

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: CS/SB 2722

INTRODUCER: Health Regulation Committee and Senator Gardiner and others

SUBJECT: Pain Management

DATE: March 29, 2010 REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	<b>Fav/CS</b>
2.			CJ	
3.			HA	
4.				
5.				
6.				

**Please see Section VIII. for Additional Information:**

- |                              |                                     |   |
|------------------------------|-------------------------------------|---|
| A. COMMITTEE SUBSTITUTE..... | <input checked="" type="checkbox"/> | Statement of Substantial Changes        |
| B. AMENDMENTS.....           | <input type="checkbox"/>            | Technical amendments were recommended   |
|                              | <input type="checkbox"/>            | Amendments were recommended             |
|                              | <input type="checkbox"/>            | Significant amendments were recommended |

**I. Summary:**

This committee substitute modifies and enhances the regulation of pain management and pain-management clinics in Florida.

The committee substitute provides for exceptions concerning the Department of Health (Department) obtaining patient consent for release of patient records and authorizes the Department to obtain patient records without a subpoena from a pain-management clinic under certain conditions.

The committee substitute sets the venue for a challenge to, and enforcement of, subpoenas and orders related to the Department’s regulation of health professions and occupations.

The committee substitute provides for additional exemptions to the registration requirements for a pain-management clinic including a clinic that: is owned by a publicly held corporation, is affiliated with an accredited medical school, does not prescribe or dispense controlled substances for the treatment of pain, or is owned by a corporate entity which is exempt from federal taxation as a charitable organization.

As a part of registering a pain-management clinic, a designated physician must be identified and certain responsibilities are assigned to the designated physician. The committee substitute provides additional grounds for disciplinary action against a licensee who serves as the designated physician of a pain-management clinic.

The committee substitute also authorizes the Department to deny an application to register a pain-management clinic, revoke or suspend a registration, or impose an administrative fine for various offenses or conditions. Additional requirements for operating a pain-management clinic are enumerated in the committee substitute.

A practitioner who practices at a pain-management clinic is required to maintain control of his or her prescription blanks and any other method used for prescribing controlled substances for pain medication and report the theft, loss, or breach of these instruments to the Department. Only a medical physician or osteopathic physician may dispense any medication, including a controlled substance, on the premises of a pain-management clinic. A practitioner who practices at a pain-management clinic must notify the applicable board upon his or her termination from the clinic.

The committee substitute establishes additional criminal violations related to:

- Knowingly operating, owning, or managing a nonregistered pain-management clinic that is required to be registered, which is a felony of the third degree; and
- 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, which is a misdemeanor of the first degree.

The Department is required to adopt rules addressing, but not limited to, what constitutes practice by a designated physician at the pain-management clinic for which the physician has assumed responsibility. The Boards of Medicine and Osteopathic Medicine are required to adopt a rule establishing the maximum number of prescriptions for certain controlled substances that may be written at a pain-management clinic daily.

This committee substitute substantially amends the following sections of the Florida Statutes: 456.037, 456.057, 456.071, 458.327, 458.331, 459.013, and 459.015.

This committee substitute creates the following sections of the Florida Statutes: 458.3265 and 459.0137.

This committee substitute repeals the following section of the Florida Statutes: 458.309(4), (5), and (6), and 459.005(3), (4), and (5).

## **II. Present Situation:**

### **Pain-Management Clinics**

In 2009,<sup>1</sup> the Legislature required all privately owned pain-management clinics, which includes clinics, facilities, or offices, that advertise for any type of pain-management services or employ a

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<sup>1</sup> See sections 3 and 4 of Chapter 2009-198, Laws of Florida (L.O.F.).

physician or osteopathic physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications to register with the Department by January 4, 2010.<sup>2</sup> Facilities licensed under ch. 395, F.S., i.e., hospitals, ambulatory surgical centers, or mobile surgical facilities, or clinics in which a majority of the physicians provide surgical services in the clinic are exempt from this registration requirement.

