

**HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS**

BILL #:	CS/CS/HB 21	FINAL HOUSE FLOOR ACTION:		
SUBJECT/SHORT TITLE	Controlled Substances	99	Y's 0	N's
SPONSOR(S):	Health & Human Services Committee; Health Quality Subcommittee; Boyd and others	GOVERNOR'S ACTION:	Approved	
COMPANION BILLS:	CS/SB 8			

SUMMARY ANALYSIS

CS/CS/HB 21 passed the House on March 1, 2018. It was amended in the Senate on March 8, 2018, and returned to the House, which concurred in the Senate amendment as amended by the House on March 9, 2018, and returned the bill to the Senate on March 9, 2018. The Senate concurred with the House amendments and the bill passed as amended on March 9, 2018.

The bill addresses opioid abuse by expanding the use of the Prescription Drug Monitoring Program (PDMP), increasing regulation of prescribers and dispensers, amending criminal laws, and making appropriations.

The bill limits the prescription for a Schedule II opioid for acute pain to a 3-day supply, or a 7-day supply if deemed medically necessary by the prescriber. The bill excludes pain related to cancer, terminal illness, palliative care, and serious traumatic injury from these prescribing limits. The bill requires regulatory boards within the Department of Health (DOH) to adopt rules establishing guidelines for prescribing controlled substances for acute pain. The bill also requires a health care practitioner to review a patient's PDMP history before prescribing or dispensing a controlled substance, with exemptions. The bill authorizes a dispensing practitioner who is approved to provide medication-assisted treatment for substance abuse disorders to dispense Schedule II and III substances for such purpose.

The bill requires all pain management clinics that claim an exemption from statutory registration requirements to obtain a certificate of exemption by January 1, 2019.

Currently, pharmacies only report dispensing controlled substances listed in Schedule II, III, and IV to the PDMP. The bill expands the reporting requirement to include certain Schedule V substances. The bill authorizes direct access to the PDMP for employees of certain federal agencies who prescribe or dispense controlled substances, and indirect access for district medical examiners under certain conditions. The bill authorizes DOH to share and exchange PDMP data with other states if certain conditions are met, and authorizes the PDMP to interface with practitioner electronic health record systems.

Chapter 893, F.S., the "Florida Comprehensive Drug Abuse Prevention and Control Act," classifies controlled substances into five schedules, based on the substance's "potential for abuse" and whether the substance has a currently accepted medical use. The bill aligns the state schedule of drugs with the federal schedule of drugs. The bill also makes it a crime to possess, purchase, deliver, or sell a tableting machine, encapsulating machine, or controlled substance counterfeiting material for the purpose of illegally manufacturing controlled substances. The bill increases the level of offense from a third-degree felony to a second-degree felony for intentionally prescribing medically unnecessary controlled substances, or medically unnecessary amounts of controlled substances.

The bill has an insignificant, positive fiscal impact on DOH from savings from pain management clinic investigations; a positive indeterminate impact on prison beds; and a possible positive, indeterminate fiscal impact on local governments. For Fiscal Year 2018-19, the bill appropriates \$27,035,532 in nonrecurring funds from the Federal Grants Trust Fund for substance abuse treatment and other services; \$26,500,000 in recurring funds from the General Revenue Fund for substance abuse treatment and upgrades to the PDMP, and \$117,700 in nonrecurring funds from the General Revenue Fund for upgrades to the PDMP.

The bill was approved by the Governor on March 19, 2018, ch. 2018-13, L.O.F., and will become effective on July 1, 2018, except as otherwise provided.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0021z.HQS

DATE: March 20, 2018

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Present Situation

Substance Abuse

Substance abuse refers to the harmful or hazardous use of psychoactive substances, including alcohol and illicit drugs.¹ Substance abuse disorders occur when the chronic use of alcohol or drugs causes significant impairment, such as health problems, disability, and failure to meet major responsibilities at work, school, or home.² Repeated drug use leads to changes in the brain's structure and function that can make a person more susceptible to developing a substance abuse disorder.³ Brain imaging studies of persons with substance abuse disorders show physical changes in areas of the brain that are critical to judgment, decision making, learning and memory, and behavior control.⁴

According to the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, a diagnosis of substance abuse disorder is based on evidence of impaired control, social impairment, risky use, and pharmacological criteria.⁵ The most common substance abuse disorders in the United States are from the use of alcohol, tobacco, cannabis, stimulants, hallucinogens, and opioids.⁶

Opioid Abuse

Opioids are psychoactive substances derived from the opium poppy, or their synthetic analogues.⁷ They are commonly used as pain relievers to treat acute and chronic pain. An individual experiences pain as a result of a series of electrical and chemical exchanges among his or her peripheral nerves, spinal cord, and brain.⁸ Opioid receptors occur naturally and are distributed widely throughout the central nervous system and in peripheral sensory and autonomic nerves.⁹ When an individual experiences pain, the body releases hormones, such as endorphins, which bind with targeted opioid receptors.¹⁰ This disrupts the transmission of pain signals through the central nervous system and reduces the perception of pain.¹¹ Opioids function in the same way by binding to specific opioid receptors in the brain, spinal cord, and gastrointestinal tract, thereby reducing the perception of pain.¹² Opioids include¹³:

¹ World Health Organization, *Substance Abuse*, available at http://www.who.int/topics/substance_abuse/en/ (last visited March 12, 2018).

² Substance Abuse and Mental Health Services Administration, *Substance Use Disorders*, available at <http://www.samhsa.gov/disorders/substance-use> (last visited March 12, 2018).

³ National Institute on Drug Abuse, *Drugs, Brains, and Behavior: The Science of Addiction*, available at <https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/drug-abuse-addiction> (last visited March 12, 2018).

⁴ Id.

⁵ *Supra* note 2.

⁶ Id.

⁷ World Health Organization, *Information Sheet on Opioid Overdose*, World Health Organization (Nov. 2014), available at http://www.who.int/substance_abuse/information-sheet/en/ (last visited March 12, 2018).

⁸ National Institute of Neurological Disorders and Stroke, *Pain: Hope through Research*, (last rev. June 28, 2017), available at <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Hope-Through-Research/Pain-Hope-Through-Research> (last visited March 12, 2018).

⁹ Gjermund Henriksen, Frode Willoch; *Brain Imaging of Opioid Receptors in the Central Nervous System*, 131 BRAIN 1171-1196 (2007), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2367693/> (last visited March 12, 2018).

¹⁰ Id.

¹¹ Id.

¹² Department of Health and Human Services- Substance Abuse and Mental Health Services Administration, *SAMHSA Opioid Overdose Prevention Toolkit: Facts for Community Members* (2013, rev. 2014) 3, available at https://www.integration.samhsa.gov/Opioid_Toolkit_Community_Members.pdf (last visited March 12, 2018).

¹³ Florida Department of Law Enforcement, Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners 2016 Annual Report*, (Nov. 2017), available at <http://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2016-Annual-Drug-Report.aspx> (last visited February 6, 2018).

- Buprenorphine (Subutex, Suboxone)
- Codeine
- Fentanyl (Duragesic, Fentora)
- Heroin
- Hydrocodone (Vicodin, Lortab, Norco)
- Hydromorphone (Dilaudid, Exalgo)
- Meperidine
- Methadone
- Morphine
- Oxycodone (OxyContin, Percodan, Percocet)
- Oxymorphone
- Tramadol

Opioids are commonly abused, with an estimated 15 million people worldwide suffering from opioid dependence.¹⁴ Opioids can create a euphoric feeling because they affect the regions of the brain involved with pleasure and reward, which can lead to abuse.¹⁵ Continued use of these drugs can lead to the development of tolerance and psychological and physical dependence.¹⁶ This dependence is characterized by a strong desire to take opioids, impaired control over opioid use, persistent opioid use despite harmful consequences, a higher priority given to opioid use than to other activities and obligations, and a physical withdrawal reaction when opioids are discontinued.¹⁷ Approximately four to six percent of patients who misuse prescription opioids transition to heroin and 80 percent of people who use heroin first misused prescription opioids.¹⁸

An overabundance of opioids in the body can lead to a fatal overdose. In addition to their presence in major pain pathways, opioid receptors are also located in the respiratory control centers of the brain.¹⁹ Opioids disrupt the transmission of signals for respiration in the identical manner that they disrupt the transmission of pain signals. This leads to a reduction, and potentially cessation, of an individual's respiration. Oxygen starvation will eventually stop vital organs like the heart, then the brain, and can lead to unconsciousness, coma, and possibly death.²⁰ Within three to five minutes without oxygen, brain damage starts to occur, soon followed by death.²¹ However, this does not occur instantaneously as people will commonly stop breathing slowly, minutes to hours after the drug or drugs were used.²² An opioid overdose can be identified by a combination of three signs and symptoms referred to as the "opioid overdose triad": pinpoint pupils, unconsciousness, and respiratory depression.²³

The drug overdose death rate involving opioids has increased by 200% since 2000 and has now become the leading cause of accidental deaths in the United States.²⁴ Nationwide, in 2016, there were 42,249 deaths that involved an opioid (licit or illicit),²⁵ and 17,087 people died from overdoses involving

¹⁴ *Supra* note 7.

¹⁵ National Institute on Health, National Institute on Drug Abuse, *Which classes of Prescription Drugs are Commonly Misused?* (rev. Aug. 2016), available at <https://www.drugabuse.gov/publications/research-reports/misuse-prescription-drugs/which-classes-prescription-drugs-are-commonly-misused> (last visited March 12, 2018).

