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 Committee on Appropriations

BILL:	CS/CS/SB 1192
INTRODUCER:	Community Affairs Committee; Health Policy Committee; and Senator Grimsley
SUBJECT:	Provision of Health Care with Controlled Substances
DATE:	April 20, 2013 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.	Toman	Yeatman	CA	**Fav/CS**
3.	Brown	Hansen	AP	**Pre-meeting**
4.				
5.				
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:

CS/CS/SB 1192 amends various statutory provisions relating to health care associated with controlled substances.

The bill has an insignificant fiscal impact on the Department of Health (DOH) that can be absorbed within existing resources.

The bill:

- Revises the requirement to register as a controlled substance providing practitioner to practitioners who prescribe more than a 30 day supply of certain controlled substances over a six-month period to one patient;
- Requires certain physicians to check the Prescription Drug Monitoring Program (PDMP) database before prescribing certain controlled substances to a new patient;
- Excludes certain physicians from standards of practice for prescribing controlled substances;
- Defines the term "abandoned" as it relates to pharmacy permits;
- Requires that the DOH serve notices to pharmacy permitees and licensees in writing and by an agent of the DOH or certified mail;

- Clarifies and adds to the types of activities that are grounds for licensure denial, revocation, or suspension, or for disciplinary action for pharmacies;
- Requires that pharmacies commence operations within 180 days of receiving a permit;
- Requires that pharmacies be supervised by a prescription department manager or consultant pharmacist of record at all times;
- Authorizes state funds to pay for the PDMP program;
- Includes pharmaceutical companies as organizations that may be considered inappropriate sources of funds for the PDMP program; and
- Preempts to the state all regulation of the licensure, activity, and operation of specified pain management clinics under certain circumstances.

The bill substantially amends the following sections of the Florida Statutes: 409.9201, 456.44, 458.331, 459.015, 465.003, 465.014, 465.015, 465.016, 465.0156, 465.0197, 465.022, 465.023, 465.1901, 499.003, 893.02, and 893.055.

The bill creates the following sections of the Florida Statutes: 465.0065, 465.1902, 893.0552.

II. Present Situation:

Controlled Substances

Controlled substances are drugs with the potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act and classifies controlled substances into five categories, known as schedules. The distinguishing factors between the different drug schedules are the "potential for abuse"[1] of the substance contained therein and whether there is a currently accepted medical use for the substance. These schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances.[2]

Schedule I controlled substances currently have no accepted medical use in treatment in the United States and therefore may not be prescribed, administered, or dispensed for medical use. These substances have a high potential for abuse and include heroin, peyote, lysergic acid diethylamide (LSD), and cannabis.[3]

Schedule II controlled substances have severely restricted medical uses and a high potential for abuse, which may lead to severe psychological or physical dependence. These drugs include morphine and its derivatives, amphetamines, cocaine, and pentobarbital.[4]

Schedule III controlled substances have lower abuse potential than Schedule II substances and have some accepted medical use, but they may still cause psychological or physical dependence. Schedule III substances include products containing less than 15 milligrams (mg) of

[1] Section 893.02(20), F.S.
[2] DEA, Office of Diversion Control, Controlled Substance Schedules, available at: www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm (last visited Apr. 4, 2013).
[3] Section 893.03(1), F.S.
[4] Section 893.03(2), F.S.

hydrocodone (such as Vicodin) or less than 90 mg of dihydrocodeine per dose (such as Tylenol #3), ketamine, and anabolic steroids.[5]

Schedule IV substances have a low potential for abuse and include propoxyphene (Darvocet), alprazolam (Xanax), and lorazepam (Ativan).[6]

Schedule V controlled substances have an extremely low potential for abuse and primarily consist of preparations containing limited quantities of certain narcotics, such as cough syrup.[7]

Any health care professional wishing to prescribe controlled substances must apply for a prescribing number from the federal Drug Enforcement Administration (DEA). Prescribing numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee.

