

1 64B8-9.0131 Standards of Practice for Physicians Practicing in Pain Management Clinics.
2 THESE RULES ARE APPLICABLE ONLY TO PHYSICIANS WHO ARE TREATING
3 PATIENTS BY PRESCRIBING OR DISPENSING CONTROLLED SUBSTANCES FOR THE
4 TREATMENT OF CHRONIC NONMALIGNANT PAIN AT A PAIN MANAGEMENT
5 CLINIC. FOR PURPOSES OF THIS RULE, THE PREVAILING STANDARD OF CARE
6 FOR THE TREATMENT OF CHRONIC PAIN IS A MULTI-DISCIPLINARY APPROACH
7 AND IS NOT PRESCRIPTION-BASED ONLY.

8 (1) Definitions.

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

11 (b) Adverse Incidents. An “adverse incident” is any incident set forth in Section
12 458.351(4)(a)-(e), Florida Statutes.

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

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

21 (e) “Mental health addiction facility” means a facility licensed pursuant to Chapters 394 or
22 397, Florida Statutes.

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

1 (a) Evaluation of Patient and Medical Diagnosis. A complete medical history and a physical
2 examination must be conducted prior to commencement of any treatment and documented in the
3 medical record. The exact components of the physical examination shall be left to the judgment
4 of the clinician who is expected to perform a physical examination proportionate to the diagnosis
5 that justifies a treatment. The medical record must, at a minimum, document the nature and
6 intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or
7 conditions, the effect of the pain on physical and psychological function, a review of prior
8 medical records, previous diagnostic studies, and history of alcohol and substance abuse. The
9 medical record shall also document the presence of one or more recognized medical indications
10 for the use of a controlled substance.

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

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

1 employ the use of a written controlled substance agreement between physician and patient
2 outlining patient responsibilities, including, but not limited to:

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

7 2. Number and frequency of all prescription refills;

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

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

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

22 (e) Consultation. The physician shall refer the patient as necessary for additional evaluation
23 and treatment in order to achieve treatment objectives. Special attention shall be given to those

1 pain patients who are at risk for misusing their medications and those whose living arrangements
2 pose a risk for medication misuse or diversion. The management of pain in patients with a
3 history of substance abuse or with a comorbid psychiatric disorder requires extra care,
4 monitoring, and documentation, and requires consultation with or referral to an expert in the
5 management of such patients.

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

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

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

21 3. Specimen collected and tested in office. A physician shall collect and test in the office the
22 specimen to be used for drug testing using CLIA-waived point-of-care test or CLIA-certified test

1 that uses a device that measures the pH, specific gravity, and temperature. Results of the drug
2 test shall be read according to the manufacturer's instructions.

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

- 5 1. The complete medical history and a physical examination, including history of drug abuse
6 or dependence;
- 7 2. Diagnostic, therapeutic, and laboratory results;
- 8 3. Evaluations and consultations;
- 9 4. Treatment objectives;
- 10 5. Discussion of risks and benefits;
- 11 6. Treatments;
- 12 7. Medications (including date, type, dosage, and quantity prescribed);
- 13 8. Instructions and agreements;
- 14 9. Periodic reviews;
- 15 10. Drug testing results;
- 16 11. A photocopy of the patient's government issued photo identification; and
- 17 12. If a written prescription for a controlled substance is given to the patient, a duplicate of
18 said prescription must be maintained in the patient's medical record.
- 19 13. Each pain management clinic physician's medical record shall contain the physician's
20 full name presented in a legible manner. In addition, each clinic must maintain a log on the
21 premises which shall contain the full name, presented in a legible manner, along with a
22 corresponding sample signature and initials of every physician, anesthesiologist assistant, and
23 physician assistant working in the clinic.

1 14. Medical records must remain current, they must be maintained in an accessible manner
2 and readily available for review and must be in full compliance with Rule 64B8-9.003, F.A.C.,
3 and Section 458.331(1)(m), F.S..

4 (h) Denial or Termination of Controlled Substance Therapy.

