HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 21 Controlled Substances
SPONSOR(S): Health Quality Subcommittee; Boyd
TIED BILLS: **IDEN./SIM. BILLS:** SB 8

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	15 Y, 0 N, As CS	Siples	McElroy
2) Appropriations Committee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Substance abuse affects millions of people in the U.S. each year. Drug overdoses have steadily increased and now represent the leading cause of accidental death in the U.S., the majority of which involve an opioid. In Florida, heroin caused 952 deaths, fentanyl caused 1,390 deaths, oxycodone caused 723 deaths, and hydrocodone caused 245 deaths in 2016. Opioid addiction has been recognized as a public health emergency on both a state and federal level. HB 21 addresses opioid abuse by expanding the use of the Prescription Drug Monitoring Program (PDMP), increasing regulation of prescribers and dispensers, and aligning state criminal statutes with federal law.

HB 21 limits the prescription for a Schedule II opioid to alleviate acute pain to a three-day supply, or a seven-day supply if deemed medically necessary by the prescriber. The bill requires Department of Health (DOH) to adopt rules establishing guidelines for prescribing controlled substances for acute pain, similar to those for chronic pain. The bill also requires a health care practitioner authorized to prescribe controlled substances to complete a board-approved 2-hour continuing education course on safely and effectively prescribing controlled substances, and to review a patient's PDMP history prior to prescribing or dispensing a controlled substance.

Currently, a pain management clinic must register with DOH unless it self-determines it is exempt from registration. The bill requires all pain management clinics that claim an exemption from registration to obtain a certificate of exemption by January 1, 2019.

The PDMP, within DOH, monitors controlled substance prescribing and dispensing. 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 Schedule V and additional information not currently collected, such as the patient's telephone number, certain information of the person picking up the controlled substance on behalf of the patient, and whether the prescription is new or a refill. The bill authorizes health care employees of the U.S. Department of Defense and the Indian Health Service who prescribe controlled substances to have direct access to the PDMP, and authorizes indirect access to the PDMP for 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 a health care practitioner and facility electronic health record systems.

Chapter 893, F.S., the "Florida Comprehensive Drug Abuse Prevention and Control Act," ("Act"), creates criminal offenses related to the manufacture, distribution, preparation, and dispensing of controlled substances. The Act classifies such 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 has a significant, negative fiscal impact on DOH to implement required upgrades for the PDMP. The bill will have an insignificant, positive fiscal impact on DOH from costs savings related to the investigation of pain management clinics. The bill has no fiscal impact on local governments.

The bill provides an effective date of July 1, 2018, except as otherwise expressly provided in the bill.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

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

[1] World Health Organization. *Substance Abuse*, available at http://www.who.int/topics/substance_abuse/en/ (last visited October 31, 2017).
[2] Substance Abuse and Mental Health Services Administration, *Substance Use Disorders,* available at http://www.samhsa.gov/disorders/substance-use (last visited October 31, 2017).
[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 October 31, 2017).
[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 October 31, 2017).
[8] National Institute of Neurological Disorders and Stroke, *Pain: Hope through Research*, (Jan. 2014), *available at* https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Hope-Through-Research/Pain-Hope-Through-Research (last visited October 31, 2017).
[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 October 31, 2017).
[10] Id.
[11] Id.

receptors in the brain, spinal cord, and gastrointestinal tract, thereby reducing the perception of pain.[12] Opioids include[13]:

- 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]

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[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 October 31, 2017).
[13] Florida Department of Law Enforcement, Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners 2016 Annual Report*, available at http://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2016-Annual-Drug-Report.aspx (last visited November 20, 2017).
[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 October 31, 2017).
[16] *Supra* note 9.
[17] *Supra* note 7.
[18] National Institute on Health, National Institute on Drug Abuse, *Opioid Overdose Crisis*, [June 2017], available at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (last visited November 20, 2017).
[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://bja.oxfordjournals.org/content/100/6/747.full (last visited October 31, 2017).
[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 October 31, 2017).
[21] Id. at 9.
[22] Id. at 9.

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 2015, more than there were 33,091 deaths that involved an opioid (licit or illicit),[25] and 15,000 people died from overdoses involving prescription opioids.[26] The most common drugs involved in such deaths were methadone, oxycodone, and hydrocodone. In 2016, in Florida, heroin caused 952 deaths, fentanyl caused 1,390 deaths, oxycodone caused 723 deaths, and hydrocodone caused 245 deaths.[27]

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 Emergency[28] and a five-point strategy for combating the opioid crisis, including: [29]

- 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:[30]

- 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;

[23] *Supra* note7.
[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 October 31, 2017).
[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 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 November 20, 2017).
[26] Centers for Disease Control and Prevention, *Prescription Opioid Overdose Data*, available at https://www.cdc.gov/drugoverdose/data/overdose.html (last visited November 20, 2017).
[27] Florida Department of Law Enforcement, Medical Examiners Commission, *Drugs Identified in Deceased Persons by Florida Medical Examiners 2016 Annual Report*, available at http://www.fdle.state.fl.us/MEC/Publications-and-Forms/Documents/Drugs-in-Deceased-Persons/2016-Annual-Drug-Report.aspx (last visited November 20, 2017).
[28] 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 October 31, 2017).
[29] U.S. Dep't of Health and Human Services, *Opioids: The Prescription Drug & Heroin Overdose Epidemic*, available at https://www.hhs.gov/opioids (last visited October 31, 2017).
[30] 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 November 28, 2017).