Controlled Substance Prescribing

As of January 1, 2012, every physician, podiatrist, or dentist who prescribes controlled substances in the state for the treatment of chronic nonmalignant pain[8] must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.[9]

Before prescribing any controlled substances for the treatment of chronic nonmalignant pain, a practitioner must document certain characteristics about the nature of the pain, success of past treatments, any underlying health problems, and history of alcohol and substance abuse.[10] The practitioner must develop a written plan for assessing the patient's risk for aberrant drug-related behavior and monitor such behavior throughout the course of controlled substance treatment.[11] Each practitioner must also enter into a controlled substance agreement with their patients; such agreements must include:

- The risks and benefits of controlled substance use, including the risk for addiction or dependence;
- The number and frequency of permitted prescriptions and refills;
- A statement of reasons for discontinuation of therapy, including violation of the agreement; and
- The requirement that a patient's chronic nonmalignant pain only be treated by one practitioner at a time unless otherwise authorized and documented.[12]

[5] Section 893.03(3), F.S.
[6] Section 893.03(4), F.S.
[7] Section 893.03 (5), F.S.
[8] "Chronic nonmalignant pain" is defined as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery. Section 456.44(1)(e), F.S.
[9] Section 456.44(2)(a) and (b), F.S.
[10] Section 456.44(3)(a), F.S.
[11] Section 456.44(3)(b), F.S.
[12] Section 456.44(3)(c)1.-3., F.S.

Patients treated for nonmalignant pain with controlled substances must be seen by their prescribing practitioners at least once every three months to monitor progress and compliance, and detailed medical records relating to such treatment must be maintained.[13] Patients at special risk for drug abuse or diversion may require co-monitoring by an addiction medicine physician or a psychiatrist.[14] Anyone with signs or symptoms of substance abuse must be immediately referred to a pain-management physician, an addiction medicine specialist, or an addiction medicine facility.[15]

Anesthesiologists, physiatrists, neurologists, and surgeons are exempt from these provisions.[16] Physicians who hold certain credentials relating to pain medicine are also exempt.[17]

Pain-Management Clinics

A pain-management clinic is any facility that advertises pain-management services or where a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.[18] Pain-management clinics are regulated by the practice acts for medical doctors and osteopathic physicians. Until January 1, 2016, all pain-management clinics must register with the DOH and meet certain provisions concerning staffing, sanitation, recordkeeping, and quality assurance.[19] Clinics are exempt from these provisions if they are:

- Licensed under ch. 395, F.S., as a hospital, ambulatory surgical center, or mobile surgical facility;
- Staffed primarily by surgeons;
- Owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million;
- Affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
- Not involved in prescribing controlled substances for the treatment of pain;
- Owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3); or
- Wholly owned and operated by anesthesiologists, physiatrists, or neurologists, or physicians holding certain credentials in pain medicine.[20]

All clinics must be owned by at least one licensed physician or be licensed as a health care clinic under ch. 400, part X, F.S., to be eligible for registration.[21] The DOH is prohibited from registering a pain-management clinic:

- Not owned by a physician or not a health care clinic licensed under part X of ch. 400, F.S.;

[13] Section 456.44(3)(d), F.S.
[14] Section 456.44(3)(e), F.S.
[15] Section 456.44(3)(g), F.S.
[16] *Id*.
[17] *Id.*
[18] Section 458.3265(1)(a)1.c. and 459.0137(1)(a)1.c., F.S.
[19] Section 458.3265 and 459.0137, F.S.
[20] Section 458.3265(1)(a)2.a.-h. and 459.0137(1)(a)2.a.-h., F.S.
[21] Section 458.3265(1)(d) and 459.0137(1)(d), F.S.

- Owned by a physician whose DEA number has ever been revoked;
- Owned by a physician whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction; or
- Owned by a physician who has been convicted of certain drug-related crimes in any jurisdiction.[22]

Pain-management clinics are inspected annually by DOH unless they hold current certification from a DOH-approved national accrediting agency.[23] The DOH may suspend or revoke clinic registration or impose administrative fines of up to $5,000 per violation for any offenses against state pain-management clinic provisions or related federal laws and rules.[24]

If the registration for a pain-management clinic is revoked for any reason, the clinic must cease to operate immediately, remove all signs or symbols identifying the facility as a pain-management clinic, and dispose of any medication on the premises.[25] No owner or operator of the clinic may own or operate another pain-management clinic for five years after revocation of registration.[26]

Prescription Drug Monitoring Program (PDMP)

In 2009, the Legislature created the PDMP in s. 893.055, F.S.[27] The PDMP uses a comprehensive electronic system/database to monitor the prescribing and dispensing of certain controlled substances.[28] Dispensers of certain controlled substances must report specified information to the PDMP database, including the name of the prescriber, the date the prescription was filled and dispensed, and the name, address, and date of birth of the person to whom the controlled substance is dispensed.[29]

