

Final Order No. DOH-10-2879 ^{DS}-MQA
FILED DATE - 12-23-10
Department of Health

STATE OF FLORIDA
DEPARTMENT OF HEALTH

By: 
Deputy Agency Clerk

IN RE:

Florida Medical Association, Inc.

**CORRECTED FINAL ORDER GRANTING PETITION FOR
DECLARATORY STATEMENT**

On or about October 27, 2010, Petitioner filed the attached Petition for Declaratory Statement with the Department of Health (Department) pursuant to section 120.565, Florida Statutes, and rule chapter 28-105 of the Florida Administrative Code.¹ Petitioner asserts that a second petitioner was named in error, and asks the Department to issue this corrected order making it the sole Petitioner for purposes of the disposition of this Petition.

The Petition asks the Department for an interpretation of sections 458.3265 and 459.0137, Florida Statutes (the applicable statutes). No comments were submitted for the Department's consideration subsequent to the filing of the Petition.

FINDINGS OF FACT

1. The Department is responsible for the registration of pain-management clinics and for imposing discipline on clinics and on unregistered pain-management clinics.

2. Unless one of the exceptions is met, the applicable statutes require the registration of all clinics "which advertise in any medium for any type of pain-management services."

¹ Petitioner also cites to "Chapter 64B-9.0132, Florida Administrative Code." The Department notes that there is no such rule.

3. Petitioner is a professional association whose members are substantially affected by the statute and have a need to know whether particular advertisements require them to become registered under the Department's interpretation of the statutes.

4. Petitioner submitted 11 specific advertisements inquiring as to which of them would require the clinic or business entity that places the advertisement to register as a pain-management clinic.

CONCLUSIONS OF LAW

5. The Department has jurisdiction and is an appropriate agency to opine on the applicable statutes as they apply to the members of Petitioner's particular set of circumstances.

6. The Department determined that Petitioner's request for the issuance of a declaratory statement should be GRANTED as follows:

- a. Advertisement 1 (Exhibit B) would not require registration.
- b. Advertisement 2 (Exhibit C) would require registration because it would be placed to obtain patients in need of pain-management services.
- c. Advertisement 3 (Exhibit D) would not require registration.
- d. Advertisement 4 (Exhibit E) would not require registration.
- e. Advertisement 5 (Exhibit F) would require registration because it includes "pain relief and symptom management."
- f. Advertisement 6 (Exhibit G) would not require registration.
- g. Advertisement 7 (Exhibit H) would not require registration.

h. Advertisement 8 (Exhibit I) would require registration because it includes treatment of facial pain and fibromyalgia/musculoskeletal pain.

i. Advertisement 9 (Exhibit J) would require registration because of the phrase "if you suffer from pain."

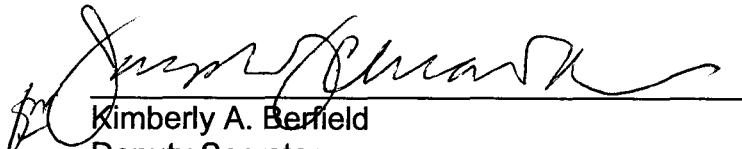
j. Advertisement 10 (Exhibit K) would require registration because it advertises a pain management clinic to serve all your pain needs.

k. Advertisement 11 (Exhibit L) would require registration because it includes a telephone number with the word "PAIN."

WHEREFORE,

IT IS HEREBY ORDERED AND ADJUDGED that the Petition for Declaratory Statement is GRANTED.

DONE AND ORDERED on December 14, 2010, nunc pro tunc, this 22ND day of December, 2010.


Kimberly A. Berfield
Deputy Secretary

NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this final order is entitled to judicial review pursuant to section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing one copy of a notice of appeal with the agency clerk of the Department of Health and a second copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First

District, or with the District Court of Appeal in the Appellate District where the party resides.
The notice of appeal must be filed within 30 days of rendition of the order to be reviewed.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been furnished by U.S. mail to Holly R. Miller, Esquire, Florida Medical Association, Inc., 123 S. Adams Street, Tallahassee, Florida 32301, this 23rd day of December, 2010.