- 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.[31] 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.[32] It additionally directs 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.[33]

Since its initial issuance, the Governor has extended public health emergency declaration several times, the most recent extension was declared with Executive Order 17-285, issued on October 27, 2017, for 60 days.[34]

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.[35] The guideline includes twelve recommendations focused on three principles:[36]

- 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.[37] 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.[38] The guideline advises three days or less is often sufficient and that more than seven days will rarely be needed.[39]

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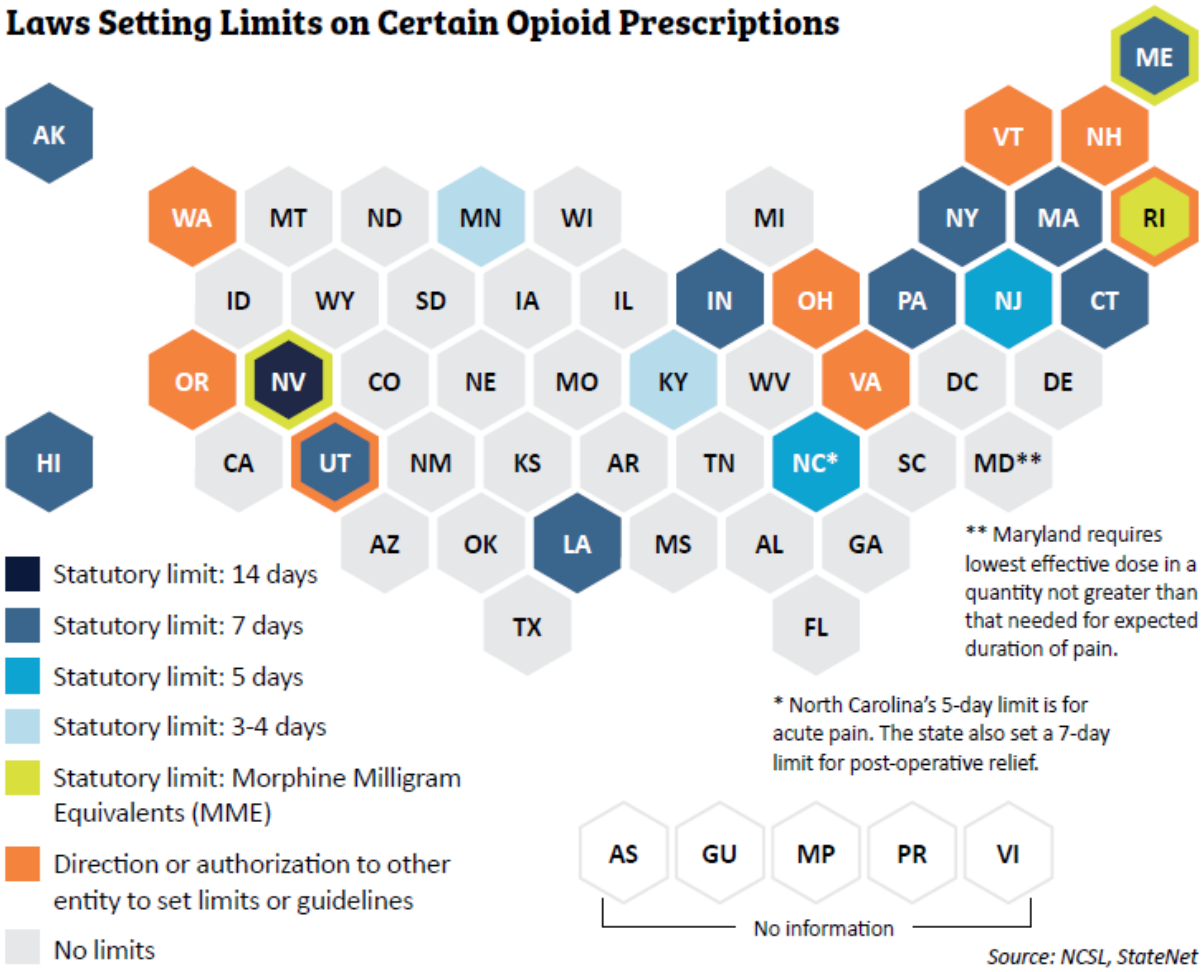
[31] Office of the Governor, Executive Order no. 17-149 (Opioid Epidemic), May 3, 2017, available at: http://www.flgov.com/wp-content/uploads/2017/05/17146.pdf (last visited October 31, 2017).
[32] Id. *See also*, Department of Health, *Gov. Scott Directs Statewide Public Health Emergency for Opioid Epidemic*, (May 3, 2017), available at http://www.floridahealth.gov/newsroom/2017/05/050317-health-emergency-opioid-epidemic.html (last visited January 2, 2018).
[33] Id.
[34] Office of the Governor, Executive Order no. 17-285 (Opioid Epidemic Extension), October 27, 2017, available at http://www.flgov.com/wp-content/uploads/orders/2017/EO_17-285.pdf (last visited November 20, 2017).
[35] Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids for Chronic Pain*, 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 November 10, 2017). Chronic pain is defined as pain that typically lasts for more than three months or past the time of normal tissue healing.
[36] Id at 15.
[37] Id at 24. Acute pain is defined as pain with abrupt onset caused by an injury or other process that is not ongoing.
[38] Centers for Disease Control and Prevention, *Guideline for Prescribing Opioids for Chronic Pain*, 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 November 10, 2017). *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 November 10, 2017).
[39] Id.

