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 Criminal Justice Committee

BILL:	CS/CS/SB 2272 & CS/SB 2722
INTRODUCER:	Criminal Justice Committee; Health Regulation Committee, and Senators Fasano, Gardiner and others
SUBJECT:	Pain Management
DATE:	April 13, 2010 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	**Fav/CS (SB 2272)**
2.	Stovall	Wilson	HR	**Fav/CS (SB 2722)**
3.	Erickson	Cannon	CJ	**Fav/CS**
4.			HA	
5.			WPSC	
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

The bill modifies and enhances the regulation of pain management and pain-management clinics in Florida. It also requires the prescription drug monitoring program's database to provide information to law enforcement agencies that might be indicative of violations of the Florida Drug Abuse Prevention and Control Act.

The bill 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 bill provides for additional exemptions to the registration requirements for a pain-management clinic including, but not limited to, 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 and maintaining the registration of a pain-management clinic, a designated physician must be identified. Certain responsibilities are assigned to the designated physician. The bill provides additional grounds for disciplinary action against a licensee who serves as the designated physician of a pain-management clinic.

The bill 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 bill.

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 take certain action. A physician may not practice medicine or osteopathic medicine if the clinic is not registered or, effective July 1, 2012, the physician has not successfully completed a pain medicine fellowship or a pain medicine residency or does not comply with rules adopted by the applicable medical boards.

The bill establishes additional criminal violations:

- It is a third degree felony to knowingly operate, own, or manage a non-registered pain-management clinic that is required to be registered.
- It is a first degree misdemeanor to knowingly prescribe or dispense, or cause to be prescribed or dispensed, controlled substances in an unregistered pain-management clinic that is required to be registered.

The Department must 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 and factors that might be indicative of certain violations of the state's laws relating to controlled substances. The Boards of Medicine and Osteopathic Medicine must adopt a rule establishing the maximum number of prescriptions for certain controlled substances that may be written at a pain-management clinic daily.

The bill substantially amends the following sections of the Florida Statutes: 456.037; 456.057; 458.327; 458.331; 459.013; 459.015; 893.055; and 893.0551.

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

This bill repeals the following sections 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,[1] 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 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.[2] 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.[3]

The current law does not limit who may own a pain-management clinic, but during the 2009 Session the Legislature enacted s. 456.0635, F.S.,[4] 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., relating to social and economic assistance, ch. 817, F.S., relating to fraudulent practices, ch. 893, F.S., relating to controlled substances, 21 U.S.C. §§ 801-970, relating to the federal controlled substances act, or 42 U.S.C. §§ 1395-1396, relating 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.[5] 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 relating to registering the clinic.

[1] See sections 3 and 4 of ch. 2009-198, L.O.F. (Laws of Florida).
[2] ss. 458.309(4) and 459.005(3), F.S.
[3] See the Department of Health Committee Substitute Analysis, Economic Statement and Fiscal Note for SB 2722, dated March 10, 2010 (on file with the Senate Health Regulation Committee).
[4] s. 24, ch. 2009-223, L.O.F.
[5] Ibid 2.

The Boards of Medicine and Osteopathic Medicine must adopt rules relating 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 must 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 reporting. Both boards are actively engaged in the rulemaking process.[6] Currently, Rules 64B8-9.013 and 64B15-14.005, F.A.C., both relating 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 must annually inspect each pain-management clinic to ensure that it complies with the rules adopted by the applicable boards relating 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. This chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. Described are the differences between controlled substance schedules:

- A Schedule I substance has a high potential for abuse and no currently accepted medical use in treatment in the United States and in its use under medical supervision does not meet accepted safety standards. Examples: heroin and methaqualone.
- A Schedule II substance has a high potential for abuse, a currently accepted but severely restricted medical use in treatment in the United States, and abuse may lead to severe psychological or physical dependence. Examples: cocaine and morphine.
- A Schedule III substance has a potential for abuse less than the substances contained in Schedules I and II, a currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. Examples: lysergic acid; ketamine; and some anabolic steroids.
- A Schedule IV substance has a low potential for abuse relative to the substances in Schedule III, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule III. Examples: alprazolam; diazepam; and phenobarbital.
- A Schedule V substance has a low potential for abuse relative to the substances in Schedule IV, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule IV. Examples: low dosage levels of codeine; certain stimulants; and certain narcotic compounds.