Angela Sanders
Deputy Agency Clerk

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STATE OF FLORIDA
DEPARTMENT OF HEALTH

RE: Petition for Declaratory Statement of
Florida Medical Association, Inc. and
David McKalp, M.D.,

Case No.: _____

Petitioners.

PETITION FOR DECLARATORY STATEMENT BEFORE THE DEPARTMENT OF HEALTH

Petitioner, the Florida Medical Association, Inc. ('FMA'), by and through undersigned counsel and pursuant to Sections 120.565, 458.3265(1)(a), and 459.0137(1)(a) Florida Statutes, and Rules Chapter 28-105 and Chapter 64B-9.0132, Florida Administrative Code, petition the Department of Health for a Final Order setting forth a Declaratory Statement on the facts and law presented herein.

1. Petitioner, FMA is a professional association dedicated to the service and assistance of Doctors of Medicine and Doctors of Osteopathic Medicine in Florida, located at 123 S. Adams Street, Tallahassee, Florida 32301 and 1430 Piedmont Drive E, Tallahassee, Florida 32308. The office telephone number is (850) 224-6496 and the facsimile number is (850) 222-8827. The FMA is organized and maintained for the benefit of the approximately 20,000 licensed Florida physicians who comprise its membership. One of the primary purposes of the FMA is to act on behalf of its members by representing their common interests before the various governmental entities of the State of Florida, including the Department of Health and its Boards.

2. The agency affected by this Petition is the Florida Department of Health (hereafter 'Department'). The statutory provisions upon which this Declaratory Statement is sought are contained in Section 458.3265 and 459.0137, Florida Statutes and rule. A copy of this law is attached for easy reference as Exhibit A.

3. The legislation eliciting this Petition is Florida Senate Bill 2272. The bill seeks to modify and enhance pain-management services and pain-management clinics in the State of Florida.

Through registration, a designated physician is identified and assigned responsibilities and held under disciplinary guidelines. The Department is authorized to deny an application to register a pain-management clinic, revoke or suspend a registration, or impose administrative fines for various offenses or conditions. Only a medical physician or osteopathic physician may dispense controlled substance medication on the premises of the clinic. A physician may not practice medicine or osteopathic medicine in a clinic that is not registered, or effective July 1, 2012, the physician has not completed a pain fellowship or residency and has not complied with the applicable medical boards.

4. On October 1, 2010, Florida Senate Bill 2272 went into effect as section 458.3265, Florida Statutes, Pain Management Clinics. Under the statute in section (1)(a) 'Registration', it outlines who must register:

(a) All privately owned pain-management clinics, facilities, or offices, hereinafter referred to as "clinics," which advertise in any medium for any type of pain-management services, or employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the department unless

5. Petitioner's members advertise their medical practices and are in the process of designing new advertisements to comply with section 458.3265, Florida Statutes, Pain Management Clinics. Petitioner and their members will be substantially affected by the registration requirements regarding advertising. As demonstrated by the strategic placement of the word 'or', advertising is not an element or factor in addition to employment. The registration requirement stating "'clinics" which advertise in any medium for any type of pain-management services' is a wholly independent and separate requirement from the employment of a physician. The concern is that this advertising requirement 'in any medium for any type of pain-management services' will broadly apply to many physicians, not just pain management specialists in pain-management clinics. This advertising requirement will result in unintended physicians registering as a pain-management clinic in efforts to comply with the law, if no clarification is made.

6. The Department, through its jurisdiction and rulemaking authority over the requirements of the registration of pain-management clinics in Florida, has the responsibility to determine whether the following physician advertisements would create an obligation under the law to register with the Department as a pain management clinic.

- a. Advertisement 1, attached and referenced as Exhibit B.
- b. Advertisement 2, attached and referenced as Exhibit C.
- c. Advertisement 3, attached and referenced as Exhibit D.
- d. Advertisement 4, attached and referenced as Exhibit E.
- e. Advertisement 5, attached and referenced as Exhibit F.
- f. Advertisement 6, attached and referenced as Exhibit G.
- g. Advertisement 7, attached and referenced as Exhibit H.
- h. Advertisement 8, attached and referenced as Exhibit I.
- i. Advertisement 9, attached and referenced as Exhibit J.
- j. Advertisement 10, attached and referenced as Exhibit K.
- k. Advertisement 11, attached and referenced as Exhibit L.

