Health Quality Subcommittee

Wednesday, January 10, 2018
4:00 PM - 5:30 PM
Mashburn Hall (306 HOB)

Richard Corcoran
Speaker

James Grant
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Quality Subcommittee

Start Date and Time:	Wednesday, January 10, 2018 04:00 pm
End Date and Time:	Wednesday, January 10, 2018 05:30 pm
Location:	Mashburn Hall (306 HOB)
Duration:	1.50 hrs

Consideration of the following bill(s):

HB 21 Controlled Substances by Boyd
HB 513 Distributing Pharmaceutical Drugs and Devices by Rommel
HB 573 Involuntary Examinations Under the Baker Act by Daniels
HB 673 Reporting Of Adverse Incidents In Planned Out-Of-Hospital Births by Magar
HB 855 Genetic Information Used for Insurance by Brodeur
HB 973 Performance of Physician Assistants and Advanced Registered Nurse Practitioners by Daniels, Plasencia
HB 6049 Medical Marijuana Growers by Jones

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Tuesday, January 9, 2018.

By request of the Chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Tuesday, January 9, 2018.

NOTICE FINALIZED on 01/08/2018 4:05PM by Krause.Jessica

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

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

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		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

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[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;

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[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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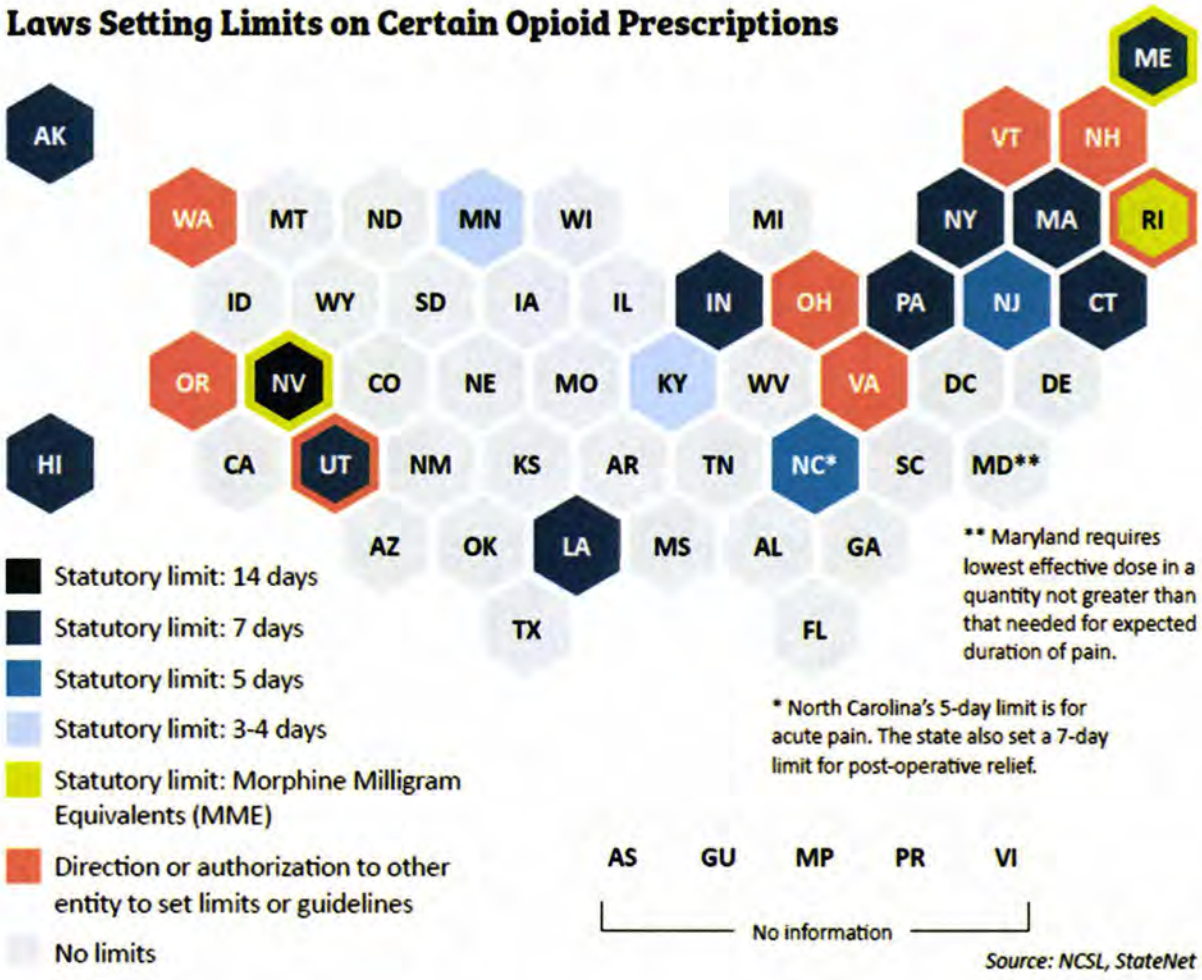
[31] Office of the Governor, Executive Order no. 17-149 (Opioid Epidemic), May 3, 2017, available at: http://www.flgov.com/wp-content/uploads/2017/05/17146.pdf (last visited October 31, 2017).
[32] Id. *See also*, Department of Health, *Gov. Scott Directs Statewide Public Health Emergency for Opioid 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

[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).

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]

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

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[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 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).

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 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

[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.

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.

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

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[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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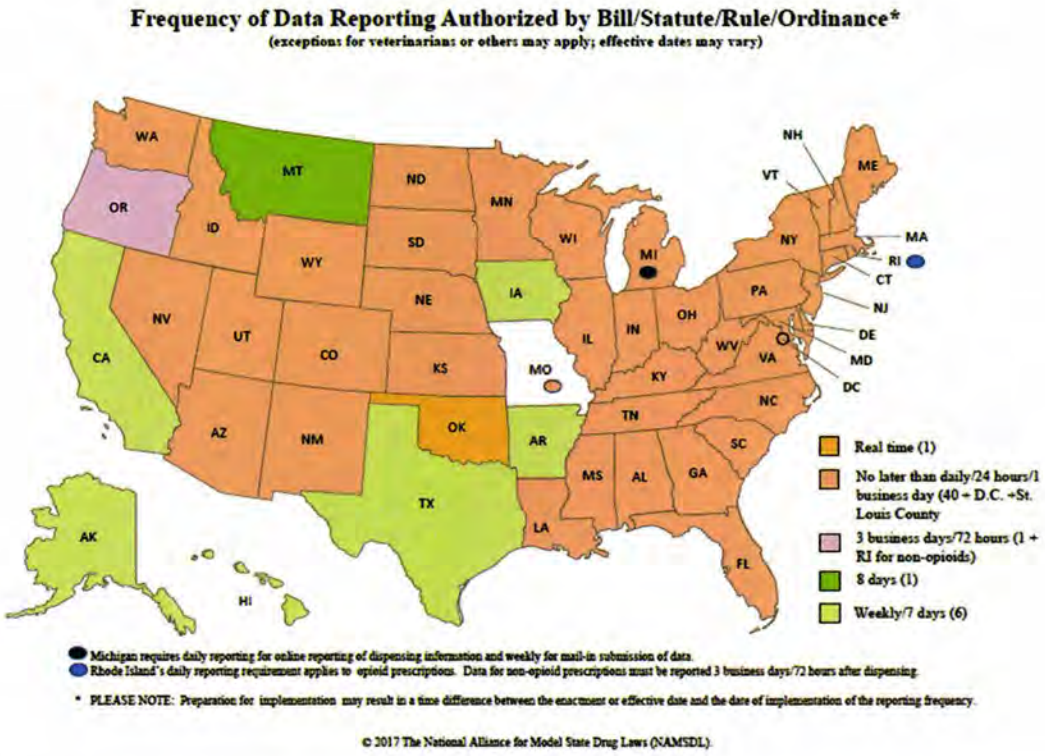
[78] Id.
[79] National Alliance for Model State Drug Laws, *Established and Operational Prescription Drug Monitoring Programs (PMPs) – Map* (July 21, 2017), available at http://www.namsdl.org/Maps/Status%20of%20PMPs%20-%20Established-Operational%20%20Map%20REV%207-21-17.pdf (last visited November 10, 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;

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[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]

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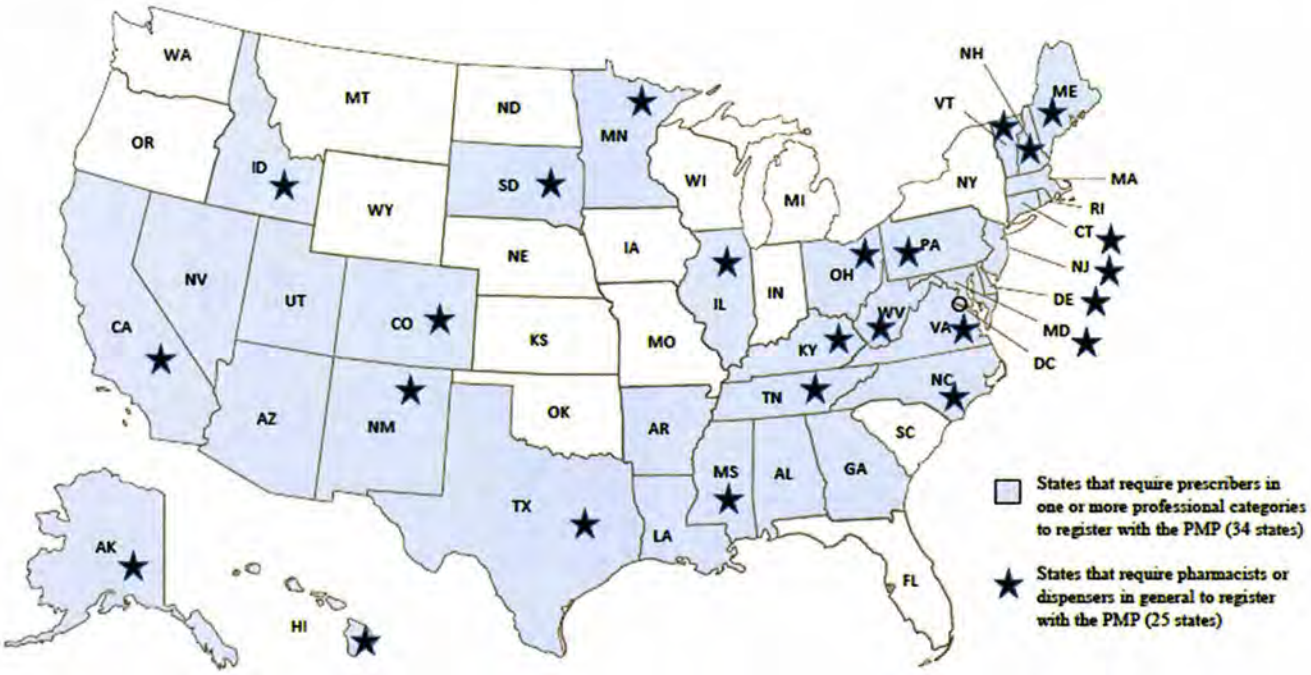
[98] The program manager is an employee of DOH who is designated to ensure the integrity of the PDMP in accordance with law (s. 893.055(1)(j), F.S.
[99] Section 893.055(7)(b), F.S.
[100] Id. *See* also 893.055(7)(c), F.S.
[101] Section 893.055(7)(c), F.S.
[102] Id.
[103] Id.
[104] Section 893.055(7)(d), 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.

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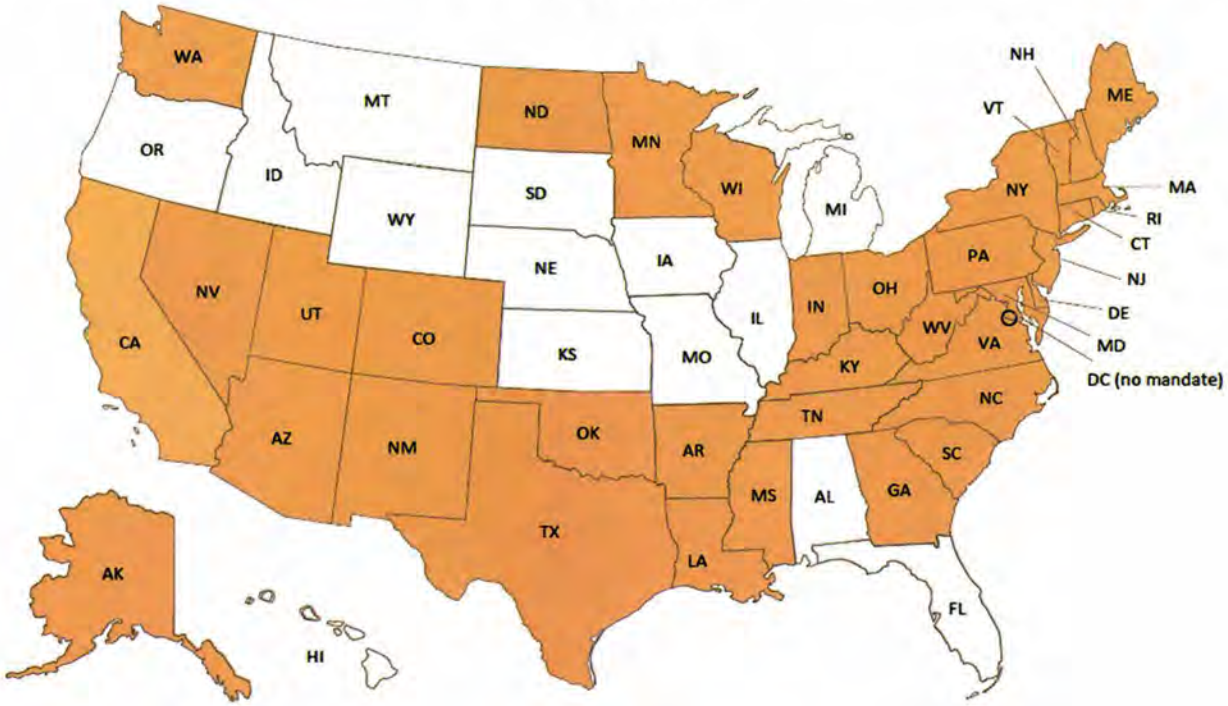
[109] National Alliance for Model State Drug Laws, *Mandated Registration with PMPs – Map*, (June 30, 2017), available at http://www.namsdl.org/library/03809318-0000-67D5-4FE157678A176DF0/ (last visited November 10, 2017).
[110] National Alliance for Model State Drug Laws, *Mandated Use of Prescription 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

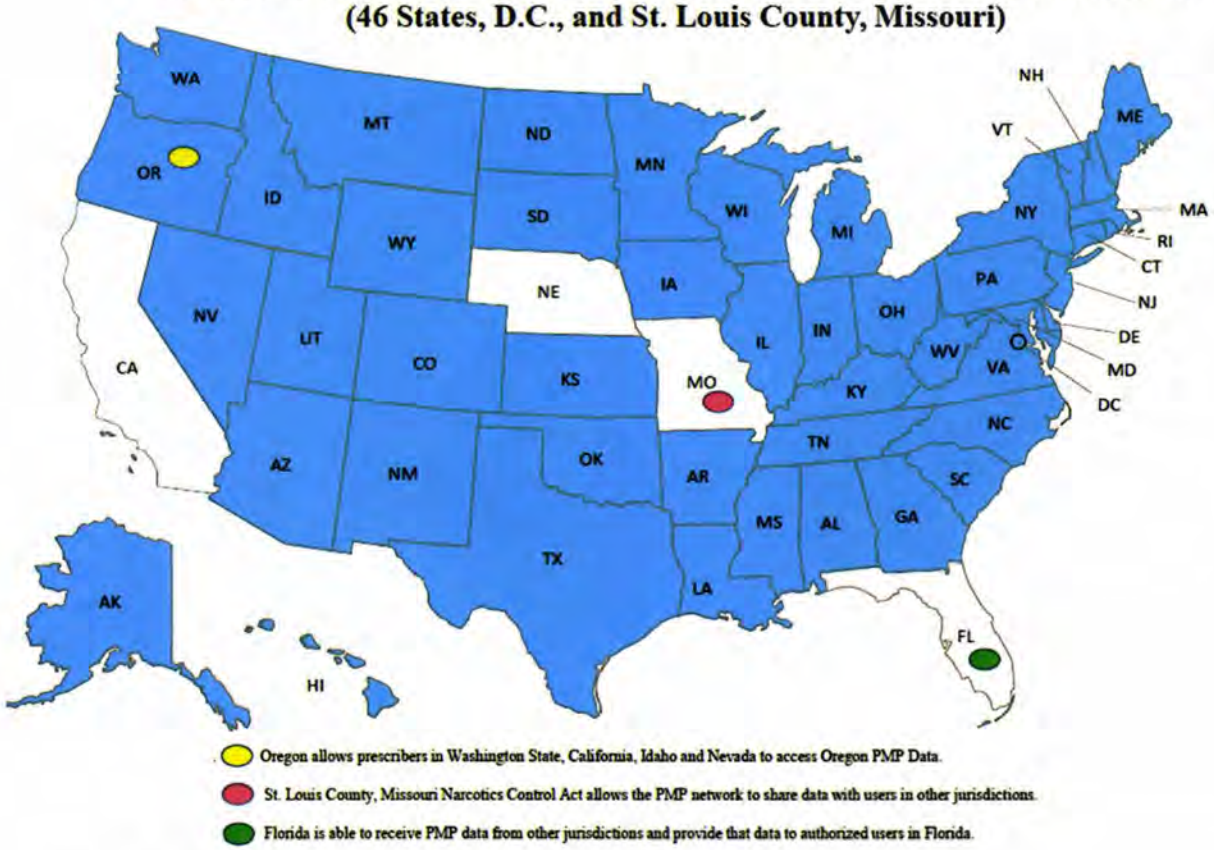
Source: National Alliance for Model State Drug Laws, available at http://www.namsdl.org/library/FE179822-E782-AA56-9E97D5E5D9F19D7B/ (last visited January 4, 2018).

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.

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[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

A bill to be entitled

An act relating to controlled substances; creating s. 456.0301, F.S.; authorizing certain boards to require practitioners to complete a specified board-approved continuing education course to obtain authorization to prescribe controlled substances as part of biennial renewal; providing exceptions; providing course requirements; prohibiting the department from renewing a license of a prescriber under specified circumstances; requiring a licensee to submit confirmation of course completion; providing for each licensing board requiring such continuing education course to include hours of completion with the total hours of continuing education required in certain circumstances; authorizing rulemaking; amending s. 456.072, F.S.; authorizing disciplinary action against practitioners for violating specified provisions relating to controlled substances; amending s. 456.44, F.S.; defining the term "acute pain"; providing for the adoption of standards of practice for the treatment of acute pain; providing that failure of a practitioner to follow specified guidelines is grounds for disciplinary action; limiting opioid prescriptions for the treatment of acute pain to a specified period under certain circumstances; authorizing prescriptions

for such opioids for an extended period if specified requirements are met; amending ss. 458.3265 and 459.0137, F.S.; requiring certain pain management clinic owners to register approved exemptions with the department; requiring certain clinics to obtain certificates of exemption; providing requirements for such certificates; authorizing rulemaking relating to specified exemptions; amending ss. 465.0155 and 465.0276, F.S.; providing requirements for pharmacists and practitioners for the dispensing of controlled substances to persons not known to them; defining the term "proper identification"; amending s. 893.03, F.S.; conforming the state controlled substances schedule to the federal controlled substances schedule; amending s. 893.055, F.S.; revising and providing definitions; revising requirements for the prescription drug monitoring program; authorizing rulemaking; requiring the department to maintain an electronic system for certain purposes to meet specified requirements; requiring certain information to be reported to the system by a specified time; specifying direct access to system information; authorizing department to enter into reciprocal agreements or contracts to share prescription drug monitoring information with certain entities;

providing requirements for such agreements; authorizing the department to enter into agreements or contracts for secure connections with practitioner electronic systems; requiring specified persons to consult the system for certain purposes within a specified time; providing exceptions to the duty of specified persons to consult the system under certain circumstances; authorizing the department to issue nondisciplinary citations to specified entities for failing to meet certain requirements; prohibiting the failure to report the dispensing of a controlled substance when required to do so; providing penalties; authorizing the department to enter into agreements or contracts for specified purposes; providing for the release of information obtained by the system; allowing specified persons to have direct access to information for the purpose of reviewing the controlled drug prescription history of a patient; providing prescriber or dispenser immunity from liability for review of patient history when acting in good faith; providing construction; prohibiting the department from specified uses of funds; authorizing the department to conduct or participate in studies for specified purposes; requiring an annual report to be submitted to the Governor and Legislature by a

specified date; providing report requirements; providing exemptions; establishing direct-support organizations for specified purposes; defining the term "direct-support organization"; requiring a direct-support organization to operate under written contract with the department; providing contract requirements; requiring the direct-support organization to obtain written approval from the department for specified purposes; authorizing rulemaking; providing for an independent annual financial audit by the direct-support organization; providing that copies of such audit be provided to specified entities; providing for future repeal of provisions relating to the direct-support organization; amending s. 893.0551, F.S.; revising provisions concerning release of information held by the prescription drug monitoring program; amending ss. 458.331, 459.015, 463.0055, 782.04, 893.13, 893.135, and 921.0022, F.S.; correcting cross-references; conforming provisions to changes made by the act; providing effective dates.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 456.0301, Florida Statutes, is created to read:

456.0301 Requirement for instruction on controlled substance prescribing.-

(1)(a) If not already required by the licensee's practice act, the appropriate board shall require each person registered with the United States Drug Enforcement Administration and authorized to prescribe controlled substances pursuant to 21 U.S.C. s. 822 to complete a board-approved 2-hour continuing education course on prescribing controlled substances as part of biennial renewal. The course must include information on the current standards regarding for prescribing controlled substances, particularly opiates, alternatives to these standards, and information on the risks of opioid addiction following all stages of treatment in the management of acute pain. The course may be offered in a distance learning format and must be included within the number of continuing education hours required by law. The department may not renew the license of any prescriber registered with the United States Drug Enforcement Administration to prescribe controlled substances that has failed to complete the course. When required by this paragraph, the course shall be completed by January 31, 2019, and at each subsequent renewal.

(b) Each such licensee shall submit confirmation of having completed such course when applying for biennial renewal.

(c) Each licensing board that requires a licensee to complete an educational course pursuant to this subsection may include the hours required for completion of the course in the total hours of continuing education required by law for such profession unless the continuing education requirements for such profession consist of fewer than 30 hours biennially.

(2) Each board may adopt rules to administer this section.

Section 2. Paragraph (gg) of subsection (1) of section 456.072, Florida Statutes, is amended to read:

456.072 Grounds for discipline; penalties; enforcement.—

(1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(gg) Engaging in a pattern of practice when prescribing medicinal drugs or controlled substances which demonstrates a lack of reasonable skill or safety to patients, a violation of any provision of this chapter or ss. 893.055 and 893.0551, a violation of the applicable practice act, or a violation of any rules adopted under this chapter or the applicable practice act of the prescribing practitioner. Notwithstanding s. 456.073(13), the department may initiate an investigation and establish such a pattern from billing records, data, or any other information obtained by the department.

Section 3. Paragraphs (a) through (g) of subsection (1) of section 456.44, Florida Statutes, are redesignated as paragraphs

(b) through (h), respectively, a new paragraph (a) is added to that subsection, subsection (3) is amended, and subsections (4) and (5) are added to that section, to read:

456.44 Controlled substance prescribing.—

(1) DEFINITIONS.—As used in this section, the term:

(a) "Acute pain" means the normal, predicted, physiological, and time-limited response to an adverse chemical, thermal, or mechanical stimulus associated with surgery, trauma, or acute illness.

(3) STANDARDS OF PRACTICE FOR TREATMENT OF CHRONIC NONMALIGNANT PAIN.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(a) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the registrant who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document 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, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall

also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

(b) Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the registrant shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

(c) The registrant shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient

is incompetent. The registrant shall use a written controlled substance agreement between the registrant and the patient outlining the patient's responsibilities, including, but not limited to:

1. Number and frequency of controlled substance prescriptions and refills.

2. Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.

3. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating registrant unless otherwise authorized by the treating registrant and documented in the medical record.

(d) The patient shall be seen by the registrant at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the registrant's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the registrant shall reevaluate the appropriateness of continued treatment. The registrant shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-

month intervals.

(e) The registrant shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or a psychiatrist.

(f) A registrant must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence.

2. Diagnostic, therapeutic, and laboratory results.

3. Evaluations and consultations.

4. Treatment objectives.

5. Discussion of risks and benefits.

6. Treatments.

7. Medications, including date, type, dosage, and quantity prescribed.

8. Instructions and agreements.

9. Periodic reviews.

10. Results of any drug testing.

11. A photocopy of the patient's government-issued photo identification.

12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.

13. The registrant's full name presented in a legible manner.

(g) A registrant shall immediately refer patients with signs or symptoms of substance abuse to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the registrant is a physician who is board-certified or board-eligible in pain management. Throughout the period of time before receiving the consultant's report, a prescribing registrant shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing registrant shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral

indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the registrant shall be documented in the patient's medical record.

