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:	SB 1386
INTRODUCER:	Senator Bogdanoff
SUBJECT:	Controlled Substances
DATE:	March 24, 2011 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HR	**Pre-meeting**
2.			CJ	
3.			BC	
4.				
5.				
6.				

I. Summary:

The bill changes the name of pain-management clinics to controlled-substance medical clinics (CS medical clinic). The bill revises the conditions requiring registration of a CS medical clinic. Under this bill a facility that employs a physician who prescribes on any given day more than 25 prescriptions of Schedule II and/or Schedule III controlled substances or employs a physician who dispenses controlled substances, with certain exceptions, must register. An additional exception for registration is provided when a majority of the physicians who provide services in the clinic primarily provide interventional pain procedures of the type routinely billed using surgical codes.

The bill prohibits a CS medical clinic from advertising services related to the dispensing of medication and adds provisions for a determination by a probable cause panel before the Department of Health (department) may take certain actions with respect to issuing a registration or revoking or suspending a registration. The bill prevents the department from revoking or suspending a CS medical clinic's registration if the clinic appoints, within a designated time frame, another designated physician to operate the clinic.

The bill authorizes an advanced registered nurse practitioner or a physician assistant to perform the patient's examination prior to and on the same day that the physician dispenses or prescribes controlled substances in a CS medical clinic. A physician is prohibited from dispensing more than a 30-day supply of controlled substances to any patient. The requirement to document in the patient's file the reason for prescribing or dispensing more than a 72-hour dose and the prohibition on dispensing more than a 72-hour supply of controlled substances in a clinic for a patient who pays for the medication by cash, check, or credit card are repealed. The bill also

repeals the requirement that effective July 1, 2012, physicians working in a clinic must have completed a pain medicine fellowship or a pain-medicine residency.

The bill requires a subpoena prior to the department obtaining patient records from a CS medical clinic when conducting investigations and a law enforcement agency must obtain a subpoena prior to accessing information in the Prescription Drug Monitoring Program (PDMP) database for investigations.

The bill authorizes the electronic transmission of patient advisory reports and requires certain health care professionals to review the reports before a controlled substance is dispensed to a patient. In addition, the PDMP database must be reviewed prior to prescribing or dispensing any controlled substance to a patient.

The time period for reporting that a controlled substance has been dispensed is reduced to 24-hours after the controlled substance is dispensed.

The bill extends until December 1, 2012, the date in which the prescription drug monitoring database is to be operational.

Reference to the Office of Drug Control and the director in the section of law relating to the PDMP are replaced with the department and the State Surgeon General.

The bill modifies the definition of a clinic under part X of ch. 400, F.S., so that the Agency for Health Care Administration (agency) may register clinics in which all health care services are paid for since currently the agency only licenses clinics that seek reimbursement from third parties.

This bill substantially amends, creates, or repeals the following sections of the Florida Statutes: 400.9905, 456.037, 456.057, 458.3265, 458.327, 458.331, 459.0137, 459.015, 465.0276, 893.055, and 893.0551.

II. Present Situation:

Prescription drug abuse is the most threatening substance abuse issue in the State of Florida.[1] The number of deaths caused by at least one prescription drug increased from 1,234 in 2003 to 2,488 in 2009 (a 102 percent increase). This translates to seven Floridians dying per day. The drugs that caused the most deaths were oxycodone; all benzodiazepines, including alprazolam; methadone; ethyl alcohol; cocaine; morphine; and hydrocodone.

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.

[1] *Florida Office of Drug Control 2010 Annual Report*, prepared by the Executive Office of the Governor.

- A Schedule I substance has a high potential for abuse and no currently accepted medical use in treatment in the United States and 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.

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.[2] 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.[3]

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.[4]

"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.[5]

"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.[6]

[2] s. 893.04(1)(f), F.S.
[3] s. 893.04(2)(e), F.S.
[4] s. 893.02(7), F.S.
[5] s. 893.02(20), F.S.
[6] s. 893.02(1), F.S.

Dispensing Practitioner

Chapter 465, F.S., relating to the practice of pharmacy, contains the provisions for a dispensing practitioner.[7] 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.

A dispensing practitioner is prohibited from dispensing more than a 72-hour supply of a controlled substance for any patient in a pain-management clinic who pays for the medication by cash, check, or credit card, except if the controlled substance is dispensed:

- To a workers' compensation patient;
- To an insured patient who pays a copayment or deductible with cash, check, or credit card; or
- As a complimentary package to the practitioner's own patient without remuneration of any kind, whether direct or indirect.[8]

Practitioners in Florida who are authorized to prescribe prescription drugs 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 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.

