

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 8

INTRODUCER: Senator Benacquisto and others

SUBJECT: Controlled Substances

DATE: January 9, 2018

REVISED: 1-12-18

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	Pre-meeting
2.			AP	
3.			RC	

I. Summary:

SB 8 amends various sections of law to increase the regulation, training, and reporting required when prescribing and dispensing controlled substances. The bill:

- Requires all prescribing practitioners to complete a 2-hour training course on the proper manner to prescribe controlled substances.
- Requires the Department of Health (DOH) to create guidelines for prescribing controlled substances for the treatment of acute pain.
- Establishes a supply limit of no more than three days for prescriptions of Schedule II opioids to the treat of acute pain. This limit is increased to seven days if determined to be medically necessary by the prescribing practitioner and with proper documentation.
- Requires clinics that are exempt from the requirement to register as a pain management clinic to obtain a certificate of exemption from the DOH.
- Requires pharmacists and dispensing practitioners to verify a patient's identity prior to dispensing controlled substances.
- Adds and reschedules substances to the various schedules of controlled substances.
- Substantially rewords the Prescription Drug Monitoring Program (PDMP) with changes including, but not limited to:
 - Including Schedule V controlled substances in the list of drugs that must be reported to the PDMP and eliminating an exemption for reporting controlled substances dispensed to minors under the age of 16;
 - Requiring prescribing practitioners to consult the PDMP before prescribing controlled substances; and
 - Allowing the DOH to coordinate and share with other state's PDMPs.

II. Present Situation:

Opioid Abuse in Florida

Both nationally and in Florida, opioid addiction and abuse has become an epidemic. By nearly every measure, the opioid crisis has become worse in recent years. The Florida Department of Law Enforcement (FDLE) reported that, when compared to 2015, 2016 saw:

- 5,725 (35 percent more) opioid-related deaths;
- 6,658 (24 percent more) individuals died with one or more prescription drugs in their system;¹
- 3,550 (40 percent more) individuals died with at least one prescription drug in their system that was identified as the cause of death;
- Occurrences of heroin increased by 31 percent and deaths caused by heroin increased by 30 percent;
- Occurrences of fentanyl increased by 80 percent and deaths caused by fentanyl increased by 97 percent;
- Occurrences of methadone (10 percent) and hydrocodone (2 percent) increased. Deaths caused by methadone (40 more) and hydrocodone (9 more) also increased;
- Occurrences of morphine increased by 38 percent and deaths caused by morphine increased by 49 percent;
- Occurrences of oxycodone increased by 28 percent and deaths caused by oxycodone also increased by 28 percent; and
- Occurrences of buprenorphine increased by 90 percent and deaths caused by buprenorphine (14 more) increased.²

Additionally, collateral impacts of controlled substance and opioid misuse have increased. For example, between 2007 and 2015 the instance of neonatal abstinence syndrome, an infant disorder that occurs when babies are exposed to drugs in the womb before birth, increased by nearly 500 percent from 536 cases to 2,487 cases and overall hospital costs that can be attributed to the opioid crisis have more than doubled between 2010 and 2015 from \$460 million to \$1.1 billion.³

History of the Opioid Crisis

In the late 1990s, pharmaceutical companies reassured the medical community that patients would not become addicted to prescription opioid pain relievers, and healthcare providers began to prescribe them at greater rates. This subsequently led to widespread diversion and misuse of these medications before it became clear that these medications could indeed be highly

¹ The drugs were identified as either the cause of death or merely present in the decedent. These drugs may have also been mixed with illicit drugs and/or alcohol. These drugs were not necessarily opioids.

² FDLE, *Drugs Identified in Deceased Persons by Florida Medical Examiners 2016 Annual Report* (Nov. 2017) <https://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2016-Annual-Drug-Report.aspx> (last visited on Jan. 6, 2018).

³ Florida Behavioral Health Association, *Florida's Opioid Crisis* (Jan. 2017) http://www.fadaa.org/links/Opioid%20Media%20Kit_FINAL.pdf, (last visited on Jan. 6, 2018).

addictive.⁴ Between the early 2000s and the early 2010s, Florida was infamous as the “pill mill capital” of the country. During that time, 93 of the top 100 oxycodone dispensing doctors in the United States were in Florida⁵ and, at one point, doctors in Florida bought 89 percent of all the Oxycodone sold in the county.⁶

Between 2009 and 2011, the Legislature enacted a series of reforms to combat prescription drug abuse. These reforms included strict regulation of pain management clinics; creating the PDMP; and stricter regulation on selling, distributing, and dispensing controlled substances.⁷ Between 2010 and 2014, deaths from prescription drugs dropped but deaths from illegal opioids, such as heroin, began to rise.⁸ As can be seen in the data above, however, more recently deaths from prescription controlled substances are once again on the rise. Early in 2017, the United States Centers for Disease Control and Prevention (CDC) declared the opioid crisis an epidemic and shortly thereafter, on May 3, 2017, Governor Rick Scott signed executive order 17-146 declaring the opioid epidemic a public health emergency in Florida.

