

**Joint Committee on Controlled Substances  
September 21, 2018  
Rosen Plaza Hotel  
9700 International Drive  
Orlando, Florida 32819**

**MEETING MINUTES**



**Board of Medicine**

Jorge Lopez, M.D.  
Hector Vila, M.D.  
Stephanie Haridopolos, M.D.  
Executive Director: Claudia Kemp, J.D.  
Board Counsel: Edward Tellechea, Esquire



**Board of Osteopathic Medicine**

Joel Rose, D.O.  
Sandra Schwemmer, D.O.  
Michelle Mendez, D.O.  
Executive Director: Kama Monroe, J.D.  
Board Counsel: Donna McNulty, Esquire



**Board of Dentistry**

T.J. Tejera, D.M.D., M.D.  
Naved Fatmi, D.M.D.  
Executive Director: Jennifer Wenhold, MSW  
Board Counsel: David Flynn, Esquire



**Board of Nursing**

Mary Julie Talmadge, D.N.P., A.R.N.P.  
Diane Forst, B.A., R.N. (Alternate)  
Executive Director: Joe Baker, Jr.  
Board Counsel: Debra Loucks, Esquire



**Board of Optometry**

Chris King, O.D.  
Steve Kepley, O.D. (Alternate)  
Executive Director: Anthony Spivey, D.B.A.  
Board Counsel: Lawrence Harris, Esquire



**Board of Pharmacy**

Jeenu Philip, BPharm  
Jeffrey Mesaros, PharmD, J.D.  
Jonathan Hickman, PharmD (Alternate)  
Executive Director: Erica White, M.B.A., J.D.  
Board Counsel: David Flynn, Esquire



**Board of Podiatric Medicine**

Mark Block, D.P.M.  
Soorena Sadri, D.P.M.  
Executive Director: Erica White  
Board Counsel: Mary Ellen Clark, Esquire

**Council on Physician Assistants**

Dayne Alonso, P.A.C.

**Staff Present:**

Jessica Sapp, Program Operations Administrator  
Nancy Murphy, Certified Paralegal  
Stephanie Loughmiller, Administrative Assistant

**Court Reporter:**

American Court Reporting  
Suzette Bragg Peterson  
425 Old Magnolia Rd.  
Crawfordville, FL 32327  
(850) 421-0058  
Braggd1@aol.com

The meeting was called to order by Dr. Vila at 1:00 p.m. EST.

Ms. Kemp opened the meeting and Dr. Vila thanked the committee specifically for the work that was put into the rule draft on standards for the prescribing of controlled substances for the treatment of acute pain.

The committee considered the proposed draft attached as Exhibit A.

The committee suggested placing a period after “guardian” and strike the remainder of the sentence in line 32.

Motion: by Dr. Tejera to amend the language as suggested  
Second: by Dr. Haridopolos  
Vote: Unanimous

The committee suggested removing “being” in line 43 and replace “in” with “of” in line 45.  
Motion: by Dr. Vila to amend the language as suggested  
Motion: by Dr. Tejera  
Vote: Unanimous

Dr. Black suggested the committee strike “requires” and replace with “are a greater risk and should be assessed to determine if they require...” in line 51.  
There was not a second to the motion so the language remains as drafted.

Motion: by Dr. Schwemmer to accept the draft rule as originally proposed  
Second: by Dr. Lopez  
Vote: Unanimous

The committee took public comment from Mr. Parrado and he expressed concerns in long term care facility in regards to having to check the PDMP each time for chronic patients. Dr. Vila informed him that would require legislative change. Dr. Mendez believes that it isn't arduous to ask the physician to follow the requirements. Dr. Vila reminded Mr. Parrado that checking the PDMP can be delegated to a designee.

Dr. Lopez believes what the committee is doing has a positive impact on the community.

Ms. McNulty referred back to line 32 of the rule draft and suggested the committee track the language in the statute.

Motion: by Dr. Schwemmer to reconsider and leave the rule language as presented so that it tracks the statute.

Second: by Dr. Vila  
Vote: Unanimous

Ms. McNulty stated the draft language will be presented to the different boards at their next board meetings.

There being no further business, the meeting adjourned at 1:35 p.m.

## CONTROLLED SUBSTANCE DRAFT RULE LANGUAGE – 6/21/18

**DRAFT VERSION OF 64B8-9.013 FOLLOWING CONSIDERATION BY THE JOINT BOARDS****64B8-9.013 Standards for the Prescribing Use of Controlled Substances for the Treatment of Acute Pain.**

The standards of practice in this rule do not supercede the level of care, skill and treatment recognized in general law related to healthcare licensure. All physicians and physician assistants who are authorized to prescribe controlled substances shall comply with the following:

## (1) Definitions.

(a) Acute Pain. For the purpose of this rule, “acute pain” is defined as the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness. The term does not include pain related to:

1. Cancer.

2. A terminal condition. For purposes of this subparagraph, the term “terminal condition” means a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered to be reversible without the administration of life-sustaining procedures, and will result in death within 1 year after diagnosis if the condition runs its normal course.