Approximately 940 pain-management clinics have registered with the Department since the law went into effect.<sup>3</sup>

The current law does not limit who may own a pain-management clinic. However, also during the 2009 Session, the Legislature enacted s. 456.0635, F.S.,<sup>4</sup> which, among other things, requires the Department to refuse to register a pain-management clinic if any principal, officer, agent, managing employee, or affiliated person of the applicant has been:

- Convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under ch. 409, F.S., related to social and economic assistance, ch. 817, F.S., related to fraudulent practices, ch. 893, F.S., related to controlled substances, 21 U.S.C. ss. 801-970, related to the federal controlled substances act, or 42 U.S.C. ss. 1395-1396, related to Medicare and Medicaid, unless the sentence and any subsequent period of probation for such conviction or pleas ended more than 15 years prior to the date of the application;
- Terminated for cause from the Florida Medicaid program pursuant to s. 409.913, F.S., unless the applicant has been in good standing with the Florida Medicaid Program for the most recent 5 years; or
- Terminated for cause, pursuant to the appeals procedures established by the state or Federal Government, from any other state Medicaid program or the federal Medicare program, unless the applicant has been in good standing with a state Medicaid program or the federal Medicare program for the most recent 5 years and the termination occurred at least 20 years prior to the date of the application.

An allopathic physician or osteopathic physician may not practice in a pain-management clinic that is required to be registered but is not registered.<sup>5</sup> Each clinic location must be registered separately. The medical director is responsible for registering the clinic if that clinic is licensed as a health care clinic under ch. 400, F.S. Otherwise, a pain-management clinic must designate a physician who is licensed as a medical physician or osteopathic physician upon registration to be responsible for complying with all requirements related to registering the clinic.

The Board of Medicine and the Board of Osteopathic Medicine are required to adopt rules related to the 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. The rules are required to address, minimally, the following subjects: facility operations, physical operations, infection control, health and safety requirements, quality assurance, patient records, training requirements for health care practitioners who are not regulated by another board, inspections, and data collection and

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<sup>2</sup> ss. 458.309(4) and 459.005(3), F.S.

<sup>3</sup> See the Department of Health Committee substitute Analysis, Economic Statement and Fiscal Note for SB 2722, dated 3/10/2010, on file with the Senate Health Regulation Committee.

<sup>4</sup> s. 24, ch. 2009-223, L.O.F.

<sup>5</sup> Ibid 2.

reporting. Both boards are actively engaged in the rulemaking process.<sup>6</sup> Currently, Rule 64B8-9.013, F.A.C., and Rule 64B15-14.005, both related to Standards for the Use of Controlled Substances for the Treatment of Pain, apply to all physicians subject to the Board of Medicine and the Board of Osteopathic Medicine, respectively. These rules have been in place for several years.

The Department is required to inspect each pain-management clinic annually to ensure that it complies with the rules adopted by the applicable boards related to the 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, unless the office is accredited by a nationally recognized accrediting agency approved by the respective board.

### **Controlled Substances**

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. The chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid. Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds.

A prescription for a controlled substance listed in Schedule II may be dispensed only upon a written prescription of a practitioner, except that in an emergency situation, as defined by the Department rule, it may be dispensed upon oral prescription but is limited to a 72-hour supply. A prescription for a controlled substance listed in Schedule II may not be refilled.<sup>7</sup> A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription issued in this state.<sup>8</sup> Currently federal law does not authorize electronic prescribing (e-prescribing) for controlled substances.<sup>9</sup>

### **Dispensing, Prescribing, and Administering**

“Dispense” means the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer thereof or to one who

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<sup>6</sup> See for example, the notices published on January 15, 2010 in the Florida Administrative Weekly for meetings / workshops in February 2010, for each board.

<sup>7</sup> s. 893.04(1)(f), F.S.

<sup>8</sup> s. 893.04(2)(e), F.S.

<sup>9</sup> The federal DEA published proposed rules that would allow practitioners to issue e-Prescriptions for controlled substances; however, these rules have not become final. See Electronic Prescriptions for Controlled Substances, 73 FR page 36722, dated June 27, 2008, available at: <<http://edocket.access.gpo.gov/2008/pdf/E8-14405.pdf>> (Last visited on March 29, 2010).

represents that it is his or her intention not to consume or use the same but to transfer the same to the ultimate consumer or user for consumption by the ultimate consumer or user.<sup>10</sup>

Prescribing is issuing a prescription. For purposes of this committee substitute, a “prescription” includes an order for drugs that is written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a practitioner licensed by the laws of the state to prescribe such drugs, issued in good faith and in the course of professional practice, intended to be filled or dispensed by another person licensed to do so.<sup>11</sup>

“Administer,” for purposes of this committee substitute, means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a person.<sup>12</sup>

### **Dispensing Practitioner**

Chapter 465, F.S., related to the practice of pharmacy, contains the provisions for a dispensing practitioner.<sup>13</sup> Under this law, a practitioner authorized by law to prescribe drugs may dispense those drugs to his or her patients in the regular course of his or her practice. If a practitioner intends to dispense drugs for human consumption for a fee or remuneration of any kind, the practitioner must register with his or her professional licensing board as a dispensing practitioner, comply with and be subject to all laws and rules applicable to pharmacists and pharmacies, and give the patient a written prescription and advise the patient that the prescription may be filled in the practitioner’s office or at any pharmacy.