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

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 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.[7] 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.[8] Currently federal law does not authorize electronic prescribing (e-prescribing) for controlled substances.[9]

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 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.[10]

Prescribing is issuing a prescription. For purposes of the bill, 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.[11]

"Administer," for purposes of the bill, means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a person.[12]

Dispensing Practitioner

Chapter 465, F.S., relating to the practice of pharmacy, contains the provisions for a dispensing practitioner.[13] Under this chapter, 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., of the Florida controlled substances act defines which practitioners may prescribe a controlled substance under

[7] s. 893.04(1)(f), F.S.
[8] s. 893.04(2)(e), F.S.
[9] 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 at p. 36722, dated June 27, 2008, available at: <http://edocket.access.gpo.gov/2008/pdf/E8-14405.pdf> (Last visited on March 29, 2010).
[10] s. 893.02(7), F.S.
[11] s. 893.02(20), F.S.
[12] s. 893.02(1), F.S.
[13] s. 465.0276, F.S.

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' right to secure the confidentiality of their health information (medical records) as a right to privacy, 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.[14]

Section 893.07, F.S., requires any person who dispenses controlled substances to make and maintain records, including prescription records, relating 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 following:

- 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 statute 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 held[15] that this statute does not require a subpoena, warrant, or prior notice to the patient. The court also held that providing 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.

Health Care Clinic License

Certain health care clinics are licensed and regulated by the Agency for Health Care Administration (Agency) under part X of ch. 400, F.S., the Health Care Clinic Act (Act). A clinic is defined as an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider.[16] However, the Act provides for numerous exceptions to the requirement for licensure and compliance with regulation under the Act.

[14] See, for example, s. 395.3025(4), F.S., relating to patient records in hospitals and s. 456.057, F.S., relating to patient records held by health care practitioners.
[15] See *State v. Carter*, 23 So.3d 798 (Fla. 1st DCA 2009).
[16] s. 400.9905(4), F.S.

Every entity that meets the definition of a "clinic" must maintain a valid license with the Agency at all times, and each clinic location must be licensed separately. Licenses are issued for a 2-year period at a fee of $2,000. The application for licensure must include: information regarding the identity of the owners, the financial officer or similarly situated person; licensed health care practitioners at the clinic and the medical director or clinic director; proof of financial ability to operate a clinic; any exclusions, permanent suspensions, or terminations from the Medicare or Medicaid programs; and proof that the clinic is in compliance with applicable rules. A level 2 background screening pursuant to ch. 435, F.S., is required of each of the persons identified in the application for clinic licensure and a license may not be granted to the clinic if any of these persons has been found guilty of, regardless of adjudication, or has entered a plea of nolo contendere or guilty to any offense prohibited under the level 2 standards for screening or a violation of insurance fraud under s. 817.234, F.S., within the past 5 years.

Prescription Drug Monitoring Program

Chapter 2009-197, L.O.F, established the prescription drug monitoring program in s. 893.005, F.S. This law requires the Department, by December 1, 2010, to design and establish a comprehensive electronic system to monitor the prescribing and dispensing of certain controlled substances. Prescribers and dispensers of certain controlled substances must report specified information to the Department for inclusion in the system.

Data regarding the dispensing of each controlled substance must be submitted to the Department no more than 15 days after the date the drug was dispensed, by a procedure and in a format established by the Department, and must include minimum information specified in the Act. Any person who knowingly fails to report the dispensing of a controlled substance commits a first-degree misdemeanor. The act provides exemptions from the data reporting requirements for controlled substances when specified acts of dispensing or administering occur.

Section 893.0551, F.S., enacted at the same time, provides for a public records exemption for certain personal information of a patient and certain information concerning health care professionals. This section sets forth enumerated exceptions for disclosure of this information after the Department ensures the legitimacy of the person's request for the information.

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 bill 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, and reasonably believes that obtaining authorization is not feasible due to the volume of the dispensing and prescribing activity and that obtaining patient authorization or a subpoena would jeopardize the investigation.

Section 3 repeals s. 458.309(4), (5), and (6), F.S., relating 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 4 of the bill.