WHEREFORE, Petitioners respectfully request that the Department of Health issue a Final Order as to each individual Exhibit attached hereto and state whether the advertisement contained therein is the type of advertisement that would require the pain management clinic, facility, or office to register as a pain management clinic as required by sections 458.3265 and 459.0137, Florida Statutes.

Respectfully submitted this 25th day of October, 2010.

By: _____

Holly R. Miller

Fla. Bar No: 56368

Florida Medical Association, Inc.

123 S. Adams Street, Tallahassee, FL 32301

(850)224-6496 hmilller@medone.org

Attorney for Petitioners

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the foregoing PETITION FOR DECLARATORY STATEMENT BEFORE THE DEPARTMENT OF HEALTH has been furnished by U.S. MAIL on this 25th day of October, 2010, to the following: Department of Health's Agency Clerk's Office, 4052 Bald Cypress Way, BIN #A02, Tallahassee, Florida 32399-1703.

EXHIBIT A

2010 Florida Statutes 458.3265 Pain-management clinics.

(1)REGISTRATION.—

(a)All privately owned pain-management clinics, facilities, or offices, hereinafter referred to as "clinics," which advertise in any medium for any type of pain-management services, or employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the department unless:

- 1.That clinic is licensed as a facility pursuant to chapter 395;
- 2.The majority of the physicians who provide services in the clinic primarily provide surgical services;
- 3.The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded \$50 million;
- 4.The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
- 5.The clinic does not prescribe or dispense controlled substances for the treatment of pain; or
- 6.The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3).

(b)Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic.

(c)As a part of registration, a clinic must designate a physician who is responsible for complying with all requirements related to registration and operation of the clinic in compliance with this section. Within 10 days after termination of a designated physician, the clinic must notify the department of the identity of another designated physician for that clinic. The designated physician shall have a full, active, and unencumbered license under this chapter or chapter 459 and shall practice at the clinic location for which the physician has assumed responsibility. Failing to have a licensed designated physician practicing at the location of the registered clinic may be the basis for a summary suspension of the clinic registration certificate as described in s. 458.073(8) for a license or s. 120.60(6).

(d)The department shall deny registration to any clinic that is not fully owned by a physician licensed under this chapter or chapter 459 or a group of physicians, each of whom is licensed under this chapter or chapter 459; or that is not a health care clinic licensed under part X of chapter 400.

(e)The department shall deny registration to any pain-management clinic owned by or with any contractual or employment relationship with a physician:

- 1.Whose Drug Enforcement Administration number has ever been revoked.
- 2.Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction.
- 3.Who has been convicted of or pleaded guilty or nolo contendere to, regardless of adjudication, an offense that constitutes a felony for receipt of illicit and diverted drugs, including a controlled substance listed in Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in this state, any other state, or the United States.

(f) If the department finds that a pain-management clinic does not meet the requirement of paragraph (d) or is owned, directly or indirectly, by a person meeting any criteria listed in paragraph (e), the department shall revoke the certificate of registration previously issued by the department. As determined by rule, the department may grant an exemption to denying a registration or revoking a previously issued registration if more than 10 years have elapsed since adjudication. As used in this subsection, the term "convicted" includes an adjudication of guilt following a plea of guilty or nolo contendere or the forfeiture of a bond when charged with a crime.

(g) The department may revoke the clinic's certificate of registration and prohibit all physicians associated with that pain-management clinic from practicing at that clinic location based upon an annual inspection and evaluation of the factors described in subsection (3).

(h) If the registration of a pain-management clinic is revoked or suspended, the designated physician of the pain-management clinic, the owner or lessor of the pain-management clinic property, the manager, and the proprietor shall cease to operate the facility as a pain-management clinic as of the effective date of the suspension or revocation.

(i) If a pain-management clinic registration is revoked or suspended, the designated physician of the pain-management clinic, the owner or lessor of the clinic property, the manager, or the proprietor is responsible for removing all signs and symbols identifying the premises as a pain-management clinic.