Regulation of Pain-Management Clinics

Chapter 2010-211, Laws of Florida, (the pill mill bill) was enacted to more aggressively regulate pain-management clinics. The requirement to register pain-management clinics and initial regulation was enacted by the 2009 Legislature.[9]

The pill mill bill requires businesses that meet the definition of a pain-management clinic to register with the department, unless exempted from registration. Ownership of pain-management clinics is limited to allopathic physicians, osteopathic physicians, or groups of allopathic physicians and osteopathic physicians, and health care clinics that are licensed under part X of ch. 400, F.S.

[7] s. 465.0276, F.S.
[8] s. 465.0276(1)(b), F.S., enacted in 2010-211.
[9] *See* sections 3 and 4 of ch. 2009-198, L.O.F.

Each pain-management clinic must designate a physician who is responsible for complying with all requirements related to registration and operation of the clinic in compliance with the law. Only a physician licensed under ch. 458, F.S., relating to the practice of medicine, (The Medical Practice Act), 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.

The pill mill bill requires allopathic physicians and osteopathic physicians practicing in a pain-management clinic to comply with specific provisions, including but not limited to:

- Performing a physical examination of a patient on the same day that he or she dispenses or prescribes a controlled substance;
- Documenting in a patient's record the reason for prescribing or dispensing more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain,[10] if he or she prescribes or dispenses in excess of that quantity; and
- Maintaining control and security of his or her prescription blanks and any other method used for prescribing controlled substances, and notifying the department within 24 hours following a theft, loss, or breach of these instruments.

The pill mill bill provides for various forms of enforcement against a pain-management clinic or practitioner through administrative means including fines and suspension or revocation of a license and through the imposition of criminal penalties. The additional criminal violations created include: a third degree felony to knowingly operate, own, or manage a non-registered pain-management clinic that is required to be registered; 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; and a third degree felony to dispense more than a 72-hour supply of controlled substances to a patient in a pain-management clinic who pays for the medication by cash, check, or credit card.

Prescription Drug Monitoring Program (PDMP)

Chapter 2009-197, L.O.F, established the PDMP 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. Vendor protests to the procurement process for a contractor to develop the PDMP have delayed implementation of the PDMP database.

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 s. 893.005, F.S. Any person who knowingly fails to report the dispensing of a controlled substance commits a first degree misdemeanor. This law provides exemptions from the data reporting requirements for controlled substances when specified acts of dispensing or administering occur.

[10] Chronic nonmalignant pain is defined as 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. *See* s. 458.3265(4), F.S., and s. 459.0137(4), F.S.

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.

As of July 2010, 34 states have operational PDMPs that have the capacity to receive and distribute controlled substance prescription information to authorized users. States with operational programs include: Alabama, Arizona, California, Colorado, Connecticut, Hawaii, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nevada, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, and Wyoming. Washington State's PDMP was operational but has been suspended due to fiscal constraints.[11]

Seven states, Alaska, Florida, Kansas, New Jersey, Oregon, South Dakota and Wisconsin and one U.S. territory (Guam) have enacted legislation to establish a PDMP, but are not fully operational. Delaware has legislation pending to establish a PDMP.

Health Care Clinics

Currently, cash-only health care clinics are not licensed by the agency. A "clinic" as defined in s. 400.9905(4), F.S., means an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services.… This definition applies only to clinics that seek reimbursement from third-party payers, such as insurance, Medicaid, Medicare, etc. Cash-only or point-of-sale clinics are not covered by this definition.

The agency indicates it has licensed approximately 200 health care clinics that are pain-management clinics which are not fully owned by medical or osteopathic physicians.[12]

III. Effect of Proposed Changes:

Section 1 amends s. 400.9905, F.S., to revise the definition of "clinic" and "portable equipment provider" for purposes of the licensure of health care clinics by the agency. "Clinic" is defined to mean an entity at which health care services are provided to individuals and which tenders charges for reimbursement *or payment* for such services, including a mobile clinic and a portable equipment provider. The definition of "portable medical equipment provider" deletes the modifier that a portable equipment provider bills third-party payors for providing portable equipment to multiple locations performing treatment or diagnostic testing of individuals.

Section 2 amends s. 456.037, F.S., to change the name of pain-management clinics to controlled-substance medical clinics.