Practitioners in Florida who are authorized to prescribe include medical physicians, physician assistants, osteopathic physicians, advanced registered nurse practitioners, podiatrists, naturopathic physicians, dentists, and veterinarians. However, s. 893.02, F.S., in the controlled substances act, defines which practitioners may prescribe a controlled substance under Florida law. A “practitioner” is defined to mean a licensed medical physician, dentist, veterinarian, osteopathic physician, naturopathic physician, or podiatrist, if such practitioner holds a valid federal controlled substance registry number. Accordingly, the prescribing of controlled substances is a privilege that is separate from the regulation of the practice of the prescribing practitioner.

### **Access to Records without Subpoena or Consent**

In Florida, patients have a constitutional right to privacy under Article I, Section 23 of the State Constitution, and judicial decisions. Although Florida courts have recognized patients’ rights to secure the confidentiality of their health information (medical records) under the right to privacy under the State Constitution, that right must be balanced with and yields to any compelling state interest. Several statutes authorize the release of patient records without consent of the person to whom they pertain.<sup>14</sup>

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<sup>10</sup> s. 893.02(7), F.S.

<sup>11</sup> s. 893.02(20), F.S.

<sup>12</sup> s. 893.02(1), F.S.

<sup>13</sup> s. 465.0276, F.S.

<sup>14</sup> See for example, s. 395.3025(4), F.S., related to patient records in hospitals and s. 456.057, F.S., related to patient records held by health care practitioners.

Section 893.07, F.S., requires any person who dispenses controlled substances to make and maintain records, including prescription records, related to the receipt and disposition of the controlled substances. The record of all controlled substances sold, administered, dispensed, or otherwise disposed of shall show the:

- Date of selling, administering, or dispensing;
- Correct name and address of the person to whom or for whose use, or the owner and species of animal for which, sold, administered, or dispensed; and
- Kind and quantity of controlled substances sold, administered, or dispensed.

This section of law further provides that the records are to be kept and made available for a period of at least 2 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled substances.

As recently as November 30, 2009, the First District Court of Appeal upheld this statute. The court held<sup>15</sup> that this statute does not require a subpoena, warrant, or prior notice to the patient; and provision of records to law enforcement in compliance with state law did not violate the federal Health Insurance Portability and Accountability Act and did not violate the defendant's state constitutional right to privacy.

### III. Effect of Proposed Changes:

**Section 1.** Amends s. 456.037, F.S., to provide that a pain-management clinic that is required to be registered is a business entity for purposes of regulation by the Division of Medical Quality Assurance in the Department.

**Section 2.** Amends s. 456.057, F.S., to provide an exception to the requirement concerning a patient's release for his or her patient records. The Department is not required to 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.

In addition, the committee substitute authorizes the Department to 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 the provisions in s. 458.3265, F.S., or s. 459.0137, F.S., governing pain-management clinics is occurring or has occurred, reasonably believes that obtaining authorization is not feasible because of the volume of activity related to prescribing and dispensing controlled substances, and reasonably believes that obtaining authorization from the patient or a subpoena would jeopardize the investigation.

**Section 3.** Amends s. 456.071, F.S., to provide that venue for a challenge to, and enforcement of, subpoenas and orders authorized under the general provisions related to health professions and occupations is in the Circuit Court for the Second Judicial Circuit (Franklin, Jefferson, Gadsden, Leon, Liberty and Wakulla Counties), in the county where the examination, investigation, or hearing is conducted, or in the county in which the person resides.

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<sup>15</sup> See *State of Florida v. Cathy L. Carter*, 23 So.3d 798, (Fla. 1st DCA 2009), 34 Fla. L. Weekly D2466.