(j) Upon the effective date of the suspension or revocation, the designated physician of the pain-management clinic shall advise the department of the disposition of the medicinal drugs located on the premises. The disposition is subject to the supervision and approval of the department. Medicinal drugs that are purchased or held by a pain-management clinic that is not registered may be deemed adulterated pursuant to s. 499.006.

(k) If the clinic's registration is revoked, any person named in the registration documents of the pain-management clinic, including persons owning or operating the pain-management clinic, may not, as an individual or as a part of a group, apply to operate a pain-management clinic for 5 years after the date the registration is revoked.

(l) The period of suspension for the registration of a pain-management clinic shall be prescribed by the department, but may not exceed 1 year.

(m) A change of ownership of a registered pain-management clinic requires submission of a new registration application.

(2) **PHYSICIAN RESPONSIBILITIES.**—These responsibilities apply to any physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

(a) A physician may not practice medicine in a pain-management clinic, as described in subsection (4), if:

1. The pain-management clinic is not registered with the department as required by this section; or

2. Effective July 1, 2012, the physician has not successfully completed a pain-medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education or a pain-medicine residency that is accredited by the Accreditation Council for Graduate Medical Education or, prior to July 1, 2012, does not comply with rules adopted by the board.

Any physician who qualifies to practice medicine in a pain-management clinic pursuant to rules adopted by the Board of Medicine as of July 1, 2012, may continue to practice medicine in a pain-management clinic as long as the physician continues to meet the qualifications set forth in the board rules. A physician who violates this paragraph is subject to disciplinary action by his or her appropriate medical regulatory board.

(b) A person may not dispense any medication, including a controlled substance, on the premises of a registered pain-management clinic unless he or she is a physician licensed under this chapter or chapter 459.

(c) A physician must perform a physical examination of a patient on the same day that he or she dispenses or prescribes a controlled substance to a patient at a pain-management clinic. If the physician prescribes or dispenses more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the physician must document in the patient's record the reason for prescribing or dispensing that quantity.

(d) A physician authorized to prescribe controlled substances who practices at a pain-management clinic is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing controlled substance pain medication. The physician shall comply with the requirements for counterfeit-resistant prescription blanks in s. 893.065 and the rules adopted pursuant to that section. The physician shall notify, in writing, the department within 24 hours following any theft or loss of a prescription blank or breach of any other method for prescribing pain medication.

(e) The designated physician of a pain-management clinic shall notify the applicable board in writing of the date of termination of employment within 10 days after terminating his or her employment with a pain-management clinic that is required to be registered under subsection (1).

(3) INSPECTION.—

(a) The department shall inspect the pain-management clinic annually, including a review of the patient records, to ensure that it complies with this section and the rules of the Board of Medicine adopted pursuant to subsection (4) unless the clinic is accredited by a nationally recognized accrediting agency approved by the Board of Medicine.

(b) During an onsite inspection, the department shall make a reasonable attempt to discuss each violation with the owner or designated physician of the pain-management clinic before issuing a formal written notification.

(c) Any action taken to correct a violation shall be documented in writing by the owner or designated physician of the pain-management clinic and verified by followup visits by departmental personnel.

(4) RULEMAKING.—

(a) The department shall adopt rules necessary to administer the registration and inspection of pain-management clinics which establish the specific requirements, procedures, forms, and fees.

(b) The department shall adopt a rule defining what constitutes practice by a designated physician at the clinic location for which the physician has assumed responsibility, as set forth in subsection (1). When adopting the rule, the department shall consider the number of clinic employees, the location of the pain-management clinic, the clinic's hours of operation, and the amount of controlled substances being prescribed, dispensed, or administered at the pain-management clinic.

(c) The Board of Medicine shall adopt a rule establishing the maximum number of prescriptions for Schedule II or Schedule III controlled substances or the controlled substance Alprazolam which may be written at any one registered pain-management clinic during any 24-hour period.

