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

THESE RULES ARE APPLICABLE ONLY TO PHYSICIANS WHO ARE TREATING PATIENTS BY PRESCRIBING OR DISPENSING CONTROLLED SUBSTANCES FOR THE TREATMENT OF CHRONIC NONMALIGNANT PAIN AT A PAIN MANAGEMENT CLINIC. FOR PURPOSES OF THIS RULE, THE PREVAILING STANDARD OF CARE FOR THE TREATMENT OF CHRONIC PAIN IS A MULTI-DISCIPLINARY APPROACH AND IS NOT PRESCRIPTION-BASED ONLY.

(1) Definitions.

(a) Controlled Substance. A “controlled substance” is any substance named or described in Schedules I-V of Section 893.03, Florida Statutes.

(b) Adverse Incidents. An “adverse incident” is any incident set forth in Section 458.351(4)(a)-(e), Florida Statutes.

(c) “Board–certified pain management physician” means a physician who possesses Board certification by a specialty board recognized by the American Board of Medical Specialties (ABMS) and holds a sub-specialty certification in pain medicine; or Board certification in pain medicine by the American Board of Pain Medicine (ABPM).

(d) “Addiction medicine specialist” means a board certified psychiatrist with a subspecialty certification in addiction medicine or who is eligible for such subspecialty certification in addiction medicine or an addiction medicine physician currently certified or eligible for certification by the American Society of Addiction Medicine (ASAM).

(e) “Mental health addiction facility” means a facility licensed pursuant to Chapters 394 or 397, Florida Statutes.

(2) Standards of Practice in Pain Management Clinics.
(a) Evaluation of Patient and Medical Diagnosis. A complete medical history and a physical examination must be conducted prior to commencement of any treatment and documented in the medical record. The exact components of the physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, 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, a review of prior medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written individualized 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 physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

(c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks and benefits of the use of controlled substances including the risks of abuse/addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The physician shall
employ the use of a written controlled substance agreement between physician and patient

outlining patient responsibilities, including, but not limited to:

1. To assure the medical necessity and safety of any controlled substances that the physician
may consider prescribing as part of the patient’s treatment plan, drug testing shall be conducted
prior to the initial issuance or dispensing of a controlled substance prescription, and thereafter,
on a random basis at least twice a year and when requested by the treating physician;

2. Number and frequency of all prescription refills;

3. Patient compliance and reasons for which drug therapy may be discontinued (i.e.,
violation of agreement); and

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

(d) Periodic Review. The patient shall be seen by the physician at regular intervals, not to
exceed three months, to assess the efficacy of treatment, assure that controlled substance therapy
remains indicated, evaluate the patient’s progress toward treatment objectives, consider adverse
drug effects and review 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 being
achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of
continued treatment. The physician shall monitor patient compliance in medication usage,
related treatment plans, controlled substance agreements, and indications of substance abuse or
diversion at a minimum of three-month intervals.

(e) Consultation. The physician shall refer the patient as necessary for additional evaluation
and treatment in order to achieve treatment objectives. Special attention shall 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 requires extra care, monitoring, and documentation, and requires consultation with or referral to an expert in the management of such patients.

(f) Patient Drug Testing. To assure the medical necessity and safety of any controlled substances that the physician may consider prescribing as part of the patient’s treatment plan, patient drug testing shall be performed in accordance with one of the collection methods set forth below and shall be conducted prior to the initial issuance or dispensing of a controlled substance prescription, and thereafter, on a random basis at least twice a year and when requested by the treating physician. Nothing in this rule shall preclude a pain-management clinic from employing additional measures to assure the integrity of the urine specimens provided by patients.

1. Referral to an outside laboratory. A physician shall send the patient to a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory;

2. Specimen collected in the pain-management clinic and sent to an outside laboratory for testing. A physician shall collect in the office the patient specimen to be used for drug testing in a device that measures pH, specific gravity, and temperature and then the specimen shall be sent to a CLIA-certified laboratory. The physician shall follow the collection procedures required by the agreement the pain-management clinic has entered into with the CLIA-certified laboratory it uses.

3. Specimen collected and tested in office. A physician shall collect and test in the office the specimen to be used for drug testing using CLIA-waived point-of-care test or CLIA-certified test
that uses a device that measures the pH, specific gravity, and temperature. Results of the drug
test shall be read according to the manufacturer’s instructions.