This subsection does not apply to a board-eligible or board-certified anesthesiologist, physiatrist, rheumatologist, or neurologist, or to a board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a board-eligible or board-certified medical specialist who has also completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is board eligible or board certified in pain medicine by the American Board of Pain Medicine, the American Board of Interventional Pain Physicians, the American Association of Physician Specialists, or a board approved by the American Board of Medical Specialties or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes. This subsection does not apply to a registrant who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395.

(4) STANDARDS OF PRACTICE FOR TREATMENT OF ACUTE PAIN.—The department shall adopt rules establishing guidelines for prescribing controlled substances for acute pain, including 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. Failure of a prescriber to follow such guidelines constitutes grounds for disciplinary action pursuant to s. 456.072(1)(gg), punishable as provided in s. 456.072(2).

(5) PRESCRIPTION SUPPLY.-

(a) Except as provided in paragraph (b), a prescription for a Schedule II opioid, as defined in s. 893.03 or 21 U.S.C. s. 812, for the treatment of acute pain must not exceed a 3-day supply.

(b) An up to 7-day supply of an opioid described in paragraph (a) may be prescribed if:

1. The practitioner, in his or her professional judgment, believes that more than a 3-day supply of such an opioid is medically necessary to treat the patient's pain as an acute medical condition.

2. The practitioner indicates "MEDICALLY NECESSARY" on the prescription.

3. The prescriber adequately documents in the patient's medical records the acute medical condition and lack of

alternative treatment options that justify deviation from the 3-day supply limit established in this subsection.

Section 4. Effective January 1, 2019, subsections (2) through (5) of section 458.3265, Florida Statutes, are renumbered as subsections (3) through (6), respectively, paragraphs (a) and (g) of subsection (1), paragraph (a) of present subsection (2), paragraph (a) of present subsection (3), and paragraph (a) of present subsection (4) are amended, and a new subsection (2) is added to that section, to read:

458.3265 Pain-management clinics.—

(1) REGISTRATION.—

(a)1. As used in this section, the term:

a. "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.

b. "Chronic nonmalignant pain" means 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.

c. "Pain-management clinic" or "clinic" means any publicly or privately owned facility:

(I) That advertises in any medium for any type of pain-

management services; or

(II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

2. Each pain-management clinic must register with the department or hold a valid certificate of exemption pursuant to subsection (2). ~~unless:~~

3. The following clinics are exempt from the registration requirement of paragraphs (c)-(m), and must apply to the department for a certificate of exemption:

a. A ~~That~~ clinic ~~is~~ licensed as a facility pursuant to chapter 395;

b. A clinic in which the majority of the physicians who provide services in the clinic primarily provide surgical services;

c. A ~~The~~ clinic ~~is~~ owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million;

d. A ~~The~~ clinic ~~is~~ affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;

e. A ~~The~~ clinic that does not prescribe controlled substances for the treatment of pain;

f. A ~~The~~ clinic ~~is~~ owned by a corporate entity exempt from

federal taxation under 26 U.S.C. s. 501(c)(3);

g. A ~~The~~ clinic ~~is~~ wholly owned and operated by one or more board-eligible or board-certified anesthesiologists, physiatrists, rheumatologists, or neurologists; or

h. A ~~The~~ clinic ~~is~~ wholly owned and operated by a physician multispecialty practice where one or more board-eligible or board-certified medical specialists, who have also completed fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education or who are also board-certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties, the American Association of Physician Specialists, or the American Osteopathic Association, perform interventional pain procedures of the type routinely billed using surgical codes.

(g) The department may revoke the clinic's certificate of registration and prohibit all physicians associated with that pain-management clinic from practicing at that clinic location based upon an annual inspection and evaluation of the factors described in subsection (4) ~~(3)~~.

(2) CERTIFICATE OF EXEMPTION.-

(a) A pain management clinic claiming an exemption from the registration requirements of subsection (1), must apply for a certificate of exemption on a form adopted in rule by the department. The form shall require the applicant to provide:

1. The name or names under which the applicant does business.

2. The address at which the pain management clinic is located.

3. The specific exemption the applicant is claiming with supporting documentation.

4. Any other information deemed necessary by the department.

(b) Within 30 days after the receipt of a complete application, the department must approve or deny the application.

(c) The certificate of exemption must be renewed biennially, except that the department may issue the initial certificates of exemption for up to 3 years in order to stagger renewal dates.

(d) A certificateholder must prominently display the certificate of exemption and make it available to the department or the board upon request.

(e) A certificate of exemption is not movable or transferable. A certificate of exemption is valid only for the applicant, qualifying owners, licenses, registrations, certifications, and services provided under a specific statutory exemption and is valid only to the specific exemption claimed and granted.

(f) A certificateholder must notify the department at

least 60 days before any anticipated relocation or name change of the pain management clinic or a change of ownership.

(g) If a pain management clinic no longer qualifies for a certificate of exemption, the certificateholder must immediately notify the department and register as a pain management clinic under subsection (1).

(3)~~(2)~~ PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

(a) A physician may not practice medicine in a pain-management clinic, as described in subsection (5)~~(4)~~, if the pain-management clinic is not registered with the department as required by this section. Any physician who qualifies to practice medicine in a pain-management clinic pursuant to rules adopted by the Board of Medicine as of July 1, 2012, may continue to practice medicine in a pain-management clinic as long as the physician continues to meet the qualifications set forth in the board rules. A physician who violates this paragraph is subject to disciplinary action by his or her appropriate medical regulatory board.

(4)~~(3)~~ INSPECTION.—

(a) The department shall inspect the pain-management clinic annually, including a review of the patient records, to ensure that it complies with this section and the rules of the

Board of Medicine adopted pursuant to subsection (5)~~(4)~~ unless the clinic is accredited by a nationally recognized accrediting agency approved by the Board of Medicine.

(5)~~(4)~~ RULEMAKING.—

(a) The department shall adopt rules necessary to administer the registration, exemption, and inspection of pain-management clinics which establish the specific requirements, procedures, forms, and fees.

Section 5. Effective January 1, 2019, subsections (2) through (5) of section 459.0137, Florida Statutes, are renumbered as subsections (3) through (6), respectively, paragraphs (a) and (g) of subsection (1), paragraph (a) of present subsection (2), paragraph (a) of present subsection (3), and paragraph (a) of present subsection (4) are amended, and a new subsection (2) is added to that section, to read:

459.0137 Pain-management clinics.—

(1) REGISTRATION.—

(a)1. As used in this section, the term:

a. "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.

b. "Chronic nonmalignant pain" means 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.

c. "Pain-management clinic" or "clinic" means any publicly or privately owned facility:

(I) That advertises in any medium for any type of pain-management services; or

(II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

2. Each pain-management clinic must register with the department or hold a valid certificate of exemption pursuant to subsection (2). ~~unless:~~

3. The following clinics are exempt from the registration requirement of paragraphs (c)-(m), and must apply to the department for a certificate of exemption:

a. A ~~That~~ clinic ~~is~~ licensed as a facility pursuant to chapter 395;

b. A clinic in which the majority of the physicians who provide services in the clinic primarily provide surgical services;

c. A ~~The~~ clinic ~~is~~ owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million;

d. A ~~The~~ clinic ~~is~~ affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;

e. A ~~The~~ clinic that does not prescribe controlled substances for the treatment of pain;

f. A ~~The~~ clinic ~~is~~ owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3);

g. A ~~The~~ clinic ~~is~~ wholly owned and operated by one or more board-eligible or board-certified anesthesiologists, physiatrists, rheumatologists, or neurologists; or

h. A ~~The~~ clinic ~~is~~ wholly owned and operated by a physician multispecialty practice where one or more board-eligible or board-certified medical specialists, who have also completed fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association or who are also board-certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties, the American Association of Physician Specialists, or the American Osteopathic Association, perform interventional pain procedures of the type routinely billed using surgical codes.

(g) The department may revoke the clinic's certificate of registration and prohibit all physicians associated with that pain-management clinic from practicing at that clinic location based upon an annual inspection and evaluation of the factors

described in subsection (4)~~(3)~~.

(2) CERTIFICATE OF EXEMPTION.-

(a) A pain management clinic claiming an exemption from the registration requirements of subsection (1), must apply for a certificate of exemption on a form adopted in rule by the department. The form shall require the applicant to provide:

1. The name or names under which the applicant does business.

2. The address at which the pain management clinic is located.

3. The specific exemption the applicant is claiming with supporting documentation.

4. Any other information deemed necessary by the department.

(b) Within 30 days after the receipt of a complete application, the department must approve or deny the application.

(c) The certificate of exemption must be renewed biennially, except that the department may issue the initial certificates of exemption for up to 3 years in order to stagger renewal dates.

(d) A certificateholder must prominently display the certificate of exemption and make it available to the department or the board upon request.

(e) A certificate of exemption is not movable or

transferable. A certificate of exemption is valid only for the applicant, qualifying owners, licenses, registrations, certifications, and services provided under a specific statutory exemption and is valid only to the specific exemption claimed and granted.

(f) A certificateholder must notify the department at least 60 days before any anticipated relocation or name change of the pain management clinic or a change of ownership.

(g) If a pain management clinic no longer qualifies for a certificate of exemption, the certificateholder must immediately notify the department and register as a pain management clinic under subsection (1).

(3)~~(2)~~ PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any osteopathic physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

(a) An osteopathic physician may not practice medicine in a pain-management clinic, as described in subsection (5)~~(4)~~, if the pain-management clinic is not registered with the department as required by this section. Any physician who qualifies to practice medicine in a pain-management clinic pursuant to rules adopted by the Board of Osteopathic Medicine as of July 1, 2012, may continue to practice medicine in a pain-management clinic as long as the physician continues to meet the qualifications set forth in the board rules. An osteopathic physician who violates

this paragraph is subject to disciplinary action by his or her appropriate medical regulatory board.

(4)~~(3)~~ INSPECTION.—

(a) The department shall inspect the pain-management clinic annually, including a review of the patient records, to ensure that it complies with this section and the rules of the Board of Osteopathic Medicine adopted pursuant to subsection (5)~~(4)~~ unless the clinic is accredited by a nationally recognized accrediting agency approved by the Board of Osteopathic Medicine.

(5)~~(4)~~ RULEMAKING.—

(a) The department shall adopt rules necessary to administer the registration, exemption, and inspection of pain-management clinics which establish the specific requirements, procedures, forms, and fees.

Section 6. Section 465.0155, Florida Statutes, is amended to read:

465.0155 Standards of practice.—

(1) Consistent with the provisions of this act, the board shall adopt by rule standards of practice relating to the practice of pharmacy which shall be binding on every state agency and shall be applied by such agencies when enforcing or implementing any authority granted by any applicable statute, rule, or regulation, whether federal or state.

(2)(a) Before dispensing a controlled substance to a

person not known to the pharmacist, the pharmacist must require the person purchasing, receiving, or otherwise acquiring the controlled substance to present valid photographic identification or other verification of his or her identity. If the person does not have proper identification, the pharmacist may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system is considered to be proper identification.

(b) This subsection does not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted.

(c) As used in this subsection, the term "proper identification" means an identification that is issued by a state or the Federal Government containing the person's photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

Section 7. Paragraph (d) is added to subsection (2) of section 465.0276, Florida Statutes, to read:

465.0276 Dispensing practitioner.—

(2) A practitioner who dispenses medicinal drugs for human consumption for fee or remuneration of any kind, whether direct or indirect, must:

(d)1. Before dispensing a controlled substance to a person not known to the dispenser, require the person purchasing, receiving, or otherwise acquiring the controlled substance to present valid photographic identification or other verification of his or her identity. If the person does not have proper identification, the dispenser may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system is considered to be proper identification.

2. This paragraph does not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted.

3. As used in this paragraph, the term "proper identification" means an identification that is issued by a state or the Federal Government containing the person's photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

Section 8. Subsections (2), (3), (4), and (5) of section 893.03, Florida Statutes, are amended to read:

893.03 Standards and schedules.—The substances enumerated in this section are controlled by this chapter. The controlled substances listed or to be listed in Schedules I, II, III, IV, and V are included by whatever official, common, usual,

chemical, trade name, or class designated. The provisions of this section shall not be construed to include within any of the schedules contained in this section any excluded drugs listed within the purview of 21 C.F.R. s. 1308.22, styled "Excluded Substances"; 21 C.F.R. s. 1308.24, styled "Exempt Chemical Preparations"; 21 C.F.R. s. 1308.32, styled "Exempted Prescription Products"; or 21 C.F.R. s. 1308.34, styled "Exempt Anabolic Steroid Products."

(2) SCHEDULE II.—A substance in Schedule II has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States, and abuse of the substance may lead to severe psychological or physical dependence. The following substances are controlled in Schedule II:

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis:

1. Opium and any salt, compound, derivative, or preparation of opium, except nalmefene or isoquinoline alkaloids of opium, including, but not limited to the following:

a. Raw opium.

b. Opium extracts.

c. Opium fluid extracts.

d. Powdered opium.

e. Granulated opium.

f. Tincture of opium.

g. Codeine.

h. Dihydroetorphine.

i.~~h.~~ Ethylmorphine.

j.~~i.~~ Etorphine hydrochloride.

k.~~j.~~ Hydrocodone and hydrocodone combination products.

l.~~k.~~ Hydromorphone.

m.~~l.~~ Levo-alphacetylmethadol (also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM).

n.~~m.~~ Metopon (methyldihydromorphinone).

o.~~n.~~ Morphine.

p. Oripavine.

q.~~o.~~ Oxycodone.

r.~~p.~~ Oxymorphone.

s.~~q.~~ Thebaine.

2. Any salt, compound, derivative, or preparation of a substance which is chemically equivalent to or identical with any of the substances referred to in subparagraph 1., except that these substances shall not include the isoquinoline alkaloids of opium.

3. Any part of the plant of the species Papaver somniferum, L.

4. Cocaine or ecgonine, including any of their

stereoisomers, and any salt, compound, derivative, or preparation of cocaine or ecgonine, except that these substances shall not include ioflupane I 123.

(b) Unless specifically excepted or unless listed in another schedule, any of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

1. Alfentanil.
2. Alphaprodine.
3. Anileridine.
4. Bezitramide.
5. Bulk propoxyphene (nondosage forms).
6. Carfentanil.
7. Dihydrocodeine.
8. Diphenoxylate.
9. Fentanyl.
10. Isomethadone.
11. Levomethorphan.
12. Levorphanol.
13. Metazocine.
14. Methadone.
15. Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenylbutane.

16. Moramide-Intermediate,2-methyl-3-morpholoino-1,1-diphenylpropane-carboxylic acid.

17. Nabilone.

18. Pethidine (meperidine).

19. Pethidine-Intermediate-A,4-cyano-1-methyl-4-phenylpiperidine.

20. Pethidine-Intermediate-B,ethyl-4-phenylpiperidine-4-carboxylate.

21. Pethidine-Intermediate-C,1-methyl-4- phenylpiperidine-4-carboxylic acid.

22. Phenazocine.

23. Phencyclidine.

24. 1-Phenylcyclohexylamine.

25. Piminodine.

26. 1-Piperidinocyclohexanecarbonitrile.

27. Racemethorphan.

28. Racemorphan.

29. Remifentanil.

30.~~29.~~ Sufentanil.

31. Tapentadol.

32. Thiafentanil.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts, isomers, optical isomers,

salts of their isomers, and salts of their optical isomers:

1. Amobarbital.

2. Amphetamine.

3. Glutethimide.

4. Lisdexamfetamine.

5.~~4.~~ Methamphetamine.

6.~~5.~~ Methylphenidate.

7.~~6.~~ Pentobarbital.

8.~~7.~~ Phenmetrazine.

9.~~8.~~ Phenylacetone.

10.~~9.~~ Secobarbital.

(d) Dronabinol (synthetic THC) in oral solution in a drug product approved by the United States Food and Drug Administration.

(3) SCHEDULE III.—A substance in Schedule III has a potential for abuse less than the substances contained in Schedules I and II and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. The following substances are controlled in Schedule III:

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following

substances having a depressant or stimulant effect on the nervous system:

1. Any substance which contains any quantity of a derivative of barbituric acid, including thiobarbituric acid, or any salt of a derivative of barbituric acid or thiobarbituric acid, including, but not limited to, butabarbital and butalbital.

2. Benzphetamine.

3. Buprenorphine.

4.~~3.~~ Chlorhexadol.

5.~~4.~~ Chlorphentermine.

6.~~5.~~ Clortermine.

7. Embutramide.

8.~~6.~~ Lysergic acid.

9.~~7.~~ Lysergic acid amide.

10.~~8.~~ Methyprylon.

11. Perampanel.

12.~~9.~~ Phendimetrazine.

13.~~10.~~ Sulfondiethylmethane.

14.~~11.~~ Sulfonethylmethane.

15.~~12.~~ Sulfonmethane.

16.~~13.~~ Tiletamine and zolazepam or any salt thereof.

(b) Nalorphine.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or

preparation containing limited quantities of any of the following controlled substances or any salts thereof:

1. Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

2. Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances.

3. Not more than 300 milligrams of hydrocodone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

4. Not more than 300 milligrams of hydrocodone per 100 milliliters or not more than 15 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients that are not controlled substances.

5. Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances.

6. Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

7. Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances.

For purposes of charging a person with a violation of s. 893.135 involving any controlled substance described in subparagraph 3. or subparagraph 4., the controlled substance is a Schedule III controlled substance pursuant to this paragraph but the weight of the controlled substance per milliliters or per dosage unit is not relevant to the charging of a violation of s. 893.135. The weight of the controlled substance shall be determined pursuant to s. 893.135(6).

(d) Anabolic steroids.

1. The term "anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids, that promotes muscle growth and includes:

a. Androsterone.

b. Androsterone acetate.

c. Boldenone.

d. Boldenone acetate.

e. Boldenone benzoate.

f. Boldenone undecylenate.

g. Chlorotestosterone (Clostebol).

h. Dehydrochlormethyltestosterone.
i. Dihydrotestosterone (Stanolone).
j. Drostanolone.
k. Ethylestrenol.
l. Fluoxymesterone.
m. Formebulone (Formebolone).
n. Mesterolone.
o. Methandrostenolone (Methandienone).
p. Methandranone.
q. Methandriol.
r. Methenolone.
s. Methyltestosterone.
t. Mibolerone.
u. Nortestosterone (Nandrolone).
v. Norethandrolone.
w. Nortestosterone decanoate.
x. Nortestosterone phenylpropionate.
y. Nortestosterone propionate.
z. Oxandrolone.
aa. Oxymesterone.
bb. Oxymetholone.
cc. Stanozolol.
dd. Testolactone.
ee. Testosterone.
ff. Testosterone acetate.

gg. Testosterone benzoate.
hh. Testosterone cypionate.
ii. Testosterone decanoate.
jj. Testosterone enanthate.
kk. Testosterone isocaproate.
ll. Testosterone oleate.
mm. Testosterone phenylpropionate.
nn. Testosterone propionate.
oo. Testosterone undecanoate.
pp. Trenbolone.
qq. Trenbolone acetate.
rr. Any salt, ester, or isomer of a drug or substance described or listed in this subparagraph if that salt, ester, or isomer promotes muscle growth.

2. The term does not include an anabolic steroid that is expressly intended for administration through implants to cattle or other nonhuman species and that has been approved by the United States Secretary of Health and Human Services for such administration. However, any person who prescribes, dispenses, or distributes such a steroid for human use is considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this paragraph.

(e) Ketamine, including any isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible

within the specific chemical designation.

(f) Dronabinol (synthetic THC) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the United States Food and Drug Administration.

(g) Any drug product containing gamma-hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under s. 505 of the Federal Food, Drug, and Cosmetic Act.

(4)(a) SCHEDULE IV.—A substance in Schedule IV has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, are controlled in Schedule IV:

1. Alfaxalone.

2.~~(a)~~ Alprazolam.

3.~~(b)~~ Barbital.

4.~~(c)~~ Bromazepam.

5.~~(iii)~~ Butorphanol tartrate.
6.~~(d)~~ Camazepam.
7.~~(jjj)~~ Carisoprodol.
8.~~(e)~~ Cathine.
9.~~(f)~~ Chloral betaine.
10.~~(g)~~ Chloral hydrate.
11.~~(h)~~ Chlordiazepoxide.
12.~~(i)~~ Clobazam.
13.~~(j)~~ Clonazepam.
14.~~(k)~~ Clorazepate.
15.~~(l)~~ Clotiazepam.
16.~~(m)~~ Cloxazolam.
17. Dexfenfluramine.
18.~~(n)~~ Delorazepam.
19. Dichloralphenazone.
20.~~(p)~~ Diazepam.
21.~~(q)~~ Diethylpropion.
22. Eluxadoline.
23.~~(r)~~ Estazolam.
24. Eszopiclone.
25.~~(s)~~ Ethchlorvynol.
26.~~(t)~~ Ethinamate.
27.~~(u)~~ Ethyl loflazepate.
28.~~(v)~~ Fencamfamin.
29.~~(w)~~ Fenfluramine.

30.~~(x)~~ Fenproporex.

31.~~(y)~~ Fludiazepam.

32.~~(z)~~ Flurazepam.

33. Fospropofol.

34.~~(aa)~~ Halazepam.

35.~~(bb)~~ Haloxazolam.

36.~~(cc)~~ Ketazolam.

37.~~(dd)~~ Loprazolam.

38.~~(ee)~~ Lorazepam.

39. Lorcaserin.

40.~~(ff)~~ Lormetazepam.

41.~~(gg)~~ Mazindol.

42.~~(hh)~~ Mebutamate.

43.~~(ii)~~ Medazepam.

44.~~(jj)~~ Mefenorex.

45.~~(kk)~~ Meprobamate.

46.~~(ll)~~ Methohexital.

47.~~(mm)~~ Methylphenobarbital.

48.~~(nn)~~ Midazolam.

49. Modafinil.

50.~~(oo)~~ Nimetazepam.

51.~~(pp)~~ Nitrazepam.

52.~~(qq)~~ Nordiazepam.

53.~~(rr)~~ Oxazepam.

54.~~(ss)~~ Oxazolam.

55.~~(tt)~~ Paraldehyde.

56.~~(uu)~~ Pemoline.

57.~~(vv)~~ Pentazocine.

58. Petrichloral.

59.~~(ww)~~ Phenobarbital.

60.~~(xx)~~ Phentermine.

61.~~(yy)~~ Pinazepam.

62.~~(zz)~~ Pipradrol.

63.~~(aaa)~~ Prazepam.

64.~~(o)~~ Propoxyphene (dosage forms).

65.~~(bbb)~~ Propylhexedrine, excluding any patent or proprietary preparation containing propylhexedrine, unless otherwise provided by federal law.

66.~~(ccc)~~ Quazepam.

67. Sibutramine.

68.~~(eee)~~ SPA[(-)-1 dimethylamino-1, 2 diphenylethane].

69. Suvorexant.

70.~~(fff)~~ Temazepam.

71.~~(ddd)~~ Tetrazepam.

72. Tramadol.

73.~~(ggg)~~ Triazolam.

74. Zaleplon.

75. Zolpidem.

76. Zopiclone.

77.~~(hhh)~~ Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) SCHEDULE V.—A substance, compound, mixture, or preparation of a substance in Schedule V has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States, and abuse of such compound, mixture, or preparation may lead to limited physical or psychological dependence relative to the substances in Schedule IV.

(a) Substances controlled in Schedule V include any compound, mixture, or preparation containing any of the following limited quantities of controlled substances, which shall include one or more active medicinal ingredients which are not controlled substances in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the controlled substance alone:

1. Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

2. Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

3. Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

4. Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

5. Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

6. Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

7. Brivaracetam.

8. Ezogabine.

9. Lacosamide.

10. Pregabalin.

~~(b) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts: Buprenorphine.~~

(b)~~(c)~~ Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers: Pyrovalerone.

Section 9. Section 893.055, Florida Statutes, is amended to read:

(Substantial rewording of section. See s. 893.055, F.S., for present text.)

893.055 Prescription drug monitoring program.—

(1) As used in this section, the term:

(a) "Administration" means the obtaining and giving of a

single dose of medicinal drugs by a legally authorized person to a patient for her or his consumption.

(b) "Active investigation" means an investigation that is being conducted with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings, or that is ongoing and continuing and for which there is a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future.

(c) "Controlled substance" means a controlled substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03 or 21 U.S.C. s. 812.

(d) "Dispense" means the transfer of possession of one or more doses of a medicinal drug by a health care practitioner to the ultimate consumer or to his or her agent.

(e) "Dispenser" means a dispensing health care practitioner or pharmacist licensed to dispense medicinal drugs in this state.

(f) "Health care practitioner" or "practitioner" means any practitioner licensed under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, chapter 465, or chapter 466.

(g) "Health care regulatory board" means any board or commission as defined in s. 456.001(1).

(h) "Law enforcement agency" means the Department of Law Enforcement, a sheriff's office in this state, a police department in this state, or a law enforcement agency of the

Federal Government which enforces the laws of this state or the United States relating to controlled substances, and which its agents and officers are empowered by law to conduct criminal investigations and make arrests.

(i) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, or an Internet pharmacy that is licensed by the department under chapter 465 and that dispenses or delivers medicinal drugs, including controlled substances to an individual or address in this state.

(j) "Prescriber" means a prescribing physician, prescribing practitioner, or other prescribing health care practitioner authorized by the laws of this state to order medicinal drugs.