(d) The Board of Medicine shall adopt rules setting forth standards of practice for physicians practicing in privately owned pain-management clinics that primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications. Such rules shall address, but need not be limited to:

1. Facility operations;

2. Physical operations;
3. Infection control requirements;
4. Health and safety requirements;
5. Quality assurance requirements;
6. Patient records;
7. Training requirements for all facility health care practitioners who are not regulated by another board;
8. Inspections; and
9. Data collection and reporting requirements.

A physician is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications when the majority of the patients seen are prescribed or dispensed controlled substance medications for the treatment of chronic nonmalignant pain. Chronic nonmalignant pain is pain unrelated to cancer which persists beyond the usual course of the disease or the injury that is the cause of the pain or more than 90 days after surgery.

(5) PENALTIES; ENFORCEMENT.—

(a) The department may impose an administrative fine on the clinic of up to \$5,000 per violation for violating the requirements of this section; chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act; chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act; or the rules of the department. In determining whether a penalty is to be imposed, and in fixing the amount of the fine, the department shall consider the following factors:

1. The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the pain-management clinic's actions or the actions of the physician, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated.
2. What actions, if any, the owner or designated physician took to correct the violations.
3. Whether there were any previous violations at the pain-management clinic.
4. The financial benefits that the pain-management clinic derived from committing or continuing to commit the violation.

(b) Each day a violation continues after the date fixed for termination of the violation as ordered by the department constitutes an additional, separate, and distinct violation.

(c) The department may impose a fine and, in the case of an owner-operated pain-management clinic, revoke or deny a pain-management clinic's registration, if the clinic's designated physician knowingly and intentionally misrepresents actions taken to correct a violation.

(d) An owner or designated physician of a pain-management clinic who concurrently operates an unregistered pain-management clinic is subject to an administrative fine of \$5,000 per day.

(e) If the owner of a pain-management clinic that requires registration fails to apply to register the clinic upon a change of ownership and operates the clinic under the new ownership, the owner is subject to a fine of \$5,000.

History.—s. 4, ch. 2010-211.

2010 Florida Statutes 459.0137 Pain-management clinics.

(1) REGISTRATION.—

(a) All privately owned pain-management clinics, facilities, or offices, hereinafter referred to as "clinics," which advertise in any medium for any type of pain-management services, or employ an osteopathic physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the department unless:

1. That clinic is licensed as a facility pursuant to chapter 395;
2. The majority of the physicians who provide services in the clinic primarily provide surgical services;
3. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded \$50 million;
4. The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
5. The clinic does not prescribe or dispense controlled substances for the treatment of pain; or
6. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3).

(b) Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic.

(c) As a part of registration, a clinic must designate an osteopathic physician who is responsible for complying with all requirements related to registration and operation of the clinic in compliance with this section. Within 10 days after termination of a designated osteopathic physician, the clinic must notify the department of the identity of another designated physician for that clinic. The designated physician shall have a full, active, and unencumbered license under chapter 458 or this chapter and shall practice at the clinic location for which the physician has assumed responsibility. Failing to have a licensed designated osteopathic physician practicing at the location of the registered clinic may be the basis for a summary suspension of the clinic registration certificate as described in s. 458.073(8) for a license or s. 120.60(6).

(d) The department shall deny registration to any clinic that is not fully owned by a physician licensed under chapter 458 or this chapter or a group of physicians, each of whom is licensed under chapter 458 or this chapter; or that is not a health care clinic licensed under part X of chapter 400.

(e) The department shall deny registration to any pain-management clinic owned by or with any contractual or employment relationship with a physician:

1. Whose Drug Enforcement Administration number has ever been revoked.
2. Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction.

3. Who has been convicted of or pleaded guilty or nolo contendere to, regardless of adjudication, an offense that constitutes a felony for receipt of illicit and diverted drugs, including a controlled substance listed in Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in this state, any other state, or the United States.

(f) If the department finds that a pain-management clinic does not meet the requirement of paragraph (d) or is owned, directly or indirectly, by a person meeting any criteria listed in paragraph (e), the department shall revoke the certificate of registration previously issued by the department. As determined by rule, the department may grant an exemption to denying a registration or revoking a previously issued registration if more than 10 years have elapsed since adjudication. As used in this subsection, the term "convicted" includes an adjudication of guilt following a plea of guilty or nolo contendere or the forfeiture of a bond when charged with a crime.

