

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 Appropriations Subcommittee on Health and Human Services

BILL: SB 450

INTRODUCER: Senators Benacquisto and Gaetz

SUBJECT: Pain Management Clinics

DATE: March 3, 2015

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Looke</u>	<u>Stovall</u>	<u>HP</u>	Favorable
2.	<u>Brown</u>	<u>Pigott</u>	<u>AHS</u>	Pre-meeting
3.	_____	_____	<u>AP</u>	_____

I. Summary:

SB 450 prevents the regulation of pain management clinics from being repealed on January 1, 2016.

The bill has no fiscal impact.

The bill is effective upon becoming a law.

II. Present Situation:

Pain Management Clinics

A pain management clinic is any facility that either advertises pain management services or a facility where a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.¹ All pain management clinics must register with the Department of Health (DOH) and meet provisions concerning staffing, sanitation, recordkeeping, and quality assurance.² Clinics are exempt from these provisions if they are:

- Licensed as a hospital, ambulatory surgical center, or mobile surgical facility;
- Staffed primarily by surgeons;
- Owned by a publicly-held corporation with total assets exceeding \$50 million;
- Affiliated with an accredited medical school;
- Not involved in prescribing controlled substances for the treatment of pain;
- Owned by a corporate entity exempt from federal taxation as a charitable organization;

¹ “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. See ss. 458.3265 and 459.0137, F.S.

² Sections 458.3265 and 459.0137, F.S. Chapter 458, F.S., is the Medical Practice Act, and Chapter 459, F.S., is the Osteopathic Medical Practice Act. The two sections regulating pain management clinics are substantively identical.

- Wholly owned and operated by board-eligible or board-certified anesthesiologists, psychiatrists, rheumatologists, or neurologists; or
- Wholly owned and operated by a physician multispecialty practice with physicians holding credentials in pain medicine and who perform interventional pain procedures routinely billed using surgical codes.

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 as a pain management clinic. Pain management clinics must also designate a physician who is responsible for complying with all the registration and operation requirements designated in ss. 458.3265 or 459.0137, F.S. A pain management clinic may not be owned by, or have a contractual or employee relationship with, a physician who has had his or her Drug Enforcement Administration (DEA) license number revoked, has had his or her application for a license to practice using controlled substances denied by any jurisdiction, or has had any convictions or pleas for illicit drug felonies within the past 10 years.

The DOH is required to conduct an annual inspection of each pain management clinic. Through the inspection, the DOH ensures the following requirements are met:

- The pain management clinic is registered with the DOH and the DOH has been notified of the designated physician;
- Every physician meets the training requirements to practice at the clinic;
- The clinic, including its grounds, buildings, furniture, appliances and equipment, is structurally sound, in good repair, clean, and free from health and safety hazards;
- Storage and handling of prescription drugs complies with ss. 499.0121 and 893.07, F.S.;
- Physicians maintain control and security of prescription blanks and other methods for prescribing controlled substances and report in writing any theft or loss of prescription blanks to the DOH within 24 hours;
- Physicians are in compliance with the requirements for counterfeit-resistant prescription blanks; and
- The designated physician has reported all adverse incidents to the DOH as set forth in s. 458.351, F.S.³

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. 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. The DOH may impose an administrative fine of up to \$5,000 per day for a clinic that operates without a registration. No owner or operator of a pain management clinic that had its registration revoked may own or operate another pain clinic for five years after such revocation.⁴

These provisions expire on January 1, 2016.

³ Department of Health, *Senate Bill 450 Analysis*, (on file with the Senate Health Policy Committee).

⁴ Section 458.3265, F.S. Similar language is found in s. 459.0137, F.S. Related rules are found in Rules 64B8-9 and 64B15-14, F.A.C.

Pain Management Clinic Regulation and Closures between 2010 and 2015

In 2009, the Florida Legislature enacted ch. 2009-198, L.O.F., which, along with establishing the prescription drug monitoring database, required all pain management clinics to register with the DOH. The DOH began registering pain management clinics on January 1, 2010, and by September 2010, had registered 943 pain management clinics in the state.⁵

In 2010, the Florida Legislature enacted ch. 2010-211, L.O.F., which created ss. 458.3265 and 459.0137, F.S. The Legislature again enhanced regulation of pain management clinics in 2011, with the passage of ch. 2011-141, L.O.F., (CS/HB 7095) which specified requirements for facility and physical operations, infection control, health and safety requirements, quality assurance, and data collection and reporting. This act also added the expiration date for the sections relating to the regulation of pain management clinics.