(k) "Program manager" means an employee of or a person contracted by the department who is designated to ensure the integrity of the prescription drug monitoring program in accordance with the requirements established in this section.

(2)(a) The department shall maintain an electronic system to collect and store controlled substance dispensing information and shall release the information as authorized in s. 893.0551. The electronic system must:

1. Not infringe upon the legitimate prescribing or dispensing of a controlled substance by a prescriber or dispenser acting in good faith and in the course of professional

practice.

2. Be consistent with standards of the American Society for Automation in Pharmacy (ASAP).

3. Comply with the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to protected health information (PHI), electronic protected health information (EPHI), and all other relevant state and federal privacy and security laws and regulations.

(b) The department may collaborate with professional health care regulatory boards, appropriate organizations, and other state agencies to identify indicators of controlled substance abuse.

(c) The department shall adopt rules necessary to implement this subsection.

(3) For each controlled substance dispensed to a patient in the state, the following information must be reported by the dispenser to the system as soon thereafter as possible but no later than the close of the next business day after the day the controlled substance is dispensed unless an extension or exemption is approved by the department:

(a) The name of the prescribing practitioner, the practitioner's federal Drug Enforcement Administration registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription.

(b) The date the prescription was filled and the method of payment, such as cash by an individual, insurance coverage through a third party, or Medicaid payment. This paragraph does not authorize the department to include individual credit card numbers or other account numbers in the system.

(c) The full name, address, telephone number, and date of birth of the person for whom the prescription was written.

(d) The name, national drug code, quantity, and strength of the controlled substance dispensed.

(e) The full name, federal Drug Enforcement Administration registration number, State of Florida Department of Health issued pharmacy permit number, and address of the pharmacy or other location from which the controlled substance was dispensed. If the controlled substance was dispensed by a practitioner other than a pharmacist, the practitioner's full name, address, federal Drug Enforcement Administration registration number, State of Florida Department of Health issued license number, and National Provider Identification (NPI).

(f) Whether the drug was dispensed as an initial prescription or a refill, and the number of refills ordered.

(g) The name of the individual picking up the controlled substance prescription and type and issuer of the identification provided.

(h) Other appropriate identifying information as

determined by department rule.

(i) All acts of administration of controlled substances are exempt from the reporting requirements of this section.

(4) The following shall have direct access to information in the system:

(a) An authorized prescriber or dispenser or his or her designee.

(b) An employee of the United States Department of Veterans Affairs, United States Department of Defense, or the Indian Health Service who provides health care services pursuant to such employment and who has the authority to prescribe controlled substances shall have access to the information in the program's system upon verification of employment.

(c) The program manager or designated program and support staff may have access to administer the system.

1. The program manager or designated program and support staff must complete a level II background screening.

2. In order to calculate performance measures pursuant to subsection (14), the program manager or program and support staff members who have been directed by the program manager to calculate performance measures may have direct access to information that contains no identifying information of any patient, physician, health care practitioner, prescriber, or dispenser.

3. The program manager or designated program and support

staff must provide the department, upon request, data that does not contain patient, physician, health care practitioner, prescriber, or dispenser identifying information for public health care and safety initiatives purposes.

4. The program manager, upon determining a pattern consistent with the department's rules established under paragraph (2)(b) may provide relevant information to the prescriber and dispenser.

5. The program manager, upon determining a pattern consistent with the rules established under paragraph (2)(b) and having cause to believe a violation of s. 893.13(7)(a)8., (8)(a), or (8)(b) has occurred, may provide relevant information to the applicable law enforcement agency.

(5) The following entities may not directly access information in the system, but may request information from the program manager or designated program and support staff:

(a) The department for investigations involving licensees authorized to prescribe or dispense controlled substances.

(b) The Attorney General for Medicaid fraud cases involving prescribed controlled substances.

(c) A law enforcement agency during active investigations of potential criminal activity, fraud, or theft regarding prescribed controlled substances.

(d) A medical examiner when conducting an authorized investigation under s. 406.11, to determine the cause of death

of an individual.

(e) An impaired practitioner consultant who is retained by the department under s. 456.076 to review the system information of an impaired practitioner program participant or a referral who has agreed to be evaluated or monitored through the program and who has separately agreed in writing to the consultant's access to and review of such information.

(f) A patient or the legal guardian or designated health care surrogate of an incapacitated patient who submits a written and notarized request that includes the patient's full name, address, phone number, date of birth, and a copy of a government-issued photo identification. A legal guardian or health care surrogate must provide the same information if he or she submits the request.

(6) The department may enter into a reciprocal agreement or contract to share prescription drug monitoring information with another state, district, or territory if the prescription drug monitoring programs of other states, districts, or territories are compatible with the Florida program.

(a) In determining compatibility, the department shall consider:

1. The safeguards for privacy of patient records and the success of the program in protecting patient privacy.

2. The persons authorized to view the data collected by the program. Comparable entities and licensed health care

practitioners in other states, districts, or territories of the United States, law enforcement agencies, the Attorney General's Medicaid Fraud Control Unit, medical regulatory boards, and, as needed, management staff that have similar duties as management staff who work with the prescription drug monitoring program as authorized in s. 893.0551 are authorized access upon approval by the department.

3. The schedules of the controlled substances that are monitored by the program.

4. The data reported to or included in the program's system.

5. Any implementing criteria deemed essential for a thorough comparison.

6. The costs and benefits to the state of sharing prescription information.

(b) The department must assess the prescription drug monitoring program's continued compatibility with the other state's, district's, or territory's program periodically.

(c) Any agreement or contract for sharing of prescription drug monitoring information between the department and another state, district, or territory shall contain the same restrictions and requirements as this section or s. 893.0551, and the information must be provided according to the department's determination of compatibility.

(7) The department may enter into agreements or contracts

to establish secure connections between the system and a prescribing or dispensing health care practitioner's electronic health recordkeeping system. The electronic health recordkeeping system owner or license holder will be responsible for ensuring that only authorized individuals have access to prescription drug monitoring program information.

(8) A prescriber or dispenser or a designee of a prescriber or dispenser must consult the system to review a patient's controlled substance dispensing history before prescribing or dispensing a controlled substance.

(a) The duty to consult the system does not apply to a prescriber or dispenser or designee of a prescriber or dispenser if the system is not operational, as determined by the department, or when it cannot be accessed by a health care practitioner because of a temporary technological or electrical failure.

(b) A prescriber or dispenser or designee of a prescriber or dispenser who does not consult the system under this subsection shall document the reason he or she did not consult the system in the patient's medical record or prescription record, and shall not prescribe or dispense greater than a 3-day supply of a controlled substance to the patient.

(c) The department shall issue a nondisciplinary citation to any prescriber or dispenser who fails to consult the system as required by this subsection.

(9) A person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(10) Information in the prescription drug monitoring program's system may be released only as provided in this subsection and s. 893.0551. The content of the system is intended to be informational only and imposes no obligations of any nature or any legal duty on a prescriber, dispenser, pharmacy, or patient. Information in the system shall be provided in accordance with s. 893.13(7)(a)8. and is not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of information in the system. The program manager and authorized persons who participate in preparing, reviewing, issuing, or any other activity related to management of the system may not be permitted or required to testify in any such civil or administrative action as to any findings, recommendations, evaluations, opinions, or other actions taken in connection with management of the system.

(11) A prescriber or dispenser, or his or her designee, may have access to the information under this section which relates to a patient of that prescriber or dispenser as needed for the purpose of reviewing the patient's controlled drug

prescription history. A prescriber or dispenser acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug monitoring program. This subsection does not create a private cause of action, and a person may not recover damages against a prescriber or dispenser authorized to access information under this subsection for accessing or failing to access such information.

(12)(a) All costs incurred by the department in administering the prescription drug monitoring program shall be funded through federal grants, private funding applied for or received by the state, or state funds appropriated in the General Appropriations Act. The department may not:

1. Commit funds for the monitoring program without ensuring funding is available; or

2. Use funds provided, directly or indirectly by prescription drug manufacturers to implement the program.

(b) The department shall cooperate with the direct-support organization established under subsection (15) in seeking federal grant funds, other nonstate grant funds, gifts, donations, or other private moneys for the department if the costs of doing so are immaterial. Immaterial costs include, but are not limited to, the costs of mailing and personnel assigned to research or apply for a grant. The department may

competitively procure and contract pursuant to s. 287.057 for any goods and services required be this section.

(13) The department shall conduct or participate in studies to examine the feasibility of enhancing the prescription drug monitoring program for the purposes of public health initiatives and statistical reporting. Such studies shall respect the privacy of the patient, the prescriber, and the dispenser. Such studies may be conducted by the department or a contracted vendor in order to:

(a) Improve the quality of health care services and safety by improving the prescribing and dispensing practices for prescription drugs;

(b) Take advantage of advances in technology;

(c) Reduce duplicative prescriptions and the overprescribing of prescription drugs; and

(d) Reduce drug abuse.

(14) The department shall annually report on performance measures to the Governor, the President of the Senate, and the Speaker of the House of Representatives by the department each December 1. Performance measures may include, but are not limited to, the following outcomes:

(a) Reduction of the rate of inappropriate use of prescription drugs through department education and safety efforts.

(b) Reduction of the quantity of pharmaceutical controlled

substances obtained by individuals attempting to engage in fraud and deceit.

(c) Increased coordination among partners participating in the prescription drug monitoring program.

(d) Involvement of stakeholders in achieving improved patient health care and safety and reduction of prescription drug abuse and prescription drug diversion.

(15) The department may establish a direct-support organization to provide assistance, funding, and promotional support for the activities authorized for the prescription drug monitoring program.

(a) As used in this subsection, the term "direct-support organization" means an organization that is:

1. A Florida corporation not for profit incorporated under chapter 617, exempted from filing fees, and approved by the Department of State.

2. Organized and operated to conduct programs and activities; raise funds; request and receive grants, gifts, and bequests of money; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or provide funding to or for the direct or indirect benefit of the department in the furtherance of the prescription drug monitoring program.

(b) The State Surgeon General shall appoint a board of

directors for the direct-support organization.

1. The board of directors shall consist of no fewer than five members who shall serve at the pleasure of the State Surgeon General.

2. The State Surgeon General shall provide guidance to members of the board to ensure that moneys received by the direct-support organization are not received from inappropriate sources. Inappropriate sources include, but are not limited to, donors, grantors, persons, or organizations that may monetarily or substantively benefit from the purchase of goods or services by the department in furtherance of the prescription drug monitoring program.

(c) The direct-support organization shall operate under written contract with the department. The contract must, at a minimum, provide for:

1. Approval of the articles of incorporation and bylaws of the direct-support organization by the department.

2. Submission of an annual budget for the approval of the department.

3. The reversion, without penalty, to the department's grants and donations trust fund for the administration of the prescription drug monitoring program of all moneys and property held in trust by the direct-support organization for the benefit of the prescription drug monitoring program if the direct-support organization ceases to exist or if the contract is

terminated.

4. The fiscal year of the direct-support organization, which must begin July 1 of each year and end June 30 of the following year.

5. The disclosure of the material provisions of the contract to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising publications, and an explanation to such donors of the distinction between the department and the direct-support organization.

6. The direct-support organization's collecting, expending, and providing of funds to the department for the development, implementation, and operation of the prescription drug monitoring program as described in this section. The direct-support organization may collect and expend funds to be used for the functions of the direct-support organization's board of directors, as necessary and approved by the department. In addition, the direct-support organization may collect and provide funding to the department in furtherance of the prescription drug monitoring program by:

a. Establishing and administering the prescription drug monitoring program's electronic system, including hardware and software.

b. Conducting studies on the efficiency and effectiveness of the program to include feasibility studies as described in

subsection (13).

c. Providing funds for future enhancements of the program within the intent of this section.

d. Providing user training of the prescription drug monitoring program, including distribution of materials to promote public awareness and education and conducting workshops or other meetings, for health care practitioners, pharmacists, and others as appropriate.

e. Providing funds for travel expenses.

f. Providing funds for administrative costs, including personnel, audits, facilities, and equipment.

g. Fulfilling all other requirements necessary to implement and operate the program as outlined in this section.

7. Certification by the department that the direct-support organization is complying with the terms of the contract in a manner consistent with and in furtherance of the goals and purposes of the prescription drug monitoring program and in the best interests of the state. Such certification must be made annually and reported in the official minutes of a meeting of the direct-support organization.

(d) The activities of the direct-support organization must be consistent with the goals and mission of the department, as determined by the department, and in the best interests of the state. The direct-support organization must obtain written approval from the department for any activities in support of

the prescription drug monitoring program before undertaking those activities.

(e) The direct-support organization shall provide for an independent annual financial audit in accordance with s. 215.981. Copies of the audit shall be provided to the department and the Office of Policy and Budget in the Executive Office of the Governor.

(f) The direct-support organization may not exercise any power under s. 617.0302(12) or (16).

(g) The direct-support organization is not considered a lobbying firm within the meaning of s.11.045.

(h) The department may permit, without charge, appropriate use of administrative services, property, and facilities of the department by the direct-support organization, subject to this section. The use must be directly in keeping with the approved purposes of the direct-support organization and may not be made at times or places that would unreasonably interfere with opportunities for the public to use such facilities for established purposes. Any moneys received from rentals of facilities and properties managed by the department may be held in a separate depository account in the name of the direct-support organization and subject to the provisions of the letter of agreement with the department. The letter of agreement must provide that any funds held in the separate depository account in the name of the direct-support organization must revert to

the department if the direct-support organization is no longer approved by the department to operate in the best interests of the state.

(i) The department may adopt rules under s. 120.54 to govern the use of administrative services, property, or facilities of the department or office by the direct-support organization.

(j) The department may not permit the use of any administrative services, property, or facilities of the state by a direct-support organization if that organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, gender, age, or national origin.

(k) This subsection is repealed October 1, 2027, unless reviewed and saved from repeal by the Legislature.

Section 10. Section 893.0551, Florida Statutes, is amended to read:

893.0551 Public records exemption for the prescription drug monitoring program.—

(1) For purposes of this section, the terms used in this section have the same meanings as provided in s. 893.055.

(2) The following information of a patient or patient's agent, a health care practitioner, a dispenser, an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy that is

contained in records held by the department under s. 893.055 is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution:

(a) Name.

(b) Address.

(c) Telephone number.

(d) Insurance plan number.

(e) Government-issued identification number.

(f) Provider number.

(g) Drug Enforcement Administration number.

(h) Any other unique identifying information or number.

(3) The department shall disclose such ~~confidential and exempt~~ information to the following persons or entities upon request and after using a verification process to ensure the legitimacy of the request as provided in s. 893.055:

(a) A health care practitioner, or his or her designee, who certifies that the information is necessary to provide medical treatment to a current patient in accordance with ss. 893.05 and 893.055.

(b) An employee of the United States Department of Veterans Affairs, United States Department of Defense, or the Indian Health Service who provides health care services pursuant to such employment and who has the authority to prescribe controlled substances shall have access to the information in the program's system upon verification of such employment.

(c) The program manager and designated support staff for administration of the program, and to provide relevant information to the prescriber, dispenser, and appropriate law enforcement agencies, in accordance with s. 893.055.

(d) The department for investigations involving licensees authorized to prescribe or dispense controlled substances. The department may request information from the program but may not have direct access to its system. The department may provide to a law enforcement agency pursuant to ss. 456.066 and 456.073 only information that is relevant to the specific controlled substances investigation that prompted the request for the information.

(e) ~~(a)~~ The Attorney General or his or her designee when working on Medicaid fraud cases involving prescribed controlled substances ~~prescription drugs~~ or when the Attorney General has initiated a review of specific identifiers of Medicaid fraud or specific identifiers that warrant a Medicaid investigation regarding prescribed controlled substances ~~prescription drugs~~. The Attorney General's Medicaid fraud investigators may not have direct access to the department's system ~~database~~. The Attorney General or his or her designee may disclose to a criminal justice agency, as defined in s. 119.011, only the ~~confidential and exempt~~ information received from the department that is relevant to an identified active investigation that prompted the request for the information.

~~(b) The department's relevant health care regulatory boards responsible for the licensure, regulation, or discipline of a practitioner, pharmacist, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a specific controlled substances investigation for prescription drugs involving a designated person. The health care regulatory boards may request information from the department but may not have direct access to its database. The health care regulatory boards may provide to a law enforcement agency pursuant to ss. 456.066 and 456.073 only information that is relevant to the specific controlled substances investigation that prompted the request for the information.~~

(f) ~~(c)~~ A law enforcement agency that has initiated an active investigation involving a specific violation of law regarding prescription drug abuse or diversion of prescribed controlled substances and that has entered into a user agreement with the department. A law enforcement agency may request information from the department but may not have direct access to its system ~~database~~. The law enforcement agency may disclose to a criminal justice agency, as defined in s. 119.011, only ~~confidential and exempt~~ information received from the department that is relevant to an identified active investigation that prompted the request for such information.

(g) A medical examiner or associate medical examiner, as

defined in s 406.06, pursuant to his or her official duties, as required by s. 406.11, to determine the cause of death of an individual. A medical examiner may request information from the department but may not have direct access to the system.

~~(f) A patient or the legal guardian or designated health care surrogate for an incapacitated patient, if applicable, making a request as provided in s. 893.055(7)(c)4.~~

(h) An impaired practitioner consultant who has been authorized in writing by a participant in, or by a referral to, the impaired practitioner program to access and review information as provided in s. 893.055(6)(e) ~~893.055(7)(c)5.~~

(i)~~(f)~~ A patient or the legal guardian or designated health care surrogate for an incapacitated patient, if applicable, making a request as provided in s. 893.055(6)(f) ~~893.055(7)(c)4~~.

(4) If the department determines consistent with its rules that a pattern of controlled substance abuse exists, the department may disclose such confidential and exempt information to the applicable law enforcement agency in accordance with s. 893.055. The law enforcement agency may disclose to a criminal justice agency, as defined in s. 119.011, only ~~confidential and exempt~~ information received from the department that is relevant to an identified active investigation that is specific to a violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b).

(5) Before disclosing ~~confidential and exempt~~ information to a criminal justice agency or a law enforcement agency pursuant to this section, the disclosing person or entity must take steps to ensure the continued confidentiality of all ~~confidential and exempt~~ information. At a minimum, these steps must include redacting any nonrelevant information.

(6) An agency or person who obtains any ~~confidential and exempt~~ information pursuant to this section must maintain the confidential and exempt status of that information and may not disclose such information unless authorized by law. Information shared with a state attorney pursuant to paragraph (3)(e) ~~(3)(a)~~ or paragraph (3)(f) ~~(3)(c)~~ may be released only in response to a discovery demand if such information is directly related to the criminal case for which the information was requested. Unrelated information may be released only upon an order of a court of competent jurisdiction.

(7) A person who willfully and knowingly violates this section commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Section 11. Paragraphs (pp) and (qq) of subsection (1) of section 458.331, Florida Statutes, are amended to read:

458.331 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(pp) Applicable to a licensee who serves as the designated physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137:

1. Registering a pain-management clinic through misrepresentation or fraud;

2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;

3. Failing to comply with any requirement of chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;

4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United States;

5. Being convicted of, or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for, any offense that would constitute a violation of this chapter;

6. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or

of the United States which relates to the practice of, or the ability to practice, a licensed health care profession;

7. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;

8. Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003(14) or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or

9. Failing to timely notify the board of the date of his or her termination from a pain-management clinic as required by s. 458.3265(3) ~~458.3265(2)~~.

(qq) Failing to timely notify the department of the theft of prescription blanks from a pain-management clinic or a breach of other methods for prescribing within 24 hours as required by s. 458.3265(3) ~~458.3265(2)~~.

Section 12. Paragraphs (rr) and (ss) of subsection (1) of section 459.015, Florida Statutes, are amended to read:

459.015 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(rr) Applicable to a licensee who serves as the designated

physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137:

1. Registering a pain-management clinic through misrepresentation or fraud;

2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;

3. Failing to comply with any requirement of chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;

4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United States;

5. Being convicted of, or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for, any offense that would constitute a violation of this chapter;

6. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the

ability to practice, a licensed health care profession;

7. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;

8. Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003(14) or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or

9. Failing to timely notify the board of the date of his or her termination from a pain-management clinic as required by s. 459.0137(3) ~~459.0137(2)~~.

(ss) Failing to timely notify the department of the theft of prescription blanks from a pain-management clinic or a breach of other methods for prescribing within 24 hours as required by s. 459.0137(3) ~~459.0137(2)~~.

Section 13. Paragraph (b) of subsection (4) of section 463.0055, Florida Statutes, is amended to read:

463.0055 Administration and prescription of ocular pharmaceutical agents.—

(4) A certified optometrist shall be issued a prescriber number by the board. Any prescription written by a certified optometrist for an ocular pharmaceutical agent pursuant to this section shall have the prescriber number printed thereon. A

certified optometrist may not administer or prescribe:

(b) A controlled substance for the treatment of chronic nonmalignant pain as defined in s. 456.44(1)(f) ~~456.44(1)(e)~~.

Section 14. Paragraph (a) of subsection (1) of section 782.04, Florida Statutes, is amended to read:

782.04 Murder.—

(1)(a) The unlawful killing of a human being:

1. When perpetrated from a premeditated design to effect the death of the person killed or any human being;

2. When committed by a person engaged in the perpetration of, or in the attempt to perpetrate, any:

a. Trafficking offense prohibited by s. 893.135(1),

b. Arson,

c. Sexual battery,

d. Robbery,

e. Burglary,

f. Kidnapping,

g. Escape,

h. Aggravated child abuse,

i. Aggravated abuse of an elderly person or disabled adult,

j. Aircraft piracy,

k. Unlawful throwing, placing, or discharging of a destructive device or bomb,

l. Carjacking,

m. Home-invasion robbery,

n. Aggravated stalking,

o. Murder of another human being,

p. Resisting an officer with violence to his or her person,

q. Aggravated fleeing or eluding with serious bodily injury or death,

r. Felony that is an act of terrorism or is in furtherance of an act of terrorism, including a felony under s. 775.30, s. 775.32, s. 775.33, s. 775.34, or s. 775.35, or

s. Human trafficking; or

3. Which resulted from the unlawful distribution by a person 18 years of age or older of any of the following substances, or mixture containing any of the following substances, when such substance or mixture is proven to be the proximate cause of the death of the user:

a. A substance controlled under s. 893.03(1);

b. Cocaine, as described in s. 893.03(2)(a)4.;

c. Opium or any synthetic or natural salt, compound, derivative, or preparation of opium;

d. Methadone;

e. Alfentanil, as described in s. 893.03(2)(b)1.;

f. Carfentanil, as described in s. 893.03(2)(b)6.;

g. Fentanyl, as described in s. 893.03(2)(b)9.;

h. Sufentanil, as described in s. 893.03(2)(b)30.

~~893.03(2)(b)29.~~; or

i. A controlled substance analog, as described in s. 893.0356, of any substance specified in sub-subparagraphs a.-h.,

is murder in the first degree and constitutes a capital felony, punishable as provided in s. 775.082.

Section 15. Paragraphs (a), (c), (d), (e), (f), and (h) of subsection (1), subsection (2), paragraphs (a) and (b) of subsection (4), and subsection (5) of section 893.13, Florida Statutes, are amended to read:

893.13 Prohibited acts; penalties.—

(1)(a) Except as authorized by this chapter and chapter 499, a person may not sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance. A person who violates this provision with respect to:

1. A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~ commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2. A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3. A controlled substance named or described in s.

893.03(5) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(c) Except as authorized by this chapter, a person may not sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance in, on, or within 1,000 feet of the real property comprising a child care facility as defined in s. 402.302 or a public or private elementary, middle, or secondary school between the hours of 6 a.m. and 12 midnight, or at any time in, on, or within 1,000 feet of real property comprising a state, county, or municipal park, a community center, or a publicly owned recreational facility. As used in this paragraph, the term "community center" means a facility operated by a nonprofit community-based organization for the provision of recreational, social, or educational services to the public. A person who violates this paragraph with respect to:

1. A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~ commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. The defendant must be sentenced to a minimum term of imprisonment of 3 calendar years unless the offense was committed within 1,000 feet of the real property comprising a child care facility as defined in s. 402.302.

2. A controlled substance named or described in s.

893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3. Any other controlled substance, except as lawfully sold, manufactured, or delivered, must be sentenced to pay a $500 fine and to serve 100 hours of public service in addition to any other penalty prescribed by law.

This paragraph does not apply to a child care facility unless the owner or operator of the facility posts a sign that is not less than 2 square feet in size with a word legend identifying the facility as a licensed child care facility and that is posted on the property of the child care facility in a conspicuous place where the sign is reasonably visible to the public.

(d) Except as authorized by this chapter, a person may not sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance in, on, or within 1,000 feet of the real property comprising a public or private college, university, or other postsecondary educational institution. A person who violates this paragraph with respect to:

1. A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5.

~~(2)(c)4.~~ commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2. A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3. Any other controlled substance, except as lawfully sold, manufactured, or delivered, must be sentenced to pay a $500 fine and to serve 100 hours of public service in addition to any other penalty prescribed by law.