(g) Patient Medical Records. The 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;
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. Periodic reviews;
10. Drug testing results;
11. A photocopy of the patient’s government issued photo identification; and
12. If a written prescription for a controlled substance is given to the patient, a duplicate of
    said prescription must be maintained in the patient’s medical record.

13. Each pain management clinic physician’s medical record shall contain the physician’s
    full name presented in a legible manner. In addition, each clinic must maintain a log on the
    premises which shall contain the full name, presented in a legible manner, along with a
    corresponding sample signature and initials of every physician, anesthesiologist assistant, and
    physician assistant working in the clinic.
14. Medical records must remain current, they must be maintained in an accessible manner and readily available for review and must be in full compliance with Rule 64B8-9.003, F.A.C., and Section 458.331(1)(m), F.S..

(h) Denial or Termination of Controlled Substance Therapy.

1. If a patient’s initial drug testing reflects the adulteration of the specimen or the presence of illegal or controlled substances, (other than medications with approved prescriptions) or when the testing result is questioned by either the patient or the physician, the specimen will be sent to a CLIA-certified laboratory for gas or liquid chromatography/mass spectrometry (GC or LC/MS) confirmation. If the result of the GC or LC/MS testing is positive, the physician shall refer the patient for further consultation with a board-certified pain management physician, an addiction medicine specialist, or from a mental health addiction facility as it pertains to drug abuse or addiction. After consultation is obtained, the physician shall document in the medical record the results of the consultation. The treating physician shall not prescribe or dispense any controlled substances until there is written concurrence of medical necessity of continued controlled substance therapy provided by a board-certified pain management physician an addiction medicine specialist, or from a mental health addiction facility. If the treating physician is a board-certified pain management physician, or an addiction specialist, the physician does not need to refer the patient for further consultation. If the physician suspects diversion, then the patient shall be discharged and all results of testing and actions taken by the physician shall be documented in the patient’s medical record.

2. For patients currently in treatment by the physician or any other physician in the same pain management clinic, patients with signs or symptoms of substance abuse, shall be immediately referred to a board-certified pain management physician, an addiction medicine
specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the
physician is board-certified or board-eligible in pain management. Throughout the period of
time prior to receiving the consultant’s report, a prescribing physician shall clearly and
completely document medical justification for continued treatment with controlled substances
and those steps taken to assure medically appropriate use of controlled substances by the patient.
Upon receipt of the consultant’s written report, the prescribing physician will incorporate the
consultant’s recommendations for continuing, modifying, or discontinuing controlled substance
therapy. The resulting changes in treatment shall be specifically documented in the patient’s
medical record.

3. For patients currently in treatment by the physician or any other physician in the same
pain management clinic, evidence or behavioral indications of diversion shall be followed by
discontinuation of controlled substance therapy and the patient shall be discharged and all results
of testing and actions taken by the physician shall be documented in the patient’s medical record.

(i) Facility and Physical Operations.
1. A pain management clinic shall be located and operated at a publicly accessible fixed
location and shall contain the following:
   a. A sign that can be viewed by the public that contains the clinic name, hours of operations,
and a street address;
   b. A publicly listed telephone number and a dedicated phone number to send and receive
faxes with a fax machine that shall be operational twenty-four hours per day;
   c. Emergency lighting and communications;
   d. Reception and waiting area;
   e. Restroom;
f. Administrative area including room for storage of medical records, supplies and equipment;

g. Private patient examination room(s);

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

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

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

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

(j) Infection Control.

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

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

   a. Geographic location, community, and population served;

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

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

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

   a. Prioritized risks;
b. Limiting unprotected exposure to pathogen;

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

d. Limiting the transmission of infections associated with the clinic's use of medical equipment, devices, and supplies.

(k) Health and Safety.

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

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

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

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

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

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

2. The identification of trends or patterns of incidents,

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

4. The documentation of these functions and periodic review no less than quarterly of such information by the medical director or designated physician.

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

(m) Data Collection and Reporting.

1. Reporting of adverse incidents. The Medical Director or Designated Physician for each pain-management clinic shall report all adverse incidents to the Department of Health as set forth in Section 458.351, Florida Statutes.

2. The Medical Director or Designated Physician shall also report to the Board of Medicine/Department, in writing, on a quarterly basis the following data:

   a. Number of new and repeat patients seen and treated at the clinic;
   b. The number of patients discharged due to drug abuse;
   c. The number of patients discharged due to drug diversion;
   d. The outcomes of patient referral or discharge; and
e. The number of patients treated at the pain clinic whose domicile is located somewhere other than in Florida. A patient’s domicile is the patient’s fixed or permanent home to which he intends to return even though he may temporarily reside elsewhere.

