

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 Rules

BILL: CS/SB 8

INTRODUCER: Health Policy Committee and Senator Benacquisto and others

SUBJECT: Controlled Substances

DATE: January 31, 2018

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Looke</u>	<u>Stovall</u>	<u>HP</u>	Fav/CS
2.	<u>Loe</u>	<u>Hansen</u>	<u>AP</u>	Favorable
3.	<u>Looke</u>	<u>Phelps</u>	<u>RC</u>	Favorable

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

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

- Restricts Medicaid managed care plans and health insurers from requiring prior authorization or step therapy or imposing any other conditions as a prerequisite to receiving medication-assisted treatment (MAT) services.
- Requires all prescribing practitioners to complete a two-hour training course on the proper manner to prescribe controlled substances.
- Requires applicable health care regulatory boards to create guidelines for prescribing controlled substances for the treatment of acute pain.
- Limits prescriptions to no more than three days of opioids listed in Schedule II to treat acute pain as defined in the bill. This limit is increased to seven days if determined to be medically necessary, and properly documented, by the prescribing practitioner.
- Requires clinics that are exempt from the requirement to register as a pain management clinic to obtain a certificate of exemption from the Department of Health (DOH).
- Requires pharmacists and dispensing practitioners to verify a patient's identity prior to dispensing controlled substances.
- Conforms an exemption allowing health care practitioners to dispense controlled substances in connection with a surgical procedure to the limits on prescribing established for Schedule II opioid medications.

- Creates an exemption to allow a physician to dispense Schedule II and III controlled substances approved by the United States Food and Drug Administration (FDA) for the MAT of his or her own patients.
- 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 Florida's PDMP data with other states' PDMPs.

The DOH will incur additional costs related to increased investigations of unlicensed pain management clinics. These costs may be offset through fees collected for initial issuance and renewal of pain management clinic exemption certificates.

The bill provides supplemental appropriations of:

- \$27,035,360 in non-recurring federal grants trust funds and \$15,520,000 in recurring general revenue funds to the DCF for substance use disorder treatment services.
 - From the \$15.5 million in recurring general revenue funds, the bill earmarks \$4.7 million of recurring general revenue funds for specific MAT drugs.
- \$6 million in recurring general revenue funds to the state courts administrator for substance abuse treatment services related to the criminal justice system. The bill requires these funds be spent on specific MAT drugs.
- \$5 million in recurring general revenue funds to the DOH to purchase naloxone for emergency medical services (EMS) responders.

The effective date of the bill is July 1, 2018, except that Sections 5, 6, 13, and 14 take effect January 1, 2019.

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 worsened 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;

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.

- 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. Overall hospital costs that can be attributed to the opioid crisis 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 health care 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 addictive.⁴ Between the early 2000s and the early 2010s, 93 of the top 100 oxycodone-dispensing doctors in the United States were in Florida,⁵ and at one point, doctors in Florida bought 89 percent of all 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 evidenced in the prescription controlled substance and opioid-related mortality data reported by the FDLE, deaths from prescription controlled substances are once

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).

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

again on the rise. In early 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 the 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: increasing the availability of Naloxone and other related medications to prevent overdose deaths, increasing the availability and funding of MAT, and establishing stricter guidelines and regulations on the prescribing and dispensing of controlled substances.

Medication-Assisted Treatment

Medication-assisted treatment is the use of medications in combination with counseling and behavioral therapies for the treatment of substance use disorders.¹⁰ Medications including buprenorphine (Suboxone and Subutex), methadone, and extended release naltrexone (Vivitrol) are effective in treating opioid use disorders. MAT medications do not substitute one addiction for another since, when properly administered, MAT medications do not cause a high but serve to reduce opioid cravings and withdrawal. Additionally, diversion of buprenorphine is uncommon and when diversion does occur it is primarily used to manage withdrawal symptoms. Patients treated with medications were more likely to remain in therapy compared to patients receiving treatment without medication.¹¹

State and Federal Prescribing Guidelines

CDC Prescribing Guidelines

The CDC has established guidelines to reduce the risk of addiction and dependency when prescribing opioids. 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.

⁹ Supra note 4

¹⁰ MAT overview, Substance Abuse and Mental Health Services Administration, available at <https://www.integration.samhsa.gov/clinical-practice/mat/mat-overview>, (last visited on Jan. 17, 2018).