(e) Except as authorized by this chapter, a person may not sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance not authorized by law in, on, or within 1,000 feet of a physical place for worship at which a church or religious organization regularly conducts religious services or within 1,000 feet of a convenience business as defined in s. 812.171. A person who violates this paragraph with respect to:

1. A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~ commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2. A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6.,

(2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3. Any other controlled substance, except as lawfully sold, manufactured, or delivered, must be sentenced to pay a $500 fine and to serve 100 hours of public service in addition to any other penalty prescribed by law.

(f) Except as authorized by this chapter, a person may not sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance in, on, or within 1,000 feet of the real property comprising a public housing facility at any time. As used in this section, the term "real property comprising a public housing facility" means real property, as defined in s. 421.03(12), of a public corporation created as a housing authority pursuant to part I of chapter 421. A person who violates this paragraph with respect to:

1. A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~ commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2. A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3. Any other controlled substance, except as lawfully sold, manufactured, or delivered, must be sentenced to pay a $500 fine and to serve 100 hours of public service in addition to any other penalty prescribed by law.

(h) Except as authorized by this chapter, a person may not sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance in, on, or within 1,000 feet of the real property comprising an assisted living facility, as that term is used in chapter 429. A person who violates this paragraph with respect to:

1. A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~ commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2. A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3. Any other controlled substance, except as lawfully sold, manufactured, or delivered, must be sentenced to pay a $500 fine and to serve 100 hours of public service in addition to any other penalty prescribed by law.

(2)(a) Except as authorized by this chapter and chapter 499, a person may not purchase, or possess with intent to

purchase, a controlled substance. A person who violates this provision with respect to:

1. A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~ commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2. A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3. A controlled substance named or described in s. 893.03(5) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(b) Except as provided in this chapter, a person may not purchase more than 10 grams of any substance named or described in s. 893.03(1)(a) or (1)(b), or any combination thereof, or any mixture containing any such substance. A person who violates this paragraph commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4) Except as authorized by this chapter, a person 18 years of age or older may not deliver any controlled substance to a person younger than 18 years of age, use or hire a person younger than 18 years of age as an agent or employee in the sale or delivery of such a substance, or use such person to assist in

avoiding detection or apprehension for a violation of this chapter. A person who violates this subsection with respect to:

(a) A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~ commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Imposition of sentence may not be suspended or deferred, and the person so convicted may not be placed on probation.

(5) A person may not bring into this state any controlled substance unless the possession of such controlled substance is authorized by this chapter or unless such person is licensed to do so by the appropriate federal agency. A person who violates this provision with respect to:

(a) A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~ commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b) A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6.,

(2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c) A controlled substance named or described in s. 893.03(5) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

Section 16. Paragraphs (c) and (f) of subsection (1) of section 893.135, Florida Statutes, are amended to read:

893.135 Trafficking; mandatory sentences; suspension or reduction of sentences; conspiracy to engage in trafficking.—

(1) Except as authorized in this chapter or in chapter 499 and notwithstanding the provisions of s. 893.13:

(c)1. A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 4 grams or more of any morphine, opium, hydromorphone, or any salt, derivative, isomer, or salt of an isomer thereof, including heroin, as described in s. 893.03(1)(b), (2)(a), (3)(c)3., or (3)(c)4., or 4 grams or more of any mixture containing any such substance, but less than 30 kilograms of such substance or mixture, commits a felony of the first degree, which felony shall be known as "trafficking in illegal drugs," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a. Is 4 grams or more, but less than 14 grams, such person

shall be sentenced to a mandatory minimum term of imprisonment of 3 years and shall be ordered to pay a fine of $50,000.

b. Is 14 grams or more, but less than 28 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 years and shall be ordered to pay a fine of $100,000.

c. Is 28 grams or more, but less than 30 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 25 years and shall be ordered to pay a fine of $500,000.

2. A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 14 grams or more of hydrocodone, as described in s. 893.03(2)(a)1.k. ~~893.03(2)(a)1.j.~~, codeine, as described in s. 893.03(2)(a)1.g., or any salt thereof, or 14 grams or more of any mixture containing any such substance, commits a felony of the first degree, which felony shall be known as "trafficking in hydrocodone," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a. Is 14 grams or more, but less than 28 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years and shall be ordered to pay a fine of $50,000.

b. Is 28 grams or more, but less than 50 grams, such

person shall be sentenced to a mandatory minimum term of imprisonment of 7 years and shall be ordered to pay a fine of $100,000.

c. Is 50 grams or more, but less than 200 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 years and shall be ordered to pay a fine of $500,000.

d. Is 200 grams or more, but less than 30 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 25 years and shall be ordered to pay a fine of $750,000.

3. A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 7 grams or more of oxycodone, as described in s. 893.03(2)(a)1.q. ~~893.03(2)(a)1.o.~~, or any salt thereof, or 7 grams or more of any mixture containing any such substance, commits a felony of the first degree, which felony shall be known as "trafficking in oxycodone," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a. Is 7 grams or more, but less than 14 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years and shall be ordered to pay a fine of $50,000.

b. Is 14 grams or more, but less than 25 grams, such person shall be sentenced to a mandatory minimum term of

imprisonment of 7 years and shall be ordered to pay a fine of $100,000.

c. Is 25 grams or more, but less than 100 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 years and shall be ordered to pay a fine of $500,000.

d. Is 100 grams or more, but less than 30 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 25 years and shall be ordered to pay a fine of $750,000.

4.a. A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 4 grams or more of:

(I) Alfentanil, as described in s. 893.03(2)(b)1.;

(II) Carfentanil, as described in s. 893.03(2)(b)6.;

(III) Fentanyl, as described in s. 893.03(2)(b)9.;

(IV) Sufentanil, as described in s. 893.03(2)(b)30. ~~893.03(2)(b)29.~~;

(V) A fentanyl derivative, as described in s. 893.03(1)(a)62.;

(VI) A controlled substance analog, as described in s. 893.0356, of any substance described in sub-sub-subparagraphs (I)-(V); or

(VII) A mixture containing any substance described in sub-

sub-subparagraphs (I)-(VI),

commits a felony of the first degree, which felony shall be known as "trafficking in fentanyl," punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

b. If the quantity involved under sub-subparagraph a.:

(I) Is 4 grams or more, but less than 14 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and shall be ordered to pay a fine of $50,000.

(II) Is 14 grams or more, but less than 28 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 years, and shall be ordered to pay a fine of $100,000.

(III) Is 28 grams or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 25 years, and shall be ordered to pay a fine of $500,000.

5. A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 30 kilograms or more of any morphine, opium, oxycodone, hydrocodone, codeine, hydromorphone, or any salt, derivative, isomer, or salt of an isomer thereof, including heroin, as described in s. 893.03(1)(b), (2)(a), (3)(c)3., or (3)(c)4., or 30 kilograms or more of any mixture containing any such substance, commits the

first degree felony of trafficking in illegal drugs. A person who has been convicted of the first degree felony of trafficking in illegal drugs under this subparagraph shall be punished by life imprisonment and is ineligible for any form of discretionary early release except pardon or executive clemency or conditional medical release under s. 947.149. However, if the court determines that, in addition to committing any act specified in this paragraph:

a. The person intentionally killed an individual or counseled, commanded, induced, procured, or caused the intentional killing of an individual and such killing was the result; or

b. The person's conduct in committing that act led to a natural, though not inevitable, lethal result,

such person commits the capital felony of trafficking in illegal drugs, punishable as provided in ss. 775.082 and 921.142. A person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

6. A person who knowingly brings into this state 60 kilograms or more of any morphine, opium, oxycodone, hydrocodone, codeine, hydromorphone, or any salt, derivative, isomer, or salt of an isomer thereof, including heroin, as described in s. 893.03(1)(b), (2)(a), (3)(c)3., or (3)(c)4., or

60 kilograms or more of any mixture containing any such substance, and who knows that the probable result of such importation would be the death of a person, commits capital importation of illegal drugs, a capital felony punishable as provided in ss. 775.082 and 921.142. A person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(f)1. Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 14 grams or more of amphetamine, as described in s. 893.03(2)(c)2., or methamphetamine, as described in s. 893.03(2)(c)5. ~~893.03(2)(c)4.~~, or of any mixture containing amphetamine or methamphetamine, or phenylacetone, phenylacetic acid, pseudoephedrine, or ephedrine in conjunction with other chemicals and equipment utilized in the manufacture of amphetamine or methamphetamine, commits a felony of the first degree, which felony shall be known as "trafficking in amphetamine," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a. Is 14 grams or more, but less than 28 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b. Is 28 grams or more, but less than 200 grams, such

person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c. Is 200 grams or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

2. Any person who knowingly manufactures or brings into this state 400 grams or more of amphetamine, as described in s. 893.03(2)(c)2., or methamphetamine, as described in s. 893.03(2)(c)5. ~~893.03(2)(c)4.~~, or of any mixture containing amphetamine or methamphetamine, or phenylacetone, phenylacetic acid, pseudoephedrine, or ephedrine in conjunction with other chemicals and equipment used in the manufacture of amphetamine or methamphetamine, and who knows that the probable result of such manufacture or importation would be the death of any person commits capital manufacture or importation of amphetamine, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

Section 17. Paragraphs (b), (c), and (e) of subsection (3) of section 921.0022, Florida Statutes, are amended to read:

921.0022 Criminal Punishment Code; offense severity ranking chart.—

(3) OFFENSE SEVERITY RANKING CHART

(b) LEVEL 2

Florida Statute	Felony Degree	Description
379.2431 (1)(e)3.	3rd	Possession of 11 or fewer marine turtle eggs in violation of the Marine Turtle Protection Act.
379.2431 (1)(e)4.	3rd	Possession of more than 11 marine turtle eggs in violation of the Marine Turtle Protection Act.
403.413(6)(c)	3rd	Dumps waste litter exceeding 500 lbs. in weight or 100 cubic feet in volume or any quantity for commercial purposes, or hazardous waste.
517.07(2)	3rd	Failure to furnish a prospectus meeting requirements.
590.28(1)	3rd	Intentional burning of lands.

784.05(3)	3rd	Storing or leaving a loaded firearm within reach of minor who uses it to inflict injury or death.
787.04(1)	3rd	In violation of court order, take, entice, etc., minor beyond state limits.
806.13(1)(b)3.	3rd	Criminal mischief; damage $1,000 or more to public communication or any other public service.
810.061(2)	3rd	Impairing or impeding telephone or power to a dwelling; facilitating or furthering burglary.
810.09(2)(e)	3rd	Trespassing on posted commercial horticulture property.
812.014(2)(c)1.	3rd	Grand theft, 3rd degree; $300

			or more but less than $5,000.
2187			
	812.014(2)(d)	3rd	Grand theft, 3rd degree; $100 or more but less than $300, taken from unenclosed curtilage of dwelling.
2188			
	812.015(7)	3rd	Possession, use, or attempted use of an antishoplifting or inventory control device countermeasure.
2189			
	817.234(1)(a)2.	3rd	False statement in support of insurance claim.
2190			
	817.481(3)(a)	3rd	Obtain credit or purchase with false, expired, counterfeit, etc., credit card, value over $300.
2191			
	817.52(3)	3rd	Failure to redeliver hired vehicle.
2192			
	817.54	3rd	With intent to defraud, obtain mortgage note, etc., by false

			representation.
2193			
	817.60(5)	3rd	Dealing in credit cards of another.
2194			
	817.60(6)(a)	3rd	Forgery; purchase goods, services with false card.
2195			
	817.61	3rd	Fraudulent use of credit cards over $100 or more within 6 months.
2196			
	826.04	3rd	Knowingly marries or has sexual intercourse with person to whom related.
2197			
	831.01	3rd	Forgery.
2198			
	831.02	3rd	Uttering forged instrument; utters or publishes alteration with intent to defraud.
2199			
	831.07	3rd	Forging bank bills, checks, drafts, or promissory notes.
2200			

831.08	3rd	Possessing 10 or more forged notes, bills, checks, or drafts.
831.09	3rd	Uttering forged notes, bills, checks, drafts, or promissory notes.
831.11	3rd	Bringing into the state forged bank bills, checks, drafts, or notes.
832.05(3)(a)	3rd	Cashing or depositing item with intent to defraud.
843.08	3rd	False personation.
893.13(2)(a)2.	3rd	Purchase of any s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., <u>(2)(c)10.,</u> (3), or (4) drugs other than cannabis.
893.147(2)	3rd	Manufacture or delivery of drug

paraphernalia.

(c) LEVEL 3

Florida Statute	Felony Degree	Description
119.10(2)(b)	3rd	Unlawful use of confidential information from police reports.
316.066 (3)(b)-(d)	3rd	Unlawfully obtaining or using confidential crash reports.
316.193(2)(b)	3rd	Felony DUI, 3rd conviction.
316.1935(2)	3rd	Fleeing or attempting to elude law enforcement officer in patrol vehicle with siren and lights activated.
319.30(4)	3rd	Possession by junkyard of motor vehicle with identification number plate removed.

319.33(1)(a)	3rd	Alter or forge any certificate of title to a motor vehicle or mobile home.
319.33(1)(c)	3rd	Procure or pass title on stolen vehicle.
319.33(4)	3rd	With intent to defraud, possess, sell, etc., a blank, forged, or unlawfully obtained title or registration.
327.35(2)(b)	3rd	Felony BUI.
328.05(2)	3rd	Possess, sell, or counterfeit fictitious, stolen, or fraudulent titles or bills of sale of vessels.
328.07(4)	3rd	Manufacture, exchange, or possess vessel with counterfeit or wrong ID number.
376.302(5)	3rd	Fraud related to reimbursement for cleanup expenses under the

			Inland Protection Trust Fund.
2222			
	379.2431 (1)(e)5.	3rd	Taking, disturbing, mutilating, destroying, causing to be destroyed, transferring, selling, offering to sell, molesting, or harassing marine turtles, marine turtle eggs, or marine turtle nests in violation of the Marine Turtle Protection Act.
2223			
	379.2431 (1)(e)6.	3rd	Possessing any marine turtle species or hatchling, or parts thereof, or the nest of any marine turtle species described in the Marine Turtle Protection Act.
2224			
	379.2431 (1)(e)7.	3rd	Soliciting to commit or conspiring to commit a violation of the Marine Turtle Protection Act.
2225			
	400.9935(4)(a)	3rd	Operating a clinic, or offering

or (b)		services requiring licensure, without a license.
400.9935(4)(e)	3rd	Filing a false license application or other required information or failing to report information.
440.1051(3)	3rd	False report of workers' compensation fraud or retaliation for making such a report.
501.001(2)(b)	2nd	Tampers with a consumer product or the container using materially false/misleading information.
624.401(4)(a)	3rd	Transacting insurance without a certificate of authority.
624.401(4)(b)1.	3rd	Transacting insurance without a certificate of authority; premium collected less than $20,000.

626.902(1)(a) & (b)	3rd	Representing an unauthorized insurer.
697.08	3rd	Equity skimming.
790.15(3)	3rd	Person directs another to discharge firearm from a vehicle.
806.10(1)	3rd	Maliciously injure, destroy, or interfere with vehicles or equipment used in firefighting.
806.10(2)	3rd	Interferes with or assaults firefighter in performance of duty.
810.09(2)(c)	3rd	Trespass on property other than structure or conveyance armed with firearm or dangerous weapon.
812.014(2)(c)2.	3rd	Grand theft; $5,000 or more but less than $10,000.

812.0145(2)(c)	3rd	Theft from person 65 years of age or older; $300 or more but less than $10,000.
815.04(5)(b)	2nd	Computer offense devised to defraud or obtain property.
817.034(4)(a)3.	3rd	Engages in scheme to defraud (Florida Communications Fraud Act), property valued at less than $20,000.
817.233	3rd	Burning to defraud insurer.
817.234 (8)(b) & (c)	3rd	Unlawful solicitation of persons involved in motor vehicle accidents.
817.234(11)(a)	3rd	Insurance fraud; property value less than $20,000.
817.236	3rd	Filing a false motor vehicle insurance application.

817.2361	3rd	Creating, marketing, or presenting a false or fraudulent motor vehicle insurance card.
817.413(2)	3rd	Sale of used goods as new.
828.12(2)	3rd	Tortures any animal with intent to inflict intense pain, serious physical injury, or death.
831.28(2)(a)	3rd	Counterfeiting a payment instrument with intent to defraud or possessing a counterfeit payment instrument.
831.29	2nd	Possession of instruments for counterfeiting driver licenses or identification cards.
838.021(3)(b)	3rd	Threatens unlawful harm to public servant.
843.19	3rd	Injure, disable, or kill police

			dog or horse.
2252			
	860.15(3)	3rd	Overcharging for repairs and parts.
2253			
	870.01(2)	3rd	Riot; inciting or encouraging.
2254			
	893.13(1)(a)2.	3rd	Sell, manufacture, or deliver cannabis (or other s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) drugs).
2255			
	893.13(1)(d)2.	2nd	Sell, manufacture, or deliver s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) drugs within 1,000 feet of university.
2256			
	893.13(1)(f)2.	2nd	Sell, manufacture, or deliver s. 893.03(1)(c), (2)(c)1.,

			(2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) drugs within 1,000 feet of public housing facility.
2257			
	893.13(4)(c)	3rd	Use or hire of minor; deliver to minor other controlled substances.
2258			
	893.13(6)(a)	3rd	Possession of any controlled substance other than felony possession of cannabis.
2259			
	893.13(7)(a)8.	3rd	Withhold information from practitioner regarding previous receipt of or prescription for a controlled substance.
2260			
	893.13(7)(a)9.	3rd	Obtain or attempt to obtain controlled substance by fraud, forgery, misrepresentation, etc.
2261			
	893.13(7)(a)10.	3rd	Affix false or forged label to

			package of controlled substance.
2262			
	893.13(7)(a)11.	3rd	Furnish false or fraudulent material information on any document or record required by chapter 893.
2263			
	893.13(8)(a)1.	3rd	Knowingly assist a patient, other person, or owner of an animal in obtaining a controlled substance through deceptive, untrue, or fraudulent representations in or related to the practitioner's practice.
2264			
	893.13(8)(a)2.	3rd	Employ a trick or scheme in the practitioner's practice to assist a patient, other person, or owner of an animal in obtaining a controlled substance.
2265			
	893.13(8)(a)3.	3rd	Knowingly write a prescription

			for a controlled substance for a fictitious person.
2266			
	893.13(8)(a)4.	3rd	Write a prescription for a controlled substance for a patient, other person, or an animal if the sole purpose of writing the prescription is a monetary benefit for the practitioner.
2267			
	918.13(1)(a)	3rd	Alter, destroy, or conceal investigation evidence.
2268			
	944.47 (1)(a)1. & 2.	3rd	Introduce contraband to correctional facility.
2269			
	944.47(1)(c)	2nd	Possess contraband while upon the grounds of a correctional institution.
2270			
	985.721	3rd	Escapes from a juvenile facility (secure detention or residential commitment facility).

(e) LEVEL 5

Florida Statute	Felony Degree	Description
316.027(2)(a)	3rd	Accidents involving personal injuries other than serious bodily injury, failure to stop; leaving scene.
316.1935(4)(a)	2nd	Aggravated fleeing or eluding.
316.80(2)	2nd	Unlawful conveyance of fuel; obtaining fuel fraudulently.
322.34(6)	3rd	Careless operation of motor vehicle with suspended license, resulting in death or serious bodily injury.
327.30(5)	3rd	Vessel accidents involving personal injury; leaving scene.
379.365(2)(c)1.	3rd	Violation of rules relating to:

			willful molestation of stone crab traps, lines, or buoys; illegal bartering, trading, or sale, conspiring or aiding in such barter, trade, or sale, or supplying, agreeing to supply, aiding in supplying, or giving away stone crab trap tags or certificates; making, altering, forging, counterfeiting, or reproducing stone crab trap tags; possession of forged, counterfeit, or imitation stone crab trap tags; and engaging in the commercial harvest of stone crabs while license is suspended or revoked.
2280			
	379.367(4)	3rd	Willful molestation of a commercial harvester's spiny lobster trap, line, or buoy.
2281			
	379.407(5)(b)3.	3rd	Possession of 100 or more undersized spiny lobsters.
2282			

381.0041(11)(b)	3rd	Donate blood, plasma, or organs knowing HIV positive.
440.10(1)(g)	2nd	Failure to obtain workers' compensation coverage.
440.105(5)	2nd	Unlawful solicitation for the purpose of making workers' compensation claims.
440.381(2)	2nd	Submission of false, misleading, or incomplete information with the purpose of avoiding or reducing workers' compensation premiums.
624.401(4)(b)2.	2nd	Transacting insurance without a certificate or authority; premium collected $20,000 or more but less than $100,000.
626.902(1)(c)	2nd	Representing an unauthorized insurer; repeat offender.
790.01(2)	3rd	Carrying a concealed firearm.

790.162	2nd	Threat to throw or discharge destructive device.
790.163(1)	2nd	False report of bomb, explosive, weapon of mass destruction, or use of firearms in violent manner.
790.221(1)	2nd	Possession of short-barreled shotgun or machine gun.
790.23	2nd	Felons in possession of firearms, ammunition, or electronic weapons or devices.
796.05(1)	2nd	Live on earnings of a prostitute; 1st offense.
800.04(6)(c)	3rd	Lewd or lascivious conduct; offender less than 18 years of age.
800.04(7)(b)	2nd	Lewd or lascivious exhibition; offender 18 years of age or

			older.
2296			
	806.111(1)	3rd	Possess, manufacture, or dispense fire bomb with intent to damage any structure or property.
2297			
	812.0145(2)(b)	2nd	Theft from person 65 years of age or older; $10,000 or more but less than $50,000.
2298			
	812.015(8)	3rd	Retail theft; property stolen is valued at $300 or more and one or more specified acts.
2299			
	812.019(1)	2nd	Stolen property; dealing in or trafficking in.
2300			
	812.131(2)(b)	3rd	Robbery by sudden snatching.
2301			
	812.16(2)	3rd	Owning, operating, or conducting a chop shop.
2302			
	817.034(4)(a)2.	2nd	Communications fraud, value $20,000 to $50,000.

817.234(11)(b)	2nd	Insurance fraud; property value $20,000 or more but less than $100,000.
817.2341(1), (2)(a) & (3)(a)	3rd	Filing false financial statements, making false entries of material fact or false statements regarding property values relating to the solvency of an insuring entity.
817.568(2)(b)	2nd	Fraudulent use of personal identification information; value of benefit, services received, payment avoided, or amount of injury or fraud, $5,000 or more or use of personal identification information of 10 or more persons.
817.611(2)(a)	2nd	Traffic in or possess 5 to 14 counterfeit credit cards or related documents.

817.625(2)(b)	2nd	Second or subsequent fraudulent use of scanning device, skimming device, or reencoder.
825.1025(4)	3rd	Lewd or lascivious exhibition in the presence of an elderly person or disabled adult.
827.071(4)	2nd	Possess with intent to promote any photographic material, motion picture, etc., which includes sexual conduct by a child.
827.071(5)	3rd	Possess, control, or intentionally view any photographic material, motion picture, etc., which includes sexual conduct by a child.
839.13(2)(b)	2nd	Falsifying records of an individual in the care and custody of a state agency involving great bodily harm or

			death.
2312			
	843.01	3rd	Resist officer with violence to person; resist arrest with violence.
2313			
	847.0135(5)(b)	2nd	Lewd or lascivious exhibition using computer; offender 18 years or older.
2314			
	847.0137 (2) & (3)	3rd	Transmission of pornography by electronic device or equipment.
2315			
	847.0138 (2) & (3)	3rd	Transmission of material harmful to minors to a minor by electronic device or equipment.
2316			
	874.05(1)(b)	2nd	Encouraging or recruiting another to join a criminal gang; second or subsequent offense.
2317			
	874.05(2)(a)	2nd	Encouraging or recruiting person under 13 years of age to join a criminal gang.

893.13(1)(a)1.	2nd	Sell, manufacture, or deliver cocaine (or other s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~ drugs).
893.13(1)(c)2.	2nd	Sell, manufacture, or deliver cannabis (or other s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (2)(c)10., (3), or (4) drugs) within 1,000 feet of a child care facility, school, or state, county, or municipal park or publicly owned recreational facility or community center.
893.13(1)(d)1.	1st	Sell, manufacture, or deliver cocaine (or other s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)5. ~~(2)(c)4.~~ drugs) within 1,000

			feet of university.
2321			
	893.13(1)(e)2.	2nd	Sell, manufacture, or deliver cannabis or other drug prohibited under s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., ~~(2)(c)5.,~~ (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., <u>(2)(c)10.,</u> (3), or (4) within 1,000 feet of property used for religious services or a specified business site.
2322			
	893.13(1)(f)1.	1st	Sell, manufacture, or deliver cocaine (or other s. 893.03(1)(a), (1)(b), (1)(d), or (2)(a), (2)(b), or <u>(2)(c)5.</u> ~~(2)(c)4.~~ drugs) within 1,000 feet of public housing facility.
2323			
	893.13(4)(b)	2nd	Use or hire of minor; deliver to minor other controlled substance.

893.1351(1)	3rd	Ownership, lease, or rental for trafficking in or manufacturing of controlled substance.

