

**HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS**

BILL #: HB 4017

FINAL HOUSE FLOOR ACTION:

SPONSOR(S): Spano and others

117 Y's

1 N's

**COMPANION
BILLS:** SB 450

GOVERNOR'S ACTION: Approved

SUMMARY ANALYSIS

HB 4017 passed the House on April 22, 2015, as SB 450.

Leading up to 2009, parts of Florida had become centers for prescription drug trafficking, particularly in opioids. The resulting increases in crime and mortality, and the resulting decrease in the quality of life experienced by Floridians, resulted in the Florida Legislature determining that pain-management clinics, as well as other entities in the drug supply chain, should be regulated to prevent these outcomes.

From 2009 to 2012, the Legislature enacted and refined a substantial set of regulations designed to combat prescription drug overprescribing and trafficking, including regulation of pain-management clinics. The law defines pain-management clinics as facilities that advertise in any medium for any type of pain-management services or where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol. The law currently requires pain-management clinic registration, inspection, reporting, and penalties for violations of several laws. The law also currently requires physicians practicing at a clinic to ensure that the clinic meets certain requirements.

The pain-management clinic statutes also include "sunset provisions," such that the two sections that regulate pain-management clinics will expire on January 1, 2016. The bill provides the sunset provisions for pain-management clinic regulations, requiring such clinics to continue to be subject to those regulations beyond January 1, 2016.

This bill does not appear to have a fiscal impact on state or local government.

The bill was approved by the Governor on May 21, 2015, ch. 2015-49, L.O.F., and became effective on that date.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Prescription Drug Trafficking

Florida had a severe prescription drug trafficking problem prior to 2011-2012 caused by many factors, including physicians prescribing without proper clinical justification in office and pain-management clinic settings, weak standards of care for physicians, and cash-based prescription drug disbursement.

So-called “pain-management clinics” in Florida became harbors for illegally trafficked drugs, including oxycodone, carisoprodol, and alprazolam.¹ Physicians could plausibly deny any illegal activity, as long as the drug traffickers would follow the same basic procedures a general patient would follow if that patient were truly in pain and in need of medication.² The cash-only pain-management clinic structure was especially effective for traffickers if the owners of the pain-management clinics were not physicians, as this specific type of clinic was unregulated by any state agency.³ From 2007 to 2009, the number of pain-management clinics in Broward County alone increased from 4 to 115.⁴ From late 2008 to early 2009, doctors in South Florida dispensed over 53% of the total oxycodone dispensed by the top 100 doctors in the United States.⁵

This increase correlated to higher mortality, higher crime, higher addiction rates, and lower quality of life in Florida.⁶ From 2006 to 2008, the number of deaths per day with lethal dose reports of prescription drugs increased from 7 to 10.⁷ Drug crime and its related costs to Florida increased substantially.⁸ From 2004 to 2008, treatment admissions related to prescription drugs rose 150%.⁹

Pain-Management Clinic Legislative History

The Legislature determined that unregulated pain-management clinics were the source of a substantial amount of drug trafficking in Florida, primarily in opioids like oxycodone, a Schedule II controlled substance.¹⁰ In 2009, the Florida Legislature established a regulatory structure for pain-management clinics.¹¹

In 2010, the Legislature created s. 458.3265 and s. 459.0137, F.S., to consolidate, clarify, and expand the standards for pain-management clinics.¹²

In 2011, the Legislature modified the standards substantially, in part by codifying rules promulgated by the Department of Health (DOH).¹³ In addition to the substantive modifications, the Legislature enacted

¹ *The Proliferation of Pain Clinics in South Florida*, Interim Report of the Broward County Grand Jury 3 (17th Jud. Cir. Fla., Nov. 19, 2009).

² *Id.* at 4.

³ *Id.* at 17.

⁴ *Id.* at 6.

⁵ *Id.* at 9.

⁶ *Id.* at 9-11.

⁷ *Id.* at 9.

⁸ *Id.* at 10-11.

⁹ *Id.* at 12.

¹⁰ See ch. 893, F.S.

¹¹ Chapter 2009-198, ss. 3, 4, Laws of Fla. The Florida Legislature also established a Prescription Drug Monitoring Program at this time. See ch. 2009-197, Laws of Fla. As of March 2014, 49 states have a Prescription Drug Monitoring Program. “The Role of a Prescription Drug Monitoring Program in Reducing Prescription Drug Diversion, Misuse, and Abuse,” U.S. DEP’T OF HEALTH & HUMAN SERVICES (June 2014).

¹² Ch. 2010-211, ss. 4, 8, Laws of Fla.

