

CHAPTER 2010-211

Committee Substitute for Committee Substitute for Senate Bill No. 2272 and Committee Substitute for Senate Bill No. 2722

An act relating to controlled substances; amending s. 456.037, F.S.; providing that pain-management clinics that are required to be registered with the Department of Health are business establishments; amending s. 456.057, F.S.; providing that the Department of Health is not required to attempt to obtain authorization from a patient for the release of the patient's medical records under certain circumstances; authorizing the department to obtain patient records without authorization or subpoena if the department has probable cause to believe that certain violations have occurred or are occurring; repealing s. 458.309(4), (5), and (6), F.S., relating to pain-management clinics; creating s. 458.3265, F.S.; requiring all privately owned pain-management clinics, or offices that primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications or by employing a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, to register with the Department of Health; providing exceptions; requiring each location of a pain-management clinic to register separately; requiring a clinic to designate a physician who is responsible for complying with requirements related to registration and operation of the clinic; requiring the department to deny registration or revoke the registration of a pain-management clinic for certain conditions; authorizing the department to revoke a clinic's certificate of registration and prohibit physicians associated with the clinic from practicing at the clinic's location; requiring a pain-management clinic to cease operating if its registration certificate is revoked or suspended; requiring certain named persons to remove all signs and symbols identifying the premises as a pain-management clinic; requiring a pain-management clinic that has had its registration revoked or suspended to advise the department of the disposition of the medicinal drugs located on the premises; providing that medicinal drugs that are purchased or held by a pain-management clinic that is not registered may be deemed adulterated; prohibiting any person acting as an individual or as part of a group from applying for a certificate to operate a pain-management clinic for a certain period after the date the person's registration certificate is revoked; providing that a change of ownership of a registered pain-management clinic requires submission of a new registration application; providing the responsibilities of a physician who provides professional services at a pain-management clinic; requiring the department to inspect pain-management clinics and its patient records; providing an exception to inspection by the department; requiring a pain-management clinic to document corrective action; requiring the department and the Board of Medicine to adopt rules; authorizing the department to impose fines, deny a clinic's registration, or revoke a clinic's registration; amending s. 458.327, F.S.; providing that the

commission of certain specified acts involving a nonregistered pain-management clinic constitutes a felony of the third degree or a misdemeanor of the first degree; amending s. 458.331, F.S.; providing additional acts that constitute grounds for disciplinary actions against health professional licensees; repealing s. 459.005(3), (4), and (5), F.S., relating to pain-management clinics; creating s. 459.0137, F.S.; requiring all privately owned pain-management clinics, or offices that primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications or by employing an osteopathic physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, to register with the department; providing exceptions; requiring each location of a pain-management clinic to register separately; requiring a clinic to designate an osteopathic physician who is responsible for complying with requirements related to registration and operation of the clinic; requiring the department to deny registration or revoke the registration of a pain-management clinic for certain conditions; authorizing the department to revoke a clinic's certificate of registration and prohibit osteopathic physicians associated with the clinic from practicing at the clinic's location; requiring a pain-management clinic to cease operating if its registration certificate is revoked or suspended; requiring certain named persons to remove all signs and symbols identifying the premises as a pain-management clinic; requiring a pain-management clinic that has had its registration revoked or suspended to advise the department of the disposition of the medicinal drugs located on the premises; providing that medicinal drugs that are purchased or held by a pain-management clinic that is not registered may be deemed adulterated; prohibiting any person acting as an individual or as part of a group from applying for a certificate to operate a pain-management clinic for a certain period after the date the person's registration certificate is revoked; providing that a change of ownership of a registered pain-management clinic requires submission of a new registration application; providing the responsibilities of an osteopathic physician who provides professional services at a pain-management clinic; requiring the department to inspect pain-management clinics and its patient records; providing an exception to inspection by the department; requiring a pain-management clinic to document corrective action; requiring the department and the Board of Osteopathic Medicine to adopt rules; authorizing the department to impose fines, deny a clinic's registration, or revoke a clinic's registration; amending s. 459.013, F.S.; providing that the commission of certain specified acts involving a nonregistered pain-management clinic constitutes a felony of the third degree or a misdemeanor of the first degree; amending s. 459.015, F.S.; providing additional acts that constitute grounds for disciplinary actions against health professional licensees; amending s. 465.0276, F.S.; prohibiting registered dispensing practitioners from dispensing more than a specified amount of certain controlled substances; providing penalties; providing exceptions; amending s. 893.055, F.S.; defining the term "program manager"; requiring that the program manager work with certain licensure boards and stakeholders to develop rules; authorizing the