¹¹ Effective Treatments of Opioid Addiction, National Institute on Drug Abuse, available at <https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction>, (last visited Jan. 17, 2018).

Florida's Prescription Drug Monitoring Program

Chapter 2009-197, Laws of Florida, established the PDMP in s. 893.055, F.S. The PDMP uses a comprehensive electronic database to monitor the prescribing and dispensing of certain controlled substances.¹⁴ The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.¹⁵ Dispensers have reported over 232 million controlled substance prescriptions to the PDMP since its inception.¹⁶ Health care practitioners began accessing the PDMP on October 17, 2011.¹⁷ Law enforcement agencies began requesting data from the PDMP in support of active criminal investigations on November 14, 2011.¹⁸

Dispensers of controlled substances listed in Schedule II, Schedule III, or Schedule IV¹⁹ must report specific information to the PDMP database each time the controlled substance is dispensed by the close of the next business day after dispensing. The information required to be reported includes the:²⁰

- 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.²¹

Certain acts of dispensing or administering are exempt from PDMP reporting. Current law exempts:

- 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 Florida.
- 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.

¹⁴ Section 893.055(2)(a), F.S.

¹⁵ 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).

¹⁶ 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).

¹⁷ *Supra* note 13

¹⁸ *Supra* note 13

¹⁹ 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).

²⁰ The specific information reported depends upon the whether the reporter is a pharmacy or practitioner.

²¹ *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.²²

Accessing the PDMP database

Section 893.0551, F.S., makes certain identifying information²³ 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.²⁴

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.²⁵ 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 2016.²⁶ Qualified physicians who are issuing physician certifications for the medical use of marijuana under s. 381.986, F.S., are currently required to review the patient's controlled drug prescription history in the PDMP.²⁷

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 investigations²⁸ 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.²⁹

²² Section 893.055(5), F.S.

²³ 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.

²⁴ Section 893.0551(2)(a)-(h), F.S.

²⁵ Section 893.055(7)(b), F.S.

²⁶ *Supra* notes 14 and 15.

²⁷ See s. 381.986(4)(a)5., F.S.

²⁸ Section 893.055(1)(h), F.S., defines an "active investigation" as an investigation 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.

²⁹ Section 893.055(7)(c)1.-5., F.S.

Indirect access means the person must request the information from the PDMP manager at the DOH. After an extensive process to validate and authenticate the request and the requestor, the PDMP manager or support staff provides the specific information requested.³⁰

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 include 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 include 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 include 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 include 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 include low dosage levels of codeine, certain stimulants, and certain narcotic compounds.

Pain Management Clinics

A pain management clinic is any facility that 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.³¹ Pain management clinics must register with the DOH and meet provisions concerning staffing, sanitation, recordkeeping, and quality assurance.³² A clinic is exempt from these provisions if it is:

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

³⁰ See s. 893.055(7)(c), F.S., and Rule 64K-1.003, F.A.C.

³¹ “Chronic nonmalignant pain” is defined as pain unrelated to cancer which persists beyond the usual course of disease or injury that is the cause of pain for more than 90 days after surgery. See ss. 458.3265 and 459.0137, F.S.

³² 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 that 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 previous 10 years.

The DOH must 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.³³

The DOH may suspend or revoke a 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, unless exempt. No owner or operator of a pain management clinic that has had its

³³ Department of Health, *Senate Bill 450 Analysis* (2016) (on file with the Senate Committee on Health Policy).

registration revoked may own or operate another pain clinic for five years after such revocation.³⁴

Currently, if a pain clinic meets one of the statutorily approved exemptions from registering with the DOH, they are not required to register or show proof of a valid exemption from registration nor are they required to meet any of the requirements established pursuant to sections 458.3265 and 459.0137, F.S. The determination as to whether the pain clinic meets one of the exemptions is made by the owner of the pain clinic and the DOH 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 DOH 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.³⁵

In 2010, when pain management clinic registration was first required by law, there were 921 registered pain management clinics. There were 259 clinics at the end of the 2016-2017 fiscal year. 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.³⁶

III. Effect of Proposed Changes:

Sections 1 and 9 amend ss. 409.967 and 627.42392, F.S., respectively, to restrict Medicaid managed care plans and health insurers from requiring prior authorization or step therapy or imposing any other conditions as a prerequisite to receiving MAT services. Section 627.42392, F.S., defines “health insurer” to include health insurers, managed care plans, and health maintenance organizations.