¹⁶ *Supra* note 9.

¹⁷ *Supra* note 7.

¹⁸ National Institute on Health, National Institute on Drug Abuse, *Opioid Overdose Crisis*, (rev. Mar. 2018), available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis> (last visited March 12, 2018).

¹⁹ K.T.S. Pattinson, *Opioids and the Control of Respiration*, BRITISH JOURNAL OF ANAESTHESIA, Volume 100, Issue 6, pp. 747-758, available at <http://bj.a.oxfordjournals.org/content/100/6/747.full> (last visited March 12, 2018).

²⁰ Harm Reduction Coalition, *Guide to Developing and Managing Overdose Prevention and Take-Home Naloxone Projects* (Fall 2012), <http://harmreduction.org/wp-content/uploads/2012/11/od-manual-final-links.pdf> (last visited March 12, 2018).

²¹ *Id.* at 9.

²² *Id.* at 9.

²³ *Supra* note 7.

²⁴ Centers for Disease Control and Prevention, *Increases in Drug and Opioid Overdose Deaths – United States, 2000-2014*, Morbidity and Mortality Weekly Report (MMWR) 64(50); 1378-82, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm?s_cid=mm6450a3_w (last visited March 12, 2018).

²⁵ Centers for Disease Control and Prevention, *Increases in Drug and Opioid Overdose Deaths – United States, 2010-2015*, Morbidity and Mortality Weekly Report (MMWR) 65(50-51); 1445-52, available at

prescription opioids.²⁶ The most common drugs involved in such deaths were methadone, oxycodone, and hydrocodone.²⁷ In 2016, in Florida, heroin caused 952 deaths, fentanyl caused 1,390 deaths, oxycodone caused 723 deaths, and hydrocodone caused 245 deaths.²⁸

National Public Health Emergency

In March 2017, President Trump established the President's Commission on Combating Drug Addiction and Opioid Crisis (Commission). Its mission is to study the scope and effectiveness of the federal response to the drug and opioid crisis and to make recommendations to the President for improving that response. The members of the Commission include Governor Chris Christie, Governor Charlie Baker, Governor Roy Cooper, Congressman Patrick Kennedy, Professor Bertha Madras, and Florida Attorney General Pam Bondi.

On October 26, 2017, President Donald Trump announced the issuance of a Nationwide Public Health Emergency²⁹ and a five-point strategy for combating the opioid crisis, including:³⁰

- Improving access to prevention, treatment, and recovery services, including the full range of medication-assisted treatments;
- Targeting availability and distribution of overdose-reversing drugs;
- Strengthening our understanding of the crisis through better public health data and reporting;
- Providing support for cutting edge research on pain and addiction; and
- Advancing practices for pain management.

On November 1, 2017, the Commission released its final report and made recommendations for:³¹

- Reducing administrative burdens associated with accessing federal funding for opioid-related and substance use disorder-related activities in the states;
- Developing and providing training related to standards of care for opioid prescribers, alternatives to opioids, and screening for substance use and mental health risks in patients;
- Enhancing the use of prescription drug monitoring programs;
- Treating opioid addiction, overdose reversal, and recovery; and
- Research and development.

Florida Public Health Emergency

On May 3, 2017, Governor Scott signed Executive Order 17-146.³² The executive order directs the State Health Officer and Surgeon General to declare a statewide public health emergency due to the opioid epidemic and to take any action necessary to protect the public health.³³ It additionally directs

https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm?utm_campaign=colorado.ourcommunitynow.com%20website&utm_source=ocn_story&utm_medium=website (last visited March 12, 2018).

²⁶ U.S. Dep't of Health and Human Services, *The Opioid Epidemic by the Numbers*, (rev. Jan. 2018), available at <https://www.hhs.gov/opioids/sites/default/files/2018-01/opioids-infographic.pdf> (last visited March 12, 2018).

²⁷ Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data*, (Aug. 1, 2017), available at <https://www.cdc.gov/drugoverdose/data/overdose.html> (last visited March 12, 2018).

²⁸ *Supra* note 13.

²⁹ The White House, Office of the Press Secretary, "President Donald J. Trump is Taking Action on Drug Addiction and the Opioid Crisis," Oct. 26, 2017, available at <https://www.whitehouse.gov/the-press-office/2017/10/26/president-donald-j-trump-taking-action-drug-addiction-and-opioid-crisis> (last visited March 12, 2018).

³⁰ U.S. Dep't of Health and Human Services, *National Opioid Crisis*, available at <https://www.hhs.gov/opioids> (last visited March 12, 2018).

³¹ The President's Commission on Combating Drug Addiction and the Opioid Crisis, *Final Report*, available at https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf (last visited March 12, 2018).

³² Office of the Governor, Executive Order no. 17-146 (Opioid Epidemic), May 3, 2017, available at: <http://www.flgov.com/wp-content/uploads/2017/05/17146.pdf> (last visited March 12, 2018).

³³ *Id.* See also, Department of Health, *Gov. Scott Directs Statewide Public Health Emergency for Opioid Epidemic*, (May 3, 2017), available at <http://www.floridahealth.gov/newsroom/2017/05/050317-health-emergency-opioid-epidemic.html> (last visited March 12, 2018).

the State Health Officer and Surgeon General to issue a standing order for opioid antagonists, such as naloxone, to ensure access to emergency responders. On May 2, 2017, the State Surgeon General and Secretary of DOH issued the Declaration of Public Health Emergency and Statewide Standing Order for Naloxone.³⁴

Since its initial issuance, the Governor has extended public health emergency declaration several times, the most recent extension was declared with Executive Order 18-47, issued on February 19, 2018, for 60 days.³⁵

CDC Guidelines for Prescribing Opioids

In March 2016, the U.S. Centers for Disease Control and Prevention (CDC) released a guideline for prescribing opioids for chronic pain.³⁶ The guideline includes twelve recommendations focused on three principles:³⁷

- Non-opioid therapy is preferred for chronic pain outside of cancer, palliative, and end-of-life care;
- When prescribing opioids, prescribe the lowest possible effective dosage to reduce the risk of opioid use disorder and overdose; and
- Providers should always exercise caution when prescribing opioids and monitor all patients closely.

The CDC guideline also addressed acute pain, as long-term opioid use commonly begins with the treatment of acute pain.³⁸ The CDC recommends that the initial prescription to treat acute pain be for the lowest effective dose of immediate-release (short acting) opioids and the quantity should be no greater than needed for the expected duration of pain severe enough to require opioids.³⁹ The guideline advises three days or less is often sufficient and that more than seven days will rarely be needed.⁴⁰

The guideline additionally recommends that a health care practitioner review the patient's history of controlled substance prescriptions using the state prescription drug monitoring program data. The data should be reviewed when starting opioid therapy, and periodically during opioid therapy. The guideline recommends reviews ranging from every prescription to once every three months.⁴¹

Twenty-four states have enacted laws limiting opioid prescriptions.⁴² These limitations vary from a three-day supply to a fourteen-day supply. Other states have directed the establishment of guidelines or limitations on the prescribing of opioids.

³⁴ Id.

³⁵ Office of the Governor, Executive Order no. 18-47 (Opioid Epidemic Extension), February 19, 2018, available at https://www.flgov.com/wp-content/uploads/orders/2018/EO_18-47.pdf (last visited March 12, 2018).

³⁶ Centers for Disease Control and Prevention, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, Morbidity and Mortality Weekly Report (MMWR) 65(1):1-49, (March 18, 2016), available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (last visited March 12, 2018). Chronic pain is defined as pain that typically lasts for more than three months or past the time of normal tissue healing.

³⁷ Id at 15.

³⁸ Id at 24. Acute pain is defined as pain with abrupt onset caused by an injury or other process that is not ongoing.

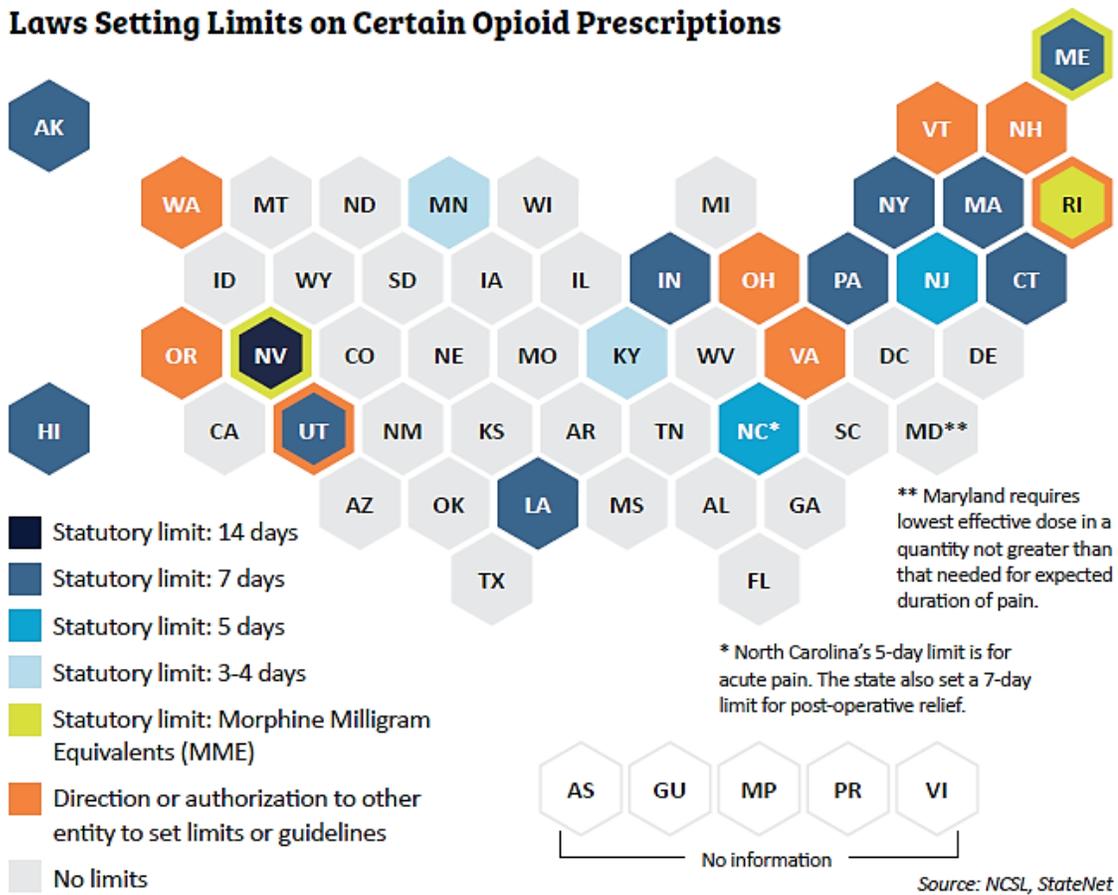
³⁹ Id. See also Centers for Disease Control and Prevention, *Factsheet: CDC Guideline for Prescribing Opioids for Chronic Pain*, available at https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf (last visited March 12, 2018).

