

1 **64B8-9.0131 Standards of Practice for Physicians Practicing in Pain Management Clinics.**

2 **64B15-14.012 Standards of Practice for Physicians Practicing in Pain Management Clinics.**

3 (1) Definitions.

4 (a) Controlled Substance. **(need definition)**

5 (b) Adverse Incidents. **(need definition)** Those incidents set forth in Section  
6 458.351(4)/459.026(4), Florida Statutes, and . . . **need to expand definition ??????**

7 (c) Collector.

8 (2) Standards of Practice in Pain Management Clinics.

9 (a) Evaluation of Patient and Medical Diagnosis. A complete medical history and  
10 physical examination must be conducted and documented in the medical record prior to  
11 commencement of any treatment. The medical record shall document the nature and intensity of  
12 the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the  
13 effect of the pain on physical and psychological function, a review of prior medical records,  
14 previous diagnostic studies, and history of alcohol and substance abuse. The medical record  
15 shall also document the presence of one or more recognized medical indications for the use of a  
16 controlled substance.

17 **OPTION FOR DISCUSSION: (a) Evaluation of Patient and Medical Diagnosis.**

18 **Prior to prescribing or dispensing controlled substances, the patient record must**

19 **include documentation of a complete medical history, physical examination, and**

20 **diagnosis made within 60 days prior to the presentation of the patient at the clinic**

21 **by a licensed physician not practicing or having any financial or ownership interest**

22 **with the pain management clinic or the patient record must include a written**

23 **referral for treatment made by a Florida licensed physician not practicing or having**

1           **any financial or ownership interest with the pain management clinic, which was**  
2           **provided within 60 days prior to the presentation of the patient at the pain clinic.**  
3           **The record shall also include a complete history and physical of the patient by the**  
4           **physician prescribing or dispensing controlled substances to the patient at the pain**  
5           **clinic prior to commencement of any treatment. The medical record shall document**  
6           **the nature and intensity of the pain, current and past treatments for pain,**  
7           **underlying or coexisting diseases or conditions, the effect of the pain on physical and**  
8           **psychological function, a review of prior medical records, previous diagnostic**  
9           **studies, and history of alcohol and substance abuse. The medical record shall also**  
10          **document the presence of one or more recognized medical indications for the use of**  
11          **a controlled substance.**

12          (b) Treatment Plan. The written individualized treatment plan shall state objectives that  
13 will be used to determine treatment success, such as pain relief and improved physical and  
14 psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments  
15 are planned. After treatment begins, the physician shall adjust drug therapy to the individual  
16 medical needs of each patient. Other treatment modalities or a rehabilitation program shall be  
17 considered depending on the etiology of the pain and the extent to which the pain is associated  
18 with physical and psychosocial impairment.

19          (c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks  
20 and benefits of the use of controlled substances with the patient, persons designated by the  
21 patient, or with the patient's surrogate or guardian if the patient is incompetent. The physician  
22 shall employ the use of a written agreement between physician and patient outlining patient  
23 responsibilities, including, but not limited to:

1           1. Urine/serum medication levels screening to be conducted prior to the initial issuance of  
2 a controlled substance prescription, and thereafter, on a random basis at least twice a year and  
3 when requested by the treating physician;

4           2. Number and frequency of all prescription refills;

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

6           4. Agreement that controlled substances for the treatment of chronic nonmalignant pain  
7 shall be prescribed by a single treating physician unless otherwise authorized by the treating  
8 physician and documented in the medical record.

9           (d) Periodic Review. The patient shall be seen by the physician at regular intervals, not  
10 to exceed three months, to assess the efficacy of treatment, assure that controlled substance  
11 therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider  
12 adverse drug effects and review the etiology of the pain. Continuation or modification of therapy  
13 shall depend on the physician's evaluation of the patient's progress. If treatment goals are not  
14 being achieved, despite medication adjustments, the physician shall reevaluate the  
15 appropriateness of continued treatment. The physician shall monitor patient compliance in  
16 medication usage, related treatment plans, and indications of substance abuse or diversion.