program manager to provide relevant information to law enforcement agencies under certain circumstances; amending s. 893.0551, F.S.; providing for disclosure of confidential and exempt information to applicable law enforcement; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (5) of section 456.037, Florida Statutes, is amended to read:

456.037 Business establishments; requirements for active status licenses; delinquency; discipline; applicability.—

(5) This section applies to any business establishment registered, permitted, or licensed by the department to do business. Business establishments include, but are not limited to, dental laboratories, electrology facilities, massage establishments, and pharmacies, and pain-management clinics required to be registered under s. 458.3265 or s. 459.0137.

Section 2. Paragraph (a) of subsection (9) of section 456.057, Florida Statutes, is amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished.—

(9)(a)1. The department may obtain patient records pursuant to a subpoena without written authorization from the patient if the department and the probable cause panel of the appropriate board, if any, find reasonable cause to believe that a health care practitioner has excessively or inappropriately prescribed any controlled substance specified in chapter 893 in violation of this chapter or any professional practice act or that a health care practitioner has practiced his or her profession below that level of care, skill, and treatment required as defined by this chapter or any professional practice act and also find that appropriate, reasonable attempts were made to obtain a patient release. Notwithstanding the foregoing, the department need not attempt to obtain a patient release when investigating an offense involving the inappropriate prescribing, overprescribing, or diversion of controlled substances and the offense involves a pain-management clinic. The department may obtain patient records without patient authorization or subpoena from any pain-management clinic required to be licensed if the department has probable cause to believe that a violation of any provision of s. 458.3265 or s. 459.0137 is occurring or has occurred and reasonably believes that obtaining such authorization is not feasible due to the volume of the dispensing and prescribing activity involving controlled substances and that obtaining patient authorization or the issuance of a subpoena would jeopardize the investigation.

2. The department may obtain patient records and insurance information pursuant to a subpoena without written authorization from the patient if the department and the probable cause panel of the appropriate board, if

any, find reasonable cause to believe that a health care practitioner has provided inadequate medical care based on termination of insurance and also find that appropriate, reasonable attempts were made to obtain a patient release.

3. The department may obtain patient records, billing records, insurance information, provider contracts, and all attachments thereto pursuant to a subpoena without written authorization from the patient if the department and probable cause panel of the appropriate board, if any, find reasonable cause to believe that a health care practitioner has submitted a claim, statement, or bill using a billing code that would result in payment greater in amount than would be paid using a billing code that accurately describes the services performed, requested payment for services that were not performed by that health care practitioner, used information derived from a written report of an automobile accident generated pursuant to chapter 316 to solicit or obtain patients personally or through an agent regardless of whether the information is derived directly from the report or a summary of that report or from another person, solicited patients fraudulently, received a kickback as defined in s. 456.054, violated the patient brokering provisions of s. 817.505, or presented or caused to be presented a false or fraudulent insurance claim within the meaning of s. 817.234(1)(a), and also find that, within the meaning of s. 817.234(1)(a), patient authorization cannot be obtained because the patient cannot be located or is deceased, incapacitated, or suspected of being a participant in the fraud or scheme, and if the subpoena is issued for specific and relevant records.

4. Notwithstanding subparagraphs 1.-3., when the department investigates a professional liability claim or undertakes action pursuant to s. 456.049 or s. 627.912, the department may obtain patient records pursuant to a subpoena without written authorization from the patient if the patient refuses to cooperate or if the department attempts to obtain a patient release and the failure to obtain the patient records would be detrimental to the investigation.

Section 3. Subsections (4), (5), and (6) of section 458.309, Florida Statutes, are repealed.