The Federal government and many states have mobilized to combat the opioid epidemic. The United States Department of Health and Human Services (HHS) has focused its efforts on five major priorities:

- Improving access to treatment and recovery services;
- Promoting use of overdose-reversing drugs;
- Strengthening our understanding of the epidemic through better public health surveillance;
- Providing support for cutting-edge research on pain and addiction; and
- Advancing better practices for pain management.⁹

Individual states have taken actions to combat the opioid crisis such as increase the availability of Naloxone and other related medications to prevent overdose deaths, increasing the availability and funding of medication assisted treatment (MAT), and establishing stricter guidelines and regulations on the prescribing and dispensing of controlled substances.

State and Federal Prescribing Guidelines

CDC Prescribing Guidelines

When prescribing opioids, the CDC has established guidelines to reduce the risk of addiction and dependency. These guidelines are applicable to both chronic and acute pain and include:

- Not using opioids as first-line therapy.
- Establishing realistic goals for pain and function and discontinuing opioid therapy if the benefits do not outweigh the risks.
- Discussing the risks and benefits with patients before and during opioid therapy.

⁴ National Institute on Drug Abuse, *Opioid Overdose Crisis*, (Jan. 2018) <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis> (last visited on Jan. 6, 2018).

⁵ Elaine Silvestrini, *Florida heals from pill mill epidemic*, TAMPA BAY TIMES, Aug. 30, 2014, available at <http://www.tbo.com/news/crime/florida-heals-from-pill-mill-epidemic-20140830/> (last visited on Jan. 6, 2018).

⁶ Lizette Alvarez, *Florida Shutting ‘Pill Mill’ Clinics*, THE NEW YORK TIMES, Aug. 31, 2011, available at <http://www.nytimes.com/2011/09/01/us/01drugs.html> (last visited on Jan. 6, 2018).

⁷ See chs. 2009-198, 2010-211, and 2011-141, Laws of Fla.