**Section 4.** Repeals s. 458.309(4), (5), and (6), F.S., related to provisions affecting pain-management clinics under the practice of allopathic medicine, to move these provisions into s. 458.3265, F.S., which is created in Section 5 of this committee substitute.

**Sections 5 and 9.** Create s. 458.3265, F.S., related to pain-management clinics under the practice of medicine, and s. 459.0137, F.S., related to pain-management clinics under the practice of osteopathic medicine. These sections combine the provisions governing the regulation of pain-management clinics in Florida into one section of law for the practice of medicine and another for the practice of osteopathic medicine. Existing provisions in current law under s. 458.309(4), (5), and (6), F.S., are moved into s. 458.3265, F.S. Similarly, existing provisions in current law under s. 459.005(3), (4), and (5), F.S., are moved into s. 459.0137, F.S.

### **Registration**

All privately owned pain-management clinics which advertise for pain-management services, or employ an allopathic or osteopathic physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the Department unless the:

- Clinic is a hospital, ambulatory surgical center, or mobile surgical center licensed under ch. 395, F.S., (in current law);
- Majority of the physicians who provide services in the clinic primarily provide surgical services (in current law);
- Clinic is a publicly held corporation whose total assets at the end of the corporation's most recent fiscal quarter exceeded \$50 million;
- Clinic is affiliated with an accredited medical school;
- Clinic does not prescribe or dispense controlled substances for the treatment of pain; or
- Clinic is owned by a corporate entity that is exempt from taxation as a charitable organization.

Each clinic location must be registered separately and each clinic must identify a designated physician who has a full, active, and unencumbered license to practice allopathic medicine or osteopathic medicine to be responsible for complying with all requirements related to registration of the clinic. This physician must practice at the location for which he or she has assumed responsibility as the designated physician.

A pain-management clinic seeking registration must be fully owned by a physician or group of physicians licensed under ch. 458, F.S., or ch. 459, F.S. In addition, the Department is required to deny registration, or revoke a registration previously issued, for any pain-management clinic that is owned by or has any contractual or employment relationship with a physician:

- Whose DEA license has ever been revoked,
- Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction, or
- Who has been convicted of, or has entered a plea of 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, in this state, any other state, or the United States.

However, the Department is authorized to adopt a rule to grant an exemption to denying a registration or revoking a previously issued registration based on these criteria if more than 10 years have elapsed since adjudication.

The Department is authorized to revoke a pain-management clinic's registration based upon an annual inspection and evaluation of compliance with these sections of law. If the registration is revoked or suspended, the pain-management clinic must cease operations as of the effective date of the suspension or revocation. The designated physician, owner or lessor of the property, the manager, or the proprietor must remove all signs and symbols identifying the premises as a pain-management clinic. The designated physician must advise the department of the disposition of the medicinal drugs located on the premises and the disposition is subject to the supervision and approval of the Department. Medicinal drugs that are purchased or held by an unregistered pain-management clinic may be deemed adulterated pursuant to the Florida Drug and Cosmetic Act.

If a pain-management clinic's registration is revoked, any person named in the registration documents 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. The Department is authorized to determine the period of suspension for a pain-management clinic's registration, not to exceed one year.

A new registration application is required to be submitted upon a change of ownership of a registered pain-management clinic.

### **Physician Responsibilities**

The responsibilities contained in this subsection of law apply to any physician who provides professional services in a pain-management clinic that is required to be registered.

A physician may not practice medicine or osteopathic medicine in an unregistered pain-management clinic. If he or she does so, his or her license is subject to review by the appropriate medical regulatory board. Only a physician licensed under ch. 458, F.S., related to the practice of allopathic medicine, or ch. 459, F.S., related to the practice of osteopathic medicine, may dispense a controlled substance on the premises of a registered pain-management clinic.

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. If the physician prescribes or dispenses more than a 72-hour dose of a controlled substance for the treatment of chronic nonmalignant pain, the physician must document in the patient's record the reason for prescribing or dispensing that excess.

However, it is a third degree felony for a physician to dispense more than a 72-hour supply of a controlled substance listed in Schedule II or Schedule III to any patient who pays by cash, check, or credit card for the medication, unless this payment method is used for a copayment or deductible required by insurance. This prohibition does not apply to practitioners who dispense medications to workers' compensation patients pursuant to ch. 440, F.S., dispense complimentary packages of medicinal drugs, or dispense in the health care system of the Department of Corrections.