Section 4. Section 458.3265, Florida Statutes, is created to read:

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. 456.073(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 plead 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.

Section 5. Section 458.327, Florida Statutes, is amended to read:

458.327 Penalty for violations.—

(1) Each of the following acts constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084:

(a) The practice of medicine or an attempt to practice medicine without a license to practice in Florida.

(b) The use or attempted use of a license which is suspended or revoked to practice medicine.

(c) Attempting to obtain or obtaining a license to practice medicine by knowing misrepresentation.

(d) Attempting to obtain or obtaining a position as a medical practitioner or medical resident in a clinic or hospital through knowing misrepresentation of education, training, or experience.

(e) Knowingly operating, owning, or managing a nonregistered pain-management clinic that is required to be registered with the Department of Health pursuant to s. 458.3265(1).

(2) Each of the following acts constitutes a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083:

(a) Knowingly concealing information relating to violations of this chapter.

(b) Making any willfully false oath or affirmation whenever an oath or affirmation is required by this chapter.

(c) Referring any patient, for health care goods or services, to a partnership, firm, corporation, or other business entity in which the physician or the physician's employer has an equity interest of 10 percent or more unless, prior to such referral, the physician notifies the patient of his or her financial interest and of the patient's right to obtain such goods or services at the location of the patient's choice. This section does not apply to the following types of equity interest:

1. The ownership of registered securities issued by a publicly held corporation or the ownership of securities issued by a publicly held corporation, the shares of which are traded on a national exchange or the over-the-counter market;

2. A physician's own practice, whether he or she is a sole practitioner or part of a group, when the health care good or service is prescribed or provided

solely for the physician’s own patients and is provided or performed by the physician or under the physician’s supervision; or

3. An interest in real property resulting in a landlord-tenant relationship between the physician and the entity in which the equity interest is held, unless the rent is determined, in whole or in part, by the business volume or profitability of the tenant or is otherwise unrelated to fair market value.

(d) Leading the public to believe that one is licensed as a medical doctor, or is engaged in the licensed practice of medicine, without holding a valid, active license.

(e) Practicing medicine or attempting to practice medicine with an inactive or delinquent license.

(f) Knowingly prescribing or dispensing, or causing to be prescribed or dispensed, controlled substances in a nonregistered pain-management clinic that is required to be registered with the Department of Health pursuant to s. 458.3265(1).

Section 6. Paragraphs (oo), (pp), and (qq) are added to subsection (1) of section 458.331, Florida Statutes, to read:

458.331 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(oo) Applicable to a licensee who serves as the designated physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137:

1. Registering a pain-management clinic through misrepresentation or fraud;

2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;

3. Failing to comply with any requirement of 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 Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;

4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United States;

5. Being convicted of, or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for any offense that would constitute a violation of this chapter;

6. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the ability to practice, a licensed health care profession;

7. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;

8. Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003(14) or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or

9. Failing to timely notify the board of the date of his or her termination from a pain-management clinic as required by s. 458.3265(2).

(pp) Failing to timely notify the department of the theft of prescription blanks from a pain-management clinic or a breach of other methods for prescribing within 24 hours as required by s. 458.3265(2).

(qq) Promoting or advertising through any communication media the use, sale, or dispensing of any controlled substance appearing on any schedule in chapter 893.

Section 7. Subsections (3), (4), and (5) of section 459.005, Florida Statutes, are repealed.

Section 8. Section 459.0137, Florida Statutes, is created to read:

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. 456.073(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 plead 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.

Section 9. Subsections (1) and (2) of section 459.013, Florida Statutes, are amended to read:

459.013 Penalty for violations.—

(1) Each of the following acts constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084:

(a) The practice of osteopathic medicine, or an attempt to practice osteopathic medicine, without an active license or certificate issued pursuant to this chapter.

(b) The practice of osteopathic medicine by a person holding a limited license, osteopathic faculty certificate, or other certificate issued under this chapter beyond the scope of practice authorized for such licensee or certificateholder.

(c) Attempting to obtain or obtaining a license to practice osteopathic medicine by knowing misrepresentation.

(d) Attempting to obtain or obtaining a position as an osteopathic medical practitioner or osteopathic medical resident in a clinic or hospital through knowing misrepresentation of education, training, or experience.