⁴⁰ Id.

⁴¹ Id.

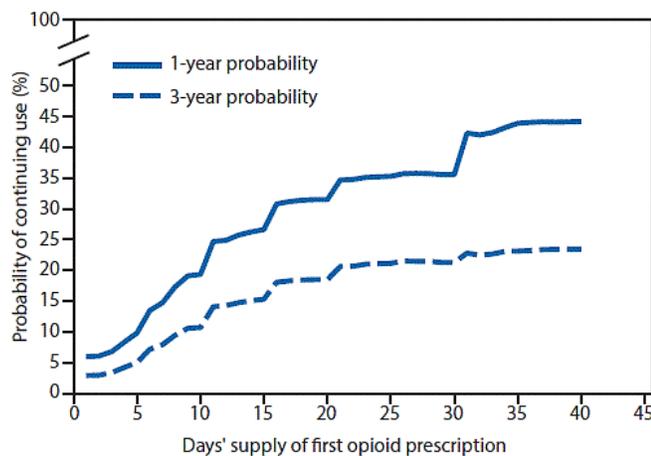
⁴² National Conference of State Legislatures, *Prescribing Policies: States Confront Opioid Overdose Epidemic*, (Sept. 8, 2017), available at <http://www.ncsl.org/research/health/prescribing-policies-states-confront-opioid-overdose-epidemic.aspx> (last visited March 12, 2018).

Laws Setting Limits on Certain Opioid Prescriptions



In 2017, the CDC conducted a study of almost 1.3 million patient records to determine risks associated with long-term opioid abuse.⁴³ The CDC found that the number of days for which the initial prescription is written has a profound effect on the probability of long-term use by a patient. Specifically, the probability of long-term use was:

One- and 3-year probabilities of continued opioid use among opioid-naïve patients, by number of days' supply* of the first opioid prescription — United States, 2006–2015⁴⁴



⁴³ Shah A, Hayes CJ, Martin BC. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*, Morbidity and Mortality Weekly Report (MMWR) 66:265–269 (March 17, 2017), available at <http://dx.doi.org/10.15585/mmwr.mm6610a1> (last visited March 12, 2018).

⁴⁴ Id. The days' supply of the first prescription is expressed in 1-day increments. If a patient had multiple prescriptions on the first day, the prescription with the longest days' supply was considered the first prescription.

The probability of long-term opioid use increases most sharply in the first days, particularly after five days, and then again after one month.⁴⁵ Approximately, one in seven persons who received a refill or had a second opioid prescription authorized were still using opioids one year after the initial prescription.⁴⁶

Controlled Substance Regulation

Controlled Substance Schedules

Chapter 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act (“the Act”), classifies controlled substances into five categories, called schedules. The Act creates criminal offenses related to the manufacture, distribution, preparation, and dispensing of the substances listed therein. The distinguishing factors between the different drug schedules are the potential for abuse⁴⁷ of the substance and whether there is a currently accepted medical use for the substance.⁴⁸

The Controlled Substance Schedules are as follows:

- Schedule I substances have a high potential for abuse and currently have no accepted medical use in the United States, including substances such as cannabis and heroin.⁴⁹
- Schedule II substances have a high potential for abuse and have a currently accepted but severely restricted medical use in the United States, including substances such as raw opium, fentanyl, and codeine.⁵⁰
- Schedule III substances have a potential for abuse less than the substances contained in Schedules I and II and have a currently accepted medical use in the United States, including substances such as stimulants and anabolic steroids.⁵¹
- Schedule IV substances have a low potential for abuse relative to substances in Schedule III and have a currently accepted medical use in the United States, including substances such as benzodiazepines and barbiturates.⁵²
- Schedule V substances have a low potential for abuse relative to the substances in Schedule IV and have a currently accepted medical use in the United States, including substances such as mixtures that contain small quantities of opiates, narcotics, or stimulants.⁵³

Under the Act, the unauthorized sale, manufacture, possession, delivery, or purchase of a controlled substance is subject to criminal penalties.⁵⁴ The severity of the criminal penalty is dependent on several factors, including the schedule in which the controlled substance is categorized, the amount of controlled substance present and the location at which the illegal activity occurs.⁵⁵

The Federal Controlled Substances Act (CSA)⁵⁶ also classifies certain substances into schedules based on potential for abuse and whether there is a currently accepted medical use for it. In

⁴⁵ Id.

⁴⁶ Id.

⁴⁷ Section 893.035(3)(a), F.S., defines “potential for abuse” to mean that a substance has properties as a central nervous system stimulant or depressant or a hallucinogen that create a substantial likelihood of its being: 1) used in amounts that create a hazard to the user’s health or safety of the community; 2) diverted from legal channels and distributed through illegal channels; or 3) taken on the user’s own initiative rather than on the basis of professional medical advice.

⁴⁸ See s. 893.03, F.S.

⁴⁹ Section 893.03(1), F.S.

⁵⁰ Section 893.03(2), F.S.

⁵¹ Section 893.03(3), F.S.

⁵² Section 893.03(4), F.S.

⁵³ Section 893.03(5), F.S.

⁵⁴ Section 893.13, F.S.

⁵⁵ Id.

⁵⁶ 21 U.S.C. s. 812. The most up to date schedules are found in 21 C.F.R. s. 1308.

determining into which schedule a drug should be placed or whether a substance should be decontrolled or rescheduled, the Drug Enforcement Agency considers:⁵⁷

- The drug's actual or relative potential for abuse.
- Scientific evidence of the drug's pharmacological effect, if known.
- The state of current scientific knowledge regarding the substance.
- Its history and current pattern of abuse.
- The scope, duration, and significance of abuse.
- What, if any, risk there is to public health.
- The drug's psychic or physiological dependence liability.
- Whether the substance is an immediate precursor of a substance already controlled.

Currently, the schedules in Florida's Act do not align with the schedules in the federal CSA. Under the federal CSA, drugs have been newly scheduled or rescheduled, creating a situation in which the unauthorized sale, manufacture, possession, delivery, or purchase of a substance may be criminal under federal law but not under state law. Additionally, where there are discrepancies between the schedules, the severity of the criminal penalties may vary between state and federal law.

Tableting Machines and Encapsulating Machines

In addition to criminalizing various drugs and substances, the federal CSA criminalizes possession of certain machinery or equipment as part of its scheme to combat the illicit manufacturing and distribution of controlled drugs in the U.S. This includes possession of tableting and encapsulating machines.⁵⁸

Federal law defines "tableting machine" as any manual, semi-automatic, or fully automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets.⁵⁹ Similarly, federal law defines "encapsulating machine" to mean any manual, semi-automatic, or fully automatic equipment which may be used to fill shells or capsules with any powdered, granular, semi-solid, or liquid material.⁶⁰

In general, tableting and encapsulating machines provide a streamlined, automated way to produce mass quantities of pharmaceutical drugs. A large-scale pharmaceutical tablet press can generate up to a million tablets per hour.⁶¹ Additionally, these machines allow the operator to print or reproduce a mark or label on a tablet or capsule. Consequently, an operator may copy the mark or label of other tablets or capsules to produce a counterfeit product, indistinguishable from the actual tablet or capsule produced by the manufacturer. Current state law defines a "counterfeit controlled substance" to mean:

- A controlled substance named or described in s. 893.03 which, or the container or labeling of which, without authorization bears the trademark, trade name, or other identifying mark, imprint, or number, or any likeness thereof, of a manufacturer other than the person who in fact manufactured the controlled substance; or
- Any substance which is falsely identified as a controlled substance named or described in s. 893.03.⁶²

The global tablet processing and packaging equipment market is estimated to be over a \$5 billion industry by 2022.⁶³ In recent years, the Department of Justice has made an effort to arrest and

⁵⁷ 21 U.S.C. s. 811(c).

⁵⁸ Tableting machines and encapsulating machines are also commonly known as "pill presses" and "capsule fillers" respectively. Federal Register, *Proposed Rules*, Vol. 81, No. 179, p. 63578 (September 15, 2016).