Section 18. Except as otherwise provided in this act, this act shall take effect July 1, 2018.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 21 (2018)

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	____	(Y/N)
ADOPTED AS AMENDED	____	(Y/N)
ADOPTED W/O OBJECTION	____	(Y/N)
FAILED TO ADOPT	____	(Y/N)
WITHDRAWN	____	(Y/N)
OTHER		

Committee/Subcommittee hearing bill: Health Quality Subcommittee

Representative Boyd offered the following:

Amendment

Remove line 1190 and insert:

(a) The department or the relevant health care regulatory board for investigations involving licensees

Remove line 1528 and insert:

(d) The department or the relevant health care regulatory board for investigations involving licensees

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 513 Distributing Pharmaceutical Drugs and Devices
SPONSOR(S): Rommel
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Langston	McElroy
2) Health & Human Services Committee			

SUMMARY ANALYSIS

Third-party logistics providers act as an intermediary between the manufacturer or distributor of prescription drugs and the consumer by providing supply chain logistics services and transportation. These entities do not take title to or have responsibility to direct the sale or disposition of the prescription drug.

The Florida Drug and Cosmetic Act, requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics. Most of the regulations relate to the distribution of prescription drugs into and within Florida. In particular, the regulations require various entities in the distribution chain, such as prescription drug manufacturers and wholesale distributors, medical device manufacturers, and third-party logistics providers to obtain permits.

The Board of Pharmacy recognizes six types of pharmacy permits, including Special Pharmacy – End Stage Renal Dialysis (ESRD). An ESRD permit is required for any person who provides dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address. Section 465.027(2), F.S., provides an exemption from pharmacy permitting requirements, including ESRD permits, for a manufacturer, or its agent, holding an active permit as a manufacturer under ch. 499, F.S., who is engaged solely in the manufacturer or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure.

Third-party logistics providers must obtain a third-party logistics provider permit to operate in Florida. Third-party logistics providers that provide dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home must also obtain an ESRD permit.

HB 513 expands the exemption from permitting requirements in s. 465.027(2), F.S., to third-party logistics providers who are engaged in the distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure.

The bill also removes the requirement that a manufacturer or its agent be engaged solely in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure to qualify for the 465.027(2), F.S., exemption.

The bill has no fiscal impact on local government, and may have a negative, indeterminate, insignificant impact on the Board of Pharmacy.

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Kidney Disease and Renal Dialysis

Chronic kidney disease is a condition in which a person gradually loses kidney function over time, and includes conditions that damage the kidneys and decrease their ability to process waste.[1] Renal dialysis is a common treatment for individuals with chronic kidney failure, and is used to:[2]

- Remove waste, salt, and extra water to prevent build up in the body.
- Maintain a safe level of certain chemicals in the blood, such as potassium, sodium, and bicarbonate.
- Control blood pressure.

Renal dialysis can be performed in a hospital, in a dialysis unit that is not part of a hospital, or in a person's home.[3] Additionally, there are two types of dialysis, hemodialysis and peritoneal dialysis.

In hemodialysis, an artificial kidney, called a hemodialyzer, is used to remove waste and extra chemicals and fluid from the blood.[4] Blood is pumped out of the body and into the hemodialyzer to be cleaned. The dialyzer, or filter, has two parts, separated by a thin membrane: one for blood and one for a washing fluid, called dialysate.[5] Blood cells and proteins remain in the blood because they are too large to pass through the membrane; however, smaller waste products, such as urea, creatinine, potassium and extra fluid pass through the membrane and are washed away.[6] The filtered blood is returned to the body when the process is complete.[7]

In peritoneal dialysis the inside lining of the stomach acts as a natural filter and wastes are taken out with dialysate, which is washed in and out of the stomach in cycles.[8] A catheter is surgically inserted into the stomach and is used to transfer the dialysate into and out of the stomach.[9] There are two kinds of peritoneal dialysis, continuous ambulatory peritoneal dialysis and automated peritoneal dialysis.[10] These are the same basic treatment; however, the former is manual and done while the person receiving treatment goes about normal daily activities, and the latter is a machine cycler that is usually done overnight, while the person is asleep.[11]

Regulation of Drugs, Devices, and Cosmetics in Florida

Part I of ch. 499, F.S., the Florida Drug and Cosmetic Act, requires the Department of Business and Professional Regulation (DBPR) to regulate drugs, devices, and cosmetics.[12] Most of the regulations

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[1] National Kidney Foundation, *About Chronic Kidney Disease*, available at https://www.kidney.org/kidneydisease/aboutckd (last visited January 7, 2018).
[2] National Kidney Foundation, *Dialysis*, https://www.kidney.org/atoz/content/dialysisinfo (last visited January 7, 2018).
[3] Id.
[4] National Kidney Foundation, *Hemodialysis*, https://www.kidney.org/atoz/content/hemodialysis (last visited January 7, 2018).
[5] National Kidney Foundation, *Peritoneal Dialysis: What You Need to Know*, https://www.kidney.org/atoz/content/peritoneal (last visited January 7, 2018).
[6] *Supra*, note 4.
[7] *Supra*, note 5.
[8] Id.
[9] Id.
[10] Id.
[11] Id.
[12] S. 27, ch. 2010-161, Laws of Fla., shifted responsibility for operation and enforcement of the Florida Drugs, Devices, and Cosmetics Act from the Department of Health to the Department of Business and Professional Regulation.

relate to the distribution of prescription drugs into and within Florida. The chapter also regulates manufacturing and distributing medical devices. In particular, the regulations require various entities in the distribution chain, such as prescription drug manufacturers and prescription drug wholesale distributors, to obtain permits. Florida has 18 distinct permits for these entities.[13]

Manufacturer Permits

DBPR offers nine different manufacturer and repackager permits for prescription drugs, over the counter drugs, cosmetics, and medical devices.

Prescription drug manufacturer permits are required for anyone that manufactures or distributes prescription drugs in Florida.[14] If someone manufactures prescription drugs outside of Florida, but distributes their prescription drugs in Florida, a nonresident prescription drug manufacturer permit is required, unless that person is permitted as a third party logistics provider.[15] Virtual permits are available for those who engages in the manufacture of prescription drugs but do not make or take physical possession of any prescription drugs.[16] An over-the-counter drug manufacturer permit is required for anyone manufacturing or repackaging over-the-counter drugs[17] and a cosmetic manufacturer permit is required for anyone manufacturing or repackaging cosmetics in Florida.[18]

A device manufacturer permit is required for anyone engaging in the manufacture, repackaging, or assembly of medical devices for human use unless the person only manufactures, repackages, or assembles medical devices or components: [19]

- Pursuant to a practitioner's order for a specific patient; or,
- That are registered with the federal Food and Drug Administration and satisfy specified statutory requirements.

Regulation of Pharmacies and Pharmacists

Pursuant to ch. 465, F.S., the Florida Board of Pharmacy, within the Department of Health, licenses and regulates the practice of pharmacy. The term "pharmacy" includes a community pharmacy,[20] an institutional pharmacy,[21] a nuclear pharmacy,[22] a special pharmacy,[23] and an internet pharmacy.[24] The

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[13] A permit is required for a prescription drug manufacturer; a prescription drug repackager; a nonresident prescription drug manufacturer; a prescription drug wholesale distributor; an out-of-state prescription drug wholesale distributor; a retail pharmacy drug wholesale distributor; a restricted prescription drug distributor; a complimentary drug distributor; a freight forwarder; a veterinary prescription drug retail establishment; a veterinary prescription drug wholesale distributor; a limited prescription drug veterinary wholesale distributor; an over-the-counter drug manufacturer; a device manufacturer; a cosmetic manufacturer; a third party logistics provider; or a health care clinic establishment. S. 499.01(1), F.S.
[14] S. 499.01(2)(a), F.S.
[15] S. 499.01(2)(c), F.S.
[16] S. 499.01(2)(a)1., F.S. and S. 499.01(2)(c), F.S.
[17] S. 499.01(2)(n), F.S.
[18] S. 499.01(2)(p), F.S. Someone that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a cosmetic manufacturer permit.
[19] S. 499.01(2)(o), F.S.
[20] A community pharmacy includes every location where medicinal drugs are compounded, dispensed, stored, or sold, or where prescriptions are filled or dispensed on an outpatient basis. S.465.003(11)(a)1., F.S.
[21] An institutional pharmacy includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold. S. 465.003(11)(a)2., F.S.
[22] A nuclear pharmacy includes every location were radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold, but does not include hospitals or the nuclear medicine facilities of hospitals. S. 465.003(11)(a)3., F.S.
[23] A special pharmacy includes every location where medicinal drugs are compounded, dispensed, stored, or sold, if not otherwise classified as a community pharmacy, institutional pharmacy, nuclear pharmacy, or internet pharmacy. S. 465.003(11)(a)4., F.S.
[24] An internet pharmacy includes locations not otherwise licensed or issued a permit pursuant to statute, within or outside of this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy. S. 465.003(11)(a)5., F.S.

board regulates the operation of pharmacies and disciplines pharmacies for failure to comply with state and federal regulations.[25]

The Board of Pharmacy recognizes six types of pharmacy permits, including Special Pharmacy - End Stage Renal Dialysis (ESRD).[26] An ESRD permit is required for any person who provides dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address.[27] To obtain an ESRD permit, an applicant must:[28]

- Complete an application and pay a $250 initial payment fee;
- Submit a legible set of fingerprint cards and $48 fee for each person having an ownership interest of at least 5 percent and any person who, directly or indirectly, manages, oversees, or controls the operation of the pharmacy, including officers and members of the board of directors, if the applicant is a corporation;
- Pass an on-site inspection;
- Provide written policies and procedures for preventing and controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships; and
- Designate a prescription department manager or consultant pharmacist of record.

Florida law provides an exemption to pharmacy permitting requirements, including ESRD permits, under limited circumstances. Specifically, s.465.027(2), F.S., exempts a manufacturer, or its agent, holding an active permit as a manufacturer under ch. 499, F.S., who is engaged solely in the manufacturer or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure from pharmacy permitting requirements if the dialysate, drugs, or devices are:

- Approved by the federal Food and Drug Administration, and
- Delivered in the original, sealed packaging to the patient for self-administration, to a health care practitioner, or an institution.

Regulation of Third-Party Logistics Providers

Third-party logistics providers act as an intermediary between the manufacturer or distributor of prescription drugs and the consumer by providing supply chain logistics services and transportation. A third party logistics provider contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf a manufacturer, wholesale distributor, or dispenser, but does not take title to or have responsibility to direct the sale or disposition of the prescription drug.[29] Third-party logistic providers must obtain a DBPR permit before operating in Florida and out-of-state third-party logistics providers must also be licensed in the state or territory from where it distributes the prescription drug.[30] Third-party logistics providers that provide dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home must also obtain an ESRD permit.

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[25] *See* ss. 465.022 and 465.023, F.S.
[26] Rule 64B16-28.100(5)(d), F.A.C.
[27] Rule 64B16-28.850(1), F.A.C.
[28] Rule 64b16-28.100(1) and (5), F.A.C.
[29] S. 499.01(2)(q), F.S.
[30] Id. If the state or territory from which the third party logistics provider originates does not require a license to operate as a third party logistics provider, the third party logistics provider must be licensed as a third party logistics provider as required under federal law.

Effect of Proposed Changes:

HB 513 expands the eligibility for the exemption from pharmacy permitting requirements in s. 465.027(2), F.S., to include third-party logistics providers who are engaged in the distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure. Third-party logistics provides will no longer be required to obtain an ESRD permit.

The bill also removes the requirement that a manufacturer be engaged *solely* in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure.

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 465.027, F.S., relating to exceptions.
Section 2: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The bill may have a negative, indeterminate, insignificant impact on the Board of Pharmacy from the loss of permitting revenues from third-party logistics providers that will no longer be required to hold an ESRD permit.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Third-party logistics providers made exempt from ch. 465, F.S., under the bill will no longer be required to pay an ESRD permitting fee, and as a result will realize a savings.

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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to distributing pharmaceutical drugs and devices; amending s. 465.027, F.S.; revising an exception to pharmacy regulations for certain manufacturers and distributors of dialysis drugs or supplies; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (2) of section 465.027, Florida Statutes, is amended to read:

465.027 Exceptions.—

(2) This chapter does ~~shall~~ not apply to a manufacturer, or its agent, holding an active manufacturer or third-party logistics provider permit ~~as a manufacturer~~ under chapter 499, to the extent the manufacturer, or its agent, is ~~and~~ engaged ~~solely~~ in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure, if the dialysate, drugs, or devices are:

(a) Approved or cleared by the United States Food and Drug Administration; and

(b) Delivered in the original, sealed packaging after receipt of a physician's order to dispense to:

1. A patient with chronic kidney failure, or the patient's

designee, for the patient's self-administration of the dialysis therapy; or

2. A health care practitioner or an institution for administration or delivery of the dialysis therapy to a patient with chronic kidney failure.

Section 2. This act shall take effect July 1, 2018.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 573 Involuntary Examinations Under the Baker Act
SPONSOR(S): Daniels and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 112

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	McElroy
2) Civil Justice & Claims Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

In 1971, the Legislature passed the Florida Mental Health Act ("Baker Act") to address the mental health needs of individuals in the state. The Baker Act allows for voluntary and, under certain circumstances, involuntary, examinations of individuals suspected of having a mental illness, and establishes procedures for courts, law enforcement, and certain health care practitioners to initiate such examinations.

Currently, the following health care practitioners may initiate the involuntary examination of a person under the Baker Act (some subject to certain training and experience requirements): a physician, a clinical psychologist, a psychiatric nurse, a mental health counselor, a marriage and family therapist, and a clinical social worker.

HB 573 adds advanced registered nurse practitioners and physician assistants to the list of health care practitioners who may initiate the involuntary examination of a person under the Baker Act.

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

The bill has an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Involuntary Examination under the Baker Act

In 1971, the Legislature passed the Florida Mental Health Act (also known as "The Baker Act"[1]), codified in part I of ch. 394, F.S., to address mental health needs in the state.[2] The Baker Act provides the authority and process for the voluntary and involuntary examination of persons who meet certain criteria, and the subsequent inpatient or outpatient placement of such individuals for treatment.

The Department of Children and Families (DCF) administers the Baker Act through receiving facilities which are designated by DCF. The receiving facility may be public or private and provides the initial examination and short-term treatment of persons who meet the criteria under the Baker Act.[3] A person who requires longer term treatment may be transported to a DCF-designated treatment facility. Treatment facilities are state owned, operated, or supported that hospitals, centers, or clinics that are provide extended treatment and hospitalization beyond what is provided in a receiving facility.[4]

Current law allows an involuntary examination if there is reason to believe a person has a mental illness and; because of the illness, the person:[5]

- Has refused a voluntary examination after explanation of the purpose of the exam or is unable to determine for himself or herself that an examination is needed; and
- Is likely to suffer from self-neglect or substantial harm to her or his well-being, or be a danger to himself or herself or others.

A person who is subject to an involuntary examination may not be held longer than 72 hours in a receiving facility.[6]

Courts, law enforcement officers, and certain health care practitioners are authorized to initiate such involuntary examinations.[7] A circuit court may enter an *ex parte* order stating a person meets the criteria for involuntary examination.[8] A law enforcement officer[9] may take a person into custody who

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[1] "The Baker Act" is named for its sponsor, Representative Maxine E. Baker, one of the first two women from Dade County elected to office in the Florida Legislature. As chair of the House Committee on Mental Health, she championed the treatment of mental illness in a manner that would not sacrifice a patient's rights and dignity. Baker served five terms as a member of the Florida House of Representatives from 1963-1972 and was instrumental in the passage of the Florida Mental Health Act. *See* University of Florida Smathers Libraries, *A Guide to the Maxine E. Baker Papers*, *available at* http://www.library.ufl.edu/spec/pkyonge/baker.htm (last visited December 13, 2017), and Department of Children and Families and University of South Florida, Department of Mental Health Law and Policy, *2014 Baker Act User Reference Guide: The Florida Mental Health Act* (2014), *available at* http://www.dcf.state.fl.us/programs/samh/mentalhealth/laws/BakerActManual.pdf (last visited December 13, 2017).

[2] Chapter 71-131, s. 1, Laws of Fla.

[3] Section 394.455(39), F.S.

[4] Section 394.455(47), F.S.

[5] Section 394.463(1), F.S. If the examination period ends on a weekend or a holiday, the person must be released no later than the next working day.

[6] Section 394.463(2)(g), F.S. For those under the age of 18, the examination must be initiated within 12 hours of arrival at the receiving facility.

[7] Section 394.463(2)(a), F.S.

[8] Id.

[9] "Law enforcement officer" means any person who is elected, appointed, or employed full time by any municipality or the state or any political subdivision thereof; who is vested with authority to bear arms and make arrests; and whose primary responsibility is the prevention and detection of crime or the enforcement of the penal, criminal, traffic, or highway laws of the state. This definition includes all certified supervisory and command personnel whose duties include, in whole or in part, the supervision, training, guidance, and management responsibilities of full-time law enforcement officers, part-time law enforcement officers, or auxiliary law enforcement officers but does not include support personnel employed by the employing agency. Section 943.10(1), F.S.

appears to meet the criteria for involuntary examination and transport them to a receiving facility for examination.[10] Health care practitioners may initiate an involuntary examination by executing the *Certificate of Professional Initiating an Involuntary Examination*, an official form adopted in rule by DCF.[11] The health care practitioner must have examined the person within the preceding 48 hours and state that the person meets the criteria for involuntary examination.[12] The Baker Act currently authorizes the following health care practitioners to initiate an involuntary examination by certificate:[13]

- A physician licensed under ch. 458, F.S., or ch. 459, F.S., who has experience in the diagnosis and treatment of mental and nervous disorders, or a physician employed by the United States Department of Veterans Affairs or Department of Defense.[14]
- A clinical psychologist, as defined in s. 490.003(7), F.S., with three years of postdoctoral experience in the practice of clinical psychology, inclusive of the experience required for licensure, or a psychologist employed by a facility operated by the United States Department of Veterans Affairs that qualifies as a receiving or treatment facility.[15]
- A psychiatric nurse who is certified as an advanced registered nurse practitioner under s. 464.012, who has a master's degree or a doctorate in psychiatric nursing, holds a national advanced practice certification as a psychiatric mental health advance practice nurse, and has two years of post-master's clinical experience under the supervision of a physician.[16]
- A mental health counselor licensed under ch. 491, F.S.
- A marriage and family therapist licensed under ch. 491, F.S.
- A clinical social worker licensed under ch. 491, F.S.

Between July 1, 2015 and June 30, 2016, there were 194,354 involuntary examinations initiated in the state. Law enforcement initiated half of the involuntary examinations (50.86 percent), followed closely by mental health professionals (47.27 percent), with the remaining initiated pursuant to *ex parte* orders by judges (1.88 percent).[17]

Physician Assistants

Physician assistant (PA) licensure in Florida is governed by ss. 458.347(7) and 459.022(7), F.S. The Department of Health (DOH) licenses PAs and the Florida Council on Physician Assistants (Council) regulates them.[18] PAs are also regulated by either the Florida Board of Medicine for PAs licensed under ch. 458, F.S., or the Florida Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S. The duty of a board and its members is to make disciplinary decisions concerning whether a doctor or PA has violated the provisions of his or her practice act.[19] There are 9,118 PAs who hold active licenses to practice in Florida.[20]

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[10] *Supra* note 7.
[11] The *Certificate of Professional Initiating an Involuntary Examination* is a form created by the DCF which must be executed by health care practitioners initiating an involuntary examination under The Baker Act. The form contains information related to the person's diagnosis and the health care practitioner's personal observations of statements and behaviors that support the involuntary examination of such person. *See* rule reference in Rule 65E-5.280, F.A.C. The form is also available at: http://www.dcf.state.fl.us/programs/samh/MentalHealth/laws/3052b.pdf (last visited December 13, 2017).
[12] Section 394.463(2)(a)3., F.S.
[13] Id.
[14] Section 394.455(32), F.S.
[15] Section 394.455(5), F.S.
[16] Section 394.455(35), F.S.
[17] Christy, A., et al., Baker Act Reporting Center, Louis de la Parte Florida Mental Health Institute, Department of Mental Health Law & Policy, University of South Florida, *Fiscal Year 2015/2016 Report Annual Report* (March 2017), available at http://www.usf.edu/cbcs/baker-act/documents/annual_report.pdf (last visited December 21, 2017).
[18] The Council consists of three physicians who are members of the Board of Medicine; one member who is a member of the Board of Osteopathic Medicine, and a physician assistant appointed by the State Surgeon General. (Sections 458.347(9) and 459.022(8), F.S.)
[19] Sections 458.347(12) and 459.022(12), F.S.
[20] Email correspondence with the Department of Health, dated December 14, 2017 (on file with the Health Quality Subcommittee).

PAs may only practice under the direct or indirect supervision of a medical doctor or doctor of osteopathic medicine with whom they have a clinical relationship.[21] A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[22] The supervising physician is responsible and liable for any acts or omissions of the PA and may not supervise more than four PAs at any time.[23]

To be licensed as a PA in Florida, an applicant must:[24]

- Submit a completed application and appropriate fees.[25]
- Complete of an approved PA training program;
- Obtain a passing score on the National Commission on Certification of Physician Assistant exam;
- Acknowledge any prior felony convictions;
- Submit to a background screening and have no disqualifying offenses;[26]
- Acknowledge any previous revocation or denial of licensure in any state; and
- A copy of course transcripts and a copy of the course description from a PA training program describing the course content in pharmacotherapy if the applicant is seeking prescribing authority.

Licenses are renewed biennially. At the time of renewal, must submit an acknowledgement that he or she has not been convicted of any felony in the previous two years and complete a physician assistant workforce survey.[27]

Florida law does not expressly allow PAs to refer for or initiate involuntary examinations under the Baker Act; however, in 2008, Attorney General Bill McCollum issued an opinion stating:

> A physician assistant pursuant to Chapter 458 or 459, Florida Statutes, may refer a patient for involuntary evaluation pursuant to section 394.463, Florida Statutes, provided that the physician assistant has experience regarding the diagnosis and treatment of mental and nervous disorders and such tasks are within the supervising physician's scope of practice.[28]

PAs are not required by law to have experience in the diagnosis and treatment of mental and nervous disorders.

Advanced Registered Nurse Practitioners

Nurses are licensure are licensed by DOH and regulated by the Board of Nursing pursuant to part I of ch. 464, F.S. Licensure requirements to practice nursing include completion of an approved educational course of study, passage of an examination approved by DOH, and acceptable criminal background screening results.[29]

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[21] Sections 458.347(2)(f) and 459.022(2)(f), F.S., define supervision as responsible supervision and control which requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.
[22] Rules 64B8-30.012 and 64B15-6.010, F.A.C.
[23] Sections 458.347(15) and 459.022(15), F.S.
[24] Sections 458.347(7) and 459.022(7), F.S.
[25] The application fee is $100 and the initial license fee is $205. *See* rr. 64B8-30.019, and 64B15-6.013, F.A.C.
[26] Section 456.0135, F.S.
[27] Sections 458.347(7)(b)-(c) and 459.022(7)(b)-(c), F.S.
[28] Op. Att'y Gen. Fla. 08-31 (2008), available at http://www.dcf.state.fl.us/programs/samh/MentalHealth/laws/agopinion.pdf (last visited December 13, 2017).
[29] Sections 464.008 and 464.009, F.S. As an alternative to licensure by examination, a nurse may also be eligible for licensure by endorsement.

A nurse who holds a current license to practice professional nursing may apply to be certified as an Advanced Registered Nurse Practitioner (ARNP), under s. 464.012, F.S., if the nurse meets one or both of the following requirements:

- Certification by a specialty board; or
- Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills.

Current law defines three categories of ARNPs: certified registered nurse anesthetists, certified nurse midwives, and nurse practitioners.[30] All ARNPs, regardless of practice category, may only practice within the framework of an established protocol and under the supervision of an allopathic or osteopathic physician or dentist.[31] ARNPs may carry out treatments as specified in statute, including:[32]

- Prescribing, dispensing, administering, or ordering any drug;[33]
- Initiating appropriate therapies for certain conditions;
- Ordering diagnostic tests and physical and occupational therapy;
- Ordering any medication for administration patients in certain facilities; and
- Performing additional functions as determined by rule.[34]

In addition to the above-allowed acts, an ARNP may also perform other acts as authorized by statute and within his or her specialty.[35] Further, if it is within an ARNP's established protocol, the ARNP may establish behavioral problems and diagnosis and make treatment recommendations.[36] There are 27,588 ARNPs who hold active licenses to practice in Florida.[37]

Currently, only ARNPs who are "psychiatric nurses" may initiate involuntary examinations under the Baker Act.[38] To qualify as a psychiatric nurse, an ARNP must have a master's or doctoral degree in psychiatric nursing, hold a national advance practice certification as a psychiatric mental health advanced practice nurse, and have two years post-master's clinical experience.[39]

Effect of Proposed Changes

HB 573 authorizes PAs and ARNPs to initiate involuntary examinations under the Baker Act. A PA or ARNP must execute a certificate stating that a person he or she examined within the preceding 48 hours appears to meet the criteria for an involuntary examination. Under current law, only a physician, clinical psychologist, psychiatric nurse, mental health counselor, marriage and family therapist or clinical social worker may initiate an involuntary examination by executing such a certificate.

The bill defines a "physician assistant" and an "advanced registered nurse practitioner" in the same manner as their respective practice acts (ss. 458.347, 459.022, and 464.003, F.S.).

The bill makes necessary conforming changes due to the statutory changes made by the bill.

