Florida Osteopathic Board Regulations

TITLE 64 DEPARTMENT OF HEALTH
DIVISION 64B15 BOARD OF OSTEOPATHIC MEDICINE
CHAPTER 64B15-14 PRACTICE REQUIREMENTS

64B15-14.005 Standards for the Use of Controlled Substances for Treatment of Pain.

(1) Pain management principles.

(a) The Board of Osteopathic Medicine recognizes that principles of quality medical practice dictate that the people of the State of Florida have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages osteopathic physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All osteopathic physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from an osteopathic physician's lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Osteopathic physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances including opioid analgesics, for a legitimate medical purpose and that is supported by appropriate documentation establishing a valid medical need and treatment plan. Accordingly, these guidelines have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. Osteopathic physicians are referred to the U.S. Agency for Health Care Policy and Research Clinical Practice Guidelines for a sound approach to the management of acute and cancer-related pain. The medical management of pain including intractable pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Osteopathic physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board of Osteopathic Medicine is obligated under the laws of the State of Florida to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Osteopathic physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(e) The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

(f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against an osteopathic physician for failing to adhere strictly to the provisions of these guidelines, if good cause is shown for such deviation. The osteopathic physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

(g) The Board will judge the validity of prescribing based on the osteopathic physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including

physical, psychological, social, and work-related factors. The following guidelines are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

(2) Definitions.

(a) Acute Pain. For the purpose of this rule, "acute pain" is defined as the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma, and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

(b) Addiction. For the purpose of this rule, "addiction" is defined as a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(c) Analgesic Tolerance. For the purpose of this rule, "analgesic tolerance" is defined as the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(d) Chronic Pain. For the purpose of this rule, "chronic pain" is defined as a pain state which is persistent.

(e) Pain. For the purpose of this rule, "pain" is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(f) Physical Dependence. For the purpose of this rule, "physical dependence" on a controlled substance is defined as a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(g) Pseudoaddiction. For the purpose of this rule, "pseudoaddiction" is defined as a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

(h) 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.

(i) Tolerance. For the purpose of this rule, "tolerance" is defined as a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

(3) Guidelines. The Board has adopted the following guidelines when evaluating the use of controlled substances for pain control:

(a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record shall document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. 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 state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the osteopathic physician shall adjust drug therapy, if necessary, to the individual medical needs of each patient. Other treatment modalities, including osteopathic manipulative treatment and applications, or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(c) Informed Consent and Agreement for Treatment. The osteopathic physician shall discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The patient shall receive prescriptions from one osteopathic physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the osteopathic physician shall employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:

1. Urine/serum medication levels screening when requested;

2. Number and frequency of all prescription refills; and

3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement).

(d) Periodic Review. Based on the individual circumstances of the patient, the osteopathic 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 osteopathic physician's evaluation of progress toward stated treatment objectives such as improvement in patient's pain intensity and improved physical and/or psychosocial function, i.e., ability to work, need of health care resources, activities of daily living, and quality of social life. If treatment goals are not being achieved, despite medication adjustments, the osteopathic physician shall reevaluate the appropriateness of continued treatment. The osteopathic physician shall monitor patient compliance in medication usage and related treatment plans.

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

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

1. The complete medical history and a physical examination, including history of drug abuse or dependence, as appropriate;

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; and

10. Periodic reviews. Records must remain current, maintained in an accessible manner, readily available for review, and must be in full compliance with *Rule 64B15-15.004*, F.A.C., and *Section 459.015(1)(o), F.S.*

(g) Compliance with Controlled Substances Laws and Regulations. To prescribe, dispense, or administer controlled substances, the osteopathic physician must be licensed in the state and comply with applicable federal and state regulations. Osteopathic physicians are referred to the Physicians Manual: An Informational Outline of the Controlled Substances Act of 1970, published by the U.S. Drug Enforcement Agency, for specific rules governing controlled substances as well as applicable state regulations.