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

1 (f) Patient urine/serum medication levels screenings conducted in pain-management  
2 clinics as set forth in subsection (2)(c) of this rule shall be performed in accordance with the  
3 following collection procedures:

4 1. Patient urine shall be collected in a room occupied solely by the person providing the  
5 urine sample.

6 2. Before each collection, to deter potential tampering, adulterating, alteration, or  
7 substitution of the specimen, the following shall occur:

8 a. Bluing agent (coloring) shall be placed in all the toilets, toilets lids shall be securely  
9 shut or security tape shall be placed over the toilet lid to prevent or detect opening;

10 b. Water sources shall be secured or otherwise made unavailable to the patient by  
11 turning off the water inlet or placing security tape over the tap handles and faucets to prevent or  
12 detect opening;

13 c. Soap, disinfectants, cleaning agents, or other possible adulterants shall be removed  
14 from the facility;

15 d. The facility shall be inspected to ensure that no foreign or unauthorized substances  
16 are present;

17 e. Ensure that access through another door or window is not possible; and

18 f. Secure areas and items such as ledges, trash receptacles, paper towel holders, and  
19 under sink areas to ensure that contaminants or adulterants have not been concealed.

20 3. Prior to entering the urination facility to provide the specimen, the patient shall be  
21 asked to remove any unnecessary outer clothing such as coats, jackets, hats, and sweaters, and to  
22 leave any briefcase, purse, or other personal belongings he or she is carrying with the outer

1 clothing. The patient shall then empty his or her pockets and display the items to ensure that no  
2 items are present that can be used to adulterate the specimen.

3 4. Before providing the specimen the patient shall wash his or her hands with liquid or  
4 cream soap and dry his or her hands under observation. The patient may not wash his or her  
5 hands again until after the specimen is provided to the collector. The patient must not be  
6 allowed any further access to water or other materials that can be used to be put into the  
7 specimen.

8 5. The collector shall provide the patient with a collection container and the patient will  
9 be required to either unwrap the container or break the seal in the presence of the collector. The  
10 collector shall then direct the patient to enter the urination facility, provide a sample of at least 45  
11 ml, not to flush the toilet, and return with the specimen as soon as possible.

12 6. After the patient provides the specimen to the collector, the collector must check the  
13 specimen temperature, volume and inspect it for unusual color and to make sure that it was not  
14 adulterated, substituted, tampered with or contains foreign objects or material. The temperature  
15 shall be checked and recorded as soon as the patient hands the specimen over but no later than  
16 four (4) minutes after the patient exits the urination facility. The acceptable temperature range is  
17 32°-38°C/90°-100°F and it is determined by reading the temperature strip originally affixed to or  
18 placed on the outside of the collection container.

19 7. Once the specimen is provided in accordance with the above provisions, the  
20 specimen shall then be secured and delivered to a Clinical Laboratory Improvement  
21 Amendments (CLIA) approved laboratory entity for analysis and testing if the physician is not  
22 using a CLIA waived test.

1           8. Nothing in this rule shall preclude a pain-management clinic from employing  
2 additional measures to assure the integrity of the urine specimens provided by patients.

3           9. In lieu of following the above procedures, the patient may be sent directly to CLIA  
4 approved laboratory entity to provide the specimen for analysis and testing.

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

7           1. The medical history and physical examination, including history of drug abuse or  
8 dependence;

9           2. Diagnostic, therapeutic, and laboratory results;

10          3. Evaluations and consultations;

11          4. Treatment objectives;

12          5. Discussion of risks and benefits;

13          6. Treatments;

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

15          8. Instructions and agreements;

16          9. Periodic reviews;

17          10. Urine/serum medication levels screening results;

18          11. A photocopy of the patient's government issued photo identification; and

19          12. If a written prescription is given to the patient, a duplicate of said prescription must  
20 be maintained in the patient's medical record.

21          13. Pain management clinic physician medical records shall contain the physician's full  
22 name presented in a legible manner along with a corresponding sample signature and initials.