Sections 4 and 8 create s. 458.3265, F.S., relating to pain-management clinics under the practice of medicine, and s. 459.0137, F.S., relating 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
Sections 458.3265(1) and 459.0137(1), F.S., provide that 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);
- The majority of the physicians who provide services in the clinic primarily provide surgical services (in current law);
- The clinic is owned by a publicly held corporation whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million;
- The physicians who provide services in the clinic primarily provide chiropractic services and do not dispense controlled substances;
- The clinic is affiliated with an accredited medical school;
- The clinic does not prescribe or dispense controlled substances for the treatment of pain; or
- The clinic is owned by a corporate entity that is exempt from federal taxation as a charitable organization.

Each clinic location must be registered separately and 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 relating to registration and operation of the clinic. If the designated physician terminates that relationship with the clinic, the identity of another designated physician must be communicated to the Department within 10 days of termination. This physician must practice at the clinic location for which he or she has assumed responsibility as the designated physician. The registration of a pain-management clinic that does not have a designated physician practicing at the clinic is subject to a summary suspension.

The Department must deny registration to any pain-management clinic that is not fully owned by a physician or group of physicians, each of whom is licensed under ch. 458, F.S., or ch. 459, F.S., or that is not licensed as a health care clinic under part X of ch. 400, F.S. In addition, the Department must deny registration, or revoke a registration previously issued, to any pain-management clinic owned by or with 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 may 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 may revoke a pain-management clinic's registration and prohibit all physicians associated with that clinic from practicing at that clinic's location based upon an annual inspection and evaluation of compliance with factors described in ss. 458.3265(3) and 459.0137(31), F.S., relating to inspections. If the clinic's registration is revoked or suspended, the clinic's designated physician, the owner or lesser of the clinic's property, and the clinic's manager and proprietor must cease operations as of the effective date of the suspension or revocation. These persons must also 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. 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 period of suspension for registration of a pain-management clinic must by prescribed by the Department, but may not exceed one year.

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

Physician Responsibilities
Sections 458.3265(2) and 459.0137(2), F.S., set forth physician responsibilities applicable 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 a pain-management clinic if:

- The clinic is not registered with the Department; or
- Effective July 1, 2012, the physician or osteopathic physician has not successfully completed a pain medicine fellowship or pain medicine residency that is accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association or does not comply with rules adopted by the Board of Medicine or the Board of Osteopathic Medicine.

The license of a physician who does not meet these requirements is subject to disciplinary action by the appropriate medical regulatory board.

Only a physician licensed under ch. 458, F.S., relating to the practice of allopathic medicine, or ch. 459, F.S., relating 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 at a pain-management clinic. 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 quantity.

A physician or 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 physician must comply with requirements for counterfeit-resistant blanks and 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 designated physician or designated osteopathic physician must 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
Sections 458.3265(3) and 459.0137(3), F.S., require the Department to annually inspect a registered pain-management clinic to ensure it complies 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. During an onsite inspection, the Department must make a reasonable attempt to discuss each violation with the owner or designated physician before issuing a formal written notification.

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
Sections 458.3265(4) and 459.0137(4), F.S., require the Department to adopt rules necessary to administer the registration and inspection of pain-management clinics which establish the specific requirements, procedures, forms, and fees. The Department must also adopt a rule

defining what constitutes practice by a designated physician at the location for which the physician has assumed responsibility as set forth in ss. 458.3265(1) and 459.0137(1), F.S. 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 must adopt a rule establishing the maximum number of prescriptions for Schedule II or Schedule III controlled substances or the controlled substance Alprazolam[17] which 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 the bill.

Penalties and Enforcement
Sections 458.3265(5) and 459.0137(5), F.S., authorize the Department to impose an administrative fine (up to $5,000) on a registered pain-management clinic for violating:

- The requirements of s. 458.3265, F.S., and s. 459.0137, F.S., relating to pain-management clinics;
- Chapter 499, F.S., relating to the Florida Drug and Cosmetic Act;
- 21 U.S.C. §§ 301-392, relating to the Federal Food, Drug, and Cosmetic Act;
- 21 U.S.C. §§ 821 et seq., relating to the Comprehensive Drug Abuse Prevention and Control Act;
- Chapter 893, F.S., relating to the Florida Comprehensive Drug Abuse Prevention and Control Act; or
- Rules of the Department.

The bill 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 may 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.