(g) The department may revoke the clinic's certificate of registration and prohibit all physicians associated with that pain-management clinic from practicing at that clinic location based upon an annual inspection and evaluation of the factors described in subsection (3).

(h) If the registration of a pain-management clinic is revoked or suspended, the designated physician of the pain-management clinic, the owner or lessor of the pain-management clinic property, the manager, and the proprietor shall cease to operate the facility as a pain-management clinic as of the effective date of the suspension or revocation.

(i) If a pain-management clinic registration is revoked or suspended, the designated physician of the pain-management clinic, the owner or lessor of the clinic property, the manager, or the proprietor is responsible for removing all signs and symbols identifying the premises as a pain-management clinic.

(j) Upon the effective date of the suspension or revocation, the designated physician of the pain-management clinic shall advise the department of the disposition of the medicinal drugs located on the premises. The disposition is subject to the supervision and approval of the department. Medicinal drugs that are purchased or held by a pain-management clinic that is not registered may be deemed adulterated pursuant to s. 499.006.

(k) If the clinic's registration is revoked, any person named in the registration documents of the pain-management clinic, including persons owning or operating the pain-management clinic, may not, as an individual or as a part of a group, make application for a permit to operate a pain-management clinic for 5 years after the date the registration is revoked.

(l) The period of suspension for the registration of a pain-management clinic shall be prescribed by the department, but may not exceed 1 year.

(m) A change of ownership of a registered pain-management clinic requires submission of a new registration application.

(2) **PHYSICIAN RESPONSIBILITIES.**—These responsibilities apply to any osteopathic physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

(a) An osteopathic physician may not practice medicine in a pain-management clinic, as described in subsection (4), if:

1. The pain-management clinic is not registered with the department as required by this section; or

2. Effective July 1, 2012, the physician has not successfully completed a pain-medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association or a pain-medicine residency that is accredited by the Accreditation Council for Graduate

Medical Education or the American Osteopathic Association or, prior to July 1, 2012, does not comply with rules adopted by the board.

Any physician who qualifies to practice medicine in a pain-management clinic pursuant to rules adopted by the Board of Osteopathic Medicine as of July 1, 2012, may continue to practice medicine in a pain-management clinic as long as the physician continues to meet the qualifications set forth in the board rules. An osteopathic physician who violates this paragraph is subject to disciplinary action by his or her appropriate medical regulatory board.

(b) A person may not dispense any medication, including a controlled substance, on the premises of a registered pain-management clinic unless he or she is a physician licensed under this chapter or chapter 458.

(c) An osteopathic physician must perform a physical examination of a patient on the same day that he or she dispenses or prescribes a controlled substance to a patient at a pain-management clinic. If the osteopathic physician prescribes or dispenses more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the osteopathic physician must document in the patient's record the reason for prescribing or dispensing that quantity.

(d) An osteopathic physician authorized to prescribe controlled substances who practices at a pain-management clinic is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing controlled substance pain medication. The osteopathic physician shall comply with the requirements for counterfeit-resistant prescription blanks in s. 893.065 and the rules adopted pursuant to that section. The osteopathic physician shall notify, in writing, the department within 24 hours following any theft or loss of a prescription blank or breach of any other method for prescribing pain medication.

(e) The designated osteopathic physician of a pain-management clinic shall notify the applicable board in writing of the date of termination of employment within 10 days after terminating his or her employment with a pain-management clinic that is required to be registered under subsection (1).

(3) INSPECTION.—

(a) The department shall inspect the pain-management clinic annually, including a review of the patient records, to ensure that it complies with this section and the rules of the Board of Osteopathic Medicine adopted pursuant to subsection (4) unless the clinic is accredited by a nationally recognized accrediting agency approved by the Board of Osteopathic Medicine.

(b) During an onsite inspection, the department shall make a reasonable attempt to discuss each violation with the owner or designated physician of the pain-management clinic before issuing a formal written notification.

(c) Any action taken to correct a violation shall be documented in writing by the owner or designated physician of the pain-management clinic and verified by followup visits by departmental personnel.