Since 2010, the DOH has administratively closed a total of 1,261 pain management clinics.⁶ Also, the total number of pain management clinics registered in Florida has fallen from 941, at the end of Fiscal Year 2010-2011, to 359, at the end of Fiscal Year 2014-2015.⁷

Currently, registered pain management clinics have improved their policies and procedures to meet the standards set out in ss. 458.3625 and 459.0137, F.S. When conducting the annual inspection of a pain management clinic, the DOH is required to make a reasonable attempt to discuss each violation with the owner or designated physician of the pain management clinic before issuing a formal written notification. The number of pain management clinics passing the inspection the first time has increased from 53 percent in Fiscal Year 2012-2013 to 85 percent in Fiscal Year 2013-2014.⁸

Effectiveness of Prescription Drug Regulations in Florida

The increased regulation of pain management clinics and other controlled substance prescribing changes correspond with significant reductions in the number of drug overdose deaths in Florida. In 2010, Florida led the nation in diverted prescription drugs which resulted in seven Floridians dying every day, as well as the many more additional deaths across the nation.⁹ A Centers for Disease Control and Prevention report published on July 4, 2014, documents a 61 percent increase in drug overdose deaths in Florida from 2003 to 2010.¹⁰ Additionally, Florida had

⁵ Supra note 3.

⁶ Department of Health, Chart of pain management clinic disciplinary actions from FY 10-11 to FY 14-15, (on file with the Senate Committee on Health Policy) *Note: this number includes clinics that have voluntarily relinquished their registration or have closed without disciplinary action being taken.*

⁷ Id.

⁸ Supra note 3.

⁹ Office of the Attorney General of Florida, *Pill Mill Initiative (2012-2015)*, available at <http://myfloridalegal.com/pages.nsf/Main/AA7AAF5CAA22638D8525791B006A30C8>, (Last visited Feb. 13, 2015)

¹⁰ The Centers for Disease Control and Prevention, *Decline in Drug Overdose Deaths after State Policy Changes — Florida, 2010–2012*, July 4, 2014, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a3.htm?s_cid=mm6326a3_w#Fig1 (Last visited Feb. 12, 2015).

become the primary destination for distributors and abusers of diverted prescription drugs through the proliferation of illegitimate pain management clinics known as pill mills.¹¹

However, instead of continuing the upward trend of the seven years between 2010 – when many of the current controlled substance prescribing regulations became effective – and 2012, drug overdose deaths in Florida fell by 16.7 percent. Also, during that period, deaths from prescription drugs declined by 23.2 percent and deaths from oxycodone declined by 52.1 percent.¹² Prescription drug deaths also continued to fall in 2013, when compared to 2012, with 8.3 percent fewer people dying with at least one prescription drug in their system that was identified as the cause of death.¹³ Additionally, the number of doctors in Florida who prescribed high volumes of narcotics fell from 98 in 2010 to 13 in 2012 and to zero in 2013.¹⁴

III. Effect of Proposed Changes:

The bill strikes the expiration date of January 1, 2016, from the regulation of pain management clinics under the Medical Practice Act in s. 458.3265, F.S., and under the Osteopathic Medical Practice Act in s. 459.0137, F.S.

The provisions in the bill are effective upon becoming law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

¹¹ Supra note 9, Pill mills are pain management clinics that serve as a front for drug traffickers and can be identified through characteristics which include: taking only cash, not taking appointments, employing armed guards, keep little to no medical records, performing only grossly inadequate physical examinations, and prescribing large doses of narcotics that exceed the boundaries of acceptable medical care.

¹² Supra note 10.

¹³ Florida Department of Law Enforcement, *Medical Examiners Commission 2013 Annual Report*, p. i, published October 2014, available at <http://www.fdle.state.fl.us/Content/getdoc/05c6ff97-00cc-49b2-9ca5-5dacd4539b1a/2013-Annual-Drug-Report.aspx> (Last visited Feb. 13, 2015).

¹⁴ Sabrina Tavernise, *Prescription Overdose Deaths in Florida Plunge After Tougher Measures, Report Says*, THE NEW YORK TIMES, July 1, 2014, available at http://www.nytimes.com/2014/07/02/health/prescription-drug-deaths-in-florida-plunge-after-tougher-laws.html?_r=0, (last visited Feb. 12, 2015). Also see supra note 10.

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

None.

B. Private Sector Impact:

SB 450 continues the current regulation of private-sector pain management clinics.

C. Government Sector Impact:

The bill continues the current regulation of pain management clinics conducted by the Department of Health.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

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

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.