23

1           **OPTION FOR DISCUSSION: 14. The patient record shall include on a separate**  
2 **document if the patient and the primary care provider or physician that made the**  
3 **diagnosis of the condition, injury or disease that pain management is being provided for,**  
4 **are both located outside of Florida. The number of such records meeting this condition**  
5 **shall be included in the reports provided to the Department as described in section**  
6 **\_\_\_\_\_.**

7 Records must remain current, they must be maintained in an accessible manner and readily  
8 available for review and must be in full compliance with (Rule 64B8-9.003, F.A.C./Rule 64B15-  
9 15.004, F.A.C.), and (Section 458.331(1)(m)/Section 459.015(1)(o), F.S.) .

10           **(h) Denial or Termination of Controlled Substance Therapy.**

11           **1. If a patient’s initial patient urine/serum medication levels screenings reflect the**  
12 **presence of controlled substances, other than medications reflected in the patient medical**  
13 **record as being prescribed, the treating physician shall not prescribe or dispense any**  
14 **controlled substances unless or until there is written concurrence of medical necessity of**  
15 **continued controlled substance therapy provided by a board certified pain management**  
16 **physician and an addiction medicine specialist or psychiatrist.**

17           2. For patients currently in treatment by the physician or any other physician in the  
18 same pain management clinic, evidence or behavioral indications of substance abuse or diversion  
19 of controlled substances shall be followed by tapering and discontinuation of controlled  
20 substance therapy. Such therapy shall be reinitiated only after obtaining written concurrence of  
21 medical necessity of continued controlled substance therapy provided by a board certified pain  
22 management physician and an addiction medicine specialist or psychiatrist.

23           **(i) Facility and Physical Operations.**

1           1. A pain management clinic shall be located and operated at a publicly accessible fixed  
2 location and shall contain the following:

3           a. A sign that can be viewed by the public that contains the clinic name, hours of  
4 operations, and a street address;

5           b. A publicly listed telephone number and a dedicated phone number to send and  
6 receive faxes with a fax machine that shall be operational twenty-four hours per day;

7           c. Emergency lighting and communications;

8           d. Reception and waiting area;

9           e. Public toilet;

10          f. Administrative area including room for storage of medical records, supplies and  
11 equipment;

12          g. Private patient examination room(s);

13          h. Treatment room(s) if treatment is being provided to the patient;

14          i. A printed sign located in a conspicuous place in the waiting room viewable by the  
15 public disclosing the name and contact information of the clinic Medical Director or Designated  
16 Physician, and the names of all physicians practicing in the clinic;

17          j. Storage and handling of prescription drugs. Clinics that store and dispense  
18 prescription drug shall comply with Section 499.0121, Florida Statutes, Section 893.07, Florida  
19 Statute, and Rule 64F-12.012, Florida Administrative Code.

20          2. Nothing in this subsection shall excuse a physician from providing any treatment or  
21 performing any medical duty without the proper equipment and materials as required by the  
22 standard of care.

23          (j) Infection Control.

1           1. The clinic shall maintain equipment and supplies to support infection prevention and  
2 control activities.

3           2. The clinic shall identify infection risks based on the following:

4           a. Geographic location, community, and population served;

5           b. The care, treatment and services it provides; and

6           c. An analysis of its infection surveillance and control data.

7           3. The clinic shall maintain written infection prevention policies and procedures that  
8 address the following:

9           a. Prioritized risks;

10          b. Limiting unprotected exposure to pathogen;

11          c. Limiting the transmission of infections associated with procedures performed in the  
12 clinic; and

13          d. Limiting the transmission of infections associated with the clinics use of medical  
14 equipment, devices, and supplies.

15          (k) Health and Safety.

16           1. The clinic, including its grounds, buildings, furniture, appliances and equipment shall  
17 be structurally sound, in good repair, clean, and free from health and safety hazards.

18           2. The clinic shall have evacuation procedures in the event of an emergency which shall  
19 include provisions for the evacuation of disabled patients and employees.

20           3. The clinic shall have a written facility-specific disaster plan which sets forth actions  
21 that will be taken in the event of clinic closure due to unforeseen disasters which shall include  
22 provisions for the protection of medical records.