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.[40]

Twenty-four states have enacted laws limiting opioid prescriptions.[41] 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.



Controlled Substance Regulation

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 abuse[42] of the substance and whether there is a currently accepted medical use for the substance.[43]

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[40] Id.
[41] 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 November 20, 2017).
[42] 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

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.[44]
- 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.[45]
- 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.[46]
- 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.[47]
- 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.[48]

Under the Act, the unauthorized sale, manufacture, possession, delivery, or purchase of a controlled substance is subject to criminal penalties.[49] 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.[50]

The Federal Controlled Substances Act[51] also classifies certain substances into schedules based on potential for abuse and whether there is a currently accepted medical use for it. In determining into which schedule a drug should be placed or whether a substance should be decontrolled or rescheduled, the Drug Enforcement Agency considers:[52]

- 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 Controlled Substances Act. Under the federal Controlled Substances Act, 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

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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.

[43] *See* s. 893.03, F.S.
[44] Section 893.03(1), F.S.
[45] Section 893.03(2), F.S.
[46] Section 893.03(3), F.S.
[47] Section 893.03(4), F.S.
[48] Section 893.03(5), F.S.
[49] Section 893.13, F.S.
[50] Id.
[51] 21 U.S.C. s. 812. The most up to date schedules are found in 21 C.F.R. s. 1308.
[52] 21 U.S.C. s. 811(c).

there are discrepancies between the schedules, the severity of the criminal penalties may vary between state and federal law.

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,[53] must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.[54] Before prescribing controlled substances to treat chronic nonmalignant pain, a practitioner must:[55]

- 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 an 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.[56] Patients at special risk for drug abuse or diversion may require consultation with or a referral to an addiction medicine physician or a psychiatrist.[57] 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.[58]

Continuing Education for Controlled Substance Prescribing

Compliance with continuing education (CE) requirements is a condition of renewal of license for health care practitioners. 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 board or DOH, if there is no board.

[53] "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.
[54] Chapter 2011-141, s. 3, Laws of Fla. (creating ss. 456.44, F.S., effective July 1, 2011).
[55] Section 456.44(3), F.S.
[56] Section 456.44(3)(d), F.S.
[57] Section 456.44(3)(e), F.S.
[58] Section 456.44(3)(g), F.S.

Although statute and 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 complete three hours of CEs each biennial renewal cycle on the safe and effective prescribing of controlled substances.[59]

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,[60] 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 eligible[61] 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 eligible[62] 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.[63]

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 of the clinic. DOH only investigates the validity of a claimed exemption from registration if it receives a formal complaint.[64]

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[59] *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.

[60] 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.

[61] "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.

[62] *See* note 21, *supra*.

[63] Sections 458.3265(1)(a)(2.), F.S., and 459.0137(1)(a)(2.), F.S.

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

Registration Requirements

Each location must be registered separately, regardless of whether it is operated under the same name or management as another clinic.[65] Additionally, a change of ownership requires submission of a new registration application.[66]

DOH must deny a pain-management clinic's registration if: [67]

- 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.[68]
- 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.[69] DOH may also revoke a clinic's registration based on deficiencies discovered during the clinic's annual inspection.[70]

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.[71] Additionally, the clinic must follow certain procedures to dispose of its medicinal drugs.[72] 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.[73] If a clinic's registration is suspended, that suspension may not exceed one year.[74]

When the pain management clinic registration was first required in 2010, there were 921 pain management clinics. [75] At the end of Fiscal Year 2016-2017, there were 259.[76] 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.

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.[77] PDMPs are designed to monitor this information for suspected abuse or diversion and provide prescribers and pharmacists

[65] Sections 458.3265(1)(b), F.S., and 459.0137(1)(b), F.S.
[66] Sections 458.3265(1)(m), F.S., and 459.0137(1)(m), F.S.
[67] 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.
[68] Sections 458.3265(1)(d), F.S., and 459.0137(1)(d), F.S.
[69] 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.
[70] Sections 458.3265(1)(g), F.S., and 459.0137(1)(g), F.S.
[71] Sections 458.3265(1)(h), (i), F.S., and 459.0137(1)(h), (i), F.S.
[72] Sections 458.3265(1)(j), F.S., and 459.0137(1)(j), F.S.
[73] Sections 458.3265(1)(k), F.S., and 459.0137(1)(k), F.S.
[74] Sections 458.3265(1)(l), F.S., and 459.0137(1)(l), F.S.
[75] *Supra* note 64.
[76] Id.
[77] 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 November 10, 2017).

with critical information regarding a patient's controlled substance prescription history.[78] As of July 2017, 49 states and the District of Columbia have an operational PDMP database.[79]

Chapter 2009-197, Laws of Fla., established Florida's PDMP within the Department of Health (DOH), and is codified in s. 893.055, F.S. The PDMP uses an electronic database system to monitor the prescribing and dispensing of certain controlled substances.[80] The PDMP database became operational in September of 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[81] Health care practitioners began accessing the PDMP database on October 17, 2011.[82]