⁵⁹ 21 U.S.C. s. 1300.02(b)(30).

⁶⁰ 21 U.S.C. s. 1300.02(b)(11).

⁶¹ American Pharmaceutical Review, *Pharmaceutical Tablet Press Machine / Rotary Tablet Press*, available at <http://www.americanpharmaceuticalreview.com/25310-Pharmaceutical-Manufacturing/25344-Pharmaceutical-Tablet-Press-Machine-Rotary-Tablet-Press/> (last visited March 14, 2018).

⁶² Section 831.31, F.S.

prosecute individuals for possessing and utilizing narcotics equipment in their efforts to combat the opioid crises.⁶⁴

The CSA makes it unlawful for any person to knowingly or intentionally manufacture, distribute, export, or import a tableting machine or encapsulating machine while knowing, intending, or having reasonable cause to believe, that it will be used to manufacture a controlled substance.⁶⁵ The CSA makes an exception for “regulated persons” who own, possess, or sell these machines. Specifically, a regulated person may use these machines as part of a regulated transaction with a regular customer.⁶⁶ The CSA provides the following definitions for the purpose of the regulated person exception:

- **Regulated person:** A person who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.⁶⁷
- **Regulated transaction:** Distribution, receipt, sale, importation, or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount of a listed chemical. This includes the distribution, importation, or exportation of a tableting or encapsulating machine.⁶⁸
- **Regular customer:** With respect to a regulated person, a customer with whom the regulated person has an established business relationship that is reported to the Attorney General.⁶⁹

Federal regulations require a regulated person to submit a detailed report of the import or export of a tableting or encapsulating machine. A tableting machine or encapsulating machine may not be imported or exported until a transaction identification has been filed by the Drug Enforcement Administration. A regulated person must submit a detailed report of all domestic regulated transactions involving a tableting machine or encapsulating machine.⁷⁰

Current state law does not criminalize the possession, purchase, delivery, or sale of tableting or encapsulating machines.

⁶³ Cision PR Newswire, *Tablet Processing & Packaging Equipment Market: Global Forecast to 2022*, (July 18, 2017), available at <https://www.prnewswire.com/news-releases/tablet-processing--packaging-equipment-market-global-forecast-to-2022-300490407.html> (last visited March 12, 2018).

⁶⁴ U.S. Dep’t of Justice, U.S. Attorney’s Office, District of New Jersey, *Pharmacist Sentenced to 78 Months in Prison for Attempting to Weaponize Deadly Toxins and Possessing Narcotics Manufacturing Equipment*, (Jan. 30, 2015), available at <https://www.justice.gov/usao-nj/pr/pharmacist-sentenced-78-months-prison-attempting-weaponize-deadly-toxins-and-possessing> (last visited March 12, 2018); See also U.S. Attorney’s Office, District of New Jersey, *New Jersey Pharmacist Admits Attempting to Weaponize Deadly Toxins and Possessing Narcotics Manufacturing Equipment*, (May 29, 2014), available at <https://www.fbi.gov/contact-us/field-offices/newyork/news/press-releases/new-jersey-pharmacist-admits-attempting-to-weaponize-deadly-toxins-and-possessing-narcotics-manufacturing-equipment> (last visited March 12, 2018).

⁶⁵ 21 U.S.C. s. 843(a).

⁶⁶ 21 U.S.C. s. 830.

⁶⁷ 21 U.S.C. s. 802(38).

⁶⁸ 21 U.S.C. s. 802(39). For exceptions to this definition, see 21 U.S.C. s. 802(39)(A)(i)-(vi).

⁶⁹ 21 U.S.C. s. 802(36).

⁷⁰ *Supra* note 66. see also Department of Justice, *Drug Enforcement Administration Reports for Regulated Machines: DEA Form 452*, available at <https://www.reginfo.gov/public/do/DownloadDocument?objectID=70597100> (last visited March 12, 2018).

Controlled Substance Prescribing for Chronic Pain in Florida

As of January 1, 2012, every physician, podiatrist, or dentist, who prescribes controlled substances in the state to treat chronic nonmalignant pain,⁷¹ must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.⁷² Before prescribing controlled substances to treat chronic nonmalignant pain, a practitioner must:⁷³

- Complete a medical history and a physical examination of the patient which must be documented in the patient's medical record and include:
 - The nature and intensity of the pain;
 - Current and past treatments for pain;
 - Underlying or coexisting diseases or conditions;
 - The effect of the pain on physical and psychological function;
 - A review of previous medical records and diagnostic studies; and
 - A history of alcohol and substance abuse;
- Develop a written plan for assessing the patient's risk for aberrant drug-related behavior and monitor such behavior throughout the course of controlled substance treatment;
- Develop a written individualized treatment plan for each patient stating the objectives that will be used to determine treatment success; and
- Enter into a controlled substance agreement with each patient that must be signed by the patient or their legal representative and by the prescribing practitioner and include:
 - The number and frequency of prescriptions and refills;
 - A statement outlining expectations for patient's compliance and reasons for which the drug therapy may be discontinued; and
 - An agreement that the patient's chronic nonmalignant pain only be treated by a single treating practitioner unless otherwise authorized and documented in the medical record.

A prescribing practitioner must see a patient being treated with controlled substances for chronic nonmalignant pain at least once every three months, and must maintain detailed medical records relating to such treatment.⁷⁴ Patients at special risk for drug abuse or diversion may require consultation with or a referral to an addiction medicine physician or a psychiatrist.⁷⁵ The prescribing practitioner must immediately refer a patient exhibiting signs or symptoms of substance abuse to a pain management physician, an addiction medicine specialist, or an addiction medicine facility.⁷⁶

Continuing Education for Controlled Substance Prescribing

Compliance with continuing education (CE) requirements is a condition of renewal of license for health care practitioners. Regulatory boards, or DOH when there is no board, require each licensee to demonstrate competence by completing CE hours during each biennial licensure cycle. The number of required CEs varies by profession. The requirements for CEs may be found in ch. 456, F.S., professional practice acts, administrative rules, or a combination of these references. Failure to comply with CE requirements may result in disciplinary action against the licensee, in accordance with the disciplinary guidelines established by the applicable regulatory board or DOH, if there is no board.

Although statute and regulatory boards may mandate continuing education topics, only two health care practitioner types must complete CEs related to the prescribing of controlled substances. Physician assistants who prescribe controlled substances and advanced registered nurse practitioners must

⁷¹ "Chronic nonmalignant pain" is defined as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery. Section 456.44(1)(e), F.S.

⁷² Chapter 2011-141, s. 3, Laws of Fla. (creating s. 456.44, F.S., effective July 1, 2011).

⁷³ Section 456.44(3), F.S.

⁷⁴ Section 456.44(3)(d), F.S.

⁷⁵ Section 456.44(3)(e), F.S.

⁷⁶ Section 456.44(3)(g), F.S.

complete three hours of CEs each biennial licensure renewal cycle on the safe and effective prescribing of controlled substances.⁷⁷

Criminal Penalties related to Controlled Substance Prescribing

It is a third-degree felony for a health care practitioner, with an intent to provide a controlled substance or combination of controlled substances that are not medically necessary to a patient or an amount of a controlled substance that is not medically necessary, to provide a controlled substance or a prescription for a controlled substance by fraud, misrepresentation, or other deception.⁷⁸ A third-degree felony is punishable by up to 5 years' imprisonment and a fine of up to \$5,000.⁷⁹

Pain Management Clinic Regulation

Section 458.3265, F.S., within the medical practice act and s. 459.0137, F.S., within the osteopathic practice act regulate the registration, management, and inspections of pain management clinics,⁸⁰ and the allopathic and osteopathic physicians employed by such clinics.

Registration

A pain management clinic must register with DOH unless:

- The clinic is licensed under ch. 395, F.S.;
- The majority of the physicians who provide services in the clinic primarily provide surgical services;
- The clinic is owned by a publicly held corporation whose shares are traded on a national exchange and whose total assets exceed \$50 million in the most recent fiscal quarter;
- The clinic is affiliated with an accredited medical school;
- The clinic does not prescribe controlled substances for pain treatment;
- The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3);
- The clinic is wholly owned and operated by one or more board eligible⁸¹ or board-certified anesthesiologists, physiatrists, rheumatologists, or neurologists; or
- The clinic is wholly owned and operated by a physician multispecialty practice where one or more board eligible⁸² or board-certified medical specialists have both (1) completed certain fellowships in pain medicine or are board-certified in pain medicine by certain boards, and (2) perform interventional pain procedures of the type routinely billed using surgical codes.⁸³

A pain management clinic claiming an exemption from registration is not required to notify DOH that it meets a statutory exemption or demonstrate its eligibility for an exemption. Further, the determination of whether the pain management clinic is exempt from registration is made by the owner or management

⁷⁷ See rr. 64B8-30.005(6), and 64B15-6.0035(6), F.A.C., for the CE requirements for a prescribing physician assistant, and s. 464.013(3)(b), F.S., for the CE requirement for advanced registered nurse practitioners.

⁷⁸ Section 893.13(7), F.S. Controlled substance refers to any substance listed in Schedule II, Schedule III, or Schedule IV.

⁷⁹ Sections 775.082 and 775.083, F.S. A repeat offender may be subject to enhanced penalties under s. 775.084, F.S.

⁸⁰ A pain management clinic is a publicly or privately owned facility that advertises in any medium for any type of pain management services or where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain. (Sections 458.3265(1)(a)1.c., F.S., and 459.0137(1)(a)1.c., F.S.)