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[30] Section 464.012(2), F.S.
[31] Section 464.012(3), F.S.
[32] Id.
[33] An ARNP may only prescribe controlled substances if he or she has graduated from a program leading to a master's or doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills. An ARNP is limited to prescribing a 7-day supply of Schedule II controlled substances. Only a psychiatric nurse may prescribe psychotropic controlled substances for the treatment of mental disorders and psychiatric mental health controlled substances for children younger than 18.
[34] Section 464.003(2), F.S., defines "advanced or specialized nursing practice" to include additional activities that an ARNP may perform as approved by the Board of Nursing.
[35] Section 464.012(4), F.S.
[36] Section 464.012(4)(c)1., F.S.
[37] Email correspondence with the Department of Health, dated December 14, 2017 (on file with the Health Quality Subcommittee).
[38] Section 394.463(2)(a), F.S.
[39] Section 394.455(35). F.S.

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 394.455, F.S., relating to definitions.
Section 2: Amends s. 394.463, F.S., relating to involuntary examinations.
Section 3: Amends s. 39.407, F.S., relating to medical, psychiatric, and psychological examination and treatment of child; physical, mental, or substance abuse examination of person with or requesting child custody.
Section 4: Amends s. 394.495, F.S., relating to child and adolescent mental health system care; programs and services.
Section 5: Amends s. 394.496, F.S., relating to service planning.
Section 6: Amends s. 394.9085, F.S., relating to behavioral provider liability.
Section 7: Amends s. 409.972, F.S., relating to mandatory and voluntary enrollment.
Section 8: Amends s. 744.2007, F.S., relating to powers and duties.
Section 9: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

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:

No additional rule-making authority is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to involuntary examinations under the Baker Act; amending s. 394.455, F.S.; defining terms; amending s. 394.463, F.S.; authorizing physician assistants and advanced registered nurse practitioners to execute a certificate under certain conditions stating that they have examined a person and find the person appears to meet the criteria for involuntary examination; amending ss. 39.407, 394.495, 394.496, 394.9085, 409.972, and 744.2007, F.S.; conforming cross-references; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Present subsections (5) through (48) of section 394.455, Florida Statutes, are redesignated as subsections (6) through (49), respectively, a new subsection (5) is added to that section, and present subsection (33) is amended, to read:

394.455 Definitions.—As used in this part, the term:

(5) "Advanced registered nurse practitioner" means a person licensed in this state to practice professional nursing and certified in advanced or specialized nursing practice, as defined in s. 464.003.

(34)~~(33)~~ "Physician assistant" has the same meaning as provided in s. 458.347(2) ~~means a person licensed under chapter~~

~~458 or chapter 459 who has experience in the diagnosis and treatment of mental disorders~~.

Section 2. Paragraph (a) of subsection (2) of section 394.463, Florida Statutes, is amended to read:

394.463 Involuntary examination.—

(2) INVOLUNTARY EXAMINATION.—

(a) An involuntary examination may be initiated by any one of the following means:

1. A circuit or county court may enter an ex parte order stating that a person appears to meet the criteria for involuntary examination and specifying the findings on which that conclusion is based. The ex parte order for involuntary examination must be based on written or oral sworn testimony that includes specific facts that support the findings. If other less restrictive means are not available, such as voluntary appearance for outpatient evaluation, a law enforcement officer, or other designated agent of the court, shall take the person into custody and deliver him or her to an appropriate, or the nearest, facility within the designated receiving system pursuant to s. 394.462 for involuntary examination. The order of the court shall be made a part of the patient's clinical record. A fee may not be charged for the filing of an order under this subsection. A facility accepting the patient based on this order must send a copy of the order to the department the next working day. The order may be submitted electronically through existing

data systems, if available. The order shall be valid only until the person is delivered to the facility or for the period specified in the order itself, whichever comes first. If no time limit is specified in the order, the order shall be valid for 7 days after the date that the order was signed.

2. A law enforcement officer shall take a person who appears to meet the criteria for involuntary examination into custody and deliver the person or have him or her delivered to an appropriate, or the nearest, facility within the designated receiving system pursuant to s. 394.462 for examination. The officer shall execute a written report detailing the circumstances under which the person was taken into custody, which must be made a part of the patient's clinical record. Any facility accepting the patient based on this report must send a copy of the report to the department the next working day.

3. A physician, physician assistant, clinical psychologist, psychiatric nurse, mental health counselor, marriage and family therapist, ~~or~~ clinical social worker, or an advanced registered nurse practitioner may execute a certificate stating that he or she has examined a person within the preceding 48 hours and finds that the person appears to meet the criteria for involuntary examination and stating the observations upon which that conclusion is based. If other less restrictive means, such as voluntary appearance for outpatient evaluation, are not available, a law enforcement officer shall

take into custody the person named in the certificate and deliver him or her to the appropriate, or nearest, facility within the designated receiving system pursuant to s. 394.462 for involuntary examination. The law enforcement officer shall execute a written report detailing the circumstances under which the person was taken into custody. The report and certificate shall be made a part of the patient's clinical record. Any facility accepting the patient based on this certificate must send a copy of the certificate to the department the next working day. The document may be submitted electronically through existing data systems, if applicable.

Section 3. Paragraph (a) of subsection (3) of section 39.407, Florida Statutes, is amended to read:

39.407 Medical, psychiatric, and psychological examination and treatment of child; physical, mental, or substance abuse examination of person with or requesting child custody.—

(3)(a)1. Except as otherwise provided in subparagraph (b)1. or paragraph (e), before the department provides psychotropic medications to a child in its custody, the prescribing physician shall attempt to obtain express and informed consent, as defined in s. 394.455 ~~s. 394.455(15)~~ and as described in s. 394.459(3)(a), from the child's parent or legal guardian. The department must take steps necessary to facilitate the inclusion of the parent in the child's consultation with the physician. However, if the parental rights of the parent have

been terminated, the parent's location or identity is unknown or cannot reasonably be ascertained, or the parent declines to give express and informed consent, the department may, after consultation with the prescribing physician, seek court authorization to provide the psychotropic medications to the child. Unless parental rights have been terminated and if it is possible to do so, the department shall continue to involve the parent in the decisionmaking process regarding the provision of psychotropic medications. If, at any time, a parent whose parental rights have not been terminated provides express and informed consent to the provision of a psychotropic medication, the requirements of this section that the department seek court authorization do not apply to that medication until such time as the parent no longer consents.

2. Any time the department seeks a medical evaluation to determine the need to initiate or continue a psychotropic medication for a child, the department must provide to the evaluating physician all pertinent medical information known to the department concerning that child.

Section 4. Subsection (3) of section 394.495, Florida Statutes, is amended to read:

394.495 Child and adolescent mental health system of care; programs and services.—

(3) Assessments must be performed by:

(a) A professional as defined in s. 394.455(6), (8), (33),

(36), or (37) ~~s. 394.455(5), (7), (32), (35), or (36)~~;

(b) A professional licensed under chapter 491; or

(c) A person who is under the direct supervision of a qualified professional as defined in s. 394.455(6), (8), (33), (36), or (37) ~~s. 394.455(5), (7), (32), (35), or (36)~~ or a professional licensed under chapter 491.

Section 5. Subsection (5) of section 394.496, Florida Statutes, is amended to read:

394.496 Service planning.—

(5) A professional as defined in s. 394.455(6), (8), (33), (36), or (37) ~~s. 394.455(5), (7), (32), (35), or (36)~~ or a professional licensed under chapter 491 must be included among those persons developing the services plan.

Section 6. Subsection (6) of section 394.9085, Florida Statutes, is amended to read:

394.9085 Behavioral provider liability.—

(6) For purposes of this section, the terms "detoxification services," "addictions receiving facility," and "receiving facility" have the same meanings as those provided in ss. 397.311(26)(a)4., 397.311(26)(a)1., and 394.455(40) ~~394.455(39)~~, respectively.

Section 7. Paragraph (b) of subsection (1) of section 409.972, Florida Statutes, is amended to read:

409.972 Mandatory and voluntary enrollment.—

(1) The following Medicaid-eligible persons are exempt

from mandatory managed care enrollment required by s. 409.965, and may voluntarily choose to participate in the managed medical assistance program:

(b) Medicaid recipients residing in residential commitment facilities operated through the Department of Juvenile Justice or a treatment facility as defined in s. 394.455(48) ~~s. 394.455(47)~~.

Section 8. Subsection (7) of section 744.2007, Florida Statutes, is amended to read:

744.2007 Powers and duties.—

(7) A public guardian may not commit a ward to a treatment facility, as defined in s. 394.455(48) ~~s. 394.455(47)~~, without an involuntary placement proceeding as provided by law.

Section 9. This act shall take effect July 1, 2018.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 673 Reporting Of Adverse Incidents In Planned Out-Of-Hospital Births
SPONSOR(S): Magar
TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 510

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

When planning for the birth of child, prospective parents may make a number of decisions about their childbirth experience, including where they want the child to be born and who they want to provide obstetrical care. There are several types of health care practitioners who may provide obstetric care: a physician, a physician assistant, a certified nurse midwife (an advanced registered nursing practitioner (ARNP) with specialized training in obstetric care), or a licensed midwife. A prospective parent may choose to have labor and childbirth occur in a hospital, birthing center, or home setting.

HB 673 requires a physician, certified nurse midwife, or licensed midwife attending a planned out-of-hospital birth to submit an adverse incident report to the Department of Health (DOH), within 15 days of the occurrence of the incident.

The bill defines an adverse incident as an event over which the physician, certified nurse midwife, or licensed midwife could exercise control and one of the following occurs during the process of childbirth:

- A maternal death that occurs after delivery or within 42 days after delivery;
- A maternal patient is transferred to a hospital intensive care unit;
- A maternal patient experiences hemorrhagic shock or requires a transfusion of more than four units of blood or blood products;
- A fetal or newborn death, including a still birth, attributable to an obstetrical delivery;
- A newborn patient is transferred to a hospital neonatal intensive care unit (NICU) due to a traumatic birth injury;
- A newborn patient is transferred to a hospital NICU 72 hours after birth if the newborn remains in the NICU for more than 72 hours; or
- Any other injury as determined by department rules.

The attending health care practitioner must provide a medical summary of the events in the adverse incident report. DOH must review each adverse incident report to determine whether the incident involves conduct for which the health care practitioner may be subject to disciplinary action by the appropriate regulatory board or if there is no board, DOH.

The bill authorizes DOH to adopt rules to develop the adverse incident form and to implement the provisions of the bill.

The bill will have an indeterminate, negative fiscal impact on the DOH related to the review of the adverse incident reports and any subsequent investigation and disciplinary cases that may result. The bill has no fiscal impact on local governments.

The bill takes effect upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Prior to giving birth, expectant parents will make a number of decisions in planning their childbirth experience. The parents may decide the location at which they would like to give birth, as well as the type of health care practitioner they would like to provide obstetrical services.[1] The decision on the type of practitioner may dictate the place where the birth may occur, and vice versa. In Florida, the health care practitioners that may attend a childbirth include a physician,[2] certified nurse midwife (CNM), and licensed midwife. Typically, there are three settings in which childbirths occur: hospitals, birthing centers, and home.[3]

Regulation of Health Care Practitioners

The Department of Health (DOH), Division of Medical Quality Assurance (MQA), is charged with the regulation of health care practitioners in this state.[4] MQA works in conjunction with regulatory boards to adopt rules and regulate health care practitioners.[5] For all health care professions regulated by MQA or regulatory boards, ch. 456, F.S., provides the general framework for licensure and regulation; however, the individual practice acts provide greater specificity for the regulation of a health care profession.

Each practice act provides licensure requirements, the scope of practice in which the health care practitioner may engage, as well disciplinary guidelines. To be licensed in this state, an applicant must meet the minimum licensure standards as provided in the practice act and any rules adopted by the regulatory board or DOH, if there is no board.

Physicians

Both allopathic and osteopathic physicians have a broad scope of practice; they may diagnose, treat, operate, or prescribe for any human disease, pain, injury, deformity, or other physical or mental condition.[6] However, a physician may be required to meet additional standards to practice in certain settings or perform certain medical acts. For example, physicians who wish to practice in a pain management clinic must meet certain training requirements.[7]

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[1] American Pregnancy Association, *Birthing Choices; Health Care Providers and Birth Locations*, (Sept. 6, 2016), available at http://americanpregnancy.org/labor-and-birth/birthing-choices/ (last visited on December 14, 2017).
[2] A physician may delegate the performance of medical acts to a physician assistant under his or her supervision unless such delegation is expressly prohibited by law. (Sections 458.347(4), and 459.022(e), F.S.) The physician remains liable for any acts or omissions of the physician assistant acting under his or her supervision or control. *See* ss. 458.347(15), and 459.022(15), F.S.
[3] Centers for Disease Control and Prevention, *Trends in Out-of-Hospital Births in the United States, 1990-2012*, (March 4, 2014), available at https://www.cdc.gov/nchs/products/databriefs/db144.htm (last visited December 18, 2017).
[4] Pursuant to s. 456.001(4), F.S., health care practitioners are defined to include acupuncturists, physicians, physician assistants, chiropractors, podiatrists, naturopaths, dentists, dental hygienists, optometrists, nurses, nursing assistants, pharmacists, midwives, speech language pathologists, nursing home administrators, occupational therapists, respiratory therapists, dieticians, athletic trainers, orthotists, prosthetists, electrologists, massage therapists, clinical laboratory personnel, medical physicists, dispensers of optical devices or hearing aids, physical therapists, psychologists, social workers, counselors, and psychotherapists, among others.
[5] Section 456.001(1), F.S.
[6] Sections 458.305(3), and 459.003(3), F.S. However, an osteopathic physician's practice is based in part on education which emphasizes the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health.
[7] Rules 64B8-9.0131 and 6415-14.0051, F.A.C.

A physician is expected to practice in a safe and competent manner.[8] A physician who fails to do so may be subject to discipline against his or her license to practice in this state.[9] For example, a physician's license may be disciplined for, among other things:

- Committing medical malpractice;[10]
- Practicing outside his or her scope of practice or performing professional responsibilities that he or she knows or has reason to know that he or she cannot perform competently;[11]
- Delegating a professional responsibility to a person he or she knows or has reason to know that such person is not qualified to perform;[12] or
- Failing to adequately supervise a physician assistant, advanced registered nurse practitioner (ARNP), or other health care practitioner acting under his or her supervision.[13]

Adverse Incident Reporting

A physician or physician assistant is required to report to DOH, any adverse incident occurring in an office practice setting within 15 days after the occurrence of the adverse incident.[14] DOH must review each report to determine if discipline against the practitioner's license is warranted.[15]

An adverse incident in an office setting is defined as an event over which the physician or licensee could exercise control and which is associated with a medical intervention and results in one of the following patient injuries:[16]

- The death of a patient;
- Brain or spinal damage to a patient;
- The performance of a surgical procedure on the wrong patient;
- If the procedure results in death; brain or spinal damage; permanent disfigurement; the fracture or dislocation of bones or joints; a limitation of neurological, physical, or sensory functions; or any condition that required the transfer of a patient, the performance of:
    - A wrong-site surgical procedure;
    - A wrong surgical procedure; or
    - A surgical repair of damage to a patient resulting from a planned surgical procedure where the damage is not a recognized specific risk as disclosed to the patient and documented through the informed consent process;
- A procedure to remove unplanned foreign objects remaining from a surgical procedure; or
- Any condition that required the transfer of a patient to a hospital from an ambulatory surgical center or any facility or any office maintained by a physician for the practice of medicine which is not licensed under ch. 395, F.S.

There is no statutory requirement for a physician to report an adverse incident that occurs outside of an office or hospital setting.

Certified Nurse Practitioners

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[8] Sections 458.301 and 459.001, F.S.
[9] Sections 458.331 and 459.015, F.S., provide the grounds for which disciplinary action may be taken against a physician's license. Section 456.072, F.S., provides grounds for discipline that apply to all licensed health care practitioners.
[10] Sections 456.331(1)(t), and 459.015(1)(x), F.S. Medical malpractice is the failure to practice medicine in accordance with the care, skill, and treatment recognized in general law related to health care licensure (s. 456.50(1)(g), F.S.
[11] Sections 458.331(1)(v) and 459.015(1)(z), F.S.
[12] Sections 458.331(1)(w) and 459.015(1)(aa), F.S.
[13] Sections 458.331(1)(dd) and 459.015(1)(hh), F.S.
[14] Sections 458.351 and 459.026, F.S.
[15] Sections 458.351(5) and 459.026(5), F.S.
[16] Sections 458.351(4) and 459.026(4), F.S.

An advanced registered nurse practitioner (ARNP) may perform advanced-level nursing acts approved by the Board of Nursing which, by virtue of postbasic specialized education, training, and experience are appropriately performed by an ARNP, in addition to the professional nursing acts that registered nurses are authorized to perform.[17] In addition to advanced or specialized nursing practices, ARNPs are authorized to practice certain medical acts, as opposed to nursing acts, as authorized within the framework of an established supervisory physician's protocol.[18]

To be eligible to be certified as an ARNP, the applicant must be licensed as a registered nurse, and have a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills or submit proof that the applicant holds a current national advanced practice certification from a board-approved nursing specialty board.[19] In Florida, an ARNP may be categorized as a certified nurse practitioner (CNP), certified nurse midwife (CNM), or certified registered nurse anesthetist (CRNA).[20]

A CNM may, to the extent authorized under a supervisory protocol, perform the following acts in a healthcare facility where midwifery services are performed or in the patient's home:[21]

- Superficial minor surgical procedures;
- Manage the patient's labor and delivery to include amniotomy, episiotomy, and repair;
- Order, initiate, perform appropriate anesthetic procedures;
- Perform postpartum examinations;
- Order appropriate medications;
- Provide family-planning services and well-woman care; and
- Manage the medical care of the normal obstetrical patient and the initial care of a newborn patient.

An ARNP is expected to practice in a safe and competent manner.[22] An ARNP who fails to do so may be subject to discipline against his or her license to practice in this state.[23] For example, an ARNP may be disciplined for failing to meet the minimum standard of care for nursing practice, including engaging in acts for which he or she is not qualified by training or experience.[24]

There is no statutory requirement for an ARNP or a CNM to report adverse incidents to DOH.

Licensed Midwives

DOH is responsible for the licensure and regulation of the practice of midwifery in this state. The Council of Licensed Midwifery assists and advises DOH on midwifery, including the development of rules relating to regulatory requirements, including but not limited to training requirements, the licensure examination, responsibilities of midwives, emergency care plans, and reports and records to be filed by licensed midwives.[25]

To be licensed as a midwife, an applicant must graduate from an approved midwifery program, and pass the licensure examination.[26] Along with an application for licensure or licensure renewal, a licensed midwife must submit a general emergency care plan which addresses consultation with other

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[17] Section 464.003(2)-(3), F.S.
[18] Id.
[19] Section 464.012(1), F.S., and Rule 64B9-4.002, F.A.C.
[20] Section 464.012(4), F.S.
[21] Section 464.012(4)(b), F.S.
[22] Section 464.002, F.S.
[23] Section 464.018, F.S., provide the grounds for which disciplinary action may be taken against the license. Section 456.072, F.S., provides grounds for discipline that apply to all licensed health care practitioners.
[24] Section 464.018(1)(n), F.S.
[25] Section 467.004, F.S.
[26] Section 467.011, F.S. Section 467.0125, F.S., provides for licensure by endorsement for applicants who hold a valid license to practice midwifery in another state.

health care providers, emergency transfer protocols, and access to neonatal intensive care units and obstetrical units or other patient care areas.[27]

A licensed midwife is responsible for ensuring the following conditions are met:[28]

- Accepting only those patients who are expect to have a normal pregnancy, labor, and delivery;
- Ensuring that each patient has signed an informed consent form developed by DOH, which informs the patient of the qualifications of the licensed midwife, the nature and risk of the procedures to be performed by the licensed midwife, and to obtain the patient's consent for the provision of midwifery services;
- Determining if the home is safe and hygienic if the patient is delivering at home;
- Voluntarily entering into a collaborative agreement with a physician for prenatal and postpartal care to women who are not expected to have a normal pregnancy, labor, and delivery within the framework of a written protocol;
- Administering prophylactic ophthalmic medication, oxygen, postpartum oxytocin, vitamin K, rho immune globulin, local anesthetic, or other medicinal drugs pursuant to a prescription issued by a practitioner licensed under ch. 458, F.S., or ch. 459, F.S.
- Providing care to mothers and infants throughout the prenatal, intrapartal, and postpartal periods in compliance with the law;
- Preparing a written plan of action with the family to ensure continuity of medical care throughout labor and delivery and to provide for immediate medical care if an emergency arises;
- Instructing the patient and family regarding the preparation of the environment and ensure the availability of equipment and supplies needed for delivery and infant care if a home birth is planned;
- Instructing the patient in the hygiene of pregnancy and nutrition as it relates to prenatal care;
- Maintaining appropriate equipment and supplies, as required by rule;
- Determining the progress of labor, and when birth is imminent, be immediately available until delivery is accomplished, including:
    - Maintaining a safe and hygienic environment;
    - Monitoring the progress of labor and the status of the fetus;
    - Recognizing the early signs of distress or complications; and
    - Enacting the written emergency plan when indicated;
- Remaining with the postpartal mother until the mother and neonate are stabilized; and
- Instilling a prophylactic into each eye of the newborn infant within one hour after birth for the prevention of neonatal ophthalmia.[29]

Annually, licensed midwives must file an "Annual Report of Midwifery Practice," by July 31.[30] The report requires each licensed midwife to detail information regarding the number of clients seen in the previous fiscal year (July 1 to June 30), the types of births performed, maternal and newborn transfers, fetal deaths (stillbirths and neonatal), and maternal deaths.

There is no statutory requirement for a licensed midwife to report adverse incidents to DOH. However, by rule, a licensed midwife must report maternal and fetal deaths, as well as maternal and newborn transfers as a part of the annual report.

Childbirth Settings

[27] Section 467.017, F.S.
[28] Section 467.015, F.S.
[29] Section 383.04, F.S.
[30] Rule 64B24-7.014, F.A.C.

In 1900, almost all childbirths in the United States occurred outside of hospital; however, by 1969 that figure had fallen to one percent of all births.[31] In 2015, 1.5 percent of all births in the U.S. occurred outside of a hospital.[32] Of those, 63.1 percent occurred in a home or residence, and 30.9 percent occurred in a freestanding birthing center.[33] In Florida, 0.9 percent of births occurred at home in 2015.[34]

Hospitals

Hospitals are licensed and regulated under ch. 395, F.S., and part II of ch. 408, F.S., by the Agency for Health Care Administration (AHCA).

Every licensed hospital is required to establish and maintain an internal risk management program that is overseen by a health care risk manager.[35] As a part of its risk management program, a hospital must have an incident reporting system which places an affirmative duty on all health care providers, as well the agents and employees of the hospital, to report adverse incidents to the risk manager within 3 business days after their occurrence.[36] The hospital must annually submit a report to AHCA summarizing the incident reports filed in the facility for that year.[37]

An adverse incident is defined as an event over which health care personnel could exercise control and which is associated with a medical intervention which results in:[38]

- One of the following patient injuries:
  - Death;
  - Brain or spinal damage;
  - Permanent disfigurement;
  - Fracture or dislocation of bones or joints;
  - A resulting limitation of neurological, physical, or sensory functions which continue after discharge from the facility
  - Any condition that requires specialized medical attention or surgical intervention resulting from a nonemergency medical intervention to which the patient has not given his or her informed consent; or
  - Any condition that required the transfer of a patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;
- The performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's medical condition;
- Required surgical repair of damage resulting from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient through the informed consent process; or
- A procedure to remove unplanned foreign objects remaining from a surgical procedure.

Any of the following adverse incidents, whether occurring in the hospital or arising from health care prior to admission, must be reported to AHCA within 15 calendar days after occurrence:[39]

- Death of a patient;

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[31] National Center for Health Statistics, *Trends in Out-Of-Hospital Births in the United States, 1990-2012*, NCHS DATA BRIEF, No. 144, (March 2014), available

[32] Joyce A. Martin, et. al., *Births: Final Data for 2015*, NATIONAL VITAL STATISTICS REPORTS, 66:1 (Jan. 5, 2017), available at https://www.cdc.gov/nchs/data/nvsr/nvsr66/nvsr66_01.pdf (last visited December 18, 2017).

[33] Id

[34] Id.

[35] Section 395.0197, F.S.

[36] Section 395.0197(1)(e), F.S.

[37] Section 395.0197(6), F.S.

[38] Section 395.0197(5), F.S.

[39] Section 395.0197(7), F.S.

- Brain or spinal damage to a patient;
- The performance of a surgical procedure on the wrong patient;
- The performance of a wrong-site surgical procedure;
- The performance of a wrong surgical procedure;
- The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's medical condition;
- The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient through the informed consent process; or
- The performance of a procedure to remove unplanned foreign objects remaining from a surgical procedure.

Birth Centers

A birth center is any facility, institution, or place, which is not an ambulatory surgical center, a hospital or in a hospital, in which births are planned to occur away from the mother's usual residence following a normal, uncomplicated, low-risk pregnancy.[40] Birth centers are licensed and regulated by AHCA under ch. 383. F.S., and part II of ch. 408, F.S.