From July 1, 2015, to June 30, 2016, in-state prescribers issued 37,048,030 controlled substance prescriptions to 7,387,884 Florida residents.[83] Of those controlled substance prescriptions, 15,372,742 were for opioids.[84]

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:[85]

- 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.[86]

Florida does not require the dispenser Schedule V drugs to the PDMP. Schedule V carry a low risk of physical or psychological dependence and consists primarily of preparations containing limited quantities of certain narcotics, such as cough preparations containing codeine.[87]

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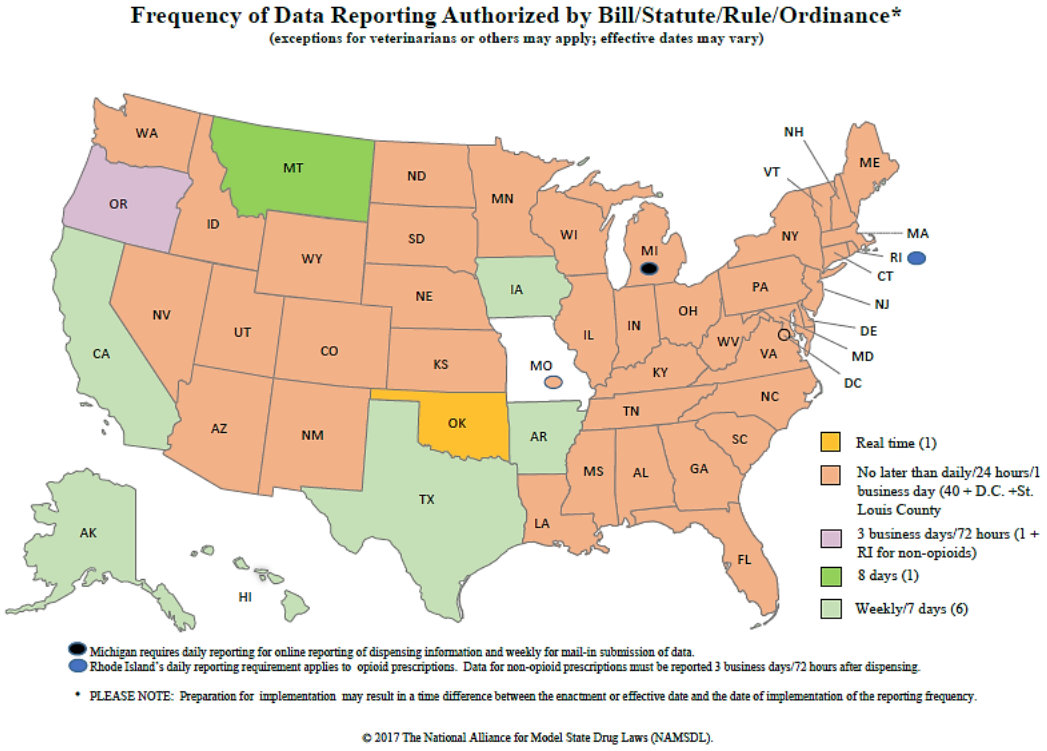
[78] Id.
[79] National Alliance for Model State Drug Laws, *Established and Operational Prescription Drug Monitoring Programs (PMPs) – Map (*July 21, 2017), available at http://www.namsdl.org/Maps/Status%20of%20PMPs%20-%20Established-Operational%20%20Map%20REV%207-21-17.pdf (last visited November 10, 2017). Missouri is the only state without a statewide PDMP. However, several counties and cities within Missouri participate in a PDMP.
[80] Section 893.055(2)(a), F.S.
[81] Florida Department of Health, *Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2015-2016 Prescription Drug Monitoring Program Annual Report*, (Dec. 1, 2016), available at http://www.floridahealth.gov/statistics-and-data/e-forcse/_documents/2016PDMPAnnualReport.pdf (last visited November 17, 2017).
[82] *Supra* note 81 at p. 22.
[83] *Supra* note 81 at p. 14.
[84] *Supra* note 106.
[85] 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.
[86] 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.
[87] U.S. Department of Justice, Drug Enforcement Administration, Diversion Control Division, *Controlled Substance Schedules*, available at https://www.deadiversion.usdoj.gov/schedules/ (last visited January 2, 2018). To qualify as a Schedule V substance, the cough preparation must contain less than 200 milligrams of codeine per 100 grams.

The time in which a dispenser must submit information to the PDMP varies across the nation. Florida requires dispensers to report dispensing a controlled substance to the PDMP by the close of the next business day.[88] As indicated below, some states require the dispenser to submit data within 24 hours or no later than the next business day, others allow three days or more, and Oklahoma requires real-time reporting.[89]



Exemptions from PDMP Reporting Requirements

The purpose of the PDMP is to track the dispensing of prescribed controlled substances to provide information to subsequent prescribing physicians and prevent the overprescribing and diversion of such substances. However, there are some circumstances in which there is inherently a low risk of controlled substances being overprescribed or diverted. The law exempts practitioners from having to report the dispensing of controlled substances in those circumstances. Specifically, the following acts are not required to be reported: [90]

- 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;

[88] Id.
[89] National Alliance for Model State Drug Laws, *Frequency of Prescription Drug Monitoring Program (PMP) Data Reporting – Map*, (July 20, 2017), available at http://www.namsdl.org/Maps/Frequency%20of%20PMP%20Data%20Reporting%20Map%206-30-17%20(7-21-17).pdf (last visited November 10, 2017).
[90] Section 893.055(5). F.S.