⁸¹ "Board eligible" means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program. Sections 458.3265(1)(a)(1)(a.), F.S., and 459.0137(1)(a)(1)(a.), F.S.

⁸² See note 21, *supra*.

⁸³ Sections 458.3265(1)(a)(2.), F.S., and 459.0137(1)(a)(2.), F.S.

of the clinic. DOH only investigates the validity of a claimed exemption from registration if it receives a formal complaint.⁸⁴

Registration Requirements

Each location must be registered separately, regardless of whether it is operated under the same name or management as another clinic.⁸⁵ Additionally, a change of ownership requires submission of a new registration application.⁸⁶

DOH must deny a pain management clinic's registration if:⁸⁷

- The clinic is neither fully owned by a physician or group of physicians licensed under ch. 458 or ch. 459, F.S.; nor health care clinic licensed under ch. 400, Part X.⁸⁸
- The clinic is owned by, has a contractual relationship with, or employs a physician:
 - Whose Drug Enforcement Administration number has ever been revoked;
 - Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction; or
 - Who has been convicted of or pleaded guilty or nolo contendere to a felony for receipt of illicit and diverted drugs, including any Schedule I-V substance, anywhere in the United States.

DOH must revoke a pain management clinic's registration if any of the above reasons for denial substantially become applicable to a registered clinic.⁸⁹ DOH may also revoke a clinic's registration based on deficiencies discovered during the clinic's annual inspection.⁹⁰

If a clinic's registration is revoked or suspended, the clinic must stop operating, and the clinic must remove all identification that the location is a pain management clinic.⁹¹ Additionally, the clinic must follow certain procedures to dispose of its medicinal drugs.⁹² A required five year cooling-off period prohibits anyone whose registration has been revoked from applying for a permit to operate a pain management clinic.⁹³ If a clinic's registration is suspended, that suspension may not exceed one year.⁹⁴

When the pain management clinic registration was first required in 2010, there were 921 pain management clinics.⁹⁵ At the end of Fiscal Year 2016-2017, there were 259.⁹⁶ It is unknown if the reduction in the number of pain management clinics is attributable to closure or to a self-determination that the pain management clinic was exempt from registration.

⁸⁴ Florida Department of Health, *Agency Legislative Bill Analysis for House Bill 21*, (Oct. 13, 2017), (on file with the Health Quality Subcommittee).

⁸⁵ Sections 458.3265(1)(b), F.S., and 459.0137(1)(b), F.S.

⁸⁶ Sections 458.3265(1)(m), F.S., and 459.0137(1)(m), F.S.

⁸⁷ Sections 458.3265(1)(e), F.S., and 459.0137(1)(e), F.S. DOH may grant an exemption to such denial for felony convictions if more than 10 years have elapsed since adjudication.

⁸⁸ Sections 458.3265(1)(d), F.S., and 459.0137(1)(d), F.S.

⁸⁹ Sections 458.3265(1)(f), F.S., and 459.0137(1)(f), F.S. DOH may grant an exemption to such revocation for felony convictions if more than 10 years have elapsed since adjudication.

⁹⁰ Sections 458.3265(1)(g), F.S., and 459.0137(1)(g), F.S.

⁹¹ Sections 458.3265(1)(h), (i), F.S., and 459.0137(1)(h), (i), F.S.

⁹² Sections 458.3265(1)(j), F.S., and 459.0137(1)(j), F.S.

⁹³ Sections 458.3265(1)(k), F.S., and 459.0137(1)(k), F.S.

⁹⁴ Sections 458.3265(1)(l), F.S., and 459.0137(1)(l), F.S.

⁹⁵ *Supra* note 84.

⁹⁶ *Id.*

Prescription Drug Monitoring Program

Prescription Drug Monitoring Programs (PDMPs) are state-run electronic databases used to track the prescribing and dispensing of certain controlled prescription drugs to patients.⁹⁷ PDMPs are designed to monitor this information for suspected abuse or diversion and provide prescribers and dispensers with critical information regarding a patient's controlled substance prescription history.⁹⁸ As of July 2017, 49 states and the District of Columbia have an operational PDMP database.⁹⁹

Chapter 2009-197, Laws of Fla., established Florida's PDMP within DOH.¹⁰⁰ The PDMP uses an electronic database system to monitor the prescribing and dispensing of certain controlled substances.¹⁰¹ The PDMP database became operational in September of 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.¹⁰² Health care practitioners began accessing the PDMP database on October 17, 2011.¹⁰³

From July 1, 2016, to June 30, 2017, in-state prescribers issued 36,196,500 controlled substance prescriptions to 6,869,616 Florida residents.¹⁰⁴ Of those controlled substance prescriptions, 15,372,742 were for opioids.¹⁰⁵

PDMP Reporting Requirements

Dispensers of controlled substances listed in Schedule II, III, or IV of the Florida Comprehensive Drug Abuse Prevention and Control Act must report specified information to the PDMP database.¹⁰⁶

- The name of the prescribing practitioner, the practitioner's federal Drug Enforcement Administration (DEA) registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription;
- The date the prescription was filled and the method of payment, such as cash by an individual or third-party payment;
- The full name, address, 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, federal DEA registration number, and address of the pharmacy, other location, or other practitioner from which the controlled substance was dispensed;
- The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's NPI; and
- Other appropriate identifying information as determined by DOH rule.¹⁰⁷

⁹⁷ Centers for Disease Control and Prevention, *What States Need to Know about PDMPs*, (last rev. Oct. 3, 2017), available at <http://www.cdc.gov/drugoverdose/pdmp/> (last visited March 12, 2018).

⁹⁸ *Id.*

⁹⁹ National Alliance for Model State Drug Laws, *Established and Operational Prescription Drug Monitoring Programs (PMPs) – Map* (July 21, 2017), available at <http://www.namsdl.org/Maps/Status%20of%20PMPs%20-%20Established-Operational%20Map%20REV%207-21-17.pdf> (last visited March 12, 2018). Missouri is the only state without a statewide PDMP.

However, several counties and cities within Missouri participate in a PDMP.

¹⁰⁰ Codified in s. 893.055, F.S.

¹⁰¹ Section 893.055(2)(a), F.S.

¹⁰² Florida Department of Health, *Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2016-2017 Prescription Drug Monitoring Program Annual Report*, (Dec. 1, 2016), available at <http://www.floridahealth.gov/statistics-and-data/e-forcse/funding/2017PDMPAnnualReport.pdf> (last visited March 12, 2016).

¹⁰³ Florida Department of Health, *Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2012-2013 Prescription Drug Monitoring Program Annual Report*, (Dec. 1, 2013), available at <http://www.floridahealth.gov/statistics-and-data/e-forcse/news-reports/documents/2012-2013pdmp-annual-report.pdf> (last visited March 12, 2016).

¹⁰⁴ *Supra* note 102 at p. 14.

¹⁰⁵ Presentation by Rebecca Poston, PDMP Program Director, "Department of Health, Florida's Prescription Drug Monitoring Program Update" Presentation before the Health Quality Subcommittee (Nov. 8, 2017), available at <http://www.myfloridahouse.gov/Sections/Documents/loaddoc.aspx?PublicationType=Committees&CommitteeId=2918&Session=2018&DocumentType=Meeting%20Packets&FileName=hqs%2011-8-17.pdf> (last visited March 12, 2018).

¹⁰⁶ Section 893.055(3), F.S.; controlled substances listed in Schedule II, III, or IV can be found in s. 893.03(2)-(4), F.S.

¹⁰⁷ Section 893.055(4), F.S. Pursuant to r. 64K-1.004(9), F.A.C., prescribers must submit the telephone number of the person for whom the prescription was written to the PDMP.

- A health care practitioner 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 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 administering or dispensing a controlled substance in the health care system of the Department of Corrections;
- A practitioner administering a controlled substance in the emergency room of a licensed hospital;
- A health care practitioner administering or dispensing a controlled substance to a person under the age of 16;
- A pharmacist or a dispensing practitioner dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient; and
- 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.

Access to PDMP Data

Direct Access

Direct access to the PDMP database is presently limited to a pharmacy, prescriber, or dispenser or the designee of a pharmacy, prescriber, or dispenser.¹¹² A pharmacy, prescriber, or dispenser has access to information in the PDMP database that relates to a patient of that pharmacy, prescriber, or dispenser, as needed, for reviewing the patient's controlled substance prescription history.¹¹³

Employees of the United States Department of Veterans Affairs (VA) who are authorized to prescribe controlled substances and hold an active, unrestricted license in another state have direct access to the PDMP.¹¹⁴ However, health care practitioners authorized to dispense controlled substance pursuant to employment with the VA do not have access to the PDMP unless they have an active, unrestricted Florida license.

The Department of Defense provides health care services to its members, retirees, and their dependents at military treatment facilities, 13 of which are located in Florida.¹¹⁵ Florida also has 20 major military installations.¹¹⁶ Military members, retirees, and their families may access health care services at either military treatment facilities, civilian health care providers, or both. Currently, health care practitioners serving military personnel, retirees, and their dependents in military treatment facilities do not have access to Florida's PDMP unless they have an active, unrestricted Florida license.

The Indian Health Service (IHS) is an agency within the U.S. Department of Health and Human Services that is responsible for providing federal health services to American Indians and Alaska Natives.¹¹⁷ There are at least four locations in Florida that provide health services to this population.¹¹⁸

¹¹² Section 893.055(7)(b), F.S.