Direct access to the PDMP database is presently limited to medical doctors, osteopathic physicians, dentists, podiatric physicians, advanced registered nurse practitioners, physician assistants, and pharmacists.[30] Indirect access to the PDMP database is provided to:

- The DOH or its relevant health care regulatory boards;
- The Attorney General for Medicaid fraud cases;
- A law enforcement agency; and
- A patient or the legal guardian, or designated health care surrogate of an incapacitated patient.[31]

[22] Section 458.3265(1)(d) and (e) and 459.0137(1)(d) and (e), F.S.
[23] Section 458.3265(3)(a) and 459.0137(3)(a), F.S.
[24] Section 458.3265(5) and 459.0137(5), F.S.
[25] Section 458.3265(1)(h)-(j) and 459.0137(1)(h)-(j), F.S.
[26] Section 458.3265(1)(k) and 459.0137(1)(k), F.S.
[27] *See* ch. 2009-197, L.O.F
[28] Section 893.055(2)(a), F.S.
[29] Section 893.055(3)(a)-(c), F.S.
[30] Section 893.055(7)(b), F.S.
[31] Section 893.055(7)(c)1.-4., F.S.

Restrictions on how DOH may fund implementation and operation of the PDMP are also included in statute. The DOH is prohibited from using state funds and any money received directly or indirectly from prescription drug manufacturers to implement the PDMP.[32] Funding for the PDMP comes from three funding sources:[33]

- Donations procured by the Florida PDMP Foundation, Inc. (Foundation), the direct-support organization authorized by s. 893.055, F.S., to fund the continuing operation of the PDMP;
- Federal grants; and
- Private grants and donations.

Section 893.0551, F.S., provides an exemption from public records for personal information of a patient and certain information concerning health care professionals related to the PDMP.[34] The statute details exceptions for disclosure of information after DOH ensures the legitimacy of the person's request for the information.[35]

The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[36] Health care practitioners began accessing the PDMP on October 17, 2011.[37] Law enforcement began requesting data from the PDMP in support of active criminal investigations on November 14, 2011.[38]

Currently, prescribers are not required to consult the PDMP database prior to prescribing a controlled substance for a patient, but may do so. Between 2011 and 2012, physicians and pharmacists used the PDMP database at least 2.6 million times.[39] Nearly 5,000 pharmacists entered 56 million prescriptions into the database.[40] Law enforcement queried the PDMP database more than 20,000 times in conjunction with active criminal investigations.[41]

[32] Section 893.055(10) and (11)(c), F.S.
[33] Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), *2011-2012 Prescription Drug Monitoring Program Annual Report*, page 7 (available at www.eforcse.com/docs/2012AnnualReport.pdf, last visited on Apr. 3, 2013. Information also came from Florida Department of Health document detailing the funding history of the PDMP, also on file with Health Quality Subcommittee staff.
[34] Section 893.0551(2)(a)-(h), F.S.
[35] Section 893.0551(3)(a)-(g), F.S.
[36] Supra, n. 32 at page 4.
[37] *Id*.
[38] *Id*.
[39] *Id*. at page 3.
[40] *Id*.
[41] *Id*.

Prescription Drug Monitoring Programs in Other States

At least 43 states have passed laws enabling PDMPs.[42] The Legislature's Office of Program Policy Analysis and Government Accountability (OPPAGA) examined the PDMPs of 26 of those states, including Florida.[43] All PDMPs examined are either run by the states in-house or by contract with private vendors. Most states do not require prescribers to register in order to use the PDMP and primarily encourage prescribers to use the database through education and outreach programs.[44]

Only three of the 26 states require prescribers to access the database prior to prescribing most or all controlled substances.[45, 46] In 17 of 23 states, including Florida, accessing the database is strictly voluntary and in the remaining six states accessing the database is only required under limited circumstances.[47]

All states reviewed have the authority to take punitive action against dispensers of prescription drugs that do not comply with their state's respective laws and rules on their state's PDMP. These punitive actions can come in the form of fines, licensure disciplinary action, and/ or criminal charges, however, states rarely use these punitive measures when dispensers do not comply with PDMP requirements.