- 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.[91] 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.[92]

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.[93] 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.[94] Florida also has 20 major military installations.[95] 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 (HIS) 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.[96] There are at least four locations in Florida that provide health services to this population.[97] 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.

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[91] Section 893.055(7)(b), F.S.
[92] Id.
[93] 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).
[94] *See* https://tricare.mil/mtf (last visited November 10, 2017).
[95] Enterprise Florida, *Florida's Military Profile*, available at http://www.enterpriseflorida.com/wp-content/uploads/Military_Install_Map.pdf (last visited November 21, 2017).
[96] Indian Health Service, *About HIS*, available at https://www.ihs.gov/aboutihs/ (last visited November 21, 2017).
[97] *See* https://www.ihs.gov/locations/includes/themes/newihstheme/display_objects/documents/Federal_Health_Care_Facilities_Map.pdf (last visited November 21, 2017). Facilities are located in Okeechobee, Clewiston, Immokalee, and Hollywood.

The program manager[98] and the program manager's designated staff, may also directly access the PDMP.[99] 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.[100]

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.[101]

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.[102] Prior to release, the PDMP program manager must verify that the request is authentic and authorized with the requesting organization.[103]

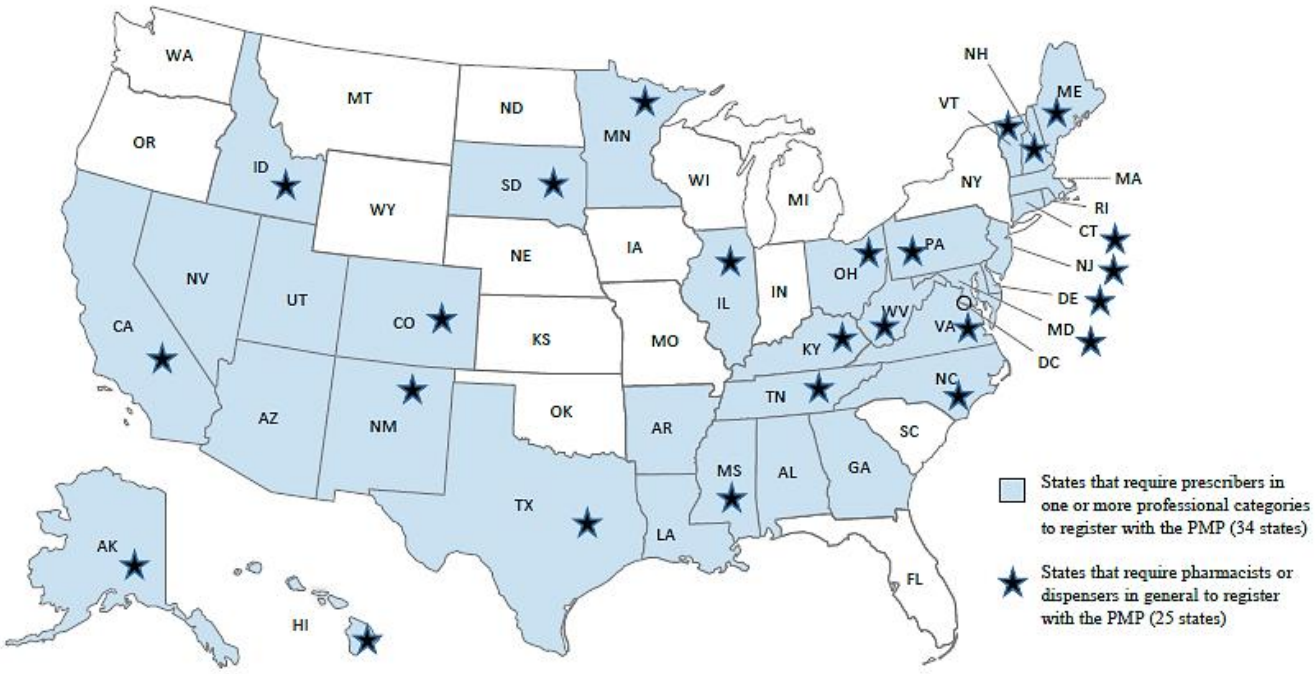
Department staff is also authorized to indirectly access the database to calculate performance measures in its annual report to the Legislature.[104] Such information must be requested of the program manager, and may not include any identifying information of the patient, prescriber, or dispenser.[105]

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.[106] 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.[107] 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.[108]

[98] 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.
[99] Section 893.055(7)(b), F.S.
[100] Id. *See* also 893.055(7)(c), F.S.
[101] Section 893.055(7)(c), F.S.
[102] Id.
[103] Id.
[104] Section 893.055(7)(d), F.S.
[105] Id.
[106] 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 Nov. 17, 2017).
[107] Id.
[108] Id.