¹¹³ *Id.*

¹¹⁴ Section 893.055(1)(d), F.S., defines health care practitioner for the purpose of the PDMP program as those practitioners who are subject to licensure or regulation by DOH under ch. 458, F.S., (Medicine), ch. 459, F.S., (Osteopathic Medicine), ch. 461, F.S., (Podiatric Medicine), ch. 462, F.S., (Naturopath), ch. 463, F.S., (Optometry), ch. 464, F.S., (Nursing), ch. 465, F.S., (Pharmacy), or ch. 466, F.S., (Dentistry).

¹¹⁵ See <https://tricare.mil/mtf> (last visited March 12, 2018).

¹¹⁶ Enterprise Florida, *Florida's Military Profile*, available at http://www.enterpriseflorida.com/wp-content/uploads/Military_Install_Map.pdf (last visited February 8, 2018).

¹¹⁷ Indian Health Service, *About IHS*, available at <https://www.ihs.gov/aboutihs/> (last visited March 12, 2018).

IHS employees who prescribe or dispense controlled substances in these facilities do not have access to Florida's PDMP unless they have an active, unrestricted Florida license.

The program manager¹¹⁹ and the program manager's designated staff, may also directly access the PDMP.¹²⁰ The program manager access is for program management or for management of the PDMP database and its system in furtherance of the program, which may include responding to requests from those with indirect access to the system.¹²¹

Indirect Access

In Florida, the following entities may indirectly access PDMP data:

- DOH and its relevant health care regulatory boards;
- The Attorney General to investigate Medicaid fraud cases involving prescribed controlled substances;
- A law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances; and
- A patient, or the legal guardian or designated health care surrogate of an incapacitated patient, for verifying the accuracy of database information.¹²²

Entities with indirect access to the PDMP database may request information from the PDMP program manager that is otherwise confidential and exempt from public disclosure under s. 893.0551, F.S.¹²³ Prior to release, the PDMP program manager must verify that the request is authentic and authorized with the requesting organization.¹²⁴

Department staff is also authorized to indirectly access the database to calculate performance measures in its annual report to the Legislature.¹²⁵ Such information must be requested of the program manager, and may not include any identifying information of the patient, prescriber, or dispenser.¹²⁶

Use of PDMP Data

A total of 17,852 health care practitioners or 27.2 percent of licensed health care practitioners who are authorized to prescribe controlled substances, are registered to use the PDMP database.¹²⁷ Pharmacists have the highest utilization rate of the PDMP; 59 percent of licensed pharmacists are registered to use the PDMP and 90.6 percent of pharmacists registered to use the PDMP have queried the database.¹²⁸ Physicians have a lower utilization rate; 20.6 percent of licensed allopathic physicians and 38.8 percent of licensed osteopathic physicians are registered to use the PDMP and of those registered to use the PDMP, 70.5 percent and 78.4 percent, respectively, have queried the database.¹²⁹

¹¹⁸ See

https://www.ihs.gov/locations/includes/themes/newihstheme/display_objects/documents/Federal_Health_Care_Facilities_Map.pdf (last visited March 12, 2018). Facilities are located in Okeechobee, Clewiston, Immokalee, Miami, and Hollywood.

¹¹⁹ The program manager is an employee of DOH who is designated to ensure the integrity of the PDMP in accordance with law (s. 893.055(1)(j), F.S.

¹²⁰ Section 893.055(7)(b), F.S.

¹²¹ Id. See also 893.055(7)(c), F.S.

¹²² Section 893.055(7)(c), F.S.

¹²³ Id.

¹²⁴ Id.

¹²⁵ Section 893.055(7)(d), F.S.

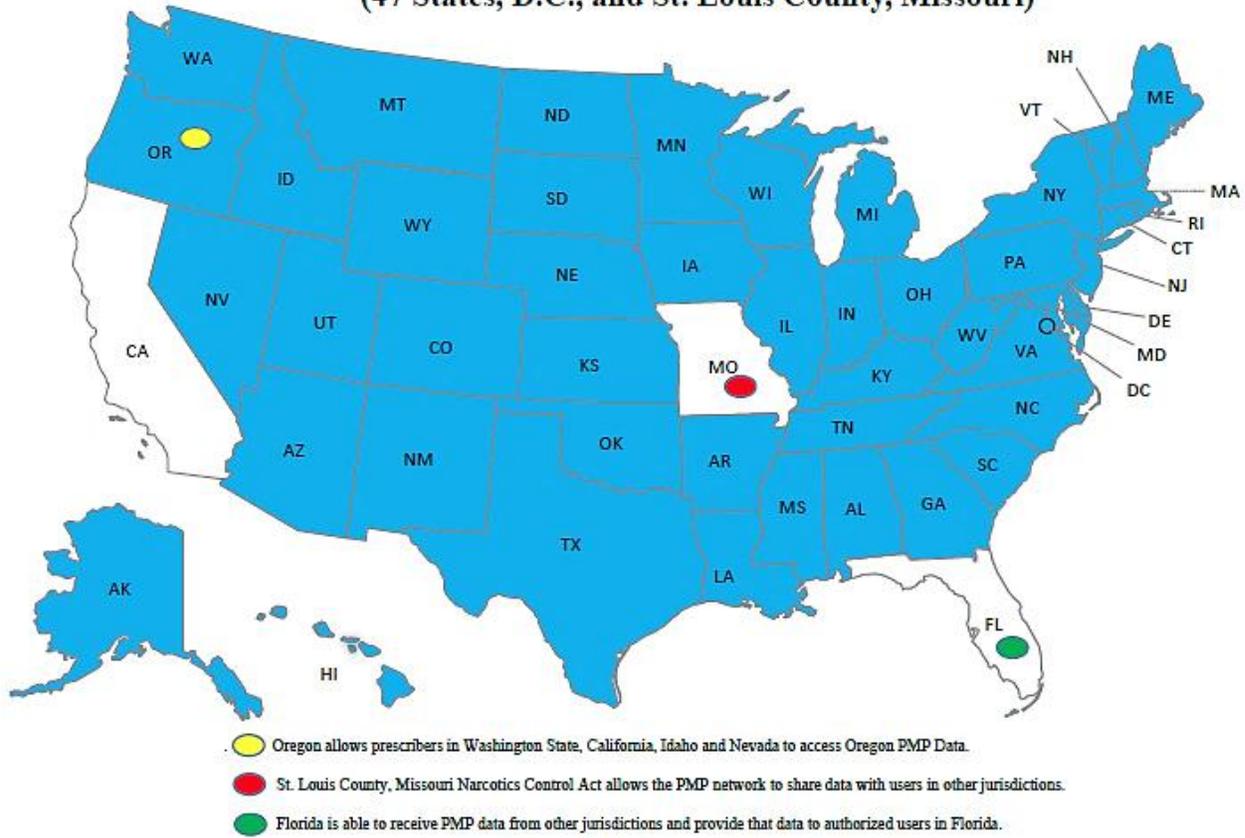
¹²⁶ Id.

¹²⁷ *Supra* note 105.

¹²⁸ Id.

¹²⁹ Id.

**State/Local Jurisdictions Legally Authorized to Share Their PMP Data with Other State/Local Jurisdictions or Users Located in other State/Local Jurisdictions
(47 States, D.C., and St. Louis County, Missouri)**



Public Records Exemption for Information in the PDMP Database

Section 893.0551, F.S.,¹³⁷ makes personal patient information and certain information concerning health care practitioners contained in the PDMP database confidential and exempt from s. 119.07(1), F.S., and Art. I, Sec. 24 of the Florida Constitution.¹³⁸ The statute makes confidential and exempt identifying information, including, but not limited to, the name, address, telephone number, insurance plan number, government-issued identification number, provider number, Drug Enforcement Administration number, or any other unique identifying number of a patient, patient’s agent, health care practitioner or practitioner as defined in s. 893.055, F.S., or an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy, which is contained in the PDMP database.

Any agency or person that obtains information pursuant to s. 893.0551, F.S., must maintain the confidential and exempt status of that information.¹³⁹

¹³⁷ The public records exemption was established in 2009 in conjunction with the PDMP. See s. 1, ch. 2009-197, Laws of Fla. Additionally, the public records exemption was reauthorized in 2014. See s. 1 ch. 2014-156, Laws of Fla.

¹³⁸ Section 893.0551(2), F.S.

¹³⁹ Section 893.0551(6), F.S. However, a law enforcement agency with lawful access to such information is permitted to disclose confidential and exempt information received from DOH to a criminal justice agency as part of an active investigation of a specific violation of law. Section 893.0551(4).

Effect of Proposed Changes

Acute Pain Treatment with Opioids

Prescription Limits for Acute Pain Treatment

The bill limits a prescription of a Schedule II opioid to alleviate acute pain to a 3-day supply, codifying the CDC guideline for the treatment of acute pain. However, a health care practitioner may prescribe up to a 7-day supply if the physician determines it is medically necessary, indicates “acute pain exception” on the prescription, and documents the justification for deviating from the 3-day supply limit in the patient’s medical record. The bill defines acute pain as the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness. This definition reflects the definition currently in rule for physicians.¹⁴⁰

Prescriptions for Opioids for Nonacute Pain

The bill excludes pain related to the following conditions from the definition of acute pain:

- Cancer;
- A terminal condition;¹⁴¹
- Pain treated with palliative care;¹⁴² and
- A traumatic injury with an Injury Severity Score of 9 or higher.¹⁴³

The prescribing limits established under the bill does not apply to these exceptions. If a prescriber writes a prescription for any Schedule II opioid that is not related to treating acute pain, the prescriber must indicate “nonacute pain” on the prescription. This requirement applies to prescriptions for chronic pain, as well as those for the conditions listed above as being excluded from the definition of acute pain. When prescribing a Schedule II opioid for a traumatic injury, the bill requires the prescribing practitioner to also prescribe an emergency opioid antagonist.