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

21 2. For patients currently in treatment by the physician or any other physician in the same
22 pain management clinic, patients with signs or symptoms of substance abuse, shall be
23 immediately referred to a board-certified pain management physician, an addiction medicine

1 specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the
2 physician is board-certified or board-eligible in pain management. Throughout the period of
3 time prior to receiving the consultant's report, a prescribing physician shall clearly and
4 completely document medical justification for continued treatment with controlled substances
5 and those steps taken to assure medically appropriate use of controlled substances by the patient.
6 Upon receipt of the consultant's written report, the prescribing physician will incorporate the
7 consultant's recommendations for continuing, modifying, or discontinuing controlled substance
8 therapy. The resulting changes in treatment shall be specifically documented in the patient's
9 medical record.

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

14 (i) Facility and Physical Operations.

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

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

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

21 c. Emergency lighting and communications;

22 d. Reception and waiting area;

23 e. Restroom;

- 1 f. Administrative area including room for storage of medical records, supplies and
2 equipment;
- 3 g. Private patient examination room(s);
- 4 h. Treatment room(s) if treatment is being provided to the patient;
- 5 i. A printed sign located in a conspicuous place in the waiting room viewable by the public
6 disclosing the name and contact information of the clinic Medical Director or Designated
7 Physician, and the names of all physicians practicing in the clinic;
- 8 j. Storage and handling of prescription drugs. Clinics that store and dispense prescription
9 drug shall comply with Section 499.0121, Florida Statutes, Section 893.07, Florida Statutes, and
10 Rule 64F-12.012, Florida Administrative Code.

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

14 (j) Infection Control.

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

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

- 18 a. Geographic location, community, and population served;
- 19 b. The care, treatment and services it provides; and
- 20 c. An analysis of its infection surveillance and control data.

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

- 23 a. Prioritized risks;

- 1 b. Limiting unprotected exposure to pathogen;
- 2 c. Limiting the transmission of infections associated with procedures performed in the
- 3 clinic; and
- 4 d. Limiting the transmission of infections associated with the clinics use of medical
- 5 equipment, devices, and supplies.

6 (k) Health and Safety.

7 1. The clinic, including its grounds, buildings, furniture, appliances and equipment shall be

8 structurally sound, in good repair, clean, and free from health and safety hazards.

9 2. The clinic shall have evacuation procedures in the event of an emergency which shall

10 include provisions for the evacuation of disabled patients and employees.

11 3. The clinic shall have a written facility-specific disaster plan which sets forth actions that

12 will be taken in the event of clinic closure due to unforeseen disasters which shall include

13 provisions for the protection of medical records and any controlled substances.

14 4. Each clinic shall have at least one employee on the premises during patient care hours

15 that is certified in Basic Life Support and is trained in reacting to accidents and medical

16 emergencies until emergency medical personnel arrive.

17 (l) Quality Assurance. Each pain management clinic shall have an ongoing quality

18 assurance program that objectively and systematically monitors and evaluates the quality and

19 appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects

20 deficiencies within the facility, alerts the Medical Director or Designated Physician to identify

21 and resolve recurring problems, and provides for opportunities to improve the facility's

22 performance and to enhance and improve the quality of care provided to the public. The Medical

1 Director or Designated Physician shall establish a quality assurance program that includes the
2 following components:

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

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

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

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

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

14 (m) Data Collection and Reporting.

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

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

20 a. Number of new and repeat patients seen and treated at the clinic;

21 b. The number of patients discharged due to drug abuse;

22 c. The number of patients discharged due to drug diversion;

23 d. The outcomes of patient referral or discharge; and

1 e. The number of patients treated at the pain clinic whose domicile is located somewhere
2 other than in Florida. A patient's domicile is the patient's fixed or permanent home to which he
3 intends to return even though he may temporarily reside elsewhere.

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

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

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

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

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

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

20 5. Until January 2012, three (3) years of full-time practice in pain-management and within
21 six months of the effective date of this rule, attendance and successful completion of 40 hours of
22 in-person, live-participatory AMA Category I CME courses in pain management that include
23 post-course evaluations and address all the following subject areas:

- 1 a. The goals of treating both short term and ongoing pain treatment;
- 2 b. Controlled substance prescribing rules, including controlled substances agreements;
- 3 c. Drug screening or testing, including usefulness and limitations;
- 4 d. The use of controlled substances in treating short-term and ongoing pain syndromes,
5 including usefulness and limitations;
- 6 e. Evidenced-based non-controlled pharmacological pain treatments;
- 7 f. Evidenced-based non-pharmacological pain treatments;
- 8 g. A complete pain medicine history and a physical examination;
- 9 h. Appropriate progress note keeping;
- 10 i. Comorbidities with pain disorders, including psychiatric and addictive disorders;
- 11 j. Drug abuse and diversion, and prevention of same;
- 12 k. Risk management; and
- 13 l. Medical ethics.