⁸ *Supra* note 3

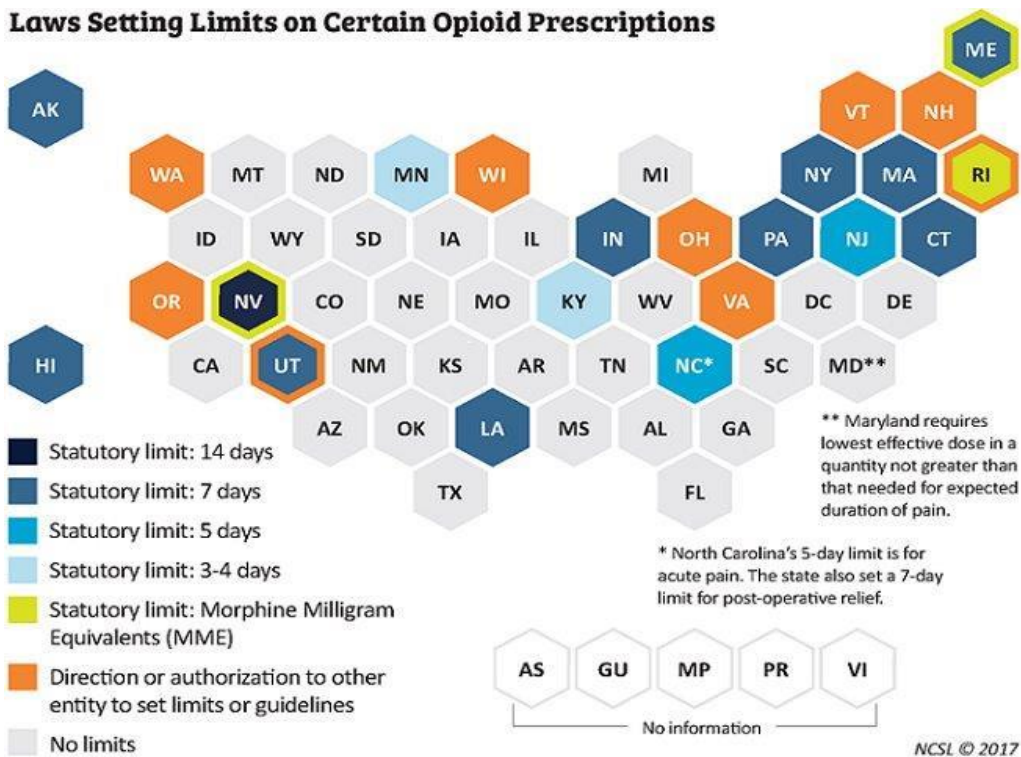
⁹ *Supra* note 4

- Using immediate-release opioids at first and use the lowest effective dose.
- Prescribing short durations for acute pain. The CDC states that, generally, three days or less will be sufficient and more than seven days will rarely be needed.
- Evaluating benefits and harms frequently (within one to four weeks of starting and at least every three months).
- Reviewing PDMP data, use urine drug testing, and avoid prescribing opioids and benzodiazepine concurrently.
- Offering treatment for opioid use disorders.¹⁰

State Opioid Prescription Limits

Beginning in 2016, more than 30 states have considered at least 130 bills related to opioid prescribing and 24 states have enacted legislation that imposes some type of limit, guideline, or requirement related to opioid prescribing. Most legislation limits first time opioid prescriptions to a certain number of days’ supply with seen days being most common. Some states have set limits as low as three days and as high as 14 days. In some cases, states may also set dosage limits using morphine milligram equivalents. Most states also specify that the dosage limits are for acute pain only or exclude chronic pain, palliative care, and cancer treatment.¹¹ Specific states’ laws can be seen on the map below:

Laws Setting Limits on Certain Opioid Prescriptions



¹⁰ CDC Guidelines for Prescribing Opioids for Chronic Pain https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf. (last visited Jan. 10, 2018).

¹¹ Prescribing policies: States Confront Opioid Overdose Epidemic, National Conference of State Legislatures, <http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx> (last visited Jan. 10, 2018). A table of specific legislation is also available at this site under the tab: “Table: Legislation.”

Florida's Prescription Drug Monitoring Program

Chapter 2009-197, Laws of Fla., established the 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.¹² The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.¹³ Dispensers have reported over 232 million controlled substance prescriptions to the PDMP since its inception.¹⁴ Health care practitioners began accessing the PDMP on October 17, 2011.¹⁵ Law enforcement agencies began requesting data from the PDMP in support of active criminal investigations on November 14, 2011.¹⁶

Dispensers of controlled substances listed in Schedule II, Schedule III, or Schedule IV¹⁷ must report specified information to the PDMP database by the close of the next business day after dispensing, each time the controlled substance is dispensed. The information required to be reported includes:¹⁸

- Name of the dispensing practitioner and Drug Enforcement Administration registration number, National Provider Identification, or other applicable identifier;
- Date the prescription is dispensed;
- Name, address, and date of birth of the person to whom the controlled substance is dispensed; and
- Name, national drug code, quantity, and strength of the controlled substance dispensed.¹⁹

Current law exempts certain acts of dispensing or administering from PDMP reporting:

- A health care practitioner when administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.
- A pharmacist or health care practitioner when administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.
- A practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections.
- A practitioner when administering a controlled substance in the emergency room of a licensed hospital.

¹² Section 893.055(2)(a), F.S.

¹³ Florida Dep't of Health, *2012-2013 Prescription Drug Monitoring Program Annual Report* (Dec. 1, 2013), available at http://www.floridahealth.gov/reports-and-data/e-forcse/news-reports/_documents/2012-2013pdmp-annual-report.pdf (last visited on Jan. 7, 2018).

¹⁴ Florida Dep't of Health, *2016-2017 Prescription Drug Monitoring Program Annual Report* (Dec. 1, 2017), available at <http://www.floridahealth.gov/statistics-and-data/e-forcse/funding/2017PDMPAnnualReport.pdf> (last visited on Jan. 7, 2017).

¹⁵ *Supra* note 11

¹⁶ *Supra* note 11

¹⁷ Currently, Florida is one of 16 states that do not require the dispensing of Schedule V controlled substances to be reported to their state's PDMP. For more details please see http://pdmpassist.org/pdf/PDMP_Substances_Tracked_20171205.pdf, (last visited on Jan. 8, 2018).