¹³ Ch. 2011-141, ss. 4, 7, Laws of Fla. In addition, the Legislature touched every point of the prescription drug chain, including manufacturing, wholesale distribution, physician dispensing, standards of care, and pharmacy regulation. Ch. 2011-141, Laws of Fla.

sunset provisions requiring the pain-management clinic regulations in s. 458.3265 and s. 459.0137, F.S., to automatically expire on January 1, 2016.¹⁴

In 2012, the Legislature further modified these standards by adding exemptions for certain types of medical practice;¹⁵ however, the Legislature left the sunset provisions intact.¹⁶

Pain-Management Clinic Regulation

Florida law defines a “pain-management clinic” as a publicly or privately owned facility that advertises in any medium for any type of pain-management services or where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol.¹⁷

Section 458.3265, F.S., within the medical practice act and s. 459.0137, F.S., within the osteopathic practice act regulate the registration, management, and inspections of pain-management clinics, and the allopathic and osteopathic physicians employed by such clinics. These sections create a registration requirement for pain-management clinics.

Registration

A pain-management clinic must register with DOH unless:

- The clinic is licensed under ch. 395, F.S.;
- The majority of the physicians who provide services in the clinic primarily provide surgical services;
- The clinic is publicly owned, with total assets exceeding \$50 million in the most recent fiscal quarter;
- The clinic is affiliated with an accredited medical school;
- The clinic does not prescribe controlled substances for pain treatment;
- The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3);
- The clinic is wholly owned and operated by one or more board eligible¹⁸ or board-certified anesthesiologists, physiatrists, rheumatologists, or neurologists; or
- The clinic is wholly owned and operated by a physician multispecialty practice where one or more board eligible¹⁹ or board-certified medical specialists have both (1) completed certain fellowships in pain medicine or are board-certified in pain medicine by certain boards, and (2) perform interventional pain procedures of the type routinely billed using surgical codes.²⁰

Each location must be registered separately, regardless of whether it is operated under the same name or management as another clinic.²¹ Additionally, a change of ownership requires submission of a new registration application.²²

DOH must deny a pain-management clinic’s registration if:

¹⁴ *Id.*
¹⁵ Ch. 2012-160, ss. 32, 33, Laws of Fla.
¹⁶ *Id.*
¹⁷ S. 458.3265(1)(a)(1.)(c.), F.S.; s. 459.0137(1)(a)(1.)(c.), F.S.
¹⁸ “Board eligible” means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program. S. 458.3265(1)(a)(1.)(a.), F.S.; s. 459.0137(1)(a)(1.)(a.), F.S.
¹⁹ See note 21, *supra*.
²⁰ S. 458.3265(1)(a)(2.), F.S.; s. 459.0137(1)(a)(2.), F.S.
²¹ S. 458.3265(1)(b), F.S.; s. 459.0137(1)(b), F.S.
²² S. 458.3265(1)(m), F.S.; s. 459.0137(1)(m), F.S.

- The clinic is neither fully owned by a physician or group of physicians licensed under ch. 458 or ch. 459, F.S.; nor health care clinic licensed under ch. 400, Part X.²³
- The clinic is owned by, has a contractual relationship with, or employs a physician:
 - Whose Drug Enforcement Administration 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 a felony for receipt of illicit and diverted drugs, including any Schedule I-V substance, anywhere in the United States.²⁴

DOH must revoke a pain-management clinic's registration if the same reasons for denial above apply to a registered clinic.²⁵ However, by rule, DOH may grant an exemption to such denial or revocation for felony convictions if more than 10 years have elapsed since adjudication.²⁶ DOH may also revoke a clinic's registration based on inspection.²⁷

If a clinic's registration is revoked or suspended, the clinic must stop operating, and the clinic must remove all identification that the location is a pain-management clinic.²⁸ Additionally, the clinic must follow certain procedures to dispose of its medicinal drugs.²⁹ A required 5 year cooling-off period prohibits anyone whose registration has been revoked from applying for a permit to operate a pain-management clinic.³⁰ If a clinic's registration is suspended, that suspension may not exceed 1 year.³¹

Pain-Management Clinic Physicians

A physician may not practice medicine at a pain-management clinic unless the clinic is registered and the physician is qualified to practice in the clinic pursuant to the governing board's rules. If a physician practices medicine at the clinic in violation of these requirements, the physician is subject to board discipline under s. 456.072, F.S.³²

Only physicians licensed under ch. 458 or ch. 459, F.S., may dispense medication at pain-management clinics,³³ however, s. 465.0276, F.S., prohibits physicians from dispensing Schedule II and Schedule III controlled substances. If a physician prescribes a controlled substance for a patient, the physician, or a physician assistant or advanced registered nurse practitioner, must perform a physical examination of the patient on the same day.³⁴ If that prescription³⁵ is for more than a 72-hour dose and for the treatment of chronic nonmalignant pain, the physician must document the reason for the quantity in the patient's record.³⁶

Every physician practicing in a pain-management clinic must ensure compliance with a list of requirements, which relate to clinic access, clinic infrastructure, patient privacy, clinic security,³⁷

²³ S. 458.3265(1)(d), F.S.; s. 459.0137(1)(d), F.S.

