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 Health Policy

BILL:	SB 1192
INTRODUCER:	Senator Grimsley
SUBJECT:	Pharmacy and Controlled Substance Prescription
DATE:	March 18, 2013 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Pre-meeting**
2.			AHS	
3.			AP	
4.				
5.				
6.				

I. Summary:

SB 1192 substantially amends various sections of the Florida Statutes to:

- Revise 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;
- Require certain physicians to check the Prescription Drug Monitoring Program database before prescribing certain controlled substances to a new patient;
- Exclude certain physicians from the standards of practice for prescribing controlled substances contained within s. 456.44, F.S.;
- Include certain clinics in the definition of pain management clinic in chs. 458 and 459, F.S.;
- Mandate that the Department of Health (DOH) deny the registration of pain management clinics that are not fully owned by a physician or group of physicians;
- Preempt to the state all regulation of the licensure, activity, and operation regarding certain health care facilities and practitioners, with some exceptions;
- Define the term "abandoned" as it relates to pharmacy permits;
- Mandate that the DOH serve notices to pharmacies in writing and by an agent of the DOH or certified mail;
- Clarify and add to the types of activities that are grounds for licensure denial, revocation, or suspension, or for disciplinary action for pharmacies;
- Require that pharmacies commence operations within 180 days of receiving a permit;
- Require that pharmacies be supervised by a prescription department manager or consultant pharmacist of record at all times;
- Authorize state funds to fund the PDMP program; and

- Exclude pharmaceutical companies from those organizations that may be considered inappropriate sources of funds for the PDMP program.

This bill substantially amends sections 409.9201, 456.44, 458.326, 458.3265, 458.331, 459.0137, 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, F.S., and creates s. 465.0065, F.S.

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 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]

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[1] S. 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 March 18, 2013).
[3] S. 893.03(1), F.S.
[4] S. 893.03(2), F.S.
[5] S. 893.03(3), F.S.
[6] S. 893.03(4), F.S.
[7] S. 893.03 (5), F.S.

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]

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]

[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] s. 456.44(2)(a) and (b), F.S.
[10] s. 456.44(3)(a), F.S.
[11] s. 456.44(3)(b), F.S.
[12] s. 456.44(3)(c)1.-3., F.S.
[13] s. 456.44(3)(d), F.S.
[14] s. 456.44(3)(e), F.S.
[15] s. 456.44(3)(g), F.S.

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 student, 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 part X of ch. 400, 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.;
- 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

[16] Id.
[17] Id.
[18] S. 458.3265(1)(a)1.c. and 459.0137(1)(a)1.c., F.S.
[19] S. 458.3265 and 459.0137, F.S.
[20] S. 458.3265(1)(a)2.a.-h. and 459.0137(1)(a)2.a.-h., F.S.
[21] S. 458.3265(1)(d) and 459.0137(1)(d), F.S.
[22] S. 458.3265(1)(d) and (e) and 459.0137(1)(d) and (e), F.S.
[23] S. 458.3265(3)(a) and 459.0137(3)(a), F.S.

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

Chapter 2009-197, L.O.F, established the Prescription Drug Monitoring Program (PDMP) in s. 893.055, F.S. The PDMP uses a comprehensive electronic system/database to monitor the prescribing and dispensing of certain controlled substances.[27] 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.[28]

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.[29] Indirect access to the PDMP database is provided to:

- 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.[30]

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.[31] Funding for the PDMP comes from three funding sources:[32]

- 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;

[24] S. 458.3265(5) and 459.0137(5), F.S.
[25] S. 458.3265(1)(h)-(j) and 459.0137(1)(h)-(j), F.S.
[26] S. 458.3265(1)(k) and 459.0137(1)(k), F.S.
[27] S. 893.055(2)(a), F.S.
[28] S. 893.055(3)(a)-(c), F.S.
[29] S. 893.055(7)(b), F.S.
[30] S. 893.055(7)(c)1.-4., F.S.
[31] S. 893.055(10) and (11)(c), F.S.
[32] 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 Mar. 18, 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.

- 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 outlined in the statute.[33] The statute details exceptions for disclosure of information after DOH ensures the legitimacy of the person's request for the information.[34]

The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[35] Health care practitioners began accessing the PDMP on October 17, 2011.[36] Law enforcement began requesting data from the PDMP in support of active criminal investigations on November 14, 2011.[37]

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.[38] Nearly 5,000 pharmacists entered 56 million prescriptions into the database.[39] Law enforcement queried the PDMP database more than 20,000 times in conjunction with active criminal investigations.[40]

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.[41]

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[42] 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;
- To 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; and

[33] s. 893.0551(2)(a)-(h), F.S.
[34] s. 893.0551(3)(a)-(g), F.S.
[35] Supra, n. 33 at page 4.
[36] Id.
[37] Id.
[38] Id. at page 3.
[39] Id.
[40] Id.
[41] DOH bill analysis on SB 1192, dated Mar. 1, 2013, on file with the Senate Health Policy Committee.
[42] Registered under ch. 458, 459, 461, or 466, F.S.