¹⁸ The specific information reported depends upon the whether the reporter is a pharmacy or practitioner.

¹⁹ *See* s. 893.055(3), F.S.

- A health care practitioner when administering or dispensing a controlled substance to a person under the age of 16.
- A pharmacist or a dispensing practitioner when dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient.
- A rehabilitative hospital, assisted living facility, or nursing home dispensing a certain dosage of a controlled substance, as needed, to a patient while the patient is present and receiving care as ordered by the patient's treating physician.²⁰

Accessing the PDMP database

Section 893.0551, F.S., makes certain identifying information²¹ of a patient or patient's agent, a health care practitioner, a dispenser, an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy that is contained in records held by the department under s. 893.055, F.S., confidential and exempt from the public records laws in s. 119.07(1), F.S., and in article I, section 24(a) of the State Constitution.²²

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 and their designees.²³ Currently, prescribers are not required to consult the PDMP database before prescribing a controlled substance for a patient however physicians and pharmacists queried the database more than 3.7 million times in 2012, over 9.3 million times in 2014, over 18.6 million times in 2015, and over 35.8 million times in 2016.²⁴ Qualified physicians who are issuing physician certifications for medical marijuana under s. 381.986, F.S., are currently required to review the patient's controlled drug prescription history in the PDMP.²⁵

Indirect access to the PDMP database is provided to:

- The DOH or certain health care regulatory boards;
- The Attorney General for Medicaid fraud cases;
- Law enforcement agencies during active investigations²⁶ involving potential criminal activity, fraud, or theft regarding prescribed controlled substances if the law enforcement agency has entered into a user agreement with the DOH;
- Patients, or the legal guardians or designated health care surrogates of incapacitated patients; and
- Impaired practitioner consultants.²⁷

²⁰ Section 893.055(5), F.S.

²¹ Such information includes name, address, telephone number, insurance plan number, government-issued identification number, provider number, and Drug Enforcement Administration number, or any other unique identifying information or number.

²² Section 893.0551(2)(a)-(h), F.S.

²³ Section 893.055(7)(b), F.S.

²⁴ *Supra* notes 12 and 13.

²⁵ See s. 381.986(4)(a)5., F.S.

²⁶ Section 893.055(1)(h), F.S., defines an "active investigation" as an investigation that is being conducted with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings, or that is ongoing and continuing and for which there is a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future.

²⁷ Section 893.055(7)(c)1.-5., F.S.

Indirect access means the person must request the information from the PDMP manager. After an extensive process to validate and authenticate the request and the requestor, the PDMP manager or support staff provides the specific information requested.²⁸

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. The scheduling of substances in Florida law is generally consistent with the Federal scheduling of substances under 21 U.S.C. s. 812:

- 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.

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.²⁹ Pain management clinics must register with the DOH and meet provisions concerning staffing, sanitation, recordkeeping, and quality assurance.³⁰ Certain clinics are exempt from these provisions if they are:

- Licensed as a hospital, ambulatory surgical center, or mobile surgical facility;
- Staffed primarily by surgeons;

²⁸ See s. 893.055(7)(c), F.S., and Rule 64k-1.003, F.A.C.

²⁹ “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 for more than 90 days after surgery. See ss. 458.3265 and 459.0137, F.S.

³⁰ 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.

- 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;
- 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.³¹

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

³¹ Department of Health, *Senate Bill 450 Analysis* (2016) (on file with the Senate Committee on Health Policy).

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.³²

Currently, if a pain clinic meets one of the statutorily approved exemptions from registering with the department, they are not required to register or to show proof of a valid exemption from registration nor are they required to meet any of the requirements set forth above. The determination as to whether the pain clinic meets one of the exemptions is made by the owner of the pain clinic and the department is unaware of which approved exemption the unregistered clinic meets and, without a formal complaint being filed, does not have the authority to inquire. If a clinic no longer qualifies for an exemption they are required to register, however because the department is not aware of clinics that qualify for an exemption from registration and inspection, it is also not aware when the clinic no longer meets the criteria for an exemption from registration.³³

In 2010 when pain clinic registration was first required by law there were 921 registered pain management clinics. At the end of fiscal year 2016-2017, there were 259. It is indeterminate how many clinics closed voluntarily because they could not meet the more stringent requirements established by law and how many were no longer registered because they self-determined they operated under one of the exemptions outlined earlier in this section.³⁴

III. Effect of Proposed Changes:

SB 8 amends and creates various sections of law related to controlled substances.

