



**STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV440A - Pain Management Clinic**



INSPECTION AUTHORITY – SECTIONS 458.3265, 459.0137, 893.09 AND CHAPTER 456, FLORIDA STATUTES

File #
Insp #

NAME OF ESTABLISHMENT	PERMIT NUMBER	DATE OF INSPECTION	
DOING BUSINESS AS			
STREET ADDRESS		TELEPHONE #	EXT
CITY	COUNTY	STATE/ZIP	

Additional Information

Physician Tracking

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AHCA Healthcare num

AHCA NUM	
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License Relations

Designated Physician

	License #	
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Pain Clinic Owner

	License #
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INV 440A - Pain Management Clinic

Pain Management Clinic Requirements

The pain-management clinic is registered with the department and the department has been notified of the designated physician. [458.3265(1)(a)2.; 459.0137(1)(a)2., F.S.]	
The designated physician practices at the clinic location. [458.3265(1)(c); 459.0137(1)(c), F.S.]	
The clinic, including its grounds, buildings, furniture, appliances and equipment is structurally sound, in good repair, clean, and free from health and safety hazards. [458.3265(3)(h)1.; 459.0137(3)(h)1., F.S.]	
The clinic has evacuation procedures in the event of an emergency which includes provisions for the evacuation of disabled patients and employees, and has a written facility specific disaster plan which includes provisions for the protection of medical records and any controlled substances. [458.3265(3)(h)2., 3.; 459.0137(3)(h)2., 3., F.S.]	
The clinic is located and operated at a publicly accessible fixed location. [458.3265(3)(f)1.; 459.0137(3)(f)1., F.S.]	
Sign containing the clinic name, hours of operations and a street address is posted where viewable by the public. [458.3265(3)(f)1.a.; 459.0137(3)(f)1.a., F.S.]	
Clinic has a publicly listed telephone number and a dedicated phone number to send and receive faxes with a fax machine that is operational twenty-four hours per day. [458.3265(3)(f)1.b.; 459.0137(3)(f)1.b., F.S.]	
Clinic has emergency lighting and communications; reception and waiting area; restroom; administrative area including room for storage of medical records, supplies and equipment; private patient examination room(s); and treatment room(s) if treatment is being provided to the patient. [458.3265(3)(f)1. c.-h.; 459.0137(3)(f)1. c.-h., F.S.]	
A printed sign disclosing the name and contact information of the clinic's Designated Physician and the names of all physicians practicing in the clinic, is located in a conspicuous place in the waiting room viewable by the public. [458.3265(3)(f)1.i.; 459.0137(3)(f)1.i., F.S.]	
Storage and handling of prescription drugs complies with Section 499.0121, Florida Statutes, Section 893.07, Florida Statutes, [458.3265(3)(f)1.j.; 459.0137(3)(f)1.j., F.S.]	
The clinic maintains equipment and supplies to support infection prevention and control activities. The clinic identifies infection risks based on geographic location, community, and population served; the care, treatment and services it provides; and an analysis of its infection surveillance and control data. [458.3265(3)(g)1.; 2. 1.-3.; 459.0137(3)(g)1.; 2. 1.-3., F.S.]	
The clinic maintains written infection prevention policy and procedure that address the following: prioritized risks; limiting unprotected exposure to pathogens; limiting the transmission of infections associated with procedures performed in the clinic; and limiting the transmission of infections associated with the clinic's use of medical equipment, devices and supplies. [458.3265(3)(g)3. a.-d.; 459.0137(3)(g)3. a.-d., F.S.]	

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Clinic has an ongoing quality assurance program that objectively and systematically monitors and evaluates quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the facility, alerts the 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. [458.3265(3)(i).; 459.0137(3)(i), F.S.]	
The designated physician has established a quality assurance program that includes the following components: the identification, investigation and analysis of the frequency and causes of adverse incidents to patients; the identification of trends or patterns of incidents; measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients; the documentation of these functions; and periodic review at least quarterly of such information by the designated physician. [458.3265(3)(i)1.-4.; 459.0137(3)(i)1.-4., F.S.]	
Designated physician reports all adverse incidents to the Department of Health as set forth in Section 458.351, Florida Statutes. [458.3265(3)(j)1.; 459.0137(3)(j) 1., F.S.]	
Designated physician reports quarterly to the Board of Medicine or Osteopathic Medicine in writing the number of new and repeat patients seen and treated at the clinic who are prescribed controlled substance medications for the treatment of chronic, non-malignant pain; the number of patients discharged due to drug abuse; the number of patients discharged due to drug diversion; and the number of patients treated at the pain clinic whose domicile is located somewhere other than in Florida. [458.3265(3)(j)2. a.-d.; 459.0137(3)(j)2. a.-d., F.S.]	
Physician maintains control and security of prescription blanks and other methods for prescribing controlled substances and reports in writing any theft or loss of prescription blanks to the department within 24 hours. [458.3265(3)(d); 459.0137(3)(d), F.S.]	
Physicians are in compliance with the requirements for counterfeit-resistant prescription blanks as defined in Section 893.065. [Sections 458.3265(3)(d); 459.0137(3)(d), F.S.]	
Dispensing is being performed in compliance with 465.0276, F.S. Only physicians licensed under chapter 458 and 459 are dispensing any medication. [Sections 458.3265(3)(b) and 459.0137(3)(b), F.S.]	
Controlled substance biennial inventory conducted. [893.07(1)(a), F.S.]	
There is no indication physicians have advertised the use, sale, or dispensing of any controlled substance appearing on any schedule in Chapter 893. [Section 458.331(1)(rr) and 459.015(1)(tt), F.S.]	
Effective January 1, 2012 all physicians have designated himself or herself as a controlled substance prescribing practitioner on the physician's practitioner profile. [456.44(2)(a), F.S.]	
All physicians practicing in this clinic have advised the Board, in writing, within 10 calendar days of beginning or ending his or her practice at this pain-management clinic. [458.3265(3)(e); 459.0137(3)(e), F.S.]	
All physicians practicing in this clinic meet the training requirements for physicians practicing in pain management clinics [64B8-9.0131; 64B15-14.0051, F.A.C.]	
At least one employee on premises is certified in basic life support. [458.3265(3)(h)4.; 459.0137(3)(h)4., F.S.]	