Section 2 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 a practitioner licensed with the DEA and authorized to prescribe controlled substances to complete a board-approved two-hour continuing education course on prescribing controlled substances when renewing his or her license.³⁷ 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 be included within the number of continuing education hours required by law. The course 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.

³⁴ 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.

³⁵ DOH, *Senate Bill 8 Analysis* (Oct. 23, 2017) (on file with the Senate Committee on Health Policy).

³⁶ *Id.*

³⁷ Beginning on January 31, 2019.

Each board may adopt rules to implement the required course.

Section 3 amends s. 456.072, F.S., to add violations of ss. 893.055 or 893.0551, F.S., relating to 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 4 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 applicable regulatory boards are required to adopt rules establishing guidelines for prescribing controlled substances for acute pain, including:

- Evaluating the patient;
- Creating and maintaining 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 these guidelines is a practice act violation.

The bill restricts a practitioner from prescribing more than a three-day supply of an opioid listed in Schedule II when treating acute pain except that up to a seven-day supply may be prescribed if:

- The practitioner, in his or her professional judgement, believes that more than a three-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 5 and 6 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 an application form in rule 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, with supporting documentation, that the applicant is claiming; 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.³⁸ A certificate holder must prominently display the certificate and make it available to the DOH or board upon request. A new certificate is required for a change of address and

³⁸ The DOH may issue initial certificates for three years in order to stagger renewal dates.

certificates 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 anticipated relocation, name change, or change of ownership. If a pain management clinic ceases to qualify for a certificate of exemption, the certificate holder must notify the DOH within three days and register as a pain management clinic or cease operations.

Sections 5 and 6 take effect January 1, 2019.

Sections 7 and 8 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 identification,³⁹ the dispenser 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 several provisions in s. 465.0276, F.S., related to the dispensing of controlled substances by health care practitioners. Current law allows health care practitioners who are authorized to prescribe medicinal drugs to dispense such drugs if they are registered with their professional licensing boards; however, current law also restricts such practitioners from dispensing Schedule II or III controlled substances unless there is a specific exemption that allows them to do so. One such exemption allows practitioners to dispense up to a 14-day supply of Schedule II or III controlled substances in connection with the performance of a surgical procedure. The bill amends this exemption to require practitioners to follow the prescribing limits established in **section 4** of the bill when dispensing Schedule II controlled substances under the exemption. The bill creates a new exemption for practitioners authorized under 21 U.S.C. 823⁴⁰ to dispense Schedule II or III controlled substances that are approved for MAT by the FDA to their own patients for MAT of opiate addiction.

Section 10 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,⁴¹ embutramide, and perampanel are added to Schedule III.
- Alfaxalone, dexfenfluramine, dichloralphenazone, eluxadoline, eszopiclone, fospropofol, lorcaserin, modafinil, petrichloral, sibutramine, suvorexant, tramadol, zaleplon, zolpidem, and zopiclone are added to Schedule IV.

³⁹ 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.

⁴⁰ Such practitioners include qualifying physicians (who must be licensed under state law and hold a specialty in addiction treatment or has had specified training) and nurse practitioners and physician assistants who are supervised by, or working in collaboration with, a qualifying physician.

⁴¹ Buprenorphine is rescheduled from Schedule V to Schedule III.

- Not more than .5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dose, and any amount of brivaracetum, ezogabine, lacosamide, and pregabalin are added to Schedule V.