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

(n) Training Requirements. Physicians prescribing or dispensing controlled substance medications in pain-management clinics registered pursuant to Section 458.309(4), Florida Statutes, shall be required to successfully complete 20-hours of CME addressing any of the subject areas set forth in subparagraph 6. below once every licensure biennium, and also must meet one of the following qualifications:

1. Board certification by a specialty board recognized by the American Board of Medical Specialties (ABMS) and holds a sub-specialty certification in pain medicine;

2. Board certification in pain medicine by the American Board of Pain Medicine (ABPM);

3. Successful completion of a post graduate training program in Pain Medicine/Management accredited by the Accreditation Council for Graduate Medical Education (ACGME) within the previous three years;

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

5. Until January 2012, three (3) years of full-time practice in pain-management and within six months of the effective date of this rule, attendance and successful completion of 40 hours of in-person, live-participatory AMA Category I CME courses in pain management that include post-course evaluations and address all the following subject areas:
1. The goals of treating both short term and ongoing pain treatment;
2. Controlled substance prescribing rules, including controlled substances agreements;
3. Drug screening or testing, including usefulness and limitations;
4. The use of controlled substances in treating short-term and ongoing pain syndromes, including usefulness and limitations;
5. Evidenced-based non-controlled pharmacological pain treatments;
6. Evidenced-based non-pharmacological pain treatments;
7. A complete pain medicine history and a physical examination;
8. Appropriate progress note keeping;
9. Comorbidities with pain disorders, including psychiatric and addictive disorders;
10. Drug abuse and diversion, and prevention of same;
11. Risk management; and
12. Medical ethics.

In addition to the CME set forth in paragraph 5. above, physicians must be able to document hospital privileges at a Florida-licensed hospital; practice under the direct supervision of a physician who is qualified in subsection 1. or 2. above; or have the practice reviewed by a Florida-licensed risk manager and document compliance with all recommendations of the risk management review.

6. After January 2012, for physicians not qualifying under 1. through 4. above, successful completion prior to working in a pain management clinic and every 2 years thereafter, of a pain-management course that is between 80 and 120-hours offered by a Florida accredited allopathic or osteopathic medical school that addresses the subject areas listed below. This completion of
this course will satisfy the requirement for the 20 hours of CME set forth subsection (n) above.

The course shall contain the following subject areas:

a. Overview
   I. Definitions
   II. Statistics
   III. Ethical implications
   IV. Societal implications
b. Anatomy and Physiology of Pain
   I. Nociception
      A. Inflammatory
      B. Nociceptive
      C. Neuropathic
   II. Nociceptive pathways
      A. Peripheral Nociceptor
      B. Spinal cord
         i. Ascending
         ii. Descending modulatory
      C. Brainstem
      D. Supraspinal
   III. Classification of Pain
      A. Acute/subacute/chronic
      B. Nociceptive versus neuropathic
      C. Cancer related versus non-cancer related
      D. Somatic versus visceral
      E. Psychosomatic versus organic/physical
   IV. Pain Pharmacology
      A. Pharmacokinetics
      B. Pharmacodynamics
   V. Peripheral and Central sensitization
c. Nociceptive Time Course
I. Acute
II. Subacute
III. Chronic/Persistent
d. Common Pain Syndromes
I. Axial Neck/Back Pain
A. Mechanical
B. Discogenic
II. Radicular Pain
III. Spinal Stenosis
IV. Failed back surgical syndrome/Post-laminectomy pain
V. Headache
A. Migraine
B. Occipital
C. Cluster
D. Tension
VI. Myofascial pain and Fibromyalgia
VII. Neuropathic Pain
A. Diabetic peripheral neuropathy
B. Post-herpetic neuralgia
C. Complex regional pain syndrome
D. Idiopathic
VII. Abdominal pain
VIII. Cancer-related pain
IX. Pain Palliation – End of life
e. Treatment Goals
I. Short term
II. Long term
f. The Pain Medicine History and Physical Examination
g. Imaging
I. Xrays
II. CT
III. MRI