State Preemption

There is currently no statutory provision that expressly preempts the regulation of operations in pharmacies, health care clinics, health care facilities, and pain-management clinics to the state of Florida. Some counties and municipalities have created ordinances for the regulation of the operation of these clinics based upon the powers and duties conveyed upon these entities in Florida Statutes.[48]

III. Effect of Proposed Changes:

Section 1 amends s. 456.44, F.S. to:

- Restrict the requirement to register as a controlled substance providing practitioner to physicians[49] who prescribe more than a 30-day supply of any Schedule I, II, or III controlled substance over a six-month period to any one patient for the treatment of chronic malignant pain;

[42] The National Conference of State Legislatures, *Prevention of Prescription Drug Overdose and Abuse*, found at: http://www.ncsl.org/issues-research/health/prevention-of-prescription-drug-overdose-and-abuse.aspx, last visited on Apr. 3, 2013.
[43] *OPPAGA Review of State Prescription Drug Monitoring Programs*, Jan. 31, 2013, on file with the Senate Health Policy Committee.
[44] Id., p. 8.
[45] Kentucky, New Mexico, and New York.
[46] Id., p. 4.
[47] These circumstances typically revolve around how often a drug is prescribed, if the drug is in a specific class or schedule, if the drug has a specific agreement, or if there is a reasonable suspicion that the patient it abusing drugs. Id.
[48] DOH bill analysis on SB 1192, dated Mar. 1, 2013, on file with the Senate Health Policy Committee.
[49] Registered under ch. 458, 459, 461, or 466, F.S.

- Require that physicians who treat new patients in a pain-management clinic, pursuant to s. 458.326, F.S., consult the PDMP database before prescribing a Schedule II or III controlled substance;
- Allow the physician to designate an agent to check the PDMP database;
- Mandate the board adopt rules to establish a penalty for not checking the PDMP database; and
- Exclude physicians who prescribe medically necessary controlled substances to residents in a nursing home and a physician licensed under ch. 458 or 459, F.S., who writes fewer than 50 total prescriptions for controlled substances for all of his or her patients during a one-year period from the standards of practice established in this section.

Section 2 amends s. 465.003, F.S., to define the term "abandoned" as used in ch. 465, F.S., relating to pharmacies, as the status of a permit of a person or entity that was issued a pharmacy permit but fails to commence pharmacy operations within 180 days after issuance of the permit without good cause or fails to follow pharmacy closure requirements as set by the board.

Section 3 creates s. 465.0065, F.S., to mandate that each notice served by the DOH under ch. 465, F.S., must be in writing and delivered personally by an agent of the DOH or by certified mail to the pharmacy permitee or licensee. If the pharmacy permitee refuses to accept service or evades service or if the agent is otherwise unable to carry out service after due diligence, the DOH may post the notice in a conspicuous place at the pharmacy or at the licensee's home or business address.

Section 4 amends s. 465.016, F.S., to clarify that violating rules adopted under ch. 893, F.S., relating to drug abuse prevention and control, and misappropriating drugs, supplies, or equipment from a pharmacy permitee constitutes grounds for denial of a license or disciplinary action.

Section 5 amends s. 465.022, F.S., to:

- Require that a pharmacy permitee commence pharmacy operations within 180 days after issuance of the permit or show good cause why operations were not commenced;
- Define commencement of operations as including, but is not limited to, acts within the scope of practice of pharmacy, ordering or receiving drugs, and other similar activities;
- Mandate that the DOH establish rules regarding the commencement of pharmacy operations; and
- Clarify that a pharmacy permitee must be supervised by a prescription department manager or consultant pharmacist of record at all times.

Section 6 amends s. 465.023, F.S., to clarify that violating rules adopted under ch. 893, F.S., relating to drug abuse prevention and control, is grounds for the DOH to revoke or suspend a permit of any pharmacy permitee.

Section 7 creates s. 465.1902, F.S., to:

- Preempt to the state all regulation of the licensure, activity, and operation of pharmacies and pharmacists as defined in ch. 465, F.S.;
- Restrict local governments or political subdivisions of the state from enacting or enforcing ordinances that imposes a levy, charge, or fee upon, or that otherwise regulate pharmacies and pharmacists as defined in ch. 465, F.S.; and
- Allow local governments and political subdivisions to enact ordinances regarding:
  - Local business taxes adopted pursuant to ch. 205, F.S.; and
  - Land use development regulations adopted pursuant to ch. 163, F.S., which include regulation of any aspect of development, including a subdivision, building construction, sign regulation, and any other regulation concerning the development of land, landscaping, or tree protection, and which do not include restrictions on pain-management services, health care services, or the prescribing of controlled substances.

