64B8-9.013 Standards for the Prescribing of Controlled Substances for the Treatment of Acute Pain.

The standards of practice in this rule do not supersede 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 Program (PDMP) or "the 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 of controlled substances for acute pain:

(a) Evaluation of the Patient. A 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.

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

(c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks and benefits of the use of controlled substances including the risk of abuse and addiction as well as physical dependence with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The discussion shall also include expected pain intensity, duration, options, use of pain medications, non-medication therapies, and common side effects. Special attention must be given to those pain patients who are at risk of misuse or diversion of their medications.

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

(e) Consultation. The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

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

1. The medical history and a physical examination, including history of drug abuse or dependence, if indicated;

2. Diagnostic, therapeutic, and laboratory results;

3. Evaluations and consultations;

4. Treatment objectives;

5. Discussion of risks and benefits;

6. Treatments;

7. Medications (including date, type, dosage, and quantity prescribed);

8. Instructions and agreements;

9. Drug testing results if indicated;

10. Justification for deviation from the 3-day prescription supply limit for a Schedule II opioid controlled substance for acute pain;

11. Outline of problems encountered when attempting to consult the Prescription Drug Monitoring Program (PDMP) or its successor, if the system was non-operational or the clinician, or his or her designee, is unable to access the PDMP due to a temporary technological or electrical failure; and

12. Periodic reviews. Records must remain current, maintained in an accessible manner, readily available for review, and must be in full compliance with rule 64B8-9.003, F.A.C., section 456.057, F.S., and section 458.331(1)(m), F.S.

(g) Compliance with Laws and Rules. Physicians and physician assistants shall at all times, remain in compliance with this rule and all state and federal laws and regulations addressing the prescribing and administration of controlled substances.

Rulemaking Authority 456.44(4), 458.309(1), 458.331(1)(v) FS. Law Implemented 456.44, 458.326, 458.331(1)(g), (t), (v) FS. History–New 12-21-99, Amended 11-10-02, 10-19-03, 10-17-10, 2-21-19.