These changes conform Florida law to federal law.⁴²

Section 11 substantially rewords s. 893.055, F.S., creating the PDMP. Many of the provisions in existing law are reordered. The section:

- Defines the terms:
 - “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.
 - “Administration” to mean the obtaining and giving of a single dose of controlled substance by a legally authorized person to a patient for his or her consumption.
 - “Controlled substance” to mean a controlled substance listed in Schedule II, III, IV, or V of s. 893.03, F.S., or 21 U.S.C. s. 812. Schedule Vs are added to the reporting requirements. Most states include the dispensing of Schedule V controlled substances in their PDMPs.⁴³
 - “Dispense” to mean the transfer of possession of one or more doses of a controlled substance by a dispenser to the ultimate consumer or to his or her agent.
 - “Dispenser” to mean a dispensing health care practitioner, pharmacy or pharmacist licensed to dispense controlled substances in or into Florida.
 - “Health care practitioner,” or “practitioner,” means any practitioner licensed under chapters 458, 459, 461, 463, 464, 465, or 466, F.S.
 - “Health care regulatory board” to have the same meaning as s. 456.001(1), F.S.
 - “Law enforcement agency” to mean the Department of Law Enforcement, a sheriff’s office or police department in Florida, 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 DOH under chapter 465 and that dispenses or delivers controlled substances, including controlled substances, to an individual or address in Florida.
 - “Prescriber” to mean a prescribing physician, practitioner, or other health care practitioner authorized by the laws of this state to order controlled substances.
 - “Program manager” to mean an employee of, or a person contracted by, the DOH who is designated to ensure the integrity of the PDMP in accordance with the requirements established in this section.

⁴² Supra note 33

⁴³ Supra note 13

- Requires the DOH to maintain an electronic system to collect and store controlled substance dispensing information and release the information as authorized in s. 893.0551, F.S.⁴⁴ The system must:
 - Not infringe on the legitimate prescribing and dispensing of controlled substances;
 - Be consistent with standards of the American Society for Automation in Pharmacy; and
 - Comply with the 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.
- Requires the dispenser, when dispensing a controlled substance to a patient, 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 was written.
 - 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; and
 - 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 PDMP system to:
 - Prescribers and dispensers and their designees;
 - Employees of the United State Department of Veterans Affairs,⁴⁵ the 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 PDMP system. The program manager or designated support staff:
 - Must complete a level II background screening;
 - May have access to de-identified data in order to calculate performance measures; and
 - Must provide the DOH de-identified data for public health care and safety initiatives;
 - The program manager:

⁴⁴ Section 893.0551, F.S., establishes the public records exemption for information in the PDMP.

⁴⁵ Employees of the US Department of Veterans Affairs were allowed access last year in Ch. 2017-169, Laws of Fla.

- May provide relevant information to the prescriber and dispenser when determining a pattern that indicates controlled substance abuse; and
 - 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 PDMP system to:
 - The DOH and its health care regulatory boards 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;⁴⁶
 - An impaired practitioner consultant who is retained by the DOH to review the PDMP 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
 - 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.⁴⁷ To determine compatibility, the DOH must consider for the other states', districts', or territories' 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 every four years 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 providers' electronic health recordkeeping system.
- Requires all prescribers and dispensers, or their designees, to consult the PDMP 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

⁴⁶ This access is newly added.

⁴⁷ This authorization to share data is newly added.

than a three-day supply of a controlled substance. The DOH is required to issue a non-disciplinary citation pursuant to the procedure in s. 456.077, F.S., to any prescriber or dispenser who fails to consult the system. Under s. 456.077, F.S., the first citation is non-disciplinary and the second and subsequent citations are disciplinary.

- 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 PDMP system from being released other than as specified in this section and s. 893.0551, F.S.
- Specifies that the content of the PDMP system is informational only.
- Restricts information in the PDMP 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 system that 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 system. The bill specifies that accessing or 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 specific performance measures for the PDMP.
- Requires the DOH to adopt rules necessary to implement this section.

Section 12 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., and to conform the section to the requirement in s. 381.986, F.S., that a qualified physician must check the PDMP prior to issuing a physician certification recommending the medical use of marijuana.

Sections 13 through 19 amend various sections of law to conform cross references to changes made in the bill.