Standards of Practice for Acute Pain Treatment

The bill requires the applicable regulatory boards within DOH to adopt rules establishing guidelines for prescribing controlled substances for acute pain, similar to guidelines established for the prescribing of controlled substances for chronic pain. Such rules must address:

- Evaluation of the patient;
- Creation and maintenance of a treatment plan;
- Obtaining informed consent and agreement for treatment;
- Periodic review of the treatment plan;
- Consultation;
- Medical record review; and
- Compliance with controlled substance laws and regulations.

A health care practitioner who fails to follow the guidelines established by DOH is subject to disciplinary action against his or her license.

¹⁴⁰ See rr. 64B8-9.013 and 64B15-14.005, F.A.C.

¹⁴¹ The bill defines “terminal condition” as a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by the treating physician to be reversible without the administration of life-sustaining procedures, and will result in death within 1 year after diagnosis if the condition runs its normal course.

¹⁴² The bill defines “palliative care” as the provision of relief for symptoms related to an incurable, progressive illness or injury.

¹⁴³ An Injury Severity Score is a method for describing trauma patients with multiple injuries and evaluating emergency care. The score ranges from 1 to 75. See Trauma.org, *Injury Severity Score*, available at <http://www.trauma.org/archive/scores/iss.html> (last visited March 12, 2018).

Continuing Education on Controlled Substance Prescribing

The bill requires a health care practitioner who is authorized to prescribe controlled substances to complete a board-approved 2-hour continuing education course, if not already required to complete such a course under his or her practice act.¹⁴⁴ All health care practitioners registered with the United States Drug Enforcement Agency to prescribe controlled substances must complete the continuing education course by January 31, 2019, and at each subsequent licensure renewal. The course must address:

- Current standards on prescribing controlled substances, particularly opiates;
- Alternatives to the current standards on controlled substance prescribing;
- Nonpharmacological therapies;
- Prescribing emergency opioid antagonists; and
- Information on the risks of opioid addiction following all stages of treatment in the management of acute pain.

The course must be offered by a statewide professional association of physicians in this state that is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category I Credit or the American Osteopathic Category 1-A continuing medical education requirement. The Florida Medical Association and the Florida Osteopathic Medical Association are the only entities that meet this criteria. The course may be taken in a long distance format and must be included in the continuing education required for the biennial renewal of a health care practitioner's license. DOH may not renew the individual's license of a prescriber who fails to complete this continuing education requirement.

Dispensing Practitioners

The bill limits a dispensing practitioner from dispensing a supply of a Schedule II opioid to the same limits provided for prescribing above: 3 days or 7 days if the practitioner determines it is medically necessary. The bill also authorizes a dispensing practitioner, who is approved to provide medically assisted treatment for opiate addiction to dispense Schedule II and Schedule III drugs for such purposes.

Pain Management Clinics

The bill requires a pain management clinic that claims an exemption from the registration requirement to apply to DOH for a certificate of exemption. The bill authorizes DOH to adopt a form by rule that requires an applicant for a certificate of exemption to provide:

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

DOH must approve or deny an application for a certificate of exemption within 30 days after receipt. Each certificate must be renewed biennially, but the initial certificate may be issued for up to three years to allow DOH to establish renewal cycles.

A pain management clinic must prominently display its certificate of exemption and make it available to DOH or the applicable board upon request. Each certificate of exemption is valid only for the applicant

¹⁴⁴ Pursuant to s. 464.013(3)(b), F.S., an advanced registered nurse practitioner must complete at least 3 hours of continuing education hours on the safe and effective prescribing of controlled substances each biennial renewal cycle. Rules 64B8-30.005(6) and 64B15-6.0035(6), F.A.C., requires physician assistants who prescribe controlled substances to complete 3 hours of continuing education on the safe and effective prescribing of controlled substance medications.

and for the exemption for which the certificate was issued. The certificate is not transferable and a new certificate must be issued if the clinic changes its address. A certificateholder must notify DOH at least 60 days before a change of ownership, name change, or if the certificateholder relocates and apply for a new certificate of exemption. The certificateholder must notify DOH within 3 days after becoming aware that it is ineligible for the specific exemption it claimed when obtaining the certificate of exemption, and either register as a pain management clinic or cease operation.

All pain management clinics in the state must either be registered with DOH as a pain management clinic or hold a certificate of exemption by January 1, 2019. There is no fee for the certificate of exemption.

Prescription Drug Monitoring Program

The bill makes changes to and reorganizes s. 893.055, F.S., relating to the prescription drug monitoring program. Although many of the substantive provisions remain unchanged, the bill makes several amendments to the section.

Mandatory Consultation

The bill requires a prescriber or dispenser or his or her designee to consult the PDMP to review a patient's controlled substance dispensing history prior to prescribing or dispensing a controlled substance for patients age 16 and older. However, a prescriber or dispenser is not required to consult the PDMP if the system is not operational, as determined by DOH, or cannot be accessed by the health care practitioner due to a temporary technological or electrical failure. In such cases, the health care practitioner must document in the patient's record the reason the PDMP was not consulted and may prescribe or dispense no more than a 3-day supply of a controlled substance. A health care practitioner who fails to consult the system as required is subject to a nondisciplinary citation for the initial offense. Any subsequent offense for failure to consult the PDMP will result in disciplinary action against the health care practitioner's license. A health care practitioner is not required to consult the PDMP when prescribing or dispensing a nonopioid Schedule V drug.¹⁴⁵

Access to the PDMP Database

The bill expands direct access to the database to employees of the U.S. Department of Veterans Affairs, Department of Defense, and Indian Health Service who have authority to **prescribe or dispense** controlled substances, upon verification of such employment. Currently, only Florida-licensed health care practitioners and **prescribers** employed by the U.S. Department of Veterans Affairs may directly access the database.

The bill also authorizes a district medical examiner to have indirect access to the database when performing an investigation, examination, or autopsy, as deemed necessary or requested by a state attorney to determine the cause of death of individual. Under such circumstances, a medical examiner may request information from the PDMP manager or program staff.

The bill changes access to non-identifying information for the purpose of reporting on performance measures in its annual report from the department to the program manager.

Data Sharing

The bill authorizes DOH to enter into a single multistate agreement or reciprocal agreements with individual states to share PDMP information with other states or jurisdiction, as long as the other states' PDMP systems are compatible with Florida's. To determine compatibility, DOH must consider:

¹⁴⁵ The bill defines a "nonopioid controlled substance" as a controlled substance that does not contain any amount of a substance listed as an opioid as defined under the state or federal controlled substance laws.

- The other state’s safeguards for the privacy of patient records and the program’s success in protecting patient privacy;
- The individuals authorized to view the information in the database and whether such access is comparable to the persons authorized in this state;
- The schedules of controlled substances that are monitored in the other state’s program;
- The data reported to or included in the other state’s system;
- Any implementing criteria deemed essential for a thorough comparison; and
- The costs and benefits to Florida of sharing prescription information.

DOH must assess such compatibility every four years. Any agreement that DOH enters into for sharing PDMP database information must contain the same restrictions on access as Florida law, including protection of privacy and public disclosure.

The bill authorizes DOH to allow the PDMP database to interface with a health care practitioner’s electronic health care recordkeeping system through a secure connection. A health practitioner is responsible for ensuring that only authorized individuals may access information from the PDMP database.

Reporting Requirements

Under current law, when controlled substances listed in Schedule II, III, and IV are dispensed, it must be reported to the PDMP. The bill expands the reporting requirement to include controlled substances listed in Schedule V, but exempts any which are non-opioids. The bill also requires the dispenser to report the following additional information that is not currently collected:

- The telephone number of the person for whom the prescription was written, in addition to the demographic information the prescriber currently inputs;¹⁴⁶
- Whether the prescription is an initial prescription or a refill, and the number of refills prescribed;
- The name of the individual picking up the controlled substance prescription and the type and issuer of the identification provided; and
- For a dispensing practitioner, other than a pharmacist, the practitioner’s DOH-issued license number.

Retention of Records

The bill requires the PDMP purges information that is more than four years old. Under current law, the PDMP may indefinitely store the information in its database.

Public Records

The bill retains the public records exemption for certain information held in the PDMP database. The bill does not exempt any additional records from public disclosure or further restrict access to such information. However, the bill expands access to such information to certain individuals. The bill authorizes the PDMP manager and designated staff to have access to such information for administration of the program and to provide information to prescribers, dispensers, and appropriate law enforcement agencies in accordance with state law. The bill also expands access to certain employees of the VA, the Department of Defense, and the Indian Health Service who prescribe or dispense controlled substances pursuant to employment with such entity. Finally, the bill authorizes a district medical examiner to have indirect access to such information when determining the cause of death of an individual. The bill reorganizes and makes other non-substantive changes to s. 893.0551, F.S., to improve readability.

¹⁴⁶ The dispenser must currently input the name, address, and date of birth of the person for whom the prescription is written (s. 893.05(3)(c), F.S.

Identification Requirement for Dispensing of Controlled Substances

The bill relocates from s. 893.055, F.S., to the pharmacy practice act (ch. 465, F.S.), an existing requirement that a pharmacist verifies the identity of an individual prior to dispensing a controlled substance. The bill does not make any substantive changes to this requirement.