²⁴ S. 458.3265(1)(e), F.S.; s. 459.0137(1)(e), F.S.

²⁵ S. 458.3265(1)(f), F.S.; s. 459.0137(1)(f), F.S.

²⁶ *Id.*

²⁷ S. 458.3265(1)(g), F.S.; s. 459.0137(1)(g), F.S.

²⁸ S. 458.3265(1)(h), (i), F.S.; s. 459.0137(1)(h), (i), F.S.

²⁹ S. 458.3265(1)(j), F.S.; s. 459.0137(1)(j), F.S.

³⁰ S. 458.3265(1)(k), F.S.; s. 459.0137(1)(k), F.S.

³¹ S. 458.3265(1)(l), F.S.; s. 459.0137(1)(l), F.S.

³² S. 458.3265(2)(a), F.S.; s. 459.0137(2)(a), F.S. Discipline may include suspension or revocation of a license or other actions available to the board. S. 465.072(2), F.S.

³³ S. 458.3265(2)(b), F.S.; s. 459.0137(2)(b), F.S.

³⁴ S. 458.3265(2)(c), F.S.; s. 459.0137(2)(c), F.S.

³⁵ Physicians are responsible for their prescription blanks (and any other method used for prescription), must comply with the security requirements of s. 893.065, F.S., and must notify DOH of any stolen or missing prescription blanks (or breach of any other method used for prescription). S. 458.3265(2)(d), F.S.; s. 459.0137(2)(d), F.S.

³⁶ S. 458.3265(2)(c), F.S.; s. 459.0137(2)(c), F.S.

³⁷ S. 458.3265(2)(f)(1.), F.S.; s. 459.0137(2)(f)(1.), F.S.

infection control,³⁸ clinic safety, and clinic personnel.³⁹ However, these requirements do not supersede the standard of care, skill, and treatment required of physicians recognized in general law related to health care licensure.⁴⁰

Designated Physicians

Each clinic must designate a physician who is responsible for complying with the registration and other requirements in the section.⁴¹ This designated, fully licensed physician must practice at the clinic, and if the clinic does not have this designated physician, the clinic is at risk for summary suspension.⁴²

A designated physician at a registered clinic must notify the governing board within 10 days after the designated physician's termination of employment at the clinic.⁴³ Any physician at a registered clinic must notify the governing board within 10 days after beginning or ending the physician's practice at the clinic.⁴⁴

The designated physician must ensure compliance with a list of quality and reporting requirements. The designated physician must implement a quality assurance program ("QAP") for each clinic to monitor and evaluate patient care, evaluate methods to improve the care, identify and correct facility deficiencies, alert the designated physician to identify and resolve recurring problems, and provide for opportunities to improve the facility's performance and enhance and improve the quality of care provided to the public. In addition, the QAP must:

- Identify, investigate, and analyze the frequency and causes of adverse incidents to patients;
- Identify trends or patterns of incidents;
- Develop measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients; and
- Document these functions which must be periodically reviewed at least every quarter by the designated physician.⁴⁵

The designated physician must report all adverse incidents to DOH pursuant to s. 458.351 or s. 459.026, F.S., as applicable, and must quarterly report to the governing board:

- The number of new and repeat patients seen and treated at the clinic who are prescribed controlled substance medications for the treatment of chronic, nonmalignant pain;
- The number of patients discharged due to drug abuse;
- The number of patients discharged due to drug diversion; and
- The number of treated at the pain clinic who have their domicile outside of Florida.⁴⁶

Inspections

DOH is required to inspect each pain-management clinic annually, unless the clinic is accredited by a board-approved agency.⁴⁷ During this inspection, DOH must make a reasonable attempt to discuss each violation with the owner or designated physician before issuing a formal written notification.⁴⁸ The

³⁸ S. 458.3265(2)(g), F.S.; s. 459.0137(2)(g), F.S.

³⁹ S. 458.3265(2)(h), F.S.; s. 459.0137(2)(h), F.S.

⁴⁰ S. 458.3265(2)(f)(2.), F.S.; s. 459.0137(2)(f)(2.), F.S.