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

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

1 this course will satisfy the requirement for the 20 hours of CME set forth subsection (n) above.

2 The course shall contain the following subject areas:

3 a. Overview

4 I. Definitions

5 II. Statistics

6 III. Ethical implications

7 IV. Societal implications

8 b. Anatomy and Physiology of Pain

9 I. Nociception

10 A. Inflammatory

11 B. Nociceptive

12 C. Neuropathic

13 II. Nociceptive pathways

14 A. Peripheral Nociceptor

15 B. Spinal cord

16 i. Ascending

17 ii. Descending modulatory

18 C. Brainstem

19 D. Supraspinal

20 III. Classification of Pain

21 A. Acute/subacute/chronic

22 B. Nociceptive versus neuropathic

23 C. Cancer related versus non-cancer related

24 D. Somatic versus visceral

25 E. Psychosomatic versus organic/physical

26 IV. Pain Pharmacology

27 A. Pharmacokinetics

28 B. Pharmacodynamics

29 V. Peripheral and Central sensitization

30 c. Nociceptive Time Course

- 1 I. Acute
- 2 II. Subacute
- 3 III. Chronic/Persistent
- 4 d. Common Pain Syndromes
- 5 I. Axial Neck/Back Pain
- 6 A. Mechanical
- 7 B. Discogenic
- 8 II. Radicular Pain
- 9 III. Spinal Stenosis
- 10 IV. Failed back surgical syndrome/Post-laminectomy pain
- 11 V. Headache
- 12 A. Migraine
- 13 B. Occipital
- 14 C. Cluster
- 15 D. Tension
- 16 VI. Myofascial pain and Fibromyalgia
- 17 VII. Neuropathic Pain
- 18 A. Diabetic peripheral neuropathy
- 19 B. Post-herpetic neuralgia
- 20 C. Complex regional pain syndrome
- 21 D. Idiopathic
- 22 VII. Abdominal pain
- 23 VIII. Cancer-related pain
- 24 IX. Pain Palliation – End of life
- 25 e. Treatment Goals
- 26 I. Short term
- 27 II. Long term
- 28 f. The Pain Medicine History and Physical Examination
- 29 g. Imaging
- 30 I. Xrays
- 31 II. CT

- 1 III. MRI
- 2 IV. Indications for plain and contrast images
- 3 V. Diagnostic usefulness and limitations of imaging
- 4 h. EMG/NCS
- 5 i. Rheumatologic Tests
- 6 j. Drug Testing
- 7 I. Urine
- 8 II. Serum
- 9 III. Other
- 10 IV. Usefulness
- 11 V. Limitations
- 12 k. Appropriate Documentation
- 13 l. Pharmacological Therapy
- 14 I. Opioids
- 15 A. Structural classification of opioids
- 16 B. Routes of administration
- 17 C. Pharmacokinetics
- 18 D. Mechanism of action
- 19 E. Equivalency
- 20 F. Indications
- 21 i. Short term
- 22 ii. Long term
- 23 G. Efficacy
- 24 H. Side effects
- 25 I. Interactions
- 26 II. Non-opiate analgesics
- 27 A. Acetaminophen
- 28 i. Mechanism of action
- 29 ii. Indications
- 30 (A) Short term
- 31 (B) Long term

- 1 iii. Efficacy
- 2 iv. Side effects
- 3 v. Interactions
- 4 B. Cyclooxygenase Inhibitors
- 5 i. Classification and implications of the classifications of cyclooxygenase inhibitors
- 6 (A) Carboxylic acids
- 7 (B) Pyrazoles
- 8 (C) Oxicams
- 9 (D) Coxibs
- 10 (E) Acetylsalicylic acids
- 11 (F) Acetic acids
- 12 (G) Propionic acids
- 13 (H) Anthranilic acids
- 14 ii. Mechanism of action
- 15 iii. Indications
- 16 (A) Short term
- 17 (B) Long term
- 18 iv. Efficacy
- 19 v. Side effects
- 20 vi. Interactions
- 21 C. Mixed Serotonergic-Noradrenergic and Mu Agonists
- 22 i. Mechanism of action
- 23 ii. Indications
- 24 (A) Short term
- 25 (B) Long term
- 26 iii. Efficacy
- 27 iv. Cautions and contraindications
- 28 v. Side effects
- 29 vi. Interactions
- 30 III. Membrane Stabilizers
- 31 A. Mechanism of action