Controlled Substance Regulation

The bill amends several sections of the 893.03, F.S., to align the state's Controlled Substance Act with the federal schedules of controlled substances. Specifically, the bill adds the following substances to Schedule II:

- Dihydroetorphine;
- Hydrocodone combination products;
- Oripavine;
- Remifentanil;
- Tapentadol;
- Thiafentanil;
- Lisdexamfetamine; and
- Dronabinol (synthetic THC) in oral solution in a drug approved by the United States Food and Drug Administration.

Similarly, the bill adds the following substances to Schedule III:

- Buprenorphine (which is being rescheduled from Schedule V);
- Embutramide; and
- Perampanel.

The bill adds the following substances to Schedule IV:

- Alfaxalone
- Dexfenfluramine;
- Dichloralphenazone;
- Eluxadoline;
- Eszopiclone;
- Fospropofol;
- Lorcaserin;
- Modafinil;
- Petrichloral;
- Sibutramine;
- Suvorexant;
- Zaleplon;
- Zolpidem; and
- Zopiclone.

Finally, the bill adds the following substances to Schedule V:

- Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine per dosage unit; and
- Unless a specific exception exists or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of:
 - Brivaracetam;

- Ezogabine;
- Lacosamide; and
- Pregabalin.

With these additions to Florida's Controlled Substance Act, the unauthorized sale, manufacture, possession, delivery, or purchase of these substances is subject to criminal penalties. Additionally, the dispensing of these controlled substances must be entered into the PDMP database.

The bill amends the Act to authorize a pharmacist to dispense a controlled substance pursuant to an electronic prescription. This aligns the state criminal laws with the state health care regulatory laws that already authorize electronic prescriptions.

Criminal Penalties related to Controlled Substance Prescribing

The bill increases the offense for a health care practitioner who intentionally provides or prescribes a medically unnecessary controlled substance or a controlled substance in an amount that is not medically necessary to a patient by fraud, misrepresentation, or other deception from a third-degree felony to a second-degree felony. As a second-degree felony, a violation is punishable by up to 15 years in prison and a fine up to \$10,000.

Tableting Machines and Encapsulating Machines

The bill prohibits the possession, purchase, delivery, sale, or possession with intent to sell or deliver a tableting machine, encapsulating machine, or controlled substance counterfeiting material where the person knows, intends, or has reasonable cause to believe it will be used to manufacture a controlled substance, including a counterfeit controlled substance. The bill establishes the following definitions:

- Encapsulating machine: Manual, semiautomatic, or fully automatic equipment used to fill shells or capsules with any powdered or granular solids or semisolid material to produce coherent solid capsules.
- Tableting machine: Manual, semiautomatic, or fully automatic equipment used to compact or mold powdered or granular solids or semisolid materials to produce coherent solid tablets.
- Controlled substance: Any substance named or described in Schedules I-V of s. 893.03.¹⁴⁷
- Controlled substance counterfeiting material: A punch, die, plate, stone, or other item designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon a drug or container or labeling thereof.
- Counterfeit controlled substance: Has the same meaning as provided in s. 831.31(2).¹⁴⁸

The bill makes a violation a third-degree felony, punishable by up to 5 years in prison and a fine up to \$5,000.¹⁴⁹ However, a violation is a second-degree felony, punishable by up to 15 years in prison and a fine up to \$10,000,¹⁵⁰ where the person knows, intends, or has reasonable cause to believe that their activity will result in the unlawful manufacture of a controlled substance or counterfeit controlled substance that contains any of the following:

- A controlled substance under s. 893.03(1);¹⁵¹
- Cocaine;
- Opium or any synthetic or natural salt, compound, derivative, or preparation of opium;
- Methadone;

¹⁴⁷ This is the same definition as provided in s. 893.02(4), F.S. See pp. 8-9 herein for a discussion on schedules.

¹⁴⁸ *Supra* note 62.

¹⁴⁹ Sections 775.082 and 775.083, F.S.

¹⁵⁰ *Id.*

¹⁵¹ These substances include, but are not limited to, benzethidine, codeine, heroin, morphine, and fentanyl derivatives.

- Alfentanil;
- Carfentanil;
- Fentanyl;
- Sufentanil; or
- A controlled substance analog¹⁵² of any substance listed above.

Similar to federal law, the bill provides an exception to the criminal conduct for a “regulated person,” so long as the regulated person’s activity with such machine is part of a regulated transaction with a regular customer or importer, in compliance with federal law under 21 U.S.C. s. 830. Under the bill, the terms regulated person, regulated transaction, regular customer, and regular importer have the same meaning as defined in 21 U.S.C. s. 802. The bill also provides an exception for permitted pharmacies licensed pharmacists, and licensed medical marijuana treatment centers whose activity with such machines is in compliance with the laws regulating their permits or licenses.

Finally, the bill makes other conforming changes throughout statutes.

The bill provides an effective date of July 1, 2018, except for provisions related to the certificate of exemption for pain management clinics, which are effective January 1, 2019.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

Appropriations

For Fiscal Year 2018-19, the bill appropriates the following:

- \$27,035,532 in nonrecurring funds from the Federal Grants Trust Fund to the Department of Children and Families (DCF), for expenditure of funds related to the second year of the State Targeted Response of the Opioid Crisis Grant, to increase access to treatment and prevent opioid overdose-related deaths through prevention, treatment, and recovery activities;
- \$14,626,911 in recurring funds from the General Revenue Fund to DCF for community-based services to include, but is not limited to, outreach, addiction treatment, and recovery services. This funding must be used to increase access to and reduce waitlists for treatment, increase efforts to engage and retain youth, pregnant women, high-risk populations, and high utilizers of acute care services in treatment. Services may include, but are not limited to, case management, residential services, outpatient services, aftercare services, and medication-assisted treatment such as methadone, buprenorphine, and naltrexone extended-release injectable;
- \$5,000,000 in recurring funds from the General Revenue Fund to DOH for the purchase of emergency opioid antagonists for distribution to emergency responders;

¹⁵² “Controlled substance analog” means a substance which, due to its chemical structure and potential for abuse is substantially similar to that of a controlled substance listed in Schedule I or Schedule II of s. 893.03, F.S., and has a stimulant, depressant, or hallucinogenic effect on the central nervous system or is represented or intended to such effect substantially similar to or greater than that of a controlled substance listed in Schedule I or Schedule II of s. 893.03, F.S. See S. 893.0356(2)(a); See also, p. 7 herein for a discussion on schedules.

- \$6,000,000 in recurring funds from the General Revenue Fund to the Office of State Court Administrator for medication-assisted treatment for individuals involved in the criminal justice system, those who have a high likelihood of becoming involved in the criminal justice system, or those who are in court-ordered, community-based drug treatment. Medication-assisted treatment may include, but is not limited to, methadone, buprenorphine, and naltrexone extended-release injectable; and
- \$873,089 in recurring funds and \$117,700 in nonrecurring funds from the General Revenue Fund to DOH for improvements to the PDMP.

Pain Management Clinics

DOH may realize cost savings associated with a reduction in the unlicensed activity investigations of pain management clinics. The average cost of an investigation is \$2,100, and in the last biennium, DOH conducted 6 investigations for a total cost of \$12,600.¹⁵³ The regulatory costs associated with issuing the certificates of exemption is less than the costs associated with unlicensed activity investigations, resulting in a cost savings.

The department will incur insignificant, nonrecurring costs associated with rulemaking. DOH will also incur nonrecurring costs associated with updating the Licensing Enforcement and Information Database System. Current resources are adequate to absorb these costs.¹⁵⁴

Criminal Justice Impacts

On February 12, 2018, the Criminal Justice Impact Conference met and determined that the bill will have a positive indeterminate impact on prison beds. The increase in the offense from a third degree felony to a second degree felony for intentionally prescribing or providing a medically unnecessary controlled substance or a controlled substance in an amount that is not medically necessary to a patient by fraud, misrepresentation, or other deception will have a positive indeterminate impact on prison beds.¹⁵⁵

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

Local governments that purchase emergency opioids antagonists for first responders may save costs associated with obtaining such drugs if they are able to obtain the drugs from DOH.

2. Expenditures:

None.

¹⁵³ *Supra* note 84.

¹⁵⁴ *Id.*

¹⁵⁵ Criminal Justice Impact Conference, *CS/HB 21 – Controlled Substances with Proposed Amendment*, available at <http://edr.state.fl.us/Content/conferences/criminaljusticeimpact/CSHB21wpa.pdf> (last visited February 22, 2018). Also, E-mail correspondence with staff of the Criminal Justice Impact Conference dated February 22, 2018, on filed with the Health Quality Subcommittee.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Prescribers may incur additional costs to comply with the continuing education course on prescribing controlled substances. Prescribers may also incur additional labor costs to comply with the requirement to consult the PDMP prior to prescribing a controlled substance. Health care practitioner offices that currently do not have the technology needed to consult the system may incur costs associated with obtaining such technology. Additionally, if a health care practitioner decides to integrate the PDMP database information with his or her patient electronic health records, the practitioner may incur costs associated with upgrading the software.

Due to the three-day limit controlled substance prescription for acute pain, some patients may incur additional costs if a health care practitioner requires an additional patient visit prior to issuing a new prescription or a prescription refill.

A pain management clinic that is exempt from registering with the department may incur minimal labor costs associated with applying for a certificate of exemption.

The bill appropriates funding for substance abuse treatment, which may enable individuals who are otherwise unable to pay for such services to obtain treatment and thereby reduce costs related to having a substance abuse disorder.

D. FISCAL COMMENTS:

None.