Section 1 creates s. 456.0301, F.S., to require that, if not already required under a licensee's individual practice act, each appropriate board must require each practitioner licensed with the DEA and authorized to prescribe controlled substances to complete a board-approved 2-hour continuing education course on prescribing controlled substances when renewing his or her license.³⁵ Each licensee must submit confirmation of completing the course when applying for licensure renewal and the DOH is prohibited from renewing the license of any practitioner who has failed to complete the course. The course may be offered in a distance learning format and must include:

- Information on the current standards regarding prescribing controlled substances, particularly opiates;
- Alternatives to these standards; and
- Information on the risks of opioid addiction following all stages of treatment in the management of acute pain

Each licensing board that requires a course may include the hours required for completion in the total hours of continuing education required by law for the board's regulated profession unless the continuing education requirements for that profession consist of fewer than 30 hours biennially.

³² 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.

³³ DOH, *Senate Bill 8 Analysis* (Oct. 23, 2017) (on file with the Senate Committee on Health Policy).

³⁴ *Id.*

³⁵ Beginning on January 31, 2019.

Each board may adopt rules to implement the required course.

Section 2 amends s. 456.072, F.S., to add violations of ss. 893.055 or 893.0551, F.S., establishing the PDMP and the public records exemption for the PDMP, to the list of actions that constitute grounds for disciplinary action against a health care practitioner.

Section 3 amends s. 456.44, F.S., to establish standards for the treatment of acute pain.

The bill defines the term “acute pain” to mean the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness. The DOH is required to adopt rules establishing guidelines for prescribing controlled substances for acute pain including:

- The evaluation of the patient;
- The creation of a treatment plan;
- Obtaining informed consent;
- Periodic review of the treatment plan;
- Consultation;
- Medical record review; and
- Compliance with controlled substances laws and regulations.

The bill specifies that failure to follow the guidelines is a practice act violation.

The bill also restricts a practitioner from prescribing more than a 3-day supply of Schedule II opioids when treating acute pain except that up to a 7-day supply may be prescribed if:

- The practitioner in his or her professional judgement believes that more than a 3-day supply is medically necessary;
- The practitioner indicates “medically necessary” on the prescription; and
- The practitioner adequately documents in the patient’s medical record the acute patient’s acute condition and lack of alternative treatment options.

Sections 4 and 5 amend ss. 458.3265, and 459.0137, F.S., respectively, to require clinics that are exempt from registration as pain management clinics to obtain a certificate of exemption from the DOH. The bill requires the DOH to adopt a form in rule that for applicants for a certificate of exemption. The form must include:

- The name or names under which the applicant does business;
- The address where the pain management clinic is located;
- The specific exemption the applicant is claiming, with supporting documentation; and
- Any other information deemed necessary by the DOH.

The DOH must approve or deny a certificate within 30 days and certificates must be renewed biennially.³⁶ A certificate holder must prominently display the certificate and make it available to the DOH or board upon request. Certificates may not be transferred and are only valid for the applicant, owners, licenses, registrations, certifications, and services provided under the specific exemption claimed. A certificate holder must notify the DOH at least 60 days before any

³⁶ The DOH may issue initial certificates for three years in order to stagger renewal dates.

anticipated relocation, name change, or change of ownership. If an exempt pain management clinic ceases to qualify for a certificate of exemption, the certificate holder must immediately notify the DOH and register as a pain management clinic.

These sections take effect January 1, 2019.

Sections 6 and 7 amend ss. 465.0155 and 465.0276, F.S., to require pharmacists and dispensing practitioners to confirm a person's identity before dispensing controlled substances to that person if he or she is not personally known to the pharmacist. If the person does not have proper identification³⁷ the pharmacist must verify the validity of the prescription and the identity of the patient with the prescriber or his or her agent. This requirement does not apply in an institutional setting or long-term care facility, including, but not limited, to an assisted living facility or a hospital.

Section 8 amends s. 893.03, F.S., to add substances to lists of controlled substances as follows:

- Dihydroetorphine, hydrocodone combination products, oripavine, remifentanyl, tapentadol, thiafentanyl, lisdexamfetamine, and dornabinol (synthetic THC) in oral solution in a drug product approved by the FDA are added to Schedule II.
- Buprenorphine,³⁸ embutramide, and perampanel are added to Schedule III.
- Alfaxalone, dexfenfluramine, dichloralphenazone, eluxadoline, eszopiclone, fospropofol, lorcaseerin, modafinil, petrichloral, sibutramine, suvorexant, tramadol, zaleplon, zolpidem, and zopiclone are added to Schedule IV.
- Not more than .5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dose and unspecified amounts of brivaracetum, ezogabine, lacosamide, and pregabalin are added to Schedule V.