Section 20 provides supplemental appropriations for the 2018-2019 fiscal year as follows:

- \$27,035,360 in nonrecurring funds from the Federal Grants Trust Fund and \$15,520,000 in recurring general revenue funds are appropriated to the Department of Children and Families (DCF) for outpatient, case management, and after care services; residential treatment; MAT, including the purchase and medical use of methadone, buprenorphine, and naltrexone extended-release injectable; peer recovery support; hospital and first responder outreach; and targeted outreach to pregnant women.
 - From the \$15.5 million in recurring general revenue funds, the DCF must use \$4,720,000 to contract with a nonprofit organization for the distribution of drugs for MAT as follows:
 - \$472,000 for methadone;
 - \$1,888,000 for buprenorphine; and
 - \$2,360,000 for naltrexone extended-release injectable.
- \$6 million in recurring general revenue funds are appropriated to the Office of the State Courts Administrator (OSCA) for treatment of substance abuse disorders in individuals involved in the criminal justice system, individuals who have a high likelihood of criminal justice involvement, or who are in court-ordered, community-based drug treatment. The OSCA must contract with a non-profit entity to make available the following drugs:
 - \$600,000 for methadone;
 - \$2.4 million for buprenorphine; and
 - \$3 million for naltrexone extended-release injectable.
- \$5 million of recurring general revenue funds are appropriated to the DOH for the purchase of naloxone to be made available to EMS responders.

Section 21 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:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The bill establishes fees for the issuance of certificates of exemption for pain management clinics.

B. Private Sector Impact:

CS/SB 8 may cost clinics that are required to obtain a certificate of exemption from the requirement to register as a pain management clinic.

The bill may cost health care practitioners who are required to attend the additional training established in the bill.

The bill may cost patients due to the supply limits imposed for prescription of opioid medications listed in Schedule II.

The bill may increase the cost of the administrative operations of health care providers who are required to consult the PDMP prior to prescribing controlled substances and do not currently do so.

Any non-profit entities that are awarded contracts with the DCF or the OSCA to provide MAT medications, pursuant to the supplemental appropriations established in the bill, will have increased revenues.

C. Government Sector Impact:

The DOH will incur additional costs related to increased investigations of unlicensed pain management clinics. These costs may be offset through fees collected for initial issuance and renewal of pain management clinic exemption certificates.⁴⁸

The bill provides appropriations as detailed in the Effects of Proposed Changes section above.

VI. Technical Deficiencies:

CS/SB 8 amends the public records exemption for the PDMP and consolidates access to the PDMP for pharmacists with other health care practitioners on lines 1669-1672. This change is a result of pharmacists being added to the definition of “health care practitioner” in s. 893.055, F.S., by the bill; however, the bill leaves out a reference to s. 893.04, F.S., when allowing access to health care practitioners that is currently incorporated into the access allowed to pharmacists by s. 893.0551(3)(e), F.S. The reference to s. 893.04, F.S., should be added to line 1671 of the bill.

VII. Related Issues:

None.

⁴⁸ Supra note 28.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 409.967, 456.072, 456.44, 458.3265, 459.0137, 465.0155, 465.0276, 627.42392, 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 and one unnumbered section of the Florida Statutes.

IX. Additional Information:**A. Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)**CS by Health Policy on January 16, 2018.**

The CS makes several substantive changes along with numerous conforming, clarifying, and technical changes. Substantive changes include:

- Restricting Medicaid and health insurers from requiring prior authorization for MAT.
- Requiring applicable boards, rather than the DOH, to establish guidelines for prescribing controlled substances to treat acute pain.
- Requiring physicians to maintain treatment plans when prescribing Schedule II opioids for the treatment of acute pain.
- Conforming provisions relating to practitioners dispensing Schedule II and Schedule III controlled substances.
- Establishing an exception to allow physicians to dispense MAT drugs to their own patients to treat substance abuse disorders.
- Modifying the definitions of “dispense” and “dispenser” within the PDMP to ensure that out-of-state dispensers must report controlled substances dispensed into the state.
- Reestablishing indirect access to the PDMP for the DOH’s health care regulatory boards.
- Eliminating language stating that the content of the PDMP creates no obligations or legal duties for prescribers, dispensers, pharmacies, or patients.
- Providing supplemental appropriations of:
 - \$27,035,360 in nonrecurring federal grants trust funds and \$15,520,000 in recurring general revenue funds to the DCF for substance use disorder treatment services.
 - From the \$15.5 million in recurring general revenue funds, the bill earmarks \$4.7 million of recurring general revenue funds for specific MAT drugs.
 - \$6 million in recurring general revenue funds to the state courts administrator for substance abuse treatment services related to the criminal justice system. The bill requires these funds be spent on specific MAT drugs.
 - \$5 million in recurring general revenue funds to the DOH to purchase naloxone for EMS responders.

B. Amendments:

None.