(4) RULEMAKING.—

(a) The department shall adopt rules necessary to administer the registration and inspection of pain-management clinics which establish the specific requirements, procedures, forms, and fees.

(b) The department shall adopt a rule defining what constitutes practice by a designated osteopathic physician at the clinic location for which the physician has assumed responsibility, as set forth in subsection (1). When adopting the rule, the department shall consider the number of clinic employees, the location of the pain-management clinic, the clinic's hours of operation, and the amount of controlled substances being prescribed, dispensed, or administered at the pain-management clinic.

(c)The Board of Osteopathic Medicine shall adopt a rule establishing the maximum number of prescriptions for Schedule II or Schedule III controlled substances or the controlled substance Alprazolam which may be written at any one registered pain-management clinic during any 24-hour period.

(d)The Board of Osteopathic Medicine shall adopt rules setting forth standards of practice for osteopathic physicians practicing in privately owned pain-management clinics that primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications. Such rules shall address, but need not be limited to:

- 1.Facility operations;
- 2.Physical operations;
- 3.Infection control requirements;
- 4.Health and safety requirements;
- 5.Quality assurance requirements;
- 6.Patient records;
- 7.Training requirements for all facility health care practitioners who are not regulated by another board;
- 8.Inspections; and
- 9.Data collection and reporting requirements.

An osteopathic physician is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications when the majority of the patients seen are prescribed or dispensed controlled substance medications for the treatment of chronic nonmalignant pain. Chronic nonmalignant pain is pain unrelated to cancer which persists beyond the usual course of the disease or the injury that is the cause of the pain or more than 90 days after surgery.

(5)PENALTIES; ENFORCEMENT.—

(a)The department may impose an administrative fine on the clinic of up to \$5,000 per violation for violating the requirements of this section; chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act; chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act; or the rules of the department. In determining whether a penalty is to be imposed, and in fixing the amount of the fine, the department shall consider the following factors:

- 1.The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the pain-management clinic's actions or the actions of the osteopathic physician, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated.
- 2.What actions, if any, the owner or designated osteopathic physician took to correct the violations.
- 3.Whether there were any previous violations at the pain-management clinic.
- 4.The financial benefits that the pain-management clinic derived from committing or continuing to commit the violation.

(b)Each day a violation continues after the date fixed for termination of the violation as ordered by the department constitutes an additional, separate, and distinct violation.

(c)The department may impose a fine and, in the case of an owner-operated pain-management clinic, revoke or deny a pain-management clinic's registration, if the clinic's designated osteopathic physician knowingly and intentionally misrepresents actions taken to correct a violation.

(d)An owner or designated osteopathic physician of a pain-management clinic who concurrently operates an unregistered pain-management clinic is subject to an administrative fine of \$5,000 per day.

(e)If the owner of a pain-management clinic that requires registration fails to apply to register the clinic upon a change of ownership and operates the clinic under the new ownership, the owner is subject to a fine of \$5,000.

History.—s. 8, ch. 2010-211.

EXHIBIT B

Advertisement to be published in the Yellowpages:

'Dr. _____:

**Specializing in the Treatment of Migraines and
Headaches.**

(850) 555-1212'

EXHIBIT C

Advertisement to be published in the Yellowpages:

'Dr. _____':

Board Certified in Pain Management

(850) 555-1212'

EXHIBIT D

Advertisement to be published in any medium:

'Back, Neck or Leg Discomfort?

For a Discussion of Surgical and Other
Treatment Options,

Call Dr. _____ (850) 555-1212'

EXHIBIT E

Advertisement to be published in any medium:

'Back, Neck, or Leg Pain?'

Learn about the latest minimally invasive surgeries performed at the Florida _____ and _____ Center.