3. Palliative care to provide relief of symptoms related to an incurable, progressive illness or injury.

4. A traumatic injury with ~~an~~ Injury Severity Score of 9 or greater.

(b) Prescription Drug Monitoring System. For the purpose of this rule, the prescription drug monitoring system is defined as the Florida Department of Health’s electronic system to collect and store controlled substance dispensing information as set forth in Section 893.055, F.S.

(c) Substance Abuse. For the purpose of this rule, “substance abuse” is defined as the use of any substances for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

(2) Standards. The nature and extent of the requirements set forth below will vary depending on the practice setting and circumstances presented to the clinician. The Board has adopted the following standards for the prescribing use of controlled substances for acute pain:

(a) Evaluation of the Patient. A focused medical history and physical examination appropriate for the patient’s clinical condition must be conducted and documented in the medical record. The medical record also shall document the presence of one or more recognized medical indications for the use of a controlled substance.

27 (b) Treatment Plan. The written treatment plan shall indicate if any further diagnostic evaluations or other  
28 treatments are planned including non-opioid medications and therapies if indicated. After treatment begins, the  
29 physician shall adjust ~~medication drug~~ therapy, if necessary, to the individual medical needs of each patient.

30 (c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks and benefits of the  
31 use of controlled substances including the risk of abuse and addiction as well as physical dependence with the  
32 patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent.  
33 The discussion shall also include expected pain intensity, duration, options, use of pain medications, ~~non-medication~~  
34 ~~therapies, and common side effects. Special attention must be given to those pain patients who are at risk of misuse~~  
35 ~~or diversion of their medications. If the patient is determined to be at high risk for medication abuse or have a~~  
36 ~~history of substance abuse, the physician shall employ the use of a written agreement between physician and patient~~  
37 ~~outlining patient responsibilities, including, but not limited to:~~

- 38 ~~1. Urine/serum medication levels screening when indicated;~~
- 39 ~~2. Number and frequency of all prescription refills; and,~~
- 40 ~~3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement).~~

41 (d) Periodic Review. Based on the ~~individual~~ circumstances ~~presented~~ ~~of the patient~~, the physician shall review  
42 the course of treatment and any new information about the etiology of the pain. Continuation or modification of  
43 therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being  
44 achieved, despite medication adjustments, the physician shall reevaluate the patient and determine the  
45 appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage and  
46 related treatment plans.

47 (e) Consultation. The physician shall refer the patient as necessary for additional evaluation and treatment in  
48 order to achieve treatment objectives. ~~Special attention must be given to those pain patients who are at risk or~~  
49 ~~misusing or diverting their medications and those whose living arrangements pose a risk for medication misuse or~~  
50 ~~diversion.~~ The management of pain in patients with a history of substance abuse or with a comorbid psychiatric  
51 disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an  
52 expert in the management of such patients.

53 (f) Medical Records. The physician is required to keep accurate and complete records to include, but not be  
54 limited to:

- 55 1. The ~~focused~~ medical history and a physical examination, including history of drug abuse or dependence, if  
56 indicated,
- 57 2. Diagnostic, therapeutic, and laboratory results,
- 58 3. Evaluations and consultations,
- 59 4. Treatment objectives,
- 60 5. Discussion of risks and benefits,
- 61 6. Treatments,
- 62 7. Medications (including date, type, dosage, and quantity prescribed),
- 63 8. Instructions and agreements,
- 64 9. Drug testing results if indicated;
- 65 10. Justification for deviation from the 3-day prescription supply limit **for a Schedule II controlled substance**  
66 for acute pain;
- 67 11. Outline of problems encountered when attempting to consult the Prescription Drug Monitoring **Program**  
68 ~~System~~ (PDMP) **or its successor**, if the system was non-operational or the clinician, or his or her designee, is unable  
69 to access the PDMP due to a temporary technological or electrical failure; and
- 70 12. Periodic reviews. Records must remain current, maintained in an accessible manner, readily available for  
71 review, and must be in full compliance with Rule 64B8-9.003, F.A.C, Section 456.057, F.S., and Section  
72 458.331(1)(m), F.S.
- 73 (g) Compliance with Laws and Rules. Physicians and physician assistants shall at all times, remain in  
74 compliance with this rule and all state and federal laws and regulations addressing the prescribing and  
75 administration of controlled substances.

Rulemaking Authority 458.309(1), 458.331(1)(v) FS. Law Implemented 458.326, 458.331(1)(g), (t), (v) FS. History—New 12-21-  
99, Amended 11-10-02, 10-19-03, 10-17-10, .