Section 3 amends s. 456.057, F.S., to require the department to obtain a subpoena prior to obtaining patient records from a CS medical clinic when investigating a violation of the laws

[11] *Id.*

[12] Agency 2011 Bill Analysis & Economic Impact Statement for SB 818, on file with the Senate Health Regulation Committee. A similar

regulating CS medical clinics. The bill clarifies that neither patient authorization nor notification to the patient is required.

Section 4 and Section 7 amend s. 458.3265, F.S., and s. 459.0137, F.S., respectively, to change the definition of the conditions subjecting a facility to regulation as a CS medical clinic. A facility that employs a physician who prescribes on any given day more than 25 prescriptions of Schedule II or Schedule III controlled substance medications, or a combination thereof, or employs a physician, who dispenses controlled substances, must register. An additional exemption to registration is included for a clinic in which the majority of the physicians who provide services in the clinic primarily provide interventional pain-management procedures.

The exemption in existing law for a clinic that does not prescribe or dispense controlled substances for the treatment of pain is repealed since it is unnecessary due to the change in the criteria requiring registration.

The bill prohibits a CS medical clinic from advertising services related to the dispensing of medication.

The bill adds requirements for a hearing by the probable cause panel before the department may find that a CS medical clinic does not meet some of the criteria for registration or before the department may revoke a registration. The criteria for registration include:

- A CS medical clinic must be owned by an allopathic physician, osteopathic physician, or group thereof, or be licensed as a health care clinic by the AHCA and
- Registration is to be denied if a CS medical clinic is owned by or has a contractual or employment relationship with a physician:
  - Whose DEA number 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 pleaded guilty or nolo contendere to, regardless of adjudication, an offense that constitute a felony for receipt of illicit and diverted drugs, including any controlled substances in this state, any other state, or the United States.

The probable cause panel of the appropriate board must find that any physician associated with the CS medical clinic whose registration is under review for revocation, knew or should have know of any of the violations at the CS medical clinic related to the patient records or rules adopted by the boards or department related to CS medical clinics.

The bill prevents the department from revoking or suspending a CS medical clinic's registration if, within 24 hours after the clinic is notified of the suspension or revocation, the clinic appoints another designated physician to operate the CS medical clinic. In addition, if a CS medical clinic's registration is revoked, any person named in the registration documents may not apply to operate another CS medical clinic for 5 years after the date the registration is revoked upon a finding by the probable cause panel, and an opportunity to be heard, that the person operating the clinic whose registration was revoked knew or should have known of the violations causing the revocation.

The bill repeals the requirement that effective July 1, 2012, unless grandfathered in, a physician practicing in a pain-management clinic must have completed a pain-management fellowship or residency.

A physician, advanced registered nurse practitioner, or physician assistant must perform an appropriate medical examination prior to or on the same day that the physician dispenses or prescribes a controlled substance in a pain management clinic.

Instead of requiring a physician who prescribes or dispenses more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain to document in the patient's record the reason for prescribing or dispensing that quantity, a physician is prohibited from dispensing more than a 30-day supply of controlled substances to any patient.

The authority for the boards to adopt rules establishing the maximum number of prescriptions for Schedule II or Schedule III controlled substances or Alprazolam that may be written in a clinic during any 24-hour hour period is repealed. Also, the rulemaking authority for training requirements for all facility health care practitioners who are not regulated by another board is repealed.

Additional conforming changes are included in the bill.

Section 5 amends s. 458.327, F.S., related to penalties for violations, to conform this section to other changes made in the bill.

Section 6 and Section 8 amend s. 458.331, F.S., and s. 459.015, F.S., respectively, to repeal one of the grounds upon which disciplinary action may be taken against the designated physician of a CS medical clinic. This provision relates to 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 ch. 458, F.S., or ch. 459, F.S., as applicable to the licensed physician.

Section 9 amends s. 465.0276, F.S., relating to dispensing practitioners in the Pharmacy Practice Act to repeal the limitation on dispensing more than a 72-hour supply of a controlled substances in a pain-management clinic for a patient who pays for the medication by cash, check, or credit card.

Section 10 amends s. 893.055, F.S., related to the prescription drug monitoring program. The bill authorizes a patient advisory report from the prescription drug monitoring database to be provided electronically to a CS medical clinic and its employed physicians, an ARPN, PA, pharmacy or a patient. These persons are required to review each patient advisory report before any controlled substance is dispensed to a patient. The dispenser and practitioners employed at or practicing at a CS medical clinic also are required to review the prescription drug monitoring database before prescribing or dispensing any controlled substance to a patient. Further, if the dispenser identifies or has any issues or concerns regarding the dispensing of the controlled substances, the dispenser is required to immediately contact the prescriber before dispensing the controlled substances.