[17] Alprazolam is the chemical name for Xanax, which is included in Schedule IV.

Sections 5 and 9 amend s. 458.327, F.S., relating to penalties under the practice of medicine, and s. 459.013, F.S., relating to penalties under the practice of osteopathic medicine, to provide that:

- It is a third degree felony to knowingly operate, own, or manage a non-registered pain-management clinic that is required to be registered.
- It is a first degree misdemeanor to knowingly prescribe or dispense, or cause to be prescribed or dispensed, controlled substances in an unregistered pain-management clinic that is required to be registered.

Sections 6 and 10 amend s. 458.331, F.S., relating to the practice of medicine, and s. 459.015, F.S., relating 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 within 24 hours as required by ss. 458.3265(2) and 459.0137(2), F.S.

Section 7 repeals s. 459.005(3), (4), and (5), F.S., relating 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 8 of the bill.

Section 11 amends s. 893.055, F.S., relating to the prescription drug monitoring program, to require the database that is created and maintained under this program to report database information directly to applicable law enforcement agencies to investigate whether any of a number of specified violations of ch. 893, F.S., has occurred regarding controlled substances in Schedules II-IV. The Department must adopt rules, based on input from various stakeholders, to identify factors that might be indicative of these specified violations. These violations[18] involve:

- A person withholding information from a practitioner from whom the person seeks to obtain a controlled substance or a prescription for a controlled substance that the person making the request has received a controlled substance or a prescription for a controlled substance of like therapeutic use from another practitioner within the previous 30 days.
- A prescribing practitioner:
  - Knowingly assisting a patient, other person, or the owner of an animal in obtaining a controlled substance through deceptive, untrue, or fraudulent representations in or related to the practice of the prescribing practitioner's professional practice;
  - Employing a trick or scheme in the practice of the prescribing practitioner's professional practice to assist a patient, other person, or the owner of an animal in obtaining a controlled substance;
  - Knowingly writing a prescription for a controlled substance for a fictitious person; or
  - Writing a prescription for a controlled substance for a patient, other person, or an animal if the sole purpose of writing such prescription is to provide a monetary benefit to, or obtain a monetary benefit for, the prescribing practitioner.

[18] This is a summary of the violations. The full text of the offenses is found in ss. 893.13(7)(a)8, 893.13(8)(a), and 893.13(8)(b), F.S.

Section 12 amends s. 893.0551, F.S., to authorize the Department to disclose otherwise confidential and exempt information to the applicable law enforcement agency as required in section 11 of the bill. The law enforcement agency may disclose this information to a criminal justice agency as defined in s. 119.01, F.S., as part of an active investigation that is specific to any of the specified violations of ch. 893, F.S. (See discussion of section 11 of the bill.)

Section 13 provides an effective date of October 1, 2010.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

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

B. Public Records/Open Meetings Issues:

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

C. Trust Funds Restrictions:

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

D. Other Constitutional Issues:

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.[19] These exceptions are generally based upon a compelling state interest in providing for the release without a patient's consent and authorization. The bill 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:

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.

[19] Ibid 16.

Information about patients and practitioners may be automatically provided to law enforcement agencies for investigation to determine whether certain violations of the Florida controlled substances act have occurred depending upon the factors identified in the Department's rule.

C. Government Sector Impact:

Regarding the original bills (SB 2272 and SB 2722), the Department indicated that additional rulemaking is required. The Department also indicated that increased disciplinary cases may occur as a result of those bills and that additional budget authority to implement the provisions of those bills was not required. Because of the significant changes that would be made in the bill, it is unknown at this time what, if any, fiscal impact the bill would have on the Department.

Sections 5 and 9 of the bill provide that:

- It is a third degree felony to knowingly operate, own, or manage a non-registered pain-management clinic that is required to be registered.
- It is a first degree misdemeanor to knowingly prescribe or dispense, or cause to be prescribed or dispensed, controlled substances in an unregistered pain-management clinic that is required to be registered.

The Criminal Justice Impact Conference (CJIC) provides the final, official estimate of the state prison bed impact, if any, of legislation. The CJIC has not yet met to consider the bill. However, a first degree misdemeanor is not punishable by a state prison sentence[20] and the third felony is unranked, which means that a first-time offender convicted of only this offense will not score a state prison sentence as the lowest permissible sentence.[21] Jail bed impact, if any, is unknown.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

[20] A first degree misdemeanor is punishable by up to 1 year in jail, a fine of up to $1,000, or imprisonment and a fine. ss. 775.082 and 775.083, F.S.