1           4. Each clinic shall have at least one employee on the premises during working hours  
2 that is certified in Basic Life Support and is trained in reacting to accidents and medical  
3 emergencies until emergency medical personnel arrive.

4           **5. ???? ACLS required for invasive procedures.**

5           **6. ???? Medicines or equipment required depending on services provided.**

6           (1) Quality Assurance. Each pain management clinic shall have an ongoing quality  
7 assurance program that objectively and systematically monitors and evaluates the quality and  
8 appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects  
9 deficiencies within the facility, alerts the Medical Director or Designated Physician to identify  
10 and resolve recurring problems, and provides for opportunities to improve the facility's  
11 performance and to enhance and improve the quality of care provided to the public. The Medical  
12 Director or Designated Physician shall establish a quality assurance program that includes the  
13 following components:

14           1. The identification, investigation, and analysis of the frequency and causes of adverse  
15 incidents to patients,

16           2. The identification of trends or patterns of incidents,

17           3. The development of measures to correct, reduce, minimize, or eliminate the risk of  
18 adverse incidents to patients, and

19           4. The documentation of these functions and periodic review no less than quarterly of  
20 such information by the treating physician.

21           5. The Quality Assurance program must be reviewed annually by a Florida-licensed risk  
22 manager and documentation of said annual review must be provided to the Department together  
23 with any corrective action plan within 30 days of the annual review and maintained for

1 inspection purposes.

2 (m) Training Requirements. Physicians prescribing controlled substance medications in  
3 pain-management clinics registered pursuant to Section 458.309(4)/459.005(4), Florida Statutes,  
4 must possess one or more of the following qualifications:

5 1. Board certification (**or Board eligible????**) in Pain Medicine/Management or  
6 Anesthesia by a board approved by the American Board of Medical Specialties or any other  
7 board approved specialty organization approved by the Board of Medicine/Board of Osteopathic  
8 Medicine and set forth in Rule 64B8-11.001(8), F.A.C./64B15-14.001, F.A.C.;

9 2. Successful completion of a post graduate training program in Pain  
10 Medicine/Management accredited by the Accreditation Council for Graduate Medical Education  
11 (ACGME)/American Osteopathic Association (AOA), College of Family Physicians of Canada  
12 (CFPC), or Royal College of Physicians and Surgeons in Canada (RCPSC) ;

13 3. Fifty (50) hours (???) per year of category I American Medical  
14 Association/American Osteopathic Association continuing medical education in Pain  
15 Medicine/Management; (EFFECTIVE DATE???) or

16 4. Current staff privileges at a Florida licensed hospital to practice pain medicine or  
17 perform pain medicine procedures.

18 (n) Data Collection and Reporting.

19 1. Reporting of adverse incidents. The Medical Director or Designated Physician for  
20 each pain-management clinic shall report all adverse incidents to the Department of Health as set  
21 forth in Section 458.351/459.026, Florida Statutes. For purposes of this rule, however, the term  
22 “adverse incident” shall include those incidents set forth in Section 458.351(4)/459.026(4),  
23 Florida Statutes, and Rule 64B8-9.0131(1)(b)/64B15-14.012(1)(b), F.A.C.

1           2. The Medical Director or Designated Physician shall also report to the Board of  
2 Medicine/Board of Osteopathic Medicine/Department, in writing, on a quarterly basis the  
3 number of patients seen, both new and repeat patients and the number of patients discharged due  
4 to drug abuse or diversion.

5           3. All physicians practicing in pain-management clinics shall advise the Board of  
6 Medicine/Board of Osteopathic Medicine/Department in writing, within 15 days of beginning or  
7 ending his or her practice at a pain-management clinic.

8  
9 64B8-9.0133 Approval of Pain Management Clinic Accrediting Organizations.

10 Criteria for Accrediting Organizations (need input)

11 **List of national accrediting organizations recommended by the Committee**

12  
13 64B8-9.0132 Requirement for Pain Management Clinic Registration; Inspection or  
14 Accreditation

15       (1) Registration.