This section adds the same definition of a CS medical clinic as used in s. 458.3265, F.S., of the Medicaid Practice Act and s. 459.0137, F.S., of the Osteopathic Medicaid Practice Act. The bill extends until December 1, 2012, the date in which the prescription drug monitoring database is to be operational.

The responsibilities of the program manager for the PDMP are expanded to include developing rules, in consultation with others, that are appropriate for identifying indicators of the diversion of controlled substances.

The time period for reporting that a controlled substance has been dispensed is reduced from 15 days to 24 hours after the controlled substance is dispensed.

The conditions under which a law enforcement agency may request, and may be granted access by the program manager to, confidential information in the database is limited to upon determination that probably cause exists that a crime is being committed and issuance of a search warrant regarding the potential criminal activity, fraud, or theft regarding prescribed controlled substances. Current law authorizes the request and release during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances.

The bill authorizes the registration fees for CS medical clinics to help fund the administration of the PDMP.

References within this section of law to the Office of Drug Control and the director of that office are replaced with the department and the State Surgeon General. A provision for the reversion of moneys that are received from rentals of certain state facilities and properties which are authorized to be held in a separate depository account in the name of the direct-support organization is eliminated in the bill.

The deadline for the department's rulemaking to administer the PDMP is extended until December 1, 2011.

Section 11 amends s. 893.0551, F.S., to conform the provisions related to the public records exemption for the PDMP with the change made concerning access by a law enforcement agency to confidential information must be pursuant to a search warrant rather than as part of an active investigation.

Section 12 provides an effective date for the act of July 1, 2011.

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 modify the conditions under which release of information that has been made confidential and exempt from the public records requirements of Art. I, s. 24(a) and (b) of the Florida Constitution may be made to a law enforcement agency.

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:

The advertising restriction in lines 352 through 356 may violate the First Amendment to the United States Constitution and Article I, Section 4 of the Florida Constitution.

The Central Hudson Test is the standard used for determining the constitutionality of a restriction on commercial speech.[13] The four prongs of the *Central Hudson* test, as modified by *Board of Trustees of State Univ. of New York v. Fox*, 492 U.S. 469, 109 S.Ct. 3028, 106 L.Ed.2d 388 (1989), are: (1) whether the speech at issue is not misleading and concerns lawful activity; (2) whether the government has a substantial interest in restricting that speech; (3) whether the regulation directly advances the asserted governmental interest; and (4) whether the regulation is narrowly tailored, but not necessarily the least restrictive means available, to serve the asserted governmental interest.

Article I, Section 4 of the Florida Constitution, related to Freedom of speech and press states:

> Every person may speak, write and publish sentiments on all subjects but shall be responsible for the abuse of that right. No law shall be passed to restrain or abridge the liberty of speech or of the press. In all criminal prosecutions and civil actions for defamation the trust may be given in evidence. If the matter charged as defamatory is true and was published with good motives, the party shall be acquitted or exonerated.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The bill authorizes registration fees for CS medical clinics but does not set a fee or range of fees, or indicate the purpose of the registration fees.

[13] *See:* ***Central Hudson Gas*** *& Elec. Corp. v. Public Service Com'n*, 447 U.S. 557, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980)

B. Private Sector Impact:

The modification to the definition of clinics in section 1 of the bill might cause additional clinics to meet the criteria for mandatory registration or exclude certain clinic from registration.

Requiring certain findings by a probable cause panel or authorizing a CS medical clinic to replace its designated physician within 24 hours after notification of an intended suspension or revocation of the registration may provide some additional protections for a CS medical clinic obtaining or maintaining registration in order to conduct business in the state.

C. Government Sector Impact:

A law enforcement agency will be required to obtain a search warrant based on probable cause before being granted access to confidential information in the PDMP database. This may prolong an investigation of potential criminal activity, fraud, or theft regarding prescribed controlled substances. Similarly, the department is required to obtain a subpoena prior to obtaining patient records from a CS medical clinic when investigating a violation of the laws regulating CS medical clinics.

VI. Technical Deficiencies:

Section 459.013, F.S., relating to penalties for violations under the Osteopathic Medical Act refers to pain-management clinics, but this bill does not rename pain-management clinics in that section of law as controlled-substance medical clinics.

VII. Related Issues:

Lines 418-419 refer to the department making a finding upon a hearing by the probable cause panel. The department does not have probable cause panels; probable cause panels operate in conjunction with the boards.

VIII. Additional Information:

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

None.

B. Amendments:

None.