- 1 B. Indications
- 2 i. Short term
- 3 ii. Long term
- 4 C. Efficacy
- 5 D. Side effects
- 6 E. Interactions
- 7 IV. Local anesthetics
- 8 A. Mechanism of action
- 9 B. Structural classification and implications
- 10 C. Indications
- 11 i. Short term
- 12 ii. Long term
- 13 D. Efficacy
- 14 E. Side effects
- 15 F. Interactions
- 16 G. Pharmacokinetics
- 17 V. Tricyclic antidepressants (TCAs) / Selective Serotonin Reuptake Inhibitors (SSRIs) /
- 18 Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)
- 19 A. Mechanism of action
- 20 B. Structural characteristics and implications
- 21 C. Indications
- 22 i. Short term
- 23 ii. Long term
- 24 D. Efficacy
- 25 E. Side effects
- 26 F. Interactions
- 27 VI. Muscle relaxants
- 28 A. History
- 29 B. Structural characteristics and implications
- 30 C. Mechanism of action
- 31 D. Indications

- 1 i. Short term
- 2 ii. Long term
- 3 F. Efficacy
- 4 G. Side effects
- 5 H. Interactions
- 6 I. Benzodiazapines
- 7 VII Viscosupplementation Agents
- 8 A. Mechanism of action
- 9 B. Structural characteristics and implications
- 10 C. Indications
- 11 i. Short term
- 12 ii. Long term
- 13 D. Efficacy
- 14 E. Side affects
- 15 F. Interactions
- 16 VIII. Toxins for Pain
- 17 A. Botulinum toxins
- 18 i. Type A
- 19 ii. Type B
- 20 B. Ziconotide
- 21 C. Mechanism of action
- 22 D. Indications
- 23 i. Short term
- 24 ii. Long term
- 25 E. Efficacy
- 26 F. Side affects
- 27 G. Interactions
- 28 IX. Alpha 2 Agonists
- 29 A. Alpha 2 Receptor Subtypes
- 30 B. Mechanism of action
- 31 C. Indications

- 1 i. Short term
- 2 ii. Long term
- 3 D. Efficacy
- 4 E. Side affects
- 5 F. Interactions
- 6 X. Cannabinoids (Endogenous/Exogenous)
- 7 A. Mechanism of action
- 8 B. Structural characteristics and implications
- 9 C. Indications
- 10 i. Short term
- 11 ii. Long term
- 12 D. Efficacy
- 13 E. Side affects
- 14 F. Interactions
- 15 XI. NMDA Antagonists
- 16 A. Mechanism of action
- 17 B. Structural characteristics and implications
- 18 C. Indications
- 19 i. Short term
- 20 ii. Long term
- 21 D. Efficacy
- 22 E. Side affects
- 23 F. Interactions
- 24 XII. Neurolytics
- 25 A. Mechanism of action
- 26 B. Structural characteristics and implications
- 27 C. Indications
- 28 i. Short term
- 29 ii. Long term
- 30 D. Efficacy
- 31 E. Side affects

- 1 F. Interactions
- 2 XIII. Glucocorticosteroids
- 3 A. Mechanism of action
- 4 B. Indications
- 5 i. Short term
- 6 ii. Long term
- 7 C. Efficacy
- 8 D. Side affects
- 9 E. Interactions
- 10 XIV. NMDA antagonists (Ketamine, dextromethorphan, memantine...)
- 11 A. Mechanism of action
- 12 B. Structural characteristics and implications
- 13 C. Indications
- 14 i. Short term
- 15 ii. Long term
- 16 D. Efficacy
- 17 E. Side effects
- 18 F. Interactions
- 19 m. Non-Pharmacological Approaches
- 20 I. Physical Modalities
- 21 A. Osteopathic Manipulative Treatment (OMT)
- 22 B. Chiropractic
- 23 C. Massage therapy
- 24 D. Physical therapy
- 25 E. Transcutaneous Electrical Nerve Stimulation (TENS)
- 26 II. Cognitive Modalities
- 27 A. Biofeedback
- 28 B. Pain coping skills
- 29 C. Cognitive behavioral therapy
- 30 D. Relaxation therapy
- 31 III. Integrative Modalities