These changes conform Florida law with federal law.³⁹

Section 9 substantially rewords s. 893.055, F.S., creating the PDMP. Many of the provisions in existing law are reordered. The section:

- Defines the terms:
 - "Administration" to mean the obtaining and giving of a single dose of medicinal drugs by a legally authorized person to a patient for her or his consumption.
 - "Active investigation" to mean an investigation that is being conducted with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings, or that is ongoing and continuing and for which there is a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future.
 - "Controlled substance" to mean a controlled substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03 or 21 U.S.C. s. 812. Schedule Vs are added to

³⁷ The bill defines "proper identification" as an identification that is issued by a state or federal government containing the person's photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B). The verification of health plan eligibility is also considered to be proper identification.

³⁸ Buprenorphine is rescheduled from Schedule V to Schedule III.

³⁹ Supra note 31

- the reporting requirements. Most states include the dispensing of Schedule V controlled substances in their PDMPs.⁴⁰
- “Dispense” to mean the transfer of possession of one or more doses of a medicinal drug by a health care practitioner to the ultimate consumer or to his or her agent.
 - “Dispenser” to mean a dispensing health care practitioner or pharmacist licensed to dispense medicinal drugs in this state.
 - “Health care practitioner” or “practitioner” means any practitioner licensed under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, chapter 465, or chapter 466.
 - “Health care regulatory board” to mean any board or commission as defined in s. 456.001(1).
 - “Law enforcement agency” to mean the Department of Law Enforcement, a sheriff’s office in this state, a police department in this state, or a law enforcement agency of the Federal Government which enforces the laws of this state or the United States relating to controlled substances, and which its agents and officers are empowered by law to conduct criminal investigations and make arrests.
 - “Pharmacy” to include a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, or an Internet pharmacy that is licensed by the department under chapter 465 and that dispenses or delivers medicinal drugs, including controlled substances to an individual or address in this state.
 - “Prescriber” to mean a prescribing physician, prescribing practitioner, or other prescribing health care practitioner authorized by the laws of this state to order medicinal drugs.
 - “Program manager” to mean an employee of or a person contracted by the department who is designated to ensure the integrity of the prescription drug monitoring program in accordance with the requirements established in this section.
- Requires the DOH to maintain an electronic system to collect and store controlled substance dispensing information and must release the information as authorized in s. 893.0551, F.S.⁴¹ The system must:
 - Not infringe on legitimate prescribing and dispensing of controlled substances;
 - Be consistent with standards of the American Society for Automation in Pharmacy; and
 - Comply with Health Insurance Portability and Accountability Act (HIPAA) and all other relevant state and federal privacy and security laws and regulations;
 - Allows the DOH to collaborate with health care regulatory boards, appropriate organizations, and other state agencies to identify indicators of controlled substance abuse.
 - Authorizes the DOH to adopt rules.
 - When dispensing a controlled substance to a patient, requires the dispenser to report the following information to the PDMP no later than the close of business the day after the controlled substance was dispensed:
 - The name of the prescribing practitioner, his or her DEA registration number, his or her National Provider Identification (NPI), and the date of the prescription.
 - The date the prescription was filled and the method of payment.
 - The full name, address, telephone number, and date of birth of the person for whom the prescription as written.

⁴⁰ Supra note 15

⁴¹Section 893.0551, F.S., establishes the public records exemption for information in the PDMP.