[21] An unranked third degree felony is a felony that is not specifically ranked in the offense severity ranking chart of the Criminal Punishment Code (s. 921.0022, F.S.). An unranked third degree felony is assigned a ranking of level 1 pursuant to s. 921.0023, F.S. A first-time offender who is convicted of this offense and has no additional offenses will score a non-prison sanction, such as probation, as the lowest permissible sentence. The court has the discretion to impose a sentence that is within a sentencing range: a non-prison sanction to up to 5 years in state prison.

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 Criminal Justice on April 13, 2010:
The CS makes the following substantive changes to CS/SB 2272:

- Changes the title to an act related to controlled substances;
- Provides an exception from registration as a pain-management clinic: The physicians who provide service in the clinic primarily provide chiropractic services and do not dispense controlled substances.
- Provides that a physician or osteopathic physician may not practice medicine in a pain-management clinic if, effective July 1, 2012, the physician does not comply with rules adopted by the applicable medical board.
- Repeals provisions related to pain-management clinics that are currently in sections of law related to rulemaking for the practice of medicine and practice of osteopathic medicine and moves these provisions to the newly created sections of law devoted to pain-management clinics;
- Deletes the provision that sets the venue for a challenge to, and enforcement of, subpoenas and orders related to the DOH's regulation of health professions and occupations;
- Eliminates a new ground upon which the medical boards may take action against the designated physician of a pain-management clinic for failing to have a licensed medical director employed by or under contract with the clinic. Instead, the CS authorizes the medical boards to pursue a summary suspension of the clinic's registration if a designated physician is not practicing at the clinic;
- Requires a pain-management clinic to notify the DOH upon replacement of the designated physician within 10 days after the termination of the predecessor;
- Requires the designated physician to be responsible for the operation of the clinic in compliance with the law;
- The medical boards must adopt rules limiting the number of prescriptions for Alprazolam (Xanax), which is a schedule IV controlled substance, that may be written at a clinic during a 24-hour period;
- Requires the prescription drug monitoring program's database to report information directly to law enforcement agencies to investigate patients who might be 'doctor shopping' or practitioners who might knowingly be assisting patients inappropriately obtain controlled substances;
- Provides for an exception to the confidentiality of certain information in the database for release of the data to law enforcement agencies that might be indicative of the violations; and
- Requires the DOH to adopt rules, based on input from various stakeholders, which identify the factors that might be indicative of these violations to prompt the system to report to the law enforcement agencies.

The CS makes the following substantive changes to CS/SB 2722:

- Changes the title to an act related to controlled substances;
- Provides an exception from registration as a pain-management clinic: The physicians who provide service in the clinic primarily provide chiropractic services and do not dispense controlled substances.
- Provides that a physician or osteopathic physician may not practice not practice medicine in a pain-management if, effective July 1, 2012, the physician has not successfully completed a pain medicine fellowship or residency or does not comply with rules adopted by the applicable medical board.
- Deletes the provision that sets the venue for a challenge to, and enforcement of, subpoenas and orders related to the DOH's regulation of health professions and occupations;
- Requires a pain-management clinic to notify the DOH upon replacement of the designated physician within 10 days after the termination of the predecessor;
- Requires the designated physician to be responsible for the operation of the clinic in compliance with the law;
- Authorizes a pain-management clinic to be owned as a licensed health care clinic in addition to being owned by physicians and osteopathic physicians;
- The medical boards must adopt rules limiting the number of prescriptions for Alprazolam (Xanax), which is a schedule IV controlled substance, that may be written at a clinic during a 24-hour period;
- Requires the prescription drug monitoring program's database to report information directly to law enforcement agencies to investigate patients who might be 'doctor shopping' or practitioners who might knowingly be assisting patients inappropriately obtain controlled substances;
- Provides for an exception to the confidentiality of certain information in the database for release of the data to law enforcement agencies that might be indicative of the violations; and
- Requires the DOH to adopt rules, based on input from various stakeholders, which identify the factors that might be indicative of these violations to prompt the system to report to the law enforcement agencies.

B. Amendments:

None.