Thirty-two states require that certain prescribers and/or dispensers register to use the state's PDMP database:[109]



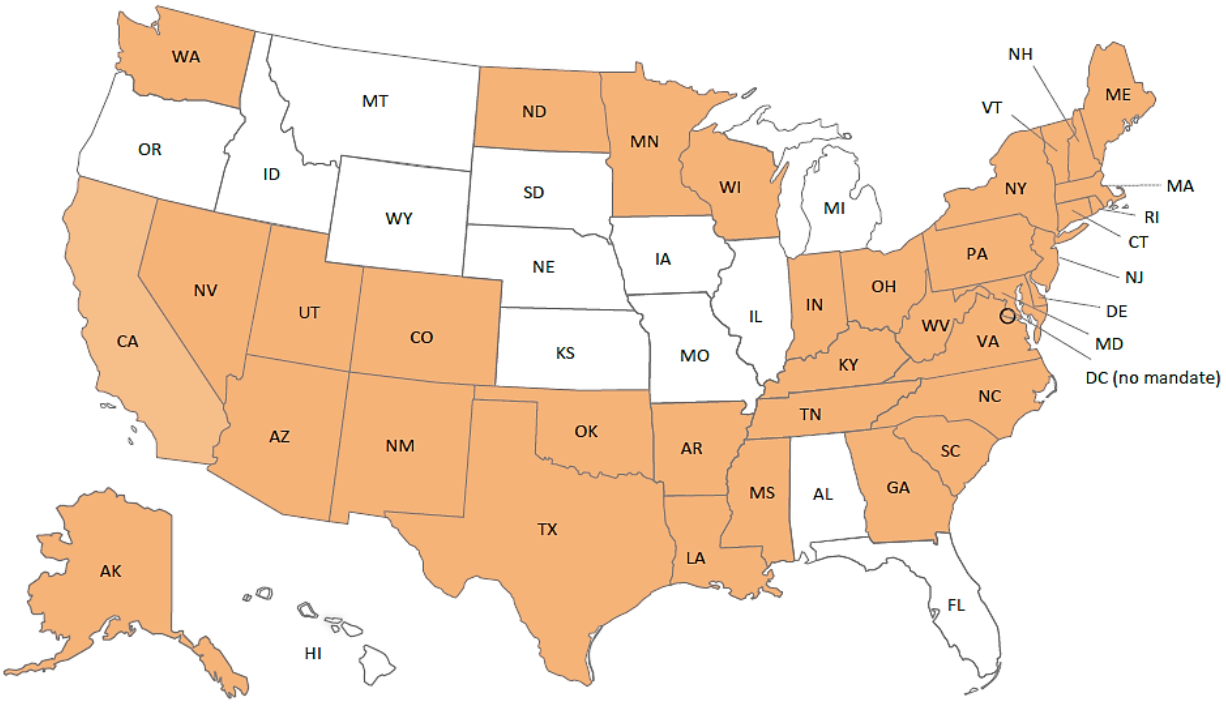
* Exceptions may apply and effective dates may vary. Preparation for implementation may result in a time difference between enactment and effective date(s) and date of implementation of the mandate.

Florida does not require health care practitioners to register to use the PDMP.

Thirty-six states mandate some use of the PDMP for prescribers, but the requirements vary by state.[110] For example, nine states require a health care practitioner to consult the PDMP at each prescribing of a designated substance.[111] Twelve states require a health care practitioner to consult the state's PDMP for the initial prescription of controlled substance for the treatment of pain, and also requires the health care practitioner to subsequently check the PDMP after the initial prescription.[112] Florida does not require prescribers to consult the database to review a patient's prescription drug history prior to prescribing a controlled substance.

[109] National Alliance for Model State Drug Laws, *Mandated Registration with PMPs – Map*, (June 30, 2017), available at http://www.namsdl.org/library/03809318-0000-67D5-4FE157678A176DF0/ (last visited November 10, 2017).
[110] National Alliance for Model State Drug Laws, *Mandated Use of Prescription Drug Monitoring Programs (PMPs) – Map,* (June 30, 2017), available at http://www.namsdl.org/library/FE179822-E782-AA56-9E97D5E5D9F19D7B/ (last visited November 10, 2017).
[111] National Alliance for Model State Drug Laws, *Mandated Use of State Prescription Monitoring Programs (PMPs): Highlights of Key State Requirements*, (June 30, 2017), available at http://www.namsdl.org/library/6735895A-CA6C-1D6B-B8064211764D65D0/ (last visited November 20, 2017). Some states require the PDMP be consulted for specific classes of drugs such as opioids, benzodiazepines, barbiturates, and/or carisoprodol and other states specify schedules of drugs (Arkansas, Oklahoma, Pennsylvania, and Texas), such as all drugs in certain schedules (Alaska, Massachusetts, New York, South Carolina, and Wisconsin).
[112] Id. These states include Arkansas, Georgia, Kentucky, Louisiana, Mississippi, New Hampshire, New Jersey, New Mexico, Rhode Island, Tennessee, Vermont, and West Virginia.