⁴¹ S. 458.3265(1)(c), F.S.; s. 459.0137(1)(c), F.S.

⁴² *Id.*

⁴³ S. 458.3265(2)(e), F.S.; s. 459.0137(2)(e), F.S.

⁴⁴ *Id.*

⁴⁵ S. 458.3265(2)(i), F.S.; s. 459.0137(2)(i), F.S.

⁴⁶ S. 458.3265(2)(j), F.S.; s. 459.0137(2)(j), F.S.

⁴⁷ S. 458.3265(3)(a), F.S.; s. 459.0137(3)(a), F.S.

⁴⁸ S. 458.3265(3)(b), F.S.; s. 459.0137(3)(b), F.S.

owner or designated physician must document any action taken to correct a violation, and DOH must verify this action with followup visits.⁴⁹

Penalties

DOH may impose a fine on a clinic of up to \$5,000 per violation⁵⁰ of:

- DOH rules;
- S. 458.3265 or s. 459.0137, F.S., relating to pain-management clinics;
- The Florida Drug and Cosmetic Act;
- The Federal Food, Drug, and Cosmetic Act;
- The Florida Comprehensive Drug Abuse Prevention and Control Act; or
- The federal Comprehensive Drug Abuse Prevention and Control Act.⁵¹

Additionally, if the clinic's designated physician knowingly and intentionally misrepresents actions taken to correct a violation, DOH may impose a fine and, if the clinic is owner-operated, may revoke or deny registration.⁵²

DOH must consider the following factors when determining the amount of the fine:

- The gravity of the violation, including the probability of death or serious harm to a patient from the clinic's or physician's action, the severity of the action or harm, and the extent of the violation;
- Actions the owner or designated physician took to correct the violation;
- Prior violations at the clinic; and
- The financial benefits that the clinic derived from the violation.⁵³

An owner or designated physician who operates an unregistered clinic is subject to a \$5,000 fine per day,⁵⁴ and an owner of a clinic who fails to apply to register the clinic upon a change of ownership and then operates the clinic under the new ownership is subject to a fine of \$5,000.⁵⁵

Sunset

In 2011, the Legislature added sunset provisions for s. 458.3265 and s. 459.0137, F.S.⁵⁶ Currently, s. 458.3265 and s. 459.0137, F.S., governing pain-management clinics, are set to expire on January 1, 2016.⁵⁷

Florida Prescription Drug Deaths

Overall prescription drug overdose deaths dropped 7.3% during 2012-2013, while oxycodone overdose deaths dropped 27.3%.⁵⁸ Oxycodone deaths have decreased a total of 64.8% when comparing deaths in 2010 to 2013.⁵⁹ From September 2010 to Fiscal Year 2013-2014, the number of registered pain-management clinics dropped from 943 to 362.⁶⁰

⁴⁹ S. 458.3265(3)(c), F.S.; s. 459.0137(3)(c), F.S.

⁵⁰ Each day a violation continues constitutes an additional violation. S. 458.3265(5)(b), F.S.; s. 459.0137(5)(b), F.S.

⁵¹ S. 458.3265(5)(a), F.S.; s. 459.0137(5)(a), F.S.

⁵² S. 458.3265(5)(c), F.S.; s. 459.0137(5)(c), F.S.

⁵³ S. 458.3265(5)(a), F.S.; s. 459.0137(5)(a), F.S.

⁵⁴ S. 458.3265(5)(d), F.S.; s. 459.0137(5)(d), F.S.

⁵⁵ S. 458.3265(5)(e), F.S.; s. 459.0137(5)(e), F.S.

⁵⁶ Ch. 2011-141, ss. 4, 7, Laws of Fla.

⁵⁷ S. 458.3265(6), F.S.; s. 459.0137(6), F.S.

⁵⁸ "Drugs Identified in Deceased Persons by Florida Medical Examiners," FLA. DEP'T OF LAW ENFORCEMENT 2013 ANNUAL REPORT i (Oct. 2014).

⁵⁹ *Id.*

⁶⁰ "2015 Agency Legislative Bill Analysis: HB 4017," FLA. DEP'T OF HEALTH (Jan. 30, 2015).

Effect of the Bill

This bill repeals the sunset provisions applicable to pain-management clinic regulations in s. 458.3265 and s. 459.0137, F.S., which would otherwise cause those sections to expire on January 1, 2016.

B. SECTION DIRECTORY:

Section 1: Amends s. 458.3265, F.S., related to pain-management clinics.

Section 2: Amends s. 459.0137, F.S., related to pain-management clinics.

Section 3: Provides that the act takes effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.