16       (a) Every Medical Director or designated physician of a pain management clinic, as  
17 defined in Section 458.309/459.005(4) and (5), Florida Statutes, shall register the clinic with the  
18 Department of Health. It is the Medical Director's or Designated Physician's responsibility to  
19 ensure that the clinic is registered, regardless of whether other physicians are practicing in the  
20 same office or whether the office is non-physician owned.

21       (b) In order to register a pain management clinic, the Medical Director or Designated  
22 Physician must comply with Department Rule 64B-4.005 and 64B-4.006, F.A.C., and provide  
23 documentation to support compliance with Rule 64B8-9.0131/64B15-14.012, F.A.C.

1 (c) The Medical Director or Designated Physician must notify the Department within 7  
2 calendar days, in writing, of any changes to the registration information.

3 (d) Documentation of registration shall be posted in a conspicuous place in the waiting  
4 room viewable by the public.

5 (2) Inspection

6 (a) Unless the Medical Director or Designated Physician has previously provided written  
7 notification of current accreditation by a nationally recognized accrediting agency approved by  
8 the Board the clinic shall submit to an annual inspection by the Department. All nationally  
9 recognized accrediting organizations shall be held to the same Board-determined practice  
10 standards for registering Florida pain management clinic sites.

11 (b) The inspection conducted pursuant to this rule shall be announced at least one week in  
12 advance of the arrival of the inspector(s). **???Prefer unannounced inspections?????**

13 (c) The Medical Director or Designated Physician shall cooperate with the inspector, make  
14 medical records available to the inspector, and be responsive to all reasonable requests.

15 (d) The Department shall determine compliance with the requirements of Rule 64B8-  
16 9.0131/64B15-14.012, F.A.C.

17 (e) If the clinic is determined to be in noncompliance, the Medical Director or Designated  
18 Physician shall be notified and shall be given a written statement at the time of inspection. Such  
19 written notice shall specify the deficiencies. Unless the deficiencies constitute an immediate and  
20 imminent danger to the public, the Medical Director or Designated Physician shall be given 30  
21 days from the date of inspection to correct any documented deficiencies and notify the  
22 Department of corrective action. Upon written notification from the Medical Director or  
23 Designated Physician that all deficiencies have been corrected, the Department is authorized to

1 re-inspect for compliance. If the Medical Director or Designated Physician fails to submit a  
2 corrective action plan within 30 days of the inspection, the Department is authorized to re-  
3 inspect the office to ensure that the deficiencies have been corrected.

4 (f) The deficiency notice and any subsequent documentation shall be reviewed for  
5 consideration of disciplinary action under any of the following circumstances:

6 1. When the initial notice of deficiencies contain deficiencies that constitute immediate  
7 and imminent danger to the public;

8 2. The Medical Director or Designated Physician fails to provide the Department with  
9 documentation of correction of all deficiencies within thirty (30) days from the date of  
10 inspection;

11 3. Upon a finding of noncompliance after a reinspection has been conducted pursuant to  
12 paragraph (2)(e) of this rule.

13 (g) Documentation of corrective action shall be considered in mitigation of any offense.

14 (h) Nothing herein shall limit the authority of the Department to investigate a complaint  
15 without prior notice.

16 (i) If the clinic is accredited by a nationally recognized accrediting agency approved by  
17 the Board, the Medical Director or Designated Physician shall submit written notification of the  
18 current accreditation survey of his or her office(s) in lieu of undergoing an inspection by the  
19 Department.

20 (j) The Medical Director or Designated Physician shall submit, within thirty (30) days of  
21 accreditation, a copy of the current accreditation survey of the clinic and shall immediately  
22 notify the Board of Medicine/Board of Osteopathic Medicine of any accreditation changes that  
23 occur. For purposes of initial registration, the Medical Director or Designated Physician shall

1 submit a copy of the most recent accreditation survey of the clinic in lieu of undergoing an  
2 inspection by the Department.

3 (k) If a provisional or conditional accreditation is received, the Medical Director or  
4 Designated Physician shall notify the Board of Medicine/Board of Osteopathic Medicine in  
5 writing and shall include a plan of correction.

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