- The name, national drug code, quantity, and strength of the controlled substance dispensed.
- The full name, DEA registration number, DOH pharmacy permit number, and address of the pharmacy where the controlled substance was dispensed or, if dispensed by a practitioner other than a pharmacist, the practitioner's name, address, DEA registration number, DOH license number, and NPI.
- Whether the drug was dispensed as an initial prescription or a refill and the number of refills ordered;
- The name of the individual picking up the controlled substance prescription and type of identification provided;
- Other appropriate identifying information as determined by the DOH in rule;
- Exempts all acts of administration from the reporting requirement.
- Eliminates an exemption for reporting the dispensing of controlled substances to minors under the age of 16.
- Grants direct access to the system to:
 - Prescribers and dispensers and their designees;
 - Employees of the United State Department of Veterans Affairs,⁴² United States Department of Defense, or the Indian Health Service who provide health care services pursuant to such employment and who have authority to prescribe controlled substances;
 - The program manager and designated support staff to administer the system. The program manager or designated support staff:
 - Must have passed a level II background screening;
 - May have access to de-identified data in order to calculate performance measures;
 - Must provide the DOH de-identified data for public health care and safety initiatives;
 - The program manager:
 - May provide relevant information to the prescriber and dispenser when determining a pattern that indicates controlled substance abuse;
 - May provide relevant information to law enforcement upon determining a pattern of controlled substance abuse and upon having cause to believe that a violation of controlled substance laws has occurred.
- Grants indirect access to the system to:
 - The DOH for investigations involving licensees authorized to prescribe or dispense controlled substances. The bill removes access for the DOH's regulatory boards;
 - The Attorney General for Medicaid fraud cases involving prescribed controlled substances;
 - A law enforcement agency during an active investigation of potential criminal activity, fraud, or theft regarding prescribed controlled substances;
 - A medical examiner when conducting an authorized investigation to determine the cause of death of an individual;⁴³
 - An impaired practitioner consultant who is retained by the DOH to review the system information of an impaired practitioner program participant or a referral who has agreed to be evaluated or monitored through the program and has agreed in writing to the consultant's access; and

⁴² Employees of the US Department of Veterans Affairs were allowed access last year in Ch. 2017-169, Laws of Fla.

⁴³ This access is newly added.

- A patient, legal guardian, or designated health care surrogate of an incapacitated patient who submits a written and notarized request including the patient's name, address, phone number, date of birth, and a copy of a government issued photo identification.
- Allows the DOH to enter into a reciprocal agreement or contract to share PDMP information with other states, districts, and territories if their PDMPs are compatible with Florida's.⁴⁴ To determine compatibility, the DOH must consider for the other state's, district's, or territory's PDMP:
 - Privacy safeguards and the program's success in protecting patient privacy;
 - The persons who are authorized to view the data collected by the program. Persons and entities in other states who are comparable to those granted access to Florida's PDMP may have access to Florida's PDMP upon approval by the DOH;
 - The schedules of controlled substances monitored;
 - Data reported to the program;
 - Any implementing criteria deemed essential; and
 - The costs and benefits to Florida of sharing prescription information.
- Requires the DOH to assess continued compatibility periodically and requires any agreements with other states to contain the same restrictions as Florida's program and s. 893.0551, F.S.
- Allows the DOH to enter into agreements and contracts to establish secure connections between the PDMP and health care provider's electronic health recordkeeping system.
- Requires all prescribers and dispensers, or their designees, to consult the system before prescribing or dispensing a controlled substance. Prescribers and dispensers are exempt from this requirement if the system is not operational or temporarily cannot be accessed. Any prescriber or dispenser who does not consult the system must document the reason why he or she could not consult the system and may not prescribe or dispense more than a 3-day supply of a controlled substance. The DOH is required to issue a non-disciplinary citation to any prescriber or dispenser who fails to consult the system.
- Establishes the penalty of a first degree misdemeanor for any person who willfully and knowingly fails to report the dispensing of a controlled substance to the PDMP.
- Restricts information in the system from being released other than as specified in this section and s. 893.0551, F.S.
- Specifies that the content of the system is informational only and imposes no legal obligations or duties on a prescriber, dispenser, pharmacy, or patient.
- Restricts information in the system from being introduced as evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient and exempts the program manager and staff from being required to testify to any findings, recommendations, evaluations, opinions, or other actions taken in connection with the management of the system.
- Allows a prescriber or dispenser, or his or her designee, to have access to information in the PDMP which relates to his or her patient as needed for the purpose of reviewing the patient's controlled substance prescription history. A prescriber or dispenser acting in good faith is immune from civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information in the PDMP. The bill specifies that accessing or

⁴⁴ This authorization to share data is newly added.

failing to access information in the system does not create a private cause of action against a prescriber or dispenser.

- Specifies that the PDMP must be funded through federal grants, private funding, or state funds appropriated in the General Appropriations Act. The DOH may not commit funds for the PDMP without ensuring funding is available and may not use funds provided directly or indirectly by prescription drug manufacturers.
- Allows the DOH to establish a direct support organization to raise funds for the PDMP and incorporates an automatic repeal date of October 1, 2027, that is in existing law unless saved from repeal by the Legislature.
- Requires the DOH to conduct or contract for studies to examine the feasibility of enhancing the PDMP for public health initiatives and statistical reporting. Such studies must respect the privacy of patients and be focused on:
 - Improving the quality of health care services and safety by improving the prescribing and dispensing practices for prescription drugs;
 - Taking advantage of advances in technology;
 - Reducing duplicative prescriptions and the overprescribing of prescription drugs; and
 - Reducing drug abuse.
- Requires the DOH to annually report to the Governor and the Legislature on specified performance measures for the PDMP.