The committee substitute requires a physician or osteopathic physician who is authorized to prescribe controlled substances and practices at a pain-management clinic to be 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 licensee is required to notify the Department in writing, within 24 hours following any theft or loss of a prescription blank or breach of any other method for prescribing pain medication. The licensee is also required to comply with the requirements for counterfeit-resistant prescription blanks in the Florida controlled substances act and the related rules.

The physician or osteopathic physician is required to notify the applicable board of the date of termination of employment within 10 days after terminating his or her employment with a pain-management clinic.

### **Inspection**

The Department is required to inspect a registered pain-management clinic annually to determine compliance with this law and applicable rules, unless the clinic is accredited by a nationally recognized accrediting agency approved by the Board of Medicine or the Board of Osteopathic Medicine. This inspection is to include a review of the patient records. The Department is required to make a reasonable attempt to discuss each violation with the owner or designated physician during the inspection.

The owner or designated physician must document in writing any action taken to correct a violation. The Department must verify the corrective action in follow-up visits.

### **Rulemaking**

The Department is required to adopt rules necessary to administer the registration and inspection of pain-management clinics. These rules are required to establish the specific requirements, procedures, forms, and fees. The Department is also required to adopt a rule defining what constitutes practice by a designated physician at the location for which he or she has assumed that responsibility. When adopting this rule, the Department is to consider: the number of clinic employees; the location of the clinic; the clinic's operating hours; and the amount of controlled substances being prescribed, dispensed, or administered at the pain-management clinic.

The Boards of Medicine and Osteopathic Medicine are required to adopt a rule establishing the maximum number of prescriptions for Schedule II or Schedule III controlled substances that may be written at any one pain-management clinic during any 24-hour period. The existing law concerning the Boards adopting rules setting forth standards of practice for physicians practicing in a privately owned pain-management clinic that primarily engages in the treatment of pain by prescribing or dispensing controlled substances is moved into this subsection from the repealed provisions in section 4 of this committee substitute.

### **Penalties and Enforcement**

The Department is authorized to impose an administrative fine on a registered pain-management clinic for violating the:

- Requirements of s. 458.3265, F.S., and s. 459.0137, F.S., related to pain-management clinics;
- Chapter 499, F.S., related to the Florida Drug and Cosmetic Act;

- 21 U.S.C. ss. 301-392, related to the Federal Food, Drug, and Cosmetic Act;
- 21 U.S.C. ss. 821 et seq., related to the Comprehensive Drug Abuse Prevention and Control Act;
- Chapter 893, F.S., related to the Florida Comprehensive Drug Abuse Prevention and Control Act; or
- Rules of the Department.

The committee substitute sets forth factors the Department must consider when determining whether a penalty is to be imposed, and the amount of the fine. Each day a violation continues after the date fixed for termination as ordered by the department constitutes an additional, separate, and distinct violation.

The Department is authorized to impose a fine and, if the pain-management clinic is an owner-operated clinic, revoke or deny a clinic's registration if the designated physician knowingly and intentionally misrepresents actions taken to correct a violation.

The Department may impose an administrative fine of \$5,000 per day on:

- An owner or designated physician who concurrently operates an unregistered pain-management clinic, or
- An owner of a pain-management clinic who fails to apply to register a clinic upon a change-of-ownership.

**Sections 6 and 10.** Amend s. 458.327, F.S., related to penalties under the practice of medicine, and s. 459.013, F.S., related to penalties under the practice of osteopathic medicine, to add that knowingly operating, owning, or managing a non-registered pain-management clinic that is required to be registered is a felony of the third degree. Knowingly prescribing or dispensing, or causing to be prescribed or dispensed, controlled substances in an unregistered pain-management clinic that is required to be registered is a misdemeanor of the first degree.

**Sections 7 and 11.** Amend s. 458.331, F.S., related to the practice of medicine, and s. 459.015, F.S., related to the practice of osteopathic medicine, to add grounds for which disciplinary action may be taken against a licensee who serves as the designated physician of a pain-management clinic. Additional grounds for disciplinary action are added for any physician who fails to timely notify the:

- Department of the theft of prescription blanks from a pain-management clinic or a breach of other methods for prescribing, or
- Applicable board upon his or her termination from a pain-management clinic.

**Section 8.** Repeals s. 459.005(3), (4), and (5), F.S., related to provisions affecting pain-management clinics under the practice of osteopathic medicine, to move these provisions into s. 459.0137, F.S., which is created in Section 9 of this committee substitute.