- Mandate that the board must adopt rules to establish a penalty for not checking the PDMP database.
- 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 less than 50 total prescriptions for controlled substances for all of his or her patients during a 1-year period from the standards of practice established in this section.

Section 2 amends s. 458.326, F.S., to require that physicians who treat new patients for intractable pain, pursuant to s. 458.326, F.S., consult the PDMP database before prescribing a Schedule II or III controlled substance, to allow the physician to designate an agent to check the PDMP database, and to mandate that the board must adopt rules to establish a penalty for not checking the PDMP database.

Section 3 and 4 amend ss. 458.3265 and 459.0137, F.S., respectively to:

- Include clinics that are owned by publicly held corporations 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 exceed $50 million in the definition of pain management clinic;
- Include clinics that are owned by corporate entities exempt from federal taxation under 26 U.S.C. s. 501(c)(3) in the definition of pain management clinic;
- Mandate that the DOH deny the registration of any clinic licensed under Part X of ch. 400, F.S., which is not fully owned by a physician or group of physicians licensed under ch. 458 or ch. 459, F.S.
- Preempt to the state all regulation of the licensure, activity, and operation of pharmacies and pharmacists as defined in ch. 465, F.S., health care facilities as defined in s. 408.07, F.S.,[43] and clinics under part X of ch. 400, F.S., including registration and licensing for pain-management clinics and practitioners;
- Restrict local governments or political subdivisions of the state from enacting or enforcing ordinances that imposes a levies, charges, or fees upon, or that otherwise regulate, pharmacies and pharmacists, health care facilities as defined in s. 408.07, F.S., and clinics under part X of ch. 400, F.S., including services provided within such facilities; 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. However, a health care facility or clinic that treats pain or provides pain-management services is a permissible use in a land use or zoning category that permits hospitals, other

[43] "Health care facility" means an ambulatory surgical center, a hospice, a nursing home, a hospital, a diagnostic-imaging center, a freestanding or hospital-based therapy center, a clinical laboratory, a home health agency, a cardiac catheterization laboratory, a medical equipment supplier, an alcohol or chemical dependency treatment center, a physical rehabilitation center, a lithotripsy center, an ambulatory care center, a birth center, or a nursing home component licensed under chapter 400 within a continuing care facility licensed under chapter 651.

health care facilities, or clinics as defined in ch. 395, F.S., s. 408.907, F.S., or under part X of ch. 400, F.S.

Section 5 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 person who is 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 6 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 and that 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.

Section 7 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 8 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 9 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 10 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.

Sections 11-20 amend various sections of the Florida Statutes to conform those sections to changes made in section 5 of the bill.

Section 21 provides an effective date of July 1, 2013.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

Section 6, article III of the Florida constitution requires every law to embrace only one subject and matter properly connected therewith, and the subject is to be briefly expressed in the title. Sections 3 and 4 of the bill preempt to the state the regulation of all health care entities and practitioners listed, and not only pharmacies and not restricted to controlled substance prescribing. As such, sections 3 and 4 may not be germane to the title of the bill ("an act relating to pharmacy and controlled substance prescription.")

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 and lives saved.

C. Government Sector Impact:

The DOH will incur non-recurring costs for rulemaking which are within their current budget.

Also, the DOH may experience an indeterminate increase in workload implementing the requirements of this bill.

VI. Technical Deficiencies:

The preemptions in sections 3 and 4 affect the licensure, activity, and operation of multiple types of health care facilities and practitioners. These preemptions currently are placed in the practice acts for allopathic and osteopathic physicians and, as such, are not placed in the correct chapters

to reach all of the health care facility types and practitioners that are listed in those sections. The preemption language should be placed in the various chapters regulating the listed facilities and practitioners.

Section 5 of the bill defines the term "abandoned" as the status of a person who is 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. However, this term, as it is used in ch. 456, F.S.,[44] applies to the pharmacy permit and not the person who holds the permit. A better definition for the term abandoned would be:

> …the status of a pharmacy permit where the person or entity issued the permit 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.

VII. Related Issues:

Sections 3 and 4 of the bill preempt to the state the regulation of all health care entities and practitioners listed, and not only pharmacies and not restricted to controlled substance prescribing. As such, sections 3 and 4 may not be germane to the title of the bill ("an act relating to pharmacy and controlled substance prescription").

Section 6 of the bill requires notices served by the DOH under ch. 465, F.S., be delivered personally by an agent of the DOH or by certified mail to the pharmacy permittee or be posted in a conspicuous place at the pharmacy. This language may be inappropriate for notices that the DOH must deliver that concern pharmacist licensees who may or may not be affiliated with any permitted pharmacy. This section should be amended to address who the DOH must deliver notices directly to licensees.

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.

[44] s. 456.018, F.S.