Section 8 amends s. 893.055, F.S., to allow the DOH to fund the PDMP program with state funds and maintain the PDMP program. This section also excludes pharmaceutical companies from those organizations that may be considered inappropriate sources of funds for the PDMP program.

Section 9 creates s. 893.0552, F.S, to preempt to the state all regulation of the licensure and activity and operation of pain management clinics as defined in ss. 458.3265 and 459.0137, F.S., in the following circumstances:

- The clinic is wholly owned and operated by a physician who performs interventional pain procedures routinely billed using surgical codes, who has never been suspended or revoked for prescribing certain controlled substances, *and who*:
  - has completed a fellowship in pain medicine approved by certain bodies,
  - is board-certified in pain medicine by specified entities, or
  - has a board certification or subcertification in pain management or pain medicine by an approved specialty board;
- The clinic is wholly owned and operated by a physician-multispecialty practice if one or more board-eligible or board-certified medical specialists has one of the qualifications specified above, performs interventional pain procedures of the type routinely billed using surgical codes, and has never been suspended or revoked for prescribing certain controlled substances; and
- Allow local governments and political subdivisions to enact ordinances regarding:
  - Local business taxes adopted pursuant to ch. 205, F.S.; and
  - Land use development regulations adopted pursuant to ch. 163, F.S.

A pain-management clinic specified in this section is permissible use in a land use or zoning category that permits hospitals and other health care facilities or clinics as defined in chapter 395 or s. 408.07, F.S.

Upon the request of a local government, a pain-management clinic must annually demonstrate that it qualifies for the preemption outlined in this section.

Sections 10-19 amend various sections of the Florida Statutes to conform those sections to changes made in Section 2 of the bill.

Section 20 provides an effective date of July 1, 2013.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

Article VII, Section 18 of the Florida Constitution prohibits laws requiring counties or municipalities to spend funds or that limit their ability to raise revenues. Subsection 18(d) provides an applicable exemption for laws determined to have an "insignificant fiscal impact," which means an amount not greater than the average statewide population for the applicable fiscal year times $0.10 or $1.9 million for FY 2012-13.[50]

It is unknown to what extent the preemption provisions of the bill may limit local government revenue generated by fines related to local ordinances governing pain-management clinics. However, if revenue losses occur and are greater than $1.9 million, the law may be unenforceable unless passed by two-thirds in each house of the Legislature.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Some physicians and health care practices may be negatively impacted from a time management perspective by the additional requirement to consult the PDMP prior to dispensing. However, to the extent that inappropriate prescribing of controlled substances is avoided, overall health care costs may be lessened.

C. Government Sector Impact:

The DOH will incur non-recurring costs for rulemaking that can be absorbed within existing resources. The DOH may also experience an indeterminate increase in workload by implementing the requirements of the bill.

[50] Based on the Demographic Estimating Conference's final population estimate for April 1, 2012, which was adopted on November 7, 2012. The Executive Summary can be found at: http://edr.state.fl.us/Content/conferences/population/demographicsummary.pdf.

Local government revenue generated from fines for pain-management clinic violations authorized by local ordinance may be reduced.

VI. Technical Deficiencies:

None.

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/CS by Community Affairs on April 9, 2013:

- Removes state preemption of the regulation of certain health care clinics and health care facilities;
- Retains exemptions from department registration for pain management clinics owned by certain publically-held corporations or not-for-profit corporations;
- Removes a requirement for physicians who treat intractable pain to consult the PDMP;
- Revises state preemption of the regulation of pain management clinics and osteopathic pain management clinics;
- Upon the request of a local government, requires a pain-management clinic to annually demonstrate that it qualifies for the above preemption; and
- Includes pharmaceutical companies as inappropriate sources of funding for PDMPs.

CS by Health Policy on Mar. 21, 2013:

The CS amends SB 1192 to:

- Place language preempting the regulation of the licensure, activity, and operation of various health care facilities and practitioners in the chapters that pertain to those facilities and practitioners;
- Allow local governments to pass ordinances which regulate pain-management clinics;
- Allow the DOH to send notices, in the manner prescribed in the bill, to pharmacy licensees;
- Amend the title to conform to the bill's contents; and
- Make technical changes.

B. Amendments:

None.