FREE SEMINARS

Wednesday, October 13, 2010
St. Petersburg 11am-5pm
Hotel Conference Center

Thursday, October 14, 2010
Clearwater 11am-5pm
Hotel Conference Center

Friday, October 15, 2010
Tampa 11am-5pm
Hotel Conference Center

**To Register, Please Call
1-850-555-1212'**

EXHIBIT F

Advertisement to be published in any medium:

Find Affordable End-of-Life Care

Services covered include:

- Physician and nursing care
- Pain relief and symptom management
- Medical equipment and supplies
- Certified nursing assistants to help with personal care
- Physical, occupational and speech therapy, and dietary counseling
- Grief support
- Emotional and spiritual support

It's never too soon to receive the support you or the person you are caring for needs. We're here for you now. Call us today.

1-850-555-1212'

EXHIBIT G

Advertisement to be published in a website on the Internet:

'Neuromuscular Conditions are diseases of nerve and muscle, such as pinched nerve, neuropathy, nerve damage, carpal tunnel syndrome, myopathy, and myasthenia. Muscle spasm, weakness, numbness, tingling, twitching, and pain can be symptoms of a neuromuscular condition.

Dystonia is an involuntary sustained muscle contraction that can cause neck spasm and pain. Dystonia can be treated with medications or with botulinum toxin (Botox).

EMG and Nerve Conduction Studies are tests of the nerves and muscles. They can help in diagnosing pinched nerves, numbness, tingling, weakness, paralysis, limb pain, back pain, herniated discs, muscle spasm, and nerve and muscle junction diseases.

Head Injury can manifest as headaches, post-concussion syndrome, or traumatic brain injury. TBI is sometimes under-recognized or overshadowed by the other injuries. It is important to be evaluated by a neurologist or other qualified specialist.

Medical Center
1234 Main Street, Anytown, Florida 33333
1-800-555-1212

Neurology is the diagnosis and treatment of neurological (brain, spinal cord, nerve, and muscle) conditions by a medical specialist.

Neurologists complete 4 years of college, 4 years of medical school, and 4 years of internship/residency. Some neurologists also do fellowship work.

_____, M.D.
1-850-555-1212'

EXHIBIT H

Advertisement to be published in any medium:

'Practicing Tomorrow's Medicine...Today!'

OBGYN Care

- Normal & High Risk Obstetrics
- Menopause & HRT Therapy
- Pelvic Pain
- Family Planning
- Contraception
- Infertility Consultation
- Laparoscopic Surgery
- HPV Vaccinations
- Menstrual Dysfunction
- Endometriosis Management
- Well Woman Exams
- 3D/4D Obstetric Ultrasound
- Gynecological Surgery
- da Vinci Robotic Surgery
- NEW: Online Patient Services provides access to:*
- Request Appointments
- Request Medication Refills
- Review Medical Information
- Online Payments
- Educational Programs and much more!

ALL PHYSICIANS ARE BOARD CERTIFIED

Medical Center
1234 Main Street, Anytown, Florida 33333
1-850-555-1212'

EXHIBIT I

Advertisement to be published in any medium:

**'This is one way to prevent a Headache.
There is a better way.**

Florida Headache and Neurology

The Florida _____ and _____ Center is a clinic specializing in the treatment of Headache, Facial Pain, Fibromyalgia/Musculoskeletal Pain and most neurological disorders. Trained in Boston at Tufts and Boston University, Dr. _____ brings with him world class knowledge and a multidisciplinary approach normally found only at large academic institutions.

Neurological care trusted by Professional Athletes and their fans.

All Major Insurances Accepted.

1-850-555-1212'

EXHIBIT J

Advertisement to be published in any medium:

'Autonomic neurology is one form of nerve damage that may afflict people with diabetes. It can be among the most annoying and difficult to treat of all diabetes complications. If you suffer from pain associated with this diabetic condition, please contact Dr. _____ at (850) 555-1212'

EXHIBIT K

Advertisement to be published in any medium:

*'Dr. _____'s **Pain Management Clinic** is
proud to serve all your pain needs. Please call us
at (850) 555- 1212'*

EXHIBIT L

Advertisement to be published in any medium:

'Florida Arthritis Clinic

It's about more than just arthritis.

Our world-class physicians have a combined 50 years' experience diagnosing and treating bone, joint and muscle conditions - from the most visible to the highly complex and unseen. Our approach is based on a combination of leading-edge techniques, the latest research and proven clinical methods.

Call us at 1-800- 555- PAIN'