A birth center may only accept those patients who are expected to have normal pregnancies and deliveries; and prior to being accepted for care, the patient must sign an informed consent form.[41] A mother and her infant must be discharged from a birth center within 24 hours after giving birth, except when:[42]

- The mother is in a deep sleep at the end of the 24-hour period; in which case, the mother must be discharged as soon after waking as feasible; or
- The 24-hour period is completed during the middle of the night.

If a mother or infant must remain in the birth center for longer than 24 hours after giving birth for a reason other than those listed above, the birth center must file a report with AHCA within 48 hours of the birth describing the circumstances and the reasons for the decision.[43]

A birth center is required for maintaining the quality of care by:[44]

- Having at least one clinical staff[45] member for every two clients in labor;
- Having a clinical staff member or qualified personnel[46] available on site during the entire time a client is in the birth center. Services during labor and delivery must be provided by a physician, certified nurse midwife, or licensed midwife, assisted by at least one other staff member under protocols developed by clinical staff;
- Ensuring all qualified personnel and clinical staff are trained in infant and adult resuscitation and requiring qualified personnel or clinical staff who is able to perform neonatal resuscitation to be present during each birth;
- Maintaining complete and accurate medical records;
- Evaluating the quality of care by reviewing clinical records;

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[40] Section 383.302(2), F.S.
[41] Section 383.31, F.S. The informed consent form must advise the patient of the qualifications of the clinical staff, the risks related to out-of-hospital births, the benefits of out-of-hospital births, and the possibility of referral or transfer if complications arise during pregnancy or childbirth with additional costs for services rendered (r. 59A-11.010, F.A.C.)
[42] Section 383.318(1), F.S., and Rule 59A-11.016(6), F.A.C.
[43] Section 383.318(1), F.S.
[44] Rule 59A-11.005(3), F.A.C.
[45] Section 383.302(3), F.S., defines "clinical staff" as individuals employed full-time or part-time by a birth center who are licensed or certified to provide care at childbirth.
[46] Rule 59A-11.002(6), F.A.C., defines "qualified staff" as an individual who is trained and competent in the services that he or she provides and is licensed or certified when required by statute or professional standard.

- Reviewing admissions with respect to eligibility, course of pregnancy and outcome, evaluation of services, condition of mother and newborn on discharge, or transfer to other providers; and
- Surveillance of infection risk and cases and the promotion of preventive and corrective program designed to minimize hazards.

A birth center must be equipped with those items needed to provide low-risk maternity care and readily available equipment to initiate emergency procedures in life-threatening events to a mother and baby.[47] Each facility must have an arrangement with a local ambulance service for the transport of emergency patients to a hospital, which must be documented in the facilities policy and procedures manual.[48]

A birth center must submit an annual report to AHCA by July 30 of each year that details, among other things:[49]

- The number of deliveries by birth weight;
- The number of maternity clients accepted for care and length of stay;
- The number of surgical procedures performed at the birth center by type;
- Maternal transfers, including the reason for the transfer, whether it occurred intrapartum or postpartum, and the length of the hospital stay;
- Newborn transfers, including the reason for the transfer, birth weight, days in hospital, and APGAR score at five and ten minutes;
- Newborn deaths; and
- Stillborn/Fetal deaths.

Home Births

The home delivery setting is not regulated. However, the health care practitioners who perform such services, including physicians, physician assistants, certified nurse midwives, and licensed midwives are regulated by their respective regulatory boards, or in the case of licensed midwives, DOH.

Effect of Proposed Changes

HB 673 requires that a physician, certified nurse midwife, or licensed midwife attending a planned out-of-hospital birth submit an adverse incident report to the Department of Health (DOH), within 15 days of the occurrence of the incident.

The bill defines an adverse incident as an event over which the physician, certified nurse midwife, or licensed midwife could exercise control and one of the following occurs during the process of childbirth:

- A maternal death that occurs after delivery or within 42 days after delivery;
- A maternal patient is transferred to a hospital intensive care unit;
- A maternal patient experiences hemorrhagic shock or requires a transfusion of more than four units of blood or blood products;
- A fetal or newborn death, including a still birth, attributable to an obstetrical delivery;
- A newborn patient is transferred to a hospital neonatal intensive care unit (NICU) due to a traumatic birth injury;
- A newborn patient is transferred to a hospital NICU 72 hours after birth if the newborn remains in the NICU for more than 72 hours; or
- Any other injury as determined by department rules.

In the adverse injury report, the attending health care practitioner must provide a medical summary of the events. DOH must review each adverse incident report to determine whether the incident involves

[47] Section 383.308(2)(a), F.S.
[48] Section 383.316, F.S.
[49] Rule 59A-11.019, F.A.C., and AHCA Form 3130-3004, (Feb. 2015).

conduct for which the health care practitioner may be subject to disciplinary action by the appropriate regulatory board or if there is no board, DOH.

The bill authorizes DOH to adopt rules to develop the adverse incident form and to implement the provisions of the bill.

The bill takes effect upon becoming law.

B. SECTION DIRECTORY:

Section 1: Creates s. 456.0495, F.S., relating to reporting adverse incidents occurring in planned out-of-hospital births.

Section 2: Provides that the act takes effect upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH will incur a recurring, indeterminate negative fiscal impact related to the increase in workload associated with the review of adverse incident reports required to be submitted under the provisions of the bill, as well associated complaints and investigations that may be generated.[50]

   DOH will incur an insignificant, nonrecurring negative fiscal impact for developing the adverse incident report form and rule-making; however, current resources are adequate to absorb such costs.[51]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care practitioners who provide planned childbirth services outside of a hospital may incur administrative costs to comply with the adverse incident reporting required by the bill.

D. FISCAL COMMENTS:

None.

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[50] DOH, *2018 Agency Legislative Bill Analysis for Senate Bill 510*, (Nov. 20, 2017), on file with the Health Quality Subcommittee. Senate Bill 510 is substantively similar to House Bill 673.

[51] Id.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not applicable.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill provides DOH with sufficient rulemaking authority to adopt rules relating to the reporting of adverse incidents that occur in planned out-of-hospital births, as well as a form for reporting such adverse incidents.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to reporting of adverse incidents in planned out-of-hospital births; creating s. 456.0495, F.S.; defining the term "adverse incident"; requiring licensed physicians, certified nurse midwives, or licensed midwives to report an adverse incident and a medical summary of events to the Department of Health within a specified timeframe; requiring the department to review adverse incident reports and determine if conduct occurred that is subject to disciplinary action; requiring the appropriate regulatory board or the department to take disciplinary action under certain circumstances; requiring the department to adopt rules; requiring the department to develop a form to be used for the reporting of adverse incidents; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 456.0495, Florida Statutes, is created to read:

456.0495 Reporting adverse incidents occurring in planned out-of-hospital births.—

(1) For purposes of this section, the term "adverse incident" means an event over which a physician licensed under

chapter 458 or chapter 459, a nurse midwife certified under part I of chapter 464, or a midwife licensed under chapter 467 could exercise control and which is associated with an attempted or completed planned out-of-hospital birth, and results in one or more of the following injuries or conditions:

(a) A maternal death that occurs during delivery or within 42 days after delivery;

(b) The transfer of a maternal patient to a hospital intensive care unit;

(c) A maternal patient who experiences hemorrhagic shock or who requires a transfusion of more than 4 units of blood or blood products;

(d) A fetal or newborn death, including a stillbirth, associated with an obstetrical delivery;

(e) A transfer of a newborn to a neonatal intensive care unit due to a traumatic physical or neurological birth injury, including any degree of a brachial plexus injury;

(f) A transfer of a newborn to a neonatal intensive care unit within the first 72 hours after birth if the newborn remains in such unit for more than 72 hours; or

(g) Any other injury as determined by department rule.

(2) A physician licensed under chapter 458 or chapter 459, a nurse midwife certified under part I of chapter 464, or a midwife licensed under chapter 467 who performs an attempted or completed planned out-of-hospital birth must report an adverse

incident, along with a medical summary of events, to the department within 15 days after the adverse incident occurs.

(3) The department shall review each incident report and determine whether the incident involves conduct by a health care practitioner which is subject to disciplinary action under s. 456.073. Disciplinary action, if any, must be taken by the appropriate regulatory board or by the department if no such board exists.

(4) The department shall adopt rules to implement this section and shall develop a form to be used for the reporting of adverse incidents.

Section 2. This act shall take effect upon becoming a law.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 855 Genetic Information Used for Insurance
SPONSOR(S): Brodeur
TIED BILLS: **IDEN./SIM. BILLS:** SB 1106

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Grabowski	McElroy

SUMMARY ANALYSIS

The availability and use of genetic tests has increased dramatically in recent years. The resulting genetic information is generally used by individuals or their physicians to determine whether any action should be taken to improve long-term wellbeing.

Since the advent of genetic testing, there have been concerns about the use of personal genetic information by third parties. In particular, there is a concern that insurers may discriminate against individuals who have genetic markers indicating a heightened risk of developing certain diseases or health conditions.

The federal Health Insurance Portability and Accountability Act of 1996 prohibits health insurers from making coverage decisions solely based on personal genetic information. The federal Genetic Information Nondiscrimination Act of 2008 extended this concept by prohibiting health insurers from using genetic information in the underwriting process, and in the setting of premiums.

Florida law also prohibits health insurers from considering genetic information, both when issuing insurance policies and when setting applicable premium rates. This prohibition, however, does not extend to issuers of life insurance, disability income insurance, and long-term care insurance policies.

HB 855 expands existing prohibitions on the use of genetic information by insurers to include entities that issue policies for life insurance, long-term care insurance, and disability income insurance. Specifically, the bill prohibits issuers of life insurance, long-term care insurance, and disability income insurance from canceling, limiting, or denying coverage and from setting differential premium rates based on personal genetic information. This prohibition is not applicable in situations where there has been a diagnosis of a condition directly related to an individual's personal genetic information.

The bill also prohibits life insurers and long-term care insurers from requiring or soliciting genetic information and from using genetic information for insurance purposes.

The bill has no fiscal impact on state or local government.

The bill has an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Regulation of Insurance in Florida

The Office of Insurance Regulation (OIR) is responsible for all activities concerning insurers and other risk bearing entities, as provided under the insurance code. OIR regulates life insurers under parts III and V of ch. 627, F.S.

OIR regulates health insurers under part VI of ch. 627, F.S., and health maintenance organizations (HMOs) under part I of ch. 641, F.S. The Agency for Health Care Administration (AHCA) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from OIR, an HMO must receive a Health Care Provider Certificate from AHCA.[1] Long-term care insurance is coverage for medical and personal care services provided in a setting other than in an acute care unit of a hospital.[2] OIR regulates long-term care insurance under part XVIII of ch. 627, F.S.

Genetic Testing

The availability and use of genetic tests has increased dramatically in recent years. As of March 2017, there were nearly 70,000 genetic testing products on the market, with an average of 10.6 new testing products entering the market *a day* since 2015.[3] A 2016 survey indicated that 5.5% of adults in the U.S. had had genetic testing. Over half of those tested did so based on a concern about future health problems for them or their children, while 18% were tested to learn more about family heritage.[4] The U.S. Centers for Disease Control and Prevention (CDC) recognizes the development of genomic tests for thousands of diseases and health conditions, while also acknowledging that such tests are not necessarily a conclusive indication that an individual will develop a particular disease or condition.[5]

A wide range of health-related DNA screenings are available. The National Institutes for Health (NIH) categorizes these tests as follows.

- ***Diagnostic testing*** - identifies a genetic condition or disease that is making or in the future will make a person ill. The results of diagnostic testing can help in treating and managing the disorder.
- ***Predictive and pre-symptomatic genetic testing*** - identifies genetic variations that increase a person's chance of developing specific diseases. This type of genetic testing may help provide information about a person's risk of developing a disease, and can help in decisions about lifestyle and health care.

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[1] S. 641.21(1) and 641.48, F.S.

[2] S. 627.9404, F.S. Long-term care services may encompass a wide array of medical, social, and personal care services required by an individual with a chronic disability. American Academy of Actuaries, *The Use of Genetic Information in Disability Income and Long-Term Care Insurance*, Issue Brief, Spring 2002, available at https://www.actuary.org/files/publications/genetic_25apr02.pdf (last visited January 7, 2018).

[3] *The Current Landscape of Genetic Testing*, Concert Genetics, March 2017, available at https://www.concertgenetics.com/wp-content/uploads/2017/05/10_ConcertGenetics_CurrentLandscapeofGeneticTesting_2017Update.pdf (last viewed Jan. 8, 2018).

[4] Harvard University T.H. Chan School of Public Health, *The Public and Genetic Editing, Testing, and Therapy*, Jan. 2016, available at https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2016/01/STAT-Harvard-Poll-Jan-2016-Genetic-Technology.pdf (last viewed Jan. 8, 2018). Genetic testing has also given rise to a novel industry aimed at providing individuals with customized data related to family ancestry, including companies like 23andMe, Ancestry.com, FamilyTree DNA, and Living DNA.

[5] U.S. Centers for Disease Control and Prevention, *Genomic Testing*, last updated July 19, 2017, available at https://www.cdc.gov/genomics/gtesting/ (last visited January 7, 2018).

- ***Carrier testing*** – identifies whether a person "carries" a genetic change that can cause a disease. Carriers usually show no signs of the disorder; however, they can pass on the genetic variation to their children, who may develop the disorder or become carriers themselves.
- ***Prenatal testing*** - identifies fetuses that have certain diseases.
- ***Pre-implantation genetic testing*** – identifies whether embryos for implantation carry genes that could cause disease. This is often done in conjunction with *in vitro* fertilization.
- ***Newborn screening*** - is used to test babies one or two days after birth to determine if those newborns have certain diseases known to cause problems with health and development.
- ***Pharmacogenetic testing*** - provides information about how certain medicines are processed in a person's body. This type of testing can help a healthcare provider choose the medicines that work best with a person's genetic makeup. For example, genetic testing is now available to guide treatments for certain cancers.
- ***Research genetic testing*** – helps scientists learn more about how genes contribute to health and disease, as well as develop gene-based treatments. Sometimes the results do not directly help the research participant, but they may benefit others in the future by helping researchers expand their understanding of the human body.[6]

One often-cited use of genetic testing involves screening of female patients for a gene mutation that can be an early predictor of breast cancer. *BRCA 1* and *BRCA 2* gene mutations are relatively rare, but women having these mutations develop breast cancer at much higher rates than those without.[7] *BRCA* testing has become increasingly prevalent among women in families with histories of breast cancer.[8]

Use of Personal Genetic Information in Insurance Markets

The now-widespread availability of genetic tests has given rise to questions and concerns over the appropriate use of genetic information. While an individual may voluntarily submit to genetic testing in an effort to gain insights into his or her own genetic history, third parties may seek to obtain this same information for other purposes, such as for use in insurance markets.

For example, insurers might use genetic information to exclude high-risk individuals from established risk pools. Insurers might also charge higher premium rates to an individual whose genetic information indicates is at an increased risk of developing a degenerative health condition.[9] Conversely, exclusion of higher-risk insureds could reduce premium inflation for those left in the risk pool.

Similarly, consumers could use personal genetic information to the detriment of insurers. For example, an individual may discover through genetic testing that he or she is likely to develop a serious health condition, and only then purchase life insurance. An insurer is at a disadvantage and cannot accurately gauge the risk posed by covering an individual in this situation.[10] Adverse selection of this nature could destabilize insurance markets if access to personal genetic information leads to widespread changes in consumer behavior.[11] Specifically, the risk-spreading ability of insurance could be compromised if only those who are likely to become ill purchase insurance.[12]

Federal Laws

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[6] U.S. Department of Health and Human Services, National Institutes for Health, *Genetic Testing: How it is Used for Healthcare*, available at https://report.nih.gov/nihfactsheets/ViewFactSheet.aspx?csid=43 (last visited January 7, 2018).
[7] McCarthy, Anne Marie and Armstrong, Katrina, "The Role of Testing for *BRCA1* and *BRCA2* Mutations in Cancer Prevention." *JAMA Intern Med.* 2014;174(7):1023–1024. doi:10.1001/jamainternmed.2014.1322, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4169670/ (last visited January 7, 2018).
[8] Id.
[9] Klitzman, Robert, Appelbaum, Paul S., Chung, Wendy K, "Should Life Insurers Have Access to Genetic Test Results?". *JAMA*. 2014;312(18):1855–1856. doi:10.1001/jama.2014.13301, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4259574/ (last visited January 7, 2018).
[10] Id.
[11] American Academy of Actuaries, *The Use of Genetic Information in Disability Income and Long-Term Care Insurance*, Issue Brief, Spring 2002, available at https://www.actuary.org/files/publications/genetic_25apr02.pdf (last visited January 7, 2018).
[12] Id.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) includes the first federal regulations on the use of personal genetic information.[13] HIPAA prohibits health insurers from utilizing "preexisting condition" exclusions based solely on an individual's genetic information. Under HIPAA, insurers can make coverage decisions using information reflecting diagnosed health conditions, but not based on genetic indicators alone.[14]

The Genetic Information Nondiscrimination Act of 2008 (GINA) extended federal patient protections by preventing health insurers from using genetic information in the underwriting of health insurance products.[15] Health insurers may not charge higher premiums or make coverage decisions based solely on an individual's genetic information. However, the prohibitions outlined in GINA do not extend to other types of insurance, such as life insurance and long-term care insurance. There are currently no federal limitations on the use of genetic information by these insurers.

State Laws

States have adopted various regulations related to the use of genetic information by insurers. In general, states address patient privacy for personal genetic information by: [16]

1. Requiring informed consent before performing genetic testing;
2. Restricting the use of genetic data by health insurance, employers or providers of long-term life care or insurance; and,
3. Limiting disclosure of the personal genetic information without the consent of the individual or defining genetic data as the 'property' of the individual.

Most states have enacted laws that prohibit genetic discrimination by health insurers.[17] A number of states have taken actions to limit or prohibit the use of genetic information in other lines of insurance as well.[18] For example, Arizona, California, Massachusetts and New Jersey restrict use of genetic information by life insurers, and Kansas, Maryland and Massachusetts restrict use by long-term care insurers. Similarly, Arizona, California, Idaho, Kansas, Massachusetts and New Jersey restrict use by disability[19] insurers.[20]

Florida Law

Section 760.40, F.S., makes the results of genetic testing the exclusive personal property of the person tested, and makes it a first degree misdemeanor to sharing test results without the informed consent of the person tested.

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[13] Hall, Mark A. and Rich, Stephen S., "Laws Restricting Health Insurers' Use of Genetic Information: Impact on Genetic Discrimination." *AJHG* 2000: 66(1): 293-307, available at https://doi.org/10.1086/302714 (last visited January 7, 2018).
[14] Id.
[15] U.S. Equal Employment Opportunity Commission, *The Genetic Information Nondiscrimination Act of 2008*, available at https://www.eeoc.gov/laws/statutes/gina.cfm (last visited January 7, 2018).
[16] Miller, Amalia R. and Tucker, Catherine E., "Privacy Protection, Personalized Medicine and Genetic Testing" (July 31, 2014), available at https://ssrn.com/abstract=2411230 (last visited January 7, 2018).
[17] Rothstein, Mark A., "Putting the Genetic Nondiscrimination Act in context." *Genetics in Medicine* 2008: 10: 655-656, available at https://www.nature.com/articles/gim200899 (last visited January 7, 2018).
[18] The National Human Genome Human Research Institute maintains a searchable database of legislation related to genetic information that has either been enacted or considered by state legislatures. U.S. Department of Health and Human Services, National Institutes of Health – National Human Genome Human Research Institute, *Genome Statute and Legislation Database*, available at https://www.genome.gov/policyethics/legdatabase/pubsearch.cfm?CFID=22285441&CFTOKEN=7fc536f1b99bbd21-2342A48B-03C6-03BE-03FEEF39A8695C0F (last visited January 7, 2018).
[19] Disability income insurance protects earned income against potential loss due to disabling injury or illness. American Academy of Actuaries, *The Use of Genetic Information in Disability Income and Long-Term Care Insurance*, Issue Brief, Spring 2002, available at https://www.actuary.org/files/publications/genetic_25apr02.pdf (last visited January 7, 2018).
[20] *Supra* note 20.

Section 627.4301, F.S., prohibits health insurers from considering genetic information, both when issuing insurance policies and when setting applicable premium rates.[21] Insurers cannot require or solicit genetic information, or employ underwriting based on the results of any genetic testing that an individual may choose to complete, and cannot use such results for any purpose. This prohibition is currently limited to self-insured health plans, fully-insured health plans, health maintenance organizations (HMOs), prepaid limited health service organizations, prepaid health clinics, fraternal benefit societies, or any other health care arrangement where risk is assumed. This section of law expressly exempts several forms of insurance from the prohibition: life insurance, and policies for disability income, long-term care, accident-only, hospital indemnity or fixed indemnity, dental, and vision.

Effect of Proposed Changes

HB 855 amends s. 627.4301, F.S., to expand existing prohibitions on the use of genetic information by including life insurance, long-term care insurance, and disability income insurance. Specifically, the bill prohibits issuers of life insurance, long-term care insurance, and disability income insurance from canceling, limiting, or denying coverage and from setting differential premium rates based on personal genetic information. This prohibition is not applicable in situations where there has been a diagnosis of a condition directly related to an individual's personal genetic information.

The bill also prohibits life insurers and long-term care insurers from requiring or soliciting genetic information and from using genetic information for insurance purposes.

The bill has an effective date of July 1, 2018 and would apply to insurance policies entered into or renewed on or after January 1, 2019.

B. SECTION DIRECTORY:

Section 1: Amends s. 627.4301, F.S., relating to the use of genetic information for insurance purposes.

Section 2: Establishes that the bill's requirements are applicable to insurance policies entered into or renewed on or after January 1, 2019.

Section 3: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

[21] See also S. 626.9706, F.S., which prohibits insurers from refusing coverage or charging higher premiums to individuals determined to carry the sickle-cell trait.

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

It is unclear whether or how, insurers of life insurance, long-term care insurance, and disability income insurance are currently using personal genetic information, so the economic impact of the bill's prohibition on its use is unknown.

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:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to genetic information used for insurance; amending s. 627.4301, F.S.; providing definitions; prohibiting the use of genetic information in the issuance of life insurance policies, long-term care policies, and disability income policies; providing applicability; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 627.4301, Florida Statutes, is amended to read:

627.4301 Genetic information for insurance purposes.—

(1) DEFINITIONS.—As used in this section, the term:

(a) "Genetic information" means information derived from genetic testing to determine the presence or absence of variations or mutations, including carrier status, in an individual's genetic material or genes that are scientifically or medically believed to cause a disease, disorder, or syndrome, or are associated with a statistically increased risk of developing a disease, disorder, or syndrome, which is asymptomatic at the time of testing. Such testing does not include routine physical examinations or chemical, blood, or urine analysis, unless conducted purposefully to obtain genetic

information, or questions regarding family history.

(b) "Health insurer" means an authorized insurer offering health insurance as defined in s. 624.603, a self-insured plan as defined in s. 624.031, a multiple-employer welfare arrangement as defined in s. 624.437, a prepaid limited health service organization as defined in s. 636.003, a health maintenance organization as defined in s. 641.19, a prepaid health clinic as defined in s. 641.402, a fraternal benefit society as defined in s. 632.601, or any health care arrangement whereby risk is assumed.

(c) "Life insurer" has the same meaning as in s. 624.602 and includes the granting of additional benefits in the event of the insured's disability.

(d) "Long-term care insurer" means an insurer that issues long-term care insurance policies as described in s. 627.9404.

(2) USE OF GENETIC INFORMATION.—

(a) In the absence of a diagnosis of a condition related to genetic information, no health insurer, life insurer, or long-term care insurer authorized to transact insurance in this state may cancel, limit, or deny coverage, or establish differentials in premium rates, based on such information.

(b) Health insurers, life insurers, and long-term care insurers may not require or solicit genetic information, use genetic test results, or consider a person's decisions or actions relating to genetic testing in any manner for any

insurance purpose.

(c) This section does not apply to the underwriting or issuance of an ~~a life insurance policy, disability income policy, long-term care policy,~~ accident-only policy, hospital indemnity or fixed indemnity policy, dental policy, or vision policy or any other actions of an insurer directly related to an ~~a life insurance policy, disability income policy, long-term care policy,~~ accident-only policy, hospital indemnity or fixed indemnity policy, dental policy, or vision policy.

Section 2. This act applies to policies entered into or renewed on or after January 1, 2019.

Section 3. This act shall take effect July 1, 2018.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 973 Performance of Physician Assistants and Advanced Registered Nurse Practitioners
SPONSOR(S): Daniels and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 708

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Siples	McElroy
2) Health & Human Services Committee			

SUMMARY ANALYSIS

Advanced registered nurse practitioners (ARNPs) are licensed registered nurses with post-graduate education in nursing that prepares them to perform advanced or specialized nursing. ARNPs may perform nursing or medical acts that are authorized pursuant to a written protocol with a physician. ARNPs may only sign those documents that are directly related to the performance of the nursing or medical acts authorized pursuant to a protocol, unless otherwise prohibited by law.

Physician assistants (PAs) complete specialized education that prepares them to perform medical services and practice as a part of a health care team. PAs practice under the delegated authority of a supervising physician. A PA may sign only those documents that are directly related to the performance of medical services performed as delegated by a supervising physician and do not, by law, require a physician's signature.