Remarks:

I have read and have had this inspection report and the violations if any explained, and the information given is true and correct to the best of my knowledge. This inspection is not deemed complete until patient records are reviewed and deemed in compliance with section 458.3265, 459.0137, and chapter 456, Florida Statutes. I understand that any action taken to correct violations shall be documented in writing by the owner or designated physician of the pain clinic and will be verified by follow up visits by the department personnel. [458.3265(3)(b), 459.0137(3)(b), F.S.]

Investigator/Sr. Pharmacist Signature:

Representative:

Date:

Date:



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INV 440B - Pain Management Clinic

Pain Management Clinic Requirement

Complete physical exam is performed by a physician, physician's assistant or advanced registered nurse practitioner on the same day that the physician prescribes a controlled substance. [458.3265(3)(c); 459.0137(3)(c), F.S.]	
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Maintains accurate, current and complete records that are accessible and readily available for review and comply with the requirements of 456.44(3)(f), the applicable practice act, and applicable board rule. The medical records must include but are not limited to:

Complete medical history and physician examination, including history of drug abuse and dependence. [456.44(3)(f)1, F.S.]	
Diagnostic, therapeutic, and laboratory results. [456.44(3)(f)2, F.S.]	
Evaluations and consultations. [456.44(3)(f)3, F.S.]	
Treatment objectives. [456.44(3)(f)4, F.S.]	
Discussion of risks and benefits. [456.44(3)(f)5, F.S.]	
Treatments. [456.44(3)(f)6, F.S.]	
Medications, including date, type, dosage, and quantity prescribed. [456.44(3)(f)7, F.S.]	
Instructions and agreements. [456.44(3)(f)8, F.S.]	
Periodic reviews. [456.44(3)(f)9, F.S.]	
Results of any drug testing. [456.44(3)(f)10, F.S.]	
A photocopy of the patient's government-issued photo identification. [456.44(3)(f)11, F.S.]	
Duplicate of all written controlled substance prescriptions. [456.44(3)(f)12, F.S.]	
The physician's full name presented in a legible manner. [456.44(3)(f)13, F.S.]	

Pain Management Clinic Requirements

Controlled substance prescriptions have the quantity of the drug prescribed in both textual and numerical format and are dated with the abbreviated month written out on the face of the prescription. [456.42(1), F.S.]	
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A written individualized treatment plan has been developed for each patient with objectives used to determine treatment success. The physician adjusts drug therapy to the individual needs of each patient. Other treatment modalities are considered. Interdisciplinary nature of treatment plan is documented. [456.44(3)(b)]	
The physician is documenting in the patient's record the reason for prescribing more than 72-hour supply of controlled substances for the treatment of chronic non-malignant pain. [458.3265(3) (c); 459.0137(3)(c), F.S.]	
Patients are seen by the physician at regular intervals, not to exceed 3 months, to assess the efficacy of treatment. Continuation or modification of therapy depends on the physician's evaluation of the patient's progress. [456.44(3)(d) F.S.]	
Patients are referred as necessary for additional evaluation and treatment in order to achieve treatment objectives with special attention given to those patients at risk for misuse of medications and those in living arrangements that pose a risk for medication misuse or diversion. [456.44(3)(e), F.S.]	
Patients with signs or symptoms of substance abuse are immediately referred to a board-certified pain management physician, addiction medicine specialist, or a mental health addiction facility unless the physician is board-certified or board-eligible in pain management. [456.44(3)(g), F.S.]	
Clear and complete medical justification for continued treatment with controlled substances and steps to ensure medically appropriate use of controlled substances is documented clearly and completely when continuing controlled substance prescribing while waiting consultant's report on patients showing signs or symptoms of substance abuse. [456.44(3)(g), F.S.]	
Physician is incorporating consultant's recommendation for continuing, modifying, or discontinuing controlled substance therapy into the treatment plan. [456.44(3)(g), F.S.]	

The physician has discussed the risks and benefits of the use of controlled substances and is using a written controlled substance agreement between the patient outlining the patient's responsibilities including, but not limited to:

Number and frequency of controlled substance prescriptions and refills. [456.44(3)(c)1, F.S.]	
Patient compliance and reasons for which drug therapy may be discontinued. [456.44(3)(c)2, F.S.]	
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. [456.44(3)(c)3, F.S.]	

Remarks:

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Investigator/Sr. Pharmacist Signature:

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