Mandated Use of PDMPs: 36 States with Specified Circumstances Requiring Provider Access



* Exceptions may apply and effective dates may vary. Preparation for implementation may result in a time difference between the enactment and effective date(s) and date of implementation of the mandate. For more information about mandated use of PMPs, please see *Mandated Use of Prescription Drug Monitoring Programs (PMPs) – Highlights of Key State Requirements*, www.namsdl.org

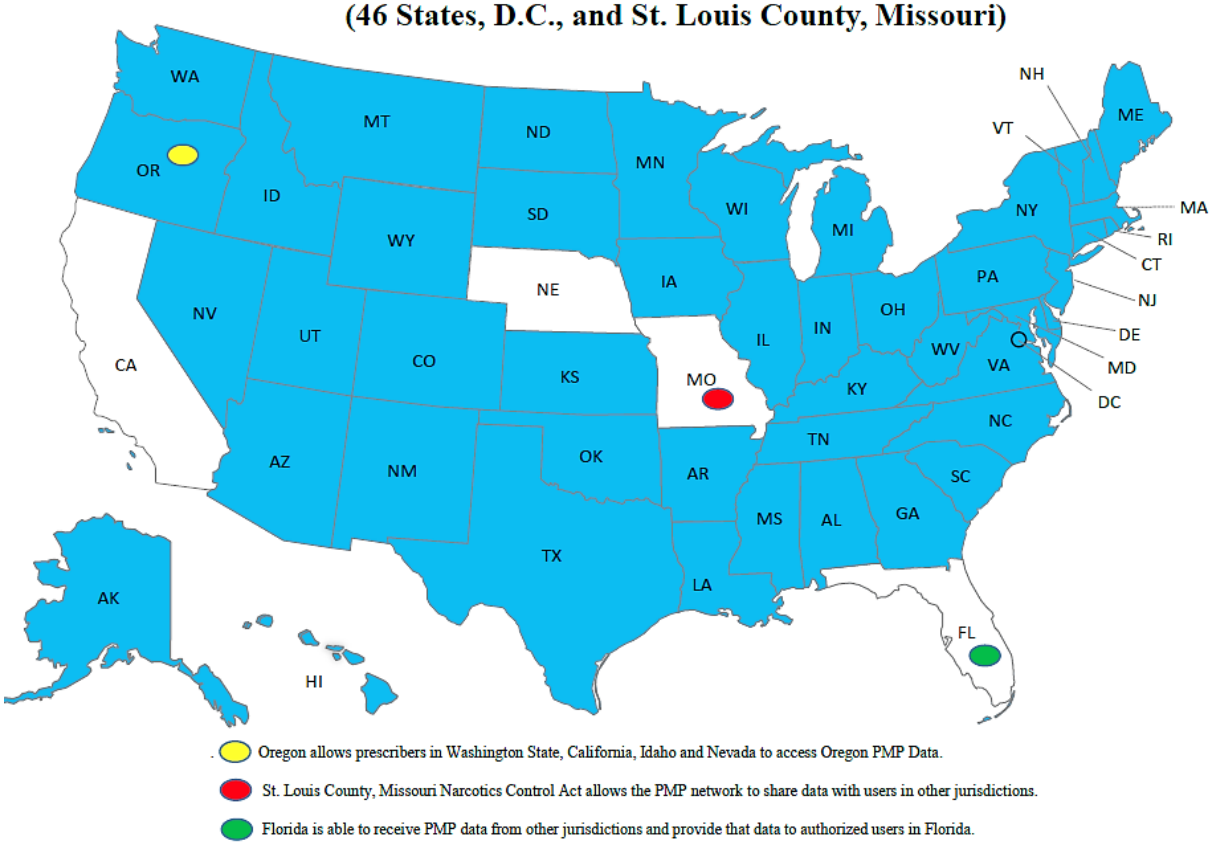
Source: National Alliance for Model State Drug Laws, available at http://www.namsdl.org/library/FE179822-E782-AA56-9E97D5E5D9F19D7B/ (last visited January 4, 2018).

Interstate Sharing of PDMP Information

Interstate sharing of prescription drug information allows health care practitioners and law enforcement to prevent and detect prescription drug abuse that crosses jurisdictional boundaries.[113] Each state that maintains a PDMP database must decide whether it will share the information maintained in its state's PDMP database with other states or jurisdictions, as well as the terms for such access. Florida is one of three states with a PDMP that does not allow other states or jurisdictions to access its database. Florida, however, has one-way access agreements with Alabama and Kentucky to allow authorized Florida PDMP users access to each of these state's PDMP databases.[114] Forty-six states authorize interstate PDMP data sharing.[115]

[113] Bureau of Justice Assistance, *Interstate Data Sharing Becomes a Reality for Prescription Drug Monitoring Programs*, available at https://www.bja.gov/JusticeToday/PMIX.pdf (last visited November 19, 2017).
[114] *Supra* note 64.
[115] National Alliance for Model State Drug Laws, *Interjurisdictional Sharing of Prescription Drug Monitoring Program Data – Map*, (July 10, 2017), available at http://www.namsdl.org/Maps/Interjurisdictional%20Sharing%20of%20Prescription%20Drug%20Monitoring%20Program%20(PMP)%20Data%20-%20Map%20(July%2010%2C%202017).pdf (last visited November 10, 2017).

State/Local Jurisdictions Legally Authorized to Share Their PMP Data with Other State/Local Jurisdictions or Users Located in other State/Local Jurisdictions (46 States, D.C., and St. Louis County, Missouri)



Public Records Exemption for Information in the PDMP Database

Section 893.0551, F.S.,[116] 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.[117] 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.[118]

[116] 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.
[117] Section 893.0551(2), F.S.
[118] 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 Schedule II opioids 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 "medically necessary" 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.[119]

Standards of Practice for Acute Pain Treatment

The bill requires 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 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.

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.[120] 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; and
- Information on the risks of opioid addiction following all stages of treatment in the management of acute pain.