**Section 12.** Provides an effective date of October 1, 2010.

**IV. Constitutional Issues:****A. Municipality/County Mandates Restrictions:**

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

**B. Public Records/Open Meetings Issues:**

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

**C. Trust Funds Restrictions:**

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

**D. Other Constitutional Issues:**

Article III, Section 6 of the Florida Constitution requires every law to embrace but one subject and matter properly connected therewith, and the subject must be briefly expressed in the title. This bill is an act relating to pain management, but section 3 of the committee substitutes addresses setting venue for challenges to, and enforcement of, subpoenas and orders related to all health professions and occupations subject to ch. 456, F.S.

Article I, Section 23 of the State Constitution provides for an individual's right to privacy. This right has been extended to medical records although there are numerous exceptions where patient consent for the release of the records is not required.<sup>16</sup> These exceptions are generally based upon a compelling state interest in providing for the release without a patient's consent and authorization. This committee substitute provides exceptions to requiring patient consent for the Department to access patient records in pain-management clinics.

**V. Fiscal Impact Statement:****A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

Due to the restrictions on ownership and registration, this committee substitute will impact the ability of some people to own and operate a pain-management clinic. Patient records concerning services and medications received through pain-management clinics might be more readily available to the Department without the judicial scrutiny afforded by the requirement to obtain a subpoena prior to accessing the patient records.

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<sup>16</sup> Ibid 16.

**C. Government Sector Impact:**

The Department indicated that additional rulemaking is required and that increased disciplinary cases may occur as a result of this bill, but additional budget authority to implement the provisions of this bill as originally filed is not required. Because of the significant changes that were made in the committee substitute, at this time, the fiscal impact to the Department for the committee substitute is not known.

**VI. Technical Deficiencies:**

Lines 238 and 605. The effective date language could be omitted since it is in the past.

Lines 274 and 642 refer to clinic ownership by a group of physicians licensed under ch. 458, F.S., or ch. 459, F.S. Neither of these chapters license group practices. It should read: or group of physicians, each of whom is licensed under ...

Lines 331 – 332 and 700 – 701 need clarification, perhaps: The period of suspension for a pain-management clinic registration shall be prescribed by the Department, but may not exceed one year.

Lines 349 – 354 and 718 – 723. The intent and requirements in these lines is not clear and they should be rewritten. It is unclear whether the requirement is a physical examination of each patient on the day in which a controlled substance is dispensed, or this is required only when the physician *prescribes* or dispenses more than a 72-hour dose.

Lines 359 – 362 and 728 – 731 require a licensee to comply with the requirements for counterfeit-resistant prescription blanks in s. 893.065, F.S., and the rules adopted pursuant to that section. The use of counterfeit-resistant prescription blanks is not required. Both s. 893.065, F.S., and the administrative rule make the use optional. It is not apparent what requirement is imposed on a licensee in these lines of this committee substitute.

Lines 383 – 388 and 753 – 759 exempt a practitioner from the prohibition on dispensing more than a 72-hour supply of certain controlled substances for cash, check, or credit card if the practitioner is dispensed complimentary packages of medicinal drugs without any payment of a fee or remuneration. This is unnecessary and misleading. A physician is prohibited under s. 499.005(17), F.S., from selling a drug sample (complimentary drug) and s. 499.005(25), F.S., from charging a dispensing fee for a prescription drug sample.

Lines 471 and 843. The meaning of the phrase “date fixed for termination” is unclear.

**VII. Related Issues:**

None.

**VIII. Additional Information:**

- A. **Committee Substitute – Statement of Substantial Changes:**  
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

**CS by Health Regulation on March 26, 2010:**

- Includes a pain–management clinic as a business establishment subject to regulation under ch. 456, F.S.;
- Authorizes the Department to access patient records at a clinic without patient authorization or by subpoena;
- Specifies venue for challenges to Department orders and subpoenas;
- Expands the provisions affecting the regulation of pain–management clinics to provide grounds to deny, revoke, or suspend a registration, regulate certain activities of physicians practicing in a clinic, require the Boards of Medicine and Osteopathic Medicine to adopt rules regulating practice at clinics, and expand the grounds upon which regulatory action against a clinic or practitioner may be based; and
- Eliminates the prohibition against a physician advertising the use, sale, or dispensing of controlled substances.

- B. **Amendments:**

None.