IV. Indications for plain and contrast images

V. Diagnostic usefulness and limitations of imaging

h. EMG/NCS

i. Rheumatologic Tests

j. Drug Testing

I. Urine

II. Serum

III. Other

IV. Usefulness

V. Limitations

k. Appropriate Documentation

l. Pharmacological Therapy

I. Opioids

A. Structural classification of opioids

B. Routes of administration

C. Pharmacokinetics

D. Mechanism of action

E. Equivalency

F. Indications

i. Short term

ii. Long term

G. Efficacy

H. Side effects

I. Interactions

II. Non-opiate analgesics

A. Acetaminophen

i. Mechanism of action

ii. Indications

(A) Short term

(B) Long term
iii. Efficacy

iv. Side effects

v. Interactions

B. Cyclooxygenase Inhibitors

i. Classification and implications of the classifications of cyclooxygenase inhibitors
(A) Carboxylic acids
(B) Pyrazoles
(C) Oxicams
(D) Coxibs
(E) Acetylsalicylic acids
(F) Acetic acids
(G) Propionic acids
(H) Anthranilic acids

ii. Mechanism of action

iii. Indications
(A) Short term
(B) Long term

iv. Efficacy

v. Side effects

vi. Interactions

C. Mixed Serotonergic-Noradreneric and Mu Agonists

i. Mechanism of action

ii. Indications
(A) Short term
(B) Long term

iii. Efficacy

iv. Cautions and contraindications

v. Side effects

vi. Interactions

III. Membrane Stabilizers

A. Mechanism of action
B. Indications
   i. Short term
   ii. Long term
C. Efficacy
D. Side effects
E. Interactions

IV. Local anesthetics
   A. Mechanism of action
   B. Structural classification and implications
   C. Indications
      i. Short term
      ii. Long term
   D. Efficacy
   E. Side effects
   F. Interactions
   G. Pharmacokinetics

V. Tricyclic antidepressants (TCAs) / Selective Serotonin Reuptake Inhibitors (SSRIs) / Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)
   A. Mechanism of action
   B. Structural characteristics and implications
   C. Indications
      i. Short term
      ii. Long term
   D. Efficacy
   E. Side effects
   F. Interactions

VI. Muscle relaxants
   A. History
   B. Structural characteristics and implications
   C. Mechanism of action
   D. Indications
i. Short term
ii. Long term
F. Efficacy
G. Side effects
H. Interactions
I. Benzodiazepines

VII. Viscosupplementation Agents
A. Mechanism of action
B. Structural characteristics and implications
C. Indications
i. Short term
ii. Long term
D. Efficacy
E. Side affects
F. Interactions

VIII. Toxins for Pain
A. Botulinum toxins
i. Type A
ii. Type B
B. Ziconotide
C. Mechanism of action
D. Indications
i. Short term
ii. Long term
E. Efficacy
F. Side affects
G. Interactions

IX. Alpha 2 Agonists
A. Alpha 2 Receptor Subtypes
B. Mechanism of action
C. Indications
i. Short term
ii. Long term
D. Efficacy
E. Side affects
F. Interactions
X. Cannabinoids (Endogenous/Exogenous)
A. Mechanism of action
B. Structural characteristics and implications
C. Indications
i. Short term
ii. Long term
D. Efficacy
E. Side affects
F. Interactions
XI. NMDA Antagonists
A. Mechanism of action
B. Structural characteristics and implications
C. Indications
i. Short term
ii. Long term
D. Efficacy
E. Side affects
F. Interactions
XII. Neurolytics
A. Mechanism of action
B. Structural characteristics and implications
C. Indications
i. Short term
ii. Long term
D. Efficacy
E. Side affects
F. Interactions