ARNPs and PAs provide comprehensive health care to patients within the scope of their education, certification, and delegated authority. Currently, ARNPs and PAs are prohibited from signing various documents associated with the care that an ARNP or PA provides. Instead, a physician's signature is required on these documents even if the physician did not provide care to the patient. Such documents include the disability certification for certain tax exemptions, a death certificate, and a certificate to initiate an involuntary examination under the Baker Act.

HB 973 authorizes allopathic and osteopathic physicians to delegate authority to ARNPs and PAs to sign, certify, stamp, verify, or endorse any document required by law to be signed by a physician. However, the bill specifically prohibits a PA or an ARNP who is not a psychiatric nurse from approving the release of an individual from a Baker Act receiving facility.

The bill has no fiscal impact on state or local government.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Advanced Registered Nurse Practitioners

Nurses are licensure are licensed by DOH and regulated by the Board of Nursing pursuant to part I of ch. 464, F.S. Licensure requirements to practice nursing include completion of an approved educational course of study, passage of an examination approved by DOH, and acceptable criminal background screening results.[1]

A nurse actively licensed to practice professional nursing may be certified as an Advanced Registered Nurse Practitioner (ARNP), under s. 464.012, F.S., if the nurse meets one or both of the following requirements:

- Certification by a specialty board; or
- Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills.

Current law defines three categories of ARNPs: certified registered nurse anesthetists, certified nurse midwives, and nurse practitioners.[2] All ARNPs, regardless of practice category, may only practice within the framework of an established protocol and under the supervision of an allopathic or osteopathic physician or dentist.[3] ARNPs may carry out treatments as specified in statute, including:[4]

- Prescribing, dispensing, administering, or ordering any drug;[5]
- Initiating appropriate therapies for certain conditions;
- Ordering diagnostic tests and physical and occupational therapy;
- Ordering any medication for administration patients in certain facilities; and
- Performing additional functions as determined by rule.[6]

In addition to the above-allowed acts, an ARNP may also perform other acts as authorized by statute and within his or her specialty.[7] Currently, there are 27,588 ARNPs who hold active licenses to practice in Florida.[8]

An ARNP may sign only those documents that are directly related to the performance of authorized nursing or medical acts performed pursuant to a physician's protocol and which do not, by law, require a physician's signature. Under current law, an ARNP may not sign, among other things, a certificate to

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[1] Sections 464.008 and 464.009, F.S. As an alternative to licensure by examination, a nurse may also be eligible for licensure by endorsement.
[2] Section 464.012(2), F.S.
[3] Section 464.012(3), F.S.
[4] Id.
[5] An ARNP may only prescribe controlled substances if he or she has graduated from a program leading to a master's or doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills. An ARNP is limited to prescribing a 7-day supply of Schedule II controlled substances. Only a psychiatric nurse may prescribe psychotropic controlled substances for the treatment of mental disorders and psychiatric mental health controlled substances for children younger than 18.
[6] Section 464.003(2), F.S., defines "advanced or specialized nursing practice" to include additional activities that an ARNP may perform as approved by the Board of Nursing.
[7] Section 464.012(4), F.S.
[8] Email correspondence with the Department of Health, dated December 14, 2017 (on file with the Health Quality Subcommittee).

initiate an involuntary examination of a person under the Baker Act,[9] a death certificate,[10] or a certification of a disability for certain tax exemptions.[11] Only an ARNP who qualifies as a psychiatric nurse[12] acting within the framework of an established protocol with a psychiatrist may authorize the release of a patient from a receiving facility.[13] If the involuntary examination was performed by psychiatrist, a psychiatric nurse may not approve the release of a patient unless it is approved by the initiating psychiatrist.[14]

Physician Assistants

Physician assistants are governed by the physician practice acts for medical doctors and doctors of osteopathic medicine. PAs are regulated by the Florida Council on Physician Assistants (Council) in conjunction with either the Board of Medicine for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S. As of December 2017, there are 9,118 PAs who hold active licenses to practice in Florida.[15]

An applicant for a PA license must apply to the Department of Health (DOH). DOH must issue a license to a person certified by the Council as having met all of the following requirements:[16]

- Complete an approved PA training program;
- Obtain a passing score on the National Commission on Certification of Physician Assistant exam;
- Acknowledge any prior felony convictions;
- Submit to a background screening and have no disqualifying offenses;[17]
- Acknowledge any previous revocation or denial of licensure in any state; and
- Provide a copy of course transcripts and a copy of the course description from a PA training program describing the course content in pharmacotherapy if the applicant is seeking prescribing authority.

PAs may only practice under the direct or indirect supervision of a medical doctor or doctor of osteopathic medicine with whom they have a clinical relationship.[18] A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[19] The supervising physician is responsible and liable for any acts or omissions of the PA and may not supervise more than four PAs at any time.[20]

The Boards have established by rule that "responsible supervision" of a PA means the ability of the supervising physician to exercise control and provide direction over the services or tasks performed by the PA. Whether the supervision of a PA is adequate, is dependent upon the:

- Complexity of the task;

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[9] The Baker Act authorizes the involuntary examination of certain individuals who, without care or treatment, pose a real and present danger to their well-being or may cause serious bodily injury to themselves or others in the near future, as evidenced by recent behavior (s. 394.463(1), F.S.)
[10] Section 382.008, F.S.
[11] Section 196.101, F.S.
[12] Section 394.455(35), F.S., defines a psychiatric nurse as an ARNP who has a master's degree or a doctorate in psychiatric nursing, holds a national advanced practice certification as a psychiatric mental health advance practice nurse, and has two years of post-master's clinical experience under the supervision of a physician.
[13] Section 394.463(2)(f), F.S. A receiving facility is a facility designated by the Department of Children and Families to provide the initial examination and short-term treatment of individuals who meet the criteria under the Baker Act.
[14] Id.
[15] Email correspondence with the Department of Health, dated December 14, 2017 (on file with the Health Quality Subcommittee).
[16] Sections 458.347(7) and 459.022(7), F.S.
[17] Section 456.0135, F.S.
[18] Sections 458.347(2)(f) and 459.022(2)(f), F.S., define supervision as responsible supervision and control which requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.
[19] Rules 64B8-30.012 and 64B15-6.010, F.A.C.
[20] Sections 458.347(15) and 459.022(15), F.S.

- Risk to the patient;
- Background, training and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.[21]

The decision to permit the PA to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.[22] A supervising physician may delegate the authority for a PA to:

- Prescribe or dispense any medicinal drug used in the supervising physician's practice unless such medication is listed in the formulary established by the Council;[23]
- Order any medication for administration to the supervising physician's patient in a hospital or other facility licensed under chapter 395, F.S., or a nursing homes licensed under part II of chapter 400, F.S.;[24] and
- Any other services that are not expressly prohibited in ch. 458, F.S., ch. 459, F.S., or the rules adopted thereunder.[25]

A PA may sign only those documents that are directly related to the performance of medical services performed as delegated by a supervising physician and which do not, by law, require a physician's signature. Under current law, a PA may not sign, among other things, a certificate to initiate an involuntary examination of a person under the Baker Act,[26] a death certificate,[27] or a certification of a disability for certain tax exemptions.[28]

Effect of Proposed Changes

HB 973 authorizes allopathic and osteopathic physicians to delegate authority to ARNPs and PAs to sign, certify, stamp, verify, or endorse any document that requires the signature, certification, stamp, verification, or endorsement of a physician. This includes, among other things, signing a disability certification, initiation of an involuntary examination of a person under the Baker Act, or a death certificate. However, the bill specifically prohibits a PA or an ARNP who is not a psychiatric nurse from approving the release of an individual from a Baker Act receiving facility.

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 458.347, F.S., relating to physician assistants.
Section 2: Amends s. 459.022, F.S., relating to physician assistants.

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[21] Rules 64B8-30.001, F.A.C., and 64B15-6.001, F.A.C.
[22] "Direct supervision" refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed. "Indirect supervision" refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication. *Supra* note 21.
[23] Sections 458.347(4)(f), F.S., and 459.022(e), F.S., directs the Council to establish a formulary listing the medical drugs that a PA may not prescribe. The formulary in Rules 64B8-30.008, F.A.C., and 64B15-6.0038, F.A.C., prohibits PAs from prescribing; general, spinal or epidural anesthetics; radiographic contrast materials; and psychiatric mental health controlled substances for children younger than 18 years of age. It also restricts the prescribing of Schedule II controlled substances to a 7-day supply. However, the rules authorize physicians to delegate to PAs the authority to order controlled substances in hospitals and other facilities licensed under ch. 395, F.S.
[24] Chapter 395, F.S., provides for the regulation and the licensure of hospitals and trauma centers, part II of ch. 400, F.S., provides for the regulation and licensure of nursing home facilities.
[25] Sections 458.347(4) and 459.022(e), F.S.
[26] *Supra* note 9.
[27] *Supra* note 10.
[28] *Supra* note 11.

Section 3: Amends s. 464.012, F.S., relating to certification of advanced registered nurse practitioners; fees; controlled substance prescribing.

Section 4: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

If a document requires a physician's signature, patients will have additional options for selecting a health care provider.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to performance of physician assistants and advanced registered nurse practitioners; amending ss. 458.347 and 459.022, F.S.; authorizing a physician assistant to sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician; providing an exception; amending s. 464.012, F.S.; authorizing an advanced registered nurse practitioner to sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician within the framework of an established protocol and under supervision; providing an exception; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (i) is added to subsection (4) of section 458.347, Florida Statutes, to read:

458.347 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(i) A supervisory physician may delegate to a licensed physician assistant the authority to sign, certify, stamp, verify, or endorse a document that requires the signature,

certification, stamp, verification, or endorsement of a physician, except that the supervisory physician may not delegate the authority to issue a written approval to release a patient from a receiving facility or its contractor under s. 394.463(2)(f).

Section 2. Paragraph (h) is added to subsection (4) of section 459.022, Florida Statutes, to read:

459.022 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(h) A supervisory physician may delegate to a licensed physician assistant the authority to sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician, except that the supervisory physician may not delegate the authority to issue a written approval to release a patient from a receiving facility or its contractor under s. 394.463(2)(f).

Section 3. Subsection (3) of section 464.012, Florida Statutes, is amended to read:

464.012 Certification of advanced registered nurse practitioners; fees; controlled substance prescribing.—

(3) An advanced registered nurse practitioner shall perform those functions authorized in this section within the framework of an established protocol which must be maintained on site at the location or locations at which an advanced

registered nurse practitioner practices. In the case of multiple supervising physicians in the same group, an advanced registered nurse practitioner must enter into a supervisory protocol with at least one physician within the physician group practice. A practitioner currently licensed under chapter 458, chapter 459, or chapter 466 shall maintain supervision for directing the specific course of medical treatment. Within the established framework, an advanced registered nurse practitioner may:

(a) Prescribe, dispense, administer, or order any drug; however, an advanced registered nurse practitioner may prescribe or dispense a controlled substance as defined in s. 893.03 only if the advanced registered nurse practitioner has graduated from a program leading to a master's or doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills.

(b) Initiate appropriate therapies for certain conditions.

(c) Perform additional functions as may be determined by rule in accordance with s. 464.003(2).

(d) Order diagnostic tests and physical and occupational therapy.

(e) Order any medication for administration to a patient in a facility licensed under chapter 395 or part II of chapter 400, notwithstanding any provisions in chapter 465 or chapter 893.

(f) Sign, certify, stamp, verify, or endorse a document

that requires the signature, certification, stamp, verification, or endorsement of a physician, except that the supervisory physician may not delegate the authority to issue a written approval to release a patient from a receiving facility or its contractor under s. 394.463(2)(f).

Section 4. This act shall take effect July 1, 2018.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 6049 Medical Marijuana Growers
SPONSOR(S): Jones
TIED BILLS: **IDEN./SIM. BILLS:** SB 1134

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Royal	McElroy
2) Health & Human Services Committee			

SUMMARY ANALYSIS

On November 8, 2016, Florida voters approved an amendment to the Florida Constitution (Fla. Const. art. X, s. 29) which allows the medical use of marijuana by patients with an enumerated debilitating medical condition. The amendment authorizes entities known as Medical Marijuana Treatment Centers (MMTCs) to be marijuana providers. During the 2017A Special Session, the legislature passed SB8-A which implements Fla Const. art. X, s. 29.

Current law requires the Department of Health (DOH) to grant MMTC licenses to dispensing organizations licensed by July 3, 2017. Current law also requires DOH to grant ten additional MMTC licenses by October 3, 2017. Among these, one of the licenses must be awarded to an applicant that is a recognized class member of Pigford v. Glickman, 185 F.R.D. 82 (D.D.C. 1999), or In Re Black Farmers Litig., 856 F. Supp. 2d 1 (D.D.C. 2011), and a Florida member of the Florida Black Farmers and Agriculturalists Association (Recognized Class Member License).

HB 6049 repeals the requirement that a Recognized Class Member License applicant be a member of the Florida Black Farmers and Agriculturalists Association. An applicant must only be a recognized class member of Pigford v. Glickman, 185 F.R.D. 82 (D.D.C. 1999), or In Re Black Farmers Litig., 856 F. Supp. 2d 1 (D.D.C. 2011) to be eligible for the Recognized Class Member License.

The bill also repeals the requirement that the license be awarded by October 3, 2017.

The bill does not have a fiscal impact on state or local governments.

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Compassionate Medical Cannabis Act

The Compassionate Medical Cannabis Act (CMCA) was enacted in 2014.[1] The CMCA legalized a low-THC and high-CBD form of low-THC cannabis[2] for medical use[3] by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms. In 2016, the legislature also amended the Right to Try Act (RTTA) to allow eligible patients with a terminal condition to receive a form of cannabis with no THC limit or CBD mandate referred to as medical cannabis.[4]

Under the CMCA, the Department of Health (DOH) was required to approve by January 1, 2015, five dispensing organizations to cultivate, process, transport, and dispense low-THC cannabis or medical cannabis with one dispensing organization in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida.

The CMCA also required DOH to approve three additional dispensing organizations upon the registration of 250,000 active qualified patients in the compassionate use registry.[5] The CMCA required one of these additional dispensing organizations to be owned and operated by a recognized class member of of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011), and a member of the Black Farmers and Agriculturalists Association.

Amendment 2

On November 8, 2016, Florida voters approved Amendment 2, Use of Marijuana for Debilitating Medical Conditions as Art. X, Sec. 29 of the Florida Constitution. The amendment authorizes patients with an enumerated debilitating medical condition to obtain medical marijuana from MMTCs.

The amendment requires DOH to register MMTCs to provide medical marijuana and related supplies to patients or their caregivers. MMTCs may acquire, cultivate, possess process, transfer, transport, sell, distribute, dispense, or administer marijuana and products containing marijuana. MMTCs may also provide related supplies and educational materials.

The amendment requires DOH to establish procedures for the registration of MMTCs that include procedures for the issuance, renewal, suspension and revocation of registration. The amendment also requires DOH to establish regulatory standards for security, record keeping, testing, labeling, inspection, and safety.

The amendment states that the legislature may enact laws consistent with the amendment.

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[1] *See* ch. 2014-157, L.O.F., ch. 2016-123, L.O.F. and s. 381.986, F.S.

[2] The act defines "low-THC cannabis," as the dried flowers of the plant *Cannabis* which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight, or the seeds, resin, or any compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. *See* s. 381.986(1)(b), F.S.

[3] Section 381.986(1)(c), F.S., defines "medical use" as "administration of the ordered amount of low-THC cannabis. The term does not include the possession, use, or administration by smoking. The term also does not include the transfer of low-THC cannabis to a person other than the qualified patient for whom it was ordered or the qualified patient's legal representative on behalf of the qualified patient." Section 381.986(1)(e), F.S., defines "smoking" as "burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer."

[4] Section 499.0295, F.S.

[5] Section 381.986(5)(c), F.S.

SB 8-A

During the 2017A Special Session, the legislature passed SB8-A which implements Fla Const. art. X, s. 29 by significantly amending the CMCA.

Current law requires DOH to grant MMTC licenses to dispensing organizations licensed by July 3, 2017.[6] Current law also requires DOH to grant ten additional MMTC licenses.[7] Among these, licenses were to be awarded by August 1, 2017 to any denied dispensing organization applicant whose application was scored by DOH and had one or more administrative or legal challenges pending as of January 1, 2017, or had a final ranking within one point of the highest final ranking applicant in its region, and proves to DOH that it has the infrastructure and ability to begin cultivating marijuana within 30 days after registration as a MMTC.[8] The remaining licenses were to be awarded by October 3, 2017, one of which must be awarded to an applicant that is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999), or *In Re Black Farmers Litig.*, 856 F. Supp. 2d 1 (D.D.C. 2011), and a Florida member of the Florida Black Farmers and Agriculturalists Association (Recognized Class Member License).[9]

DOH must grant 4 additional MMTC licenses when the patient population reaches 100,000 and 4 additional MMTC licenses for every additional 100,000 patients thereafter.[10]

On September 22, 2017, Columbus Smith (Smith) filed a lawsuit challenging the requirement that a Recognized Class Member License applicant be a member of the Florida Black Farmers and Agriculturalists Association.[11] Smith is a recognized class member of Pigford v. Glickman, 185 F.R.D. 82 (D.D.C. 1999), or In Re Black Farmers Litig., 856 F. Supp. 2d 1 (D.D.C. 2011) but is not a member of the Florida Black Farmers and Agriculturalists Association. Smith also seeks an injunction to enjoin DOH from awarding a Recognized Class Member License. DOH has not granted any of the 10 additional MMTC licenses that it was required to grant by October 3, 2017, due to this lawsuit.

Effect of the Bill

HB 6049 repeals the requirement that a Recognized Class Member License applicant be a member of the Florida Black Farmers and Agriculturalists Association. An applicant must only be a recognized class member of Pigford v. Glickman, 185 F.R.D. 82 (D.D.C. 1999), or In Re Black Farmers Litig., 856 F. Supp. 2d 1 (D.D.C. 2011) to be eligible for the Recognized Class Member License.

The bill also repeals the requirement that the license be awarded by October 3, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.986, F.S., relating to Medical Marijuana Treatment Centers.
Section 2: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

[6] Section 381.986(8)(a)1, F.S.
[7] Section 381.986(8)(a)2, F.S.
[8] Section 381.986(8)(a)2.a, F.S.
[9] Section 381.986(8)(a)2.b, F.S
[10] Section 381.986(8)(a)4, F.S.
[11] Smith v. Florida Department of Health, case number 17-CA-1972, in the Circuit Court for the Second Judicial Circuit of Florida.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to medical marijuana growers; amending s. 381.986, F.S.; deleting a requirement that the Department of Health grant a medical marijuana treatment center license to a member of a specified association; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Paragraph (a) of subsection (8) of section 381.986, Florida Statutes, is amended to read:

381.986 Medical use of marijuana.—

(8) MEDICAL MARIJUANA TREATMENT CENTERS.—

(a) The department shall license medical marijuana treatment centers to ensure reasonable statewide accessibility and availability as necessary for qualified patients registered in the medical marijuana use registry and who are issued a physician certification under this section.

1. As soon as practicable, but no later than July 3, 2017, the department shall license as a medical marijuana treatment center any entity that holds an active, unrestricted license to cultivate, process, transport, and dispense low-THC cannabis, medical cannabis, and cannabis delivery devices, under former s. 381.986, Florida Statutes 2016, before July 1, 2017, and which meets the requirements of this section. In addition to the

authority granted under this section, these entities are authorized to dispense low-THC cannabis, medical cannabis, and cannabis delivery devices ordered pursuant to former s. 381.986, Florida Statutes 2016, which were entered into the compassionate use registry before July 1, 2017, and are authorized to begin dispensing marijuana under this section on July 3, 2017. The department may grant variances from the representations made in such an entity's original application for approval under former s. 381.986, Florida Statutes 2014, pursuant to paragraph (e).

2. The department shall license as medical marijuana treatment centers 10 applicants that meet the requirements of this section, under the following parameters:

a. As soon as practicable, but no later than August 1, 2017, the department shall license any applicant whose application was reviewed, evaluated, and scored by the department and which was denied a dispensing organization license by the department under former s. 381.986, Florida Statutes 2014; which had one or more administrative or judicial challenges pending as of January 1, 2017, or had a final ranking within one point of the highest final ranking in its region under former s. 381.986, Florida Statutes 2014; which meets the requirements of this section; and which provides documentation to the department that it has the existing infrastructure and technical and technological ability to begin cultivating marijuana within 30 days after registration as a medical

marijuana treatment center.

b. As soon as practicable, ~~but no later than October 3, 2017,~~ the department shall license one applicant that is a recognized class member of Pigford v. Glickman, 185 F.R.D. 82 (D.D.C. 1999), or In Re Black Farmers Litig., 856 F. Supp. 2d 1 (D.D.C. 2011) ~~and is a member of the Black Farmers and Agriculturalists Association-Florida Chapter~~. An applicant licensed under this sub-subparagraph is exempt from the requirements of subparagraphs (b)1. and 2.

c. As soon as practicable, but no later than October 3, 2017, the department shall license applicants that meet the requirements of this section in sufficient numbers to result in 10 total licenses issued under this subparagraph, while accounting for the number of licenses issued under sub-subparagraphs a. and b.

3. For up to two of the licenses issued under subparagraph 2., the department shall give preference to applicants that demonstrate in their applications that they own one or more facilities that are, or were, used for the canning, concentrating, or otherwise processing of citrus fruit or citrus molasses and will use or convert the facility or facilities for the processing of marijuana.

4. Within 6 months after the registration of 100,000 active qualified patients in the medical marijuana use registry, the department shall license four additional medical marijuana

treatment centers that meet the requirements of this section. Thereafter, the department shall license four medical marijuana treatment centers within 6 months after the registration of each additional 100,000 active qualified patients in the medical marijuana use registry that meet the requirements of this section.

5. Dispensing facilities are subject to the following requirements:

a. A medical marijuana treatment center may not establish or operate more than a statewide maximum of 25 dispensing facilities, unless the medical marijuana use registry reaches a total of 100,000 active registered qualified patients. When the medical marijuana use registry reaches 100,000 active registered qualified patients, and then upon each further instance of the total active registered qualified patients increasing by 100,000, the statewide maximum number of dispensing facilities that each licensed medical marijuana treatment center may establish and operate increases by five.

b. A medical marijuana treatment center may not establish more than the maximum number of dispensing facilities allowed in each of the Northwest, Northeast, Central, Southwest, and Southeast Regions. The department shall determine a medical marijuana treatment center's maximum number of dispensing facilities allowed in each region by calculating the percentage of the total statewide population contained within that region

and multiplying that percentage by the medical marijuana treatment center's statewide maximum number of dispensing facilities established under sub-subparagraph a., rounded to the nearest whole number. The department shall ensure that such rounding does not cause a medical marijuana treatment center's total number of statewide dispensing facilities to exceed its statewide maximum. The department shall initially calculate the maximum number of dispensing facilities allowed in each region for each medical marijuana treatment center using county population estimates from the Florida Estimates of Population 2016, as published by the Office of Economic and Demographic Research, and shall perform recalculations following the official release of county population data resulting from each United States Decennial Census. For the purposes of this subparagraph:

(I) The Northwest Region consists of Bay, Calhoun, Escambia, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Okaloosa, Santa Rosa, Taylor, Wakulla, Walton, and Washington Counties.

(II) The Northeast Region consists of Alachua, Baker, Bradford, Clay, Columbia, Dixie, Duval, Flagler, Gilchrist, Hamilton, Lafayette, Levy, Marion, Nassau, Putnam, St. Johns, Suwannee, and Union Counties.

(III) The Central Region consists of Brevard, Citrus, Hardee, Hernando, Indian River, Lake, Orange, Osceola, Pasco,

Pinellas, Polk, Seminole, St. Lucie, Sumter, and Volusia Counties.

(IV) The Southwest Region consists of Charlotte, Collier, DeSoto, Glades, Hendry, Highlands, Hillsborough, Lee, Manatee, Okeechobee, and Sarasota Counties.

(V) The Southeast Region consists of Broward, Miami-Dade, Martin, Monroe, and Palm Beach Counties.

c. If a medical marijuana treatment center establishes a number of dispensing facilities within a region that is less than the number allowed for that region under sub-subparagraph b., the medical marijuana treatment center may sell one or more of its unused dispensing facility slots to other licensed medical marijuana treatment centers. For each dispensing facility slot that a medical marijuana treatment center sells, that medical marijuana treatment center's statewide maximum number of dispensing facilities, as determined under sub-subparagraph a., is reduced by one. The statewide maximum number of dispensing facilities for a medical marijuana treatment center that purchases an unused dispensing facility slot is increased by one per slot purchased. Additionally, the sale of a dispensing facility slot shall reduce the seller's regional maximum and increase the purchaser's regional maximum number of dispensing facilities, as determined in sub-subparagraph b., by one for that region. For any slot purchased under this sub-subparagraph, the regional restriction applied to that slot's

location under sub-subparagraph b. before the purchase shall remain in effect following the purchase. A medical marijuana treatment center that sells or purchases a dispensing facility slot must notify the department within 3 days of sale.

d. This subparagraph shall expire on April 1, 2020.

If this subparagraph or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this act which can be given effect without the invalid provision or application, and to this end, the provisions of this subparagraph are severable.

Section 2. This act shall take effect July 1, 2018.