(e) Knowingly operating, owning, or managing a nonregistered pain-management clinic that is required to be registered with the Department of Health pursuant to s. 459.0137(1).

(2) Each of the following acts constitutes a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083:

(a) Knowingly concealing information relating to violations of this chapter.

(b) Making any willfully false oath or affirmation whenever an oath or affirmation is required by this chapter.

(c) The practice of medicine as a resident or intern without holding a valid current registration pursuant to s. 459.021.

(d) Knowingly prescribing or dispensing, or causing to be prescribed or dispensed, controlled substances in a nonregistered pain-management clinic that is required to be registered with the Department of Health pursuant to s. 459.0137(1).

Section 10. Paragraphs (qq), (rr), and (ss) are added to subsection (1) of section 459.015, Florida Statutes, to read:

459.015 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(qq) Applicable to a licensee who serves as the designated physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137:

1. Registering a pain-management clinic through misrepresentation or fraud;

2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;

3. Failing to comply with any requirement of 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 Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;

4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United States;

5. Being convicted of, or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for any offense that would constitute a violation of this chapter;

6. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the ability to practice, a licensed health care profession;

7. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;

8. Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003(14) or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or

9. Failing to timely notify the board of the date of his or her termination from a pain-management clinic as required by s. 459.0137(2).

(rr) Failing to timely notify the department of the theft of prescription blanks from a pain-management clinic or a breach of other methods for prescribing within 24 hours as required by s. 459.0137(2).

(ss) Promoting or advertising through any communication media the use, sale, or dispensing of any controlled substance appearing on any schedule in chapter 893.

Section 11. Subsection (1) of section 465.0276, Florida Statutes, is amended to read:

465.0276 Dispensing practitioner.—

(1)(a) A person may not dispense medicinal drugs unless licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section.

(b) A practitioner registered under this section may not dispense more than a 72-hour supply of a controlled substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03 for any patient who pays for the medication by cash, check, or credit card in a clinic registered under s. 458.3265 or s. 459.0137. A practitioner who violates this paragraph commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. This paragraph does not apply to:

1. A practitioner who dispenses medication to a workers' compensation patient pursuant to chapter 440.

2. A practitioner who dispenses medication to an insured patient who pays by cash, check, or credit card to cover any applicable copayment or deductible.

3. The dispensing of complimentary packages of medicinal drugs to the practitioner's own patients in the regular course of her or his practice without the payment of a fee or remuneration of any kind, whether direct or indirect, as provided in subsection (5).

Section 12. Paragraph (j) is added to subsection (1), paragraph (d) is added to subsection (2), and paragraph (f) is added to subsection (7) of section 893.055, Florida Statutes, to read:

893.055 Prescription drug monitoring program.—

(1) As used in this section, the term:

(j) "Program manager" means an employee of or a person contracted by the Department of Health who is designated to ensure the integrity of the prescription drug monitoring program in accordance with the requirements established in paragraphs (2)(a) and (b).

(2)

(d) The program manager shall work with professional health care licensure boards and the stakeholders listed in paragraph (b) to develop rules appropriate for identifying indicators of controlled substance abuse.

(7)

(f) The program manager, upon determining a pattern consistent with the rules established under paragraph (2)(c) and having cause to believe a violation of s. 893.13(7)(a)8., (8)(a), or (8)(b) has occurred, may provide relevant information to the applicable law enforcement agency.

Section 13. Subsections (4), (5), and (6) of section 893.0551, Florida Statutes, are renumbered as subsections (5), (6), and (7), respectively, and subsection (4) is added to that section, to read:

893.0551 Public records exemption for the prescription drug monitoring program.—

(4) The department shall disclose such confidential and exempt information to the applicable law enforcement agency in accordance with s. 893.055(7)(b)2. The law enforcement agency may disclose the confidential and exempt information received from the department to a criminal justice agency as defined in s. 119.011 as part of an active investigation that is specific to a violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b).

Section 14. This act shall take effect October 1, 2010.

Approved by the Governor June 4, 2010.

Filed in Office Secretary of State June 4, 2010.