Section 10 amends s. 893.0551, F.S., to amend the public records exemption for the PDMP to conform to changes made to s. 893.055, F.S.

Sections 11-17 amends various sections of law to conform cross references to changes made in the bill.

Section 18 establishes an effective date of July 1, 2018, unless otherwise specified in the bill.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

Lines 1547-1558 of the bill amend the public records exemption for the PDMP to remove language allowing access to PDMP information for the DOH's relevant health care regulatory boards. Section 24, Art. X of the State Constitution requires that laws narrowing access to public records be enacted separately from other issues. As such, the change removing the boards' access to information in the PDMP may require a separate bill.

C. Trust Funds Restrictions:

None.

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

None.

B. Private Sector Impact:

SB 8 may have an indeterminate negative fiscal impact on clinics that are required to obtain a certificate of exemption from the requirement to register as a pain management clinic.

The bill may have an indeterminate negative fiscal impact on health care practitioners who are required to attend the additional training established in the bill.

The bill may have an indeterminate fiscal impact on patients due to the supply limits imposed for Schedule II opioid prescriptions.

The bill may have a negative fiscal impact on the administrative operations of health care providers who are required to consult the PDMP prior to prescribing controlled substances.

C. Government Sector Impact:

SB 8 may have an indeterminate negative fiscal impact on the DOH related to increased investigations of unlicensed pain management clinics that may be offset through fees collected for initial issuance and renewal of pain management clinic exemption certificates.⁴⁵

VI. Technical Deficiencies:

Lines 116-117 of the bill require that the newly added continuing education for certain health care practitioners be counted towards those practitioner's required continuing education hours required by law. However, lines 125-130 grant the relevant health care regulatory boards the authority to determine if such hours count towards the continuing education hours required by law and state that the hours may not count if the practitioner is required to take less than 30 hours of continuing education. These lines are in conflict with each other and the bill should be amended so that these provisions align.

Lines 310-313 refer to a "Schedule II opioid, as defined in s. 893.03 or 21 U.S.C. s. 812." In s. 893.03, F.S., controlled substances are listed and not defined. The bill should be amended to refer to controlled substances listed in s. 893.03, F.S.

All substances listed as controlled substances in Schedule V incorporate amounts of the substance that require it to be controlled. Substances added to Schedule V on lines 1028-1031 of

⁴⁵ Supra note 26.

the bill do not include amounts. The bill should be amended to clarify an amount or that these substances are controlled regardless of the amount.

Throughout section 9 the bill uses the terms “controlled substance,” “prescription drug,” and “medicinal drug” interchangeably. These terms have different meanings and the PDMP is focused on the reporting of the dispensing of controlled substances, a term that is defined within the section. As such, the terms “prescription drug” and “medicinal drug” should be changed to “controlled substance” where appropriate within the section.

Lines 1581 and 1584 incorporate a cross reference to s. 893.055(6)(e) and (6)(f), F.S. As amended by the bill, these cross references should be to s. 893.055(5)(e) and (5)(f), F.S.

VII. Related Issues:

Sections 4 and 5 of the bill require clinics that are exempt from the requirement to register as a pain management clinic to obtain a certificate of exemption. These sections specify that such certificates are not “moveable.” It is unclear what the term moveable means in this context and the bill should be amended for clarity. Additionally, the sections require that, should a clinic no longer qualify for the exemption, it must “immediately” notify the DOH. Immediate notification may be impractical or impossible, the bill should be amended to incorporate a time frame for an exempt clinic to provide the DOH with notification if it no longer qualifies for the exemption.

Section 9 of the bill defines the term “dispenser” as a dispensing health care practitioner or pharmacist licensed to dispense medicinal drugs in this state. This term may not require out of state pharmacies to report dispensing controlled substances into the state. The term should be amended to include dispensing “in and into” the state.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 456.072, 456.44, 458.3265, 459.0137, 465.0155, 465.0276, 893.03, 893.055, 893.0551, 458.331, 459.015, 463.0055, 782.04, 893.13, 893.135, and 921.0022.

This bill creates section 456.0301 of the Florida Statutes.

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.