[119] *See* rr. 64B8-9.013 and 64B15-14.005, F.A.C.

[120] 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.

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.

Pain Management Clinics

The bill requires a pain management clinic that claims an exemption from the 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; and
- The specific exemption that the applicant is claiming, along with supporting documentation.

DOH must approve or deny an application for a certificate of exemption with has 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 and for the exemption for which the certificate was issued. The certificate is not transferable or movable. 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 immediately notify DOH and either apply for a new certificate of exemption or register as a pain management clinic if the certificateholder becomes ineligible for the specific exemption claimed for in its certificate of exemption.

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. 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.

Access to the PDMP Database

The bill expands direct access to the database to employees of the Department of Defense and the Indian Health Service who have authority to prescribe 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 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 reciprocal agreements 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:

- 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 continue to monitor such compatibility on a periodic basis. 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. 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;[121]
- 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.

[121] 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.

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 controlled substances pursuant to employment with such entity. Finally, the bill authorizes a 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.

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 substances. 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;
- 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.

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.

B. SECTION DIRECTORY:

Section 1: Creates s. 456.0301, F.S., relating to requirement for instruction on controlled substance prescribing.
Section 2: Amends s. 456.072, F.S., relating to grounds for discipline; penalties; enforcement.
Section 3: Amends s. 456.44, F.S., relating to controlled substance prescribing.
Section 4: Amends s. 458.3265, F.S., relating to pain-management clinics.
Section 5: Amends s. 459.0137, F.S., relating to pain-management clinics.
Section 6: Amends s. 465.0155, F.S., relating to standards of practice.
Section 7: Amends s. 465.0276, F.S., relating to dispensing practitioner.
Section 8: Amends s. 893.03, F.S., relating to standards and schedules.
Section 9: Amends s. 893.055, F.S., relating to prescription drug monitoring program.
Section 10: Amends s. 893.0551, F.S., relating to public records exemption for the prescription drug monitoring program.
Section 11: Amends s. 458.331, F.S., relating to grounds for disciplinary action; action by the board and department.
Section 12: Amends s. 459.015, F.S., relating to grounds for disciplinary action; action by the board and department.
Section 13: Amends s. 463.0055, F.S., relating to administration and prescription of ocular pharmaceutical agents.
Section 14: Amends s. 782.04, F.S., relating to murder.
Section 15: Amends s. 893.13, F.S., relating to prohibited acts; penalties.
Section 16: Amends s. 893.135, F.S., relating to trafficking; mandatory sentences; suspension or reduction of sentences; conspiracy to engage in trafficking.
Section 17: Amends s. 921.0022, F.S., relating to Criminal Punishment Code; offense severity ranking chart.
Section 18: Provides an effective date of July 1, 2018, except as otherwise provided in the bill.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

DOH may realize costs 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.[122] The regulatory costs of associated with issuing the certificates of exemption (see expenditures below) is less than by the costs associated with unlicensed activity investigations resulting in a costs savings.

2. Expenditures:

Pain Management Clinics

DOH estimates that 200 pain management clinics will apply for a certificate of exemption. Based on Fiscal Year 2016-2017 experience, the Board of Medicine can manage a licensee pool of 2,681 per FTE, which equates to .07 FTE to manage the anticipated workload associated with issuing the certificates of exemptions.[123] Based on the LBR standards (salary + 43% benefits), the cost for a Regulatory Specialist II would be $2,795. The department will incur non-recurring costs of $100 associated with rulemaking. DOH will also incur nonrecurring costs associated with updating the Licensing Enforcement and Information Database System, which current resources are adequate to absorb.[124]

Standards of Practice for the Treatment of Acute Pain

DOH may incur insignificant, nonrecurring costs associated with rulemaking to establish standards of practice for treating acute pain.

PDMP

DOH will incur costs associated with upgrading the PDMP software to accommodate interstate data sharing, as well as integration with electronic health records systems. In its Fiscal Year 2018-2019 legislative budget request, DOH requests $873,079 of recurring and $117,700 of nonrecurring general revenue funds to update the PDMP to a new prescription monitoring platform and to access additional features offered by the current vendor.[125]

DOH has executed a contract extension with the current vendor which expires March 2018. DOH plans to execute another one-year contract extension in March 2018 while concurrently competitively procuring services to operate, host, and maintain the PDMP.[126]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

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[122] *Supra* note 64.
[123] Id. According to DOH, this estimate takes into consideration expenditures required for prosecutions. E-mail correspondence with DOH staff dated November 28, 2017, on file with Health Quality Subcommittee.
[124] Id.
[125] DOH, 2018-2019 Legislative Budget Request, Exhibit D-3A, Expenditures by Issue and Appropriation, pp. 216-217, available at http://floridafiscalportal.state.fl.us/Document.aspx?ID=17210&DocType=PDF (last visited November 20, 2017).
[126] Telephone conversation with DOH staff on November 15, 2017.

2. Expenditures:

None.

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 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.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The rule-making authority created by the bill for the continuing education, prescribing guidelines, and certificates of exemption for pain management clinics is sufficient to implement those provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 10, 2018, the Health Quality Subcommittee adopted an amendment that reinstates current law which allows health care regulatory boards indirect access to the PDMP for investigations involving licensees who are authorized to prescribe controlled substances.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.