XIII. Glucocorticosteroids
A. Mechanism of action

B. Indications
i. Short term
ii. Long term

C. Efficacy

D. Side affects

E. Interactions

XIV. NMDA antagonists (Ketamine, dextromethorphan, memantine…)
A. Mechanism of action

B. Structural characteristics and implications

C. Indications
i. Short term
ii. Long term

D. Efficacy

E. Side effects

F. Interactions

m. Non-Pharmacological Approaches

I. Physical Modalities
A. Osteopathic Manipulative Treatment (OMT)

B. Chiropractic

C. Massage therapy

D. Physical therapy

E. Transcutaneous Electrical Nerve Stimulation (TENS)

II. Cognitive Modalities
A. Biofeedback

B. Pain coping skills

C. Cognitive behavioral therapy

D. Relaxation therapy

III. Integrative Modalities
A. Acupuncture
B. Laser therapy
C. Cranial electronic stimulation
D. Herbal therapies

IV. Interventional Modalities
A. Evidence for diagnostic injections
B. Evidence for therapeutic injections
C. Basics of fluoroscopy
D. Radiation safety
E. Basics of ultrasonography
F. Trigger point injections
G. Prolotherapy
H. Nerve blocks
i. Peripheral nerve blocks
ii. Medial and lateral branch nerve blocks
I. Joint injections
J. Facet joint injections
K. Epidural steroid injections (ESIs)
i. Interlaminar
ii. Transforaminal
iii. Caudal
iv. Cervical/Thoracis/Lumbar
L. Selective nerve root injections
M. Sympathic/Ganglion blocks
N. Neuraxial Adhesiolysis Procedures
O. Procedures
P. Continuous and Pulsed Radiofrequency treatments
Q. Intrathecal drug delivery
R. Spinal cord stimulators
S. Peripheral nerve stimulators
T. Diagnostic discography
U.   Intradiscal electrothermal therapies
V.   Percutaneous discetomy (>=4 types)
W.   Neurosurgical interventions
n.   Psychosocial Aspects of Pain
I.   Treatment of pain in individuals with a history of substance abuse or addiction
II.  Screening, evaluation, and treatment of mood disorders in individuals affected by pain
III. Assessment of risk for dependence and addiction
IV.  Strategies for managing patients who develop addiction or an abusive pattern of medication use
V.   Addiction in the health care professional
VI.  Detoxification
o.   Legal Aspects of Pain Medicine
I.   Controlled substance prescribing rules
II.  Controlled substance ordering rules
III. Dispensing practitioner rules
IV.  Prescribing rules
V.   Penalties for violations of rules
VI.  Pain management agreements
VII. Requirements for reporting
VIII. Drug abuse and diversion
A.   Recognition
B.   Treatment
C.   Termination of prescriptions
IX.  Online prescribing
X.   Consultation requirements
XI. Patient termination letters
(o) After the effective date of this rule, any newly registering pain management clinic shall assure that at any time the clinic is open and patients are being seen, there is at least one board-certified pain management physician on the premises.
Rulemaking Authority: 458.309 (5), FS.
Law Implemented: 458.309 (4), (5), FS.
History: New

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

(1) Registration.

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

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

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

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

(2) Inspection

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

(b) The Department shall conduct unannounced annual inspections of pain clinics pursuant
(c) The Medical Director or Designated Physician shall cooperate with the inspector(s), make medical records available to the inspector, and be responsive to all reasonable requests.

(d) The inspector(s) shall determine compliance with the requirements of Rule 64B8-9.0131, F.A.C. This shall include review of between 25 and 50 patient records for patients who are treated for pain, selected by the inspector(s) at random for each physician practicing in the clinic or who has practiced in the clinic during the past six months.

(e) If the clinic is determined to be in noncompliance, the Medical Director or Designated Physician shall be notified and shall be given a written statement at the time of inspection. Such written notice shall specify the deficiencies. Unless the deficiencies constitute an immediate and imminent danger to the public, the Medical Director or Designated Physician shall be given 30 days from the date of inspection to correct any documented deficiencies and notify the Department of corrective action. Upon written notification from the Medical Director or Designated Physician that all deficiencies have been corrected, the Department is authorized to re-inspect for compliance. If the Medical Director or Designated Physician fails to submit a corrective action plan within 30 days of the inspection, the Department is authorized to re-inspect the office to ensure that the deficiencies have been corrected.

(f) The written results of the inspection, deficiency notice and any subsequent documentation shall be forwarded to the Department. This shall include:

1. Whether the deficiencies constituted an immediate and serious danger to the public;
2. Whether the Medical Director or Designated Physician provided the Department with documentation of correction of all deficiencies within 30 days from the date of inspection; and
3. The results of any reinspection.
(g) The Department shall review the results of the inspection(s) and determine whether action against the clinic registration is merited.

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

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

(j) The Medical Director or Designated Physician shall submit, within thirty (30) days of accreditation, a copy of the current accreditation survey of the clinic and shall immediately notify the Board of Medicine of any accreditation changes that occur. For purposes of initial registration, the Medical Director or Designated Physician shall submit a copy of the most recent accreditation survey of the clinic in lieu of undergoing an inspection by the Department.

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

Rulemaking Authority: 458.309 (4), FS.

Law Implemented: 458.309 (4), FS.

History: New