- 1 A. Acupuncture
- 2 B. Laser therapy
- 3 C. Cranial electronic stimulation
- 4 D. Herbal therapies
- 5 IV. Interventional Modalities
- 6 A. Evidence for diagnostic injections
- 7 B. Evidence for therapeutic injections
- 8 C. Basics of fluoroscopy
- 9 D. Radiation safety
- 10 E. Basics of ultrasonography
- 11 F. Trigger point injections
- 12 G. Prolotherapy
- 13 H. Nerve blocks
- 14 i. Peripheral nerve blocks
- 15 ii. Medial and lateral branch nerve blocks
- 16 I. Joint injections
- 17 J. Facet joint injections
- 18 K. Epidural steroid injections (ESIs)
- 19 i. Interlaminar
- 20 ii. Transforaminal
- 21 iii. Caudal
- 22 iv. Cervical/Thoracic/Lumbar
- 23 L. Selective nerve root injections
- 24 M. Sympathic/Ganglion blocks
- 25 N. Neuraxial Adhesiolysis Procedures
- 26 O. Procedures
- 27 P. Continuous and Pulsed Radiofrequency treatments
- 28 Q. Intrathecal drug delivery
- 29 R. Spinal cord stimulators
- 30 S. Peripheral nerve stimulators
- 31 T. Diagnostic discography

- 1 U. Intradiscal electrothermal therapies
- 2 V. Percutaneous discectomy (≥ 4 types)
- 3 W. Neurosurgical interventions
- 4 n. Psychosocial Aspects of Pain
- 5 I. Treatment of pain in individuals with a history of substance abuse or addiction
- 6 II. Screening, evaluation, and treatment of mood disorders in individuals affected by pain
- 7 III. Assessment of risk for dependence and addiction
- 8 IV. Strategies for managing patients who develop addiction or an abusive pattern of
- 9 medication use
- 10 V. Addiction in the health care professional
- 11 VI. Detoxification
- 12 o. Legal Aspects of Pain Medicine
- 13 I. Controlled substance prescribing rules
- 14 II. Controlled substance ordering rules
- 15 III. Dispensing practitioner rules
- 16 IV. Prescribing rules
- 17 V. Penalties for violations of rules
- 18 VI. Pain management agreements
- 19 VII. Requirements for reporting
- 20 VIII. Drug abuse and diversion
- 21 A. Recognition
- 22 B. Treatment
- 23 C. Termination of prescriptions
- 24 IX. Online prescribing
- 25 X. Consultation requirements
- 26 XI. Patient termination letters
- 27 (o) After the effective date of this rule, any newly registering pain management clinic shall
- 28 assure that at any time the clinic is open and patients are being seen, there is at least one board-
- 29 certified pain management physician on the premises.
- 30 Rulemaking Authority: 458.309 (5), FS.
- 31 Law Implemented: 458.309 (4), (5), FS.

1 History: New

2
3 64B8-9.0132 Requirement for Pain Management Clinic Registration; Inspection or
4 Accreditation

5 (1) Registration.

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

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

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

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

18 (2) Inspection

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

24 (b) The Department shall conduct unannounced annual inspections of pain clinics pursuant

1 to this rule.

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

4 (d) The inspector(s) shall determine compliance with the requirements of Rule 64B8-
5 9.0131, F.A.C. This shall include review of between 25 and 50 patient records for patients who
6 are treated for pain, selected by the inspector(s) at random for each physician practicing in the
7 clinic or who has practiced in the clinic during the past six months.

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

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

- 20 1. Whether the deficiencies constituted an immediate and serious danger to the public;
- 21 2. Whether the Medical Director or Designated Physician provided the Department with
22 documentation of correction of all deficiencies within 30 days from the date of inspection; and
- 23 3. The results of any reinspection.

1 (g) The Department shall review the results of the inspection(s) and determine whether
2 action against the clinic registration is merited.

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

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

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

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

17 Rulemaking Authority: 458.309 (4), FS.

18 Law Implemented: 458.309 (4), FS.

19 History: New

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