussion:**

Mr. Winters thanked the committee for inviting him to speak and offered to answer any questions. Mr. Philip informed the committee that he participates on the Drug Wholesale Distributor Advisory Council as a Pharmacy representative, which was appointed under DBPR. Mr. Winters stated that the Drug Wholesale Distributor Advisory Council helps DBPR to better understand and regulate the drug-supply chain. He informed the committee that this council meets quarterly to discuss items and issues related to drug-supply chain regulation and that DBPR licenses under 11,000 individuals both in and out of state who ship drugs throughout Florida. Mr. Meshad thanked Mr. Winters for his time and asked him to send any future information related to the committee's discussion to board staff for the next agenda.

### **c. Rebecca R, Poston, BPharm, MHL, FCCM - Program Director, E-FORCSE - Florida's Prescription Drug Monitoring Program**

#### **Discussion:**

Ms. Poston provided a brief PowerPoint presentation and some statistics from the PDMP annual report as a snapshot of what is happening. One statistic she gave is that over 7.8 million people are in the PDMP system in Florida, which has a population of 20 million,

implying that almost half of the state uses controlled substances. Ms. Poston thanked the committee for allowing her to present. Mr. Meshad thanked Ms. Poston for her presentation and for all her hard work. Ms. Poston informed the committee that she will be presenting at the multi-board meeting in November.

### **3. Rule 64B16-27.831, F.A.C. – The Standards of Practice for the Filing of Controlled Substances Prescriptions; Electronic Prescribing; Mandatory Education.**

#### Discussion:

Mr. Meshad invited Mr. Flynn to provide a brief overview of the changes made to Rule 63B16-27.831, FAC. Mr. Flynn informed the committee that the proposed changes made are a result of their discussion from the August meeting and the last Legislative Committee meeting. The following changes were discussed:

- (6)(a) – after the biennium on September 30, 2019, “Validation of Prescriptions for Controlled Substances” must be taken as a live-interactive or in-person CE course.
- (6)(b) – a 1-hour CE course on Opioid Addiction Prevention must be taken
- (6)(c) – credit will be awarded to applicants for licensure who took courses within (6)(a) and (6)(b) at an accredited pharmacy school
- (6)(d) – courses within (6)(a) and (6)(b) count towards the required 30 hours of CEs for renewal and 10 hours of CEs that must be live.

Mr. Meshad asked if the committee agreed with making “Validation of Prescriptions for Controlled Substances” a live course. Dr. Mesaros stated that he learns more effectively through home-based courses because he can move at his own pace. Ms. Rivera agreed with Dr. Mesaros through an example of her own experience. Dr. Mikhael stated that he learns better live and believes that everyone learns differently and the option should be left to the practitioner.

Michael Jackson, Executive Vice-President and CEO of the Florida Pharmacy Association, pointed out that there are licensees living out of state, potentially making the live-requirement difficult. He also stated that all live courses may not be similar and therefore may not all teach at the standards the committee expects.

Philip remarked that Florida is one of the few states that has such prescriptive CE requirements in comparison to other states that leave it up to Pharmacists to determine what they need, based on their practice setting. Mr. Jackson agreed with Mr. Philip and thanked the committee for their continued efforts in progressing continuing education.

Dr. Weizer stated that this year, she attended live validation programs with FSHP and a regional society. She added that both addressed many items such as opiate prevention and counseling. Dr. Weizer also said she has approved some of these programs as a member of the Tripartite company and explained what she looks for in their education curriculum.

Mr. Meshad suggested refining the definition for the validation course instead of requiring a separate course for addiction prevention, which Dr. Weizer agreed with.

Bob Parrado, a former board member, added that education should not just cover addiction prevention, but should also include treatment. He informed the board that he has been working on

a CE course which will include prevention, treatment, resources for counseling, and disposal methods. Mr. Meshad recognized Mr. Parrado for evolving his program, which everyone should do.

Mr. Jackson stated that he believed programs should include education informing pharmacists where they can refer patients for help with addiction or other problems. Mr. Meshad agreed with Mr. Jackson.

Mr. Philip recommended placing this on the agenda for the next meeting so potential topics for a revised course could be gathered. He further suggested asking stakeholders to provide what that content should look like. Mr. Meshad agreed and added PRN as a resource to reach out to since they are experts on the counseling side.

Mr. Flynn stated that he would leave the rule as-is and add course content. Mr. Meshad agreed and asked anyone with suggestions to send their material to board staff for the December agenda. Mr. Philip asked if the new CE requirements should be effective as soon as possible or after the biennium. It was decided that this would be discussed at a later date.

A motion was made by Philip to open Rule 64B16-27.831, FAC. for development. Motion passed unanimously.

#### **4. Old Business / New Business**

None.

#### **5. Public Comment**

None.

#### **6. Adjournment**

The meeting adjourned at 11:28 a.m.