Health Quality Subcommittee

Tuesday, March 28, 2017
12:00 PM – 3:00 PM
Webster Hall (212 Knott)

Richard Corcoran
Speaker

Cary Pigman
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Quality Subcommittee

Start Date and Time: Tuesday, March 28, 2017 12:00 pm

End Date and Time: Tuesday, March 28, 2017 03:00 pm

Location: Webster Hall (212 Knott)

Duration: 3.00 hrs

Consideration of the following bill(s):

HB 1397 Medical Use of Marijuana by Rodrigues

Consideration of the following proposed committee bill(s):

PCB HQS 17-03 -- Pub. Rec./Medical Marijuana Use Registry
PCB HQS 17-04 -- Direct Support Organization of the Prescription Drug Monitoring Program

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Monday, March 27, 2017.

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., Monday, March 27, 2017.

NOTICE FINALIZED on 03/24/2017 4:02PM by Iseminger.Bobbye

HB 1397

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1397 Medical Use of Marijuana
SPONSOR(S): Rodrigues
TIED BILLS: **IDEN./SIM. BILLS:**

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

SUMMARY ANALYSIS

HB 1397 implements Art. X, Sec. 29 of the Florida Constitution, which allows the use of marijuana by patients with debilitating medical conditions.

The Compassionate Medical Cannabis Act (CMCA) (ss. 381.986, 499.0295 F.S.) legalized a low-THC and high-CBD form of cannabis for medical use by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms, and legalized medical cannabis without any THC limit or CBD mandate for the terminally ill. The CMCA required the Department of Health (DOH) to approve dispensing organizations to cultivate, process and dispense low-THC cannabis and medical cannabis and provided regulatory standards for those activities. The CMCA also established criteria for physicians to meet to order low-THC cannabis or medical cannabis for patients.

On November 7, 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. It also requires DOH to establish regulations regarding the licensure of and regulatory standards for MMTCs and issue identification cards to patients and caregivers. The amendment imposes deadlines for DOH to adopt rules and begin registering MMTCs and issuing identification cards. The amendment also creates a cause of action for any Florida citizen if DOH fails to meet those deadlines.

The bill implements Fla. Const. art X, s. 29 by significantly amending the CMCA. The bill sets requirements for MMTC licensure and regulatory standards for cultivating, processing, testing, packaging, labeling, dispensing, transporting and advertising medical marijuana. The bill establishes requirements for physicians to certify patients for medical use. The bill also specifies criteria for qualified patients and caregivers to meet in order to use and administer marijuana. The bill grants DOH regulatory oversight and authorizes DOH to create a registry and identification card system for patients and caregivers.

The bill grants DOH limited emergency rulemaking authority to ensure DOH can implement the amendment and this bill by the deadlines set forth in the amendment. The bill also establishes procedures for the cause of action against DOH for failure to meet the amendment's deadlines and provides DOH with affirmative defenses.

The bill exempts marijuana for medical use from sales tax. The bill preempts to the state the regulation of cultivation, processing and delivery of marijuana but authorizes local ordinances that determine number and location of dispensing facilities.

The bill makes the necessary conforming changes throughout the Florida statutes.

The bill has a range of fiscal impacts on DOH, Department of Highway Safety and Motor Vehicles (DHSMV), Florida Department of Law Enforcement (FDLE, and the University of Florida College of Pharmacy. It has negative fiscal impact on local governments. See Fiscal Analysis.

The bill takes effect upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

BACKGROUND

Cannabis

Marijuana, also called cannabis, has been used for a variety of health conditions for at least 3,000 years.[1] Currently, the U.S. Food and Drug Administration (FDA) has not approved the use of cannabis to treat any health condition due to the lack of research to show that the benefits of using cannabis outweigh the risks.[2] However, based on the scientific study of cannabinoids, which are chemicals contained in cannabis, the FDA has approved two synthetic prescription drugs that contain certain cannabinoids.[3]

Although there are more than 100 cannabinoids in a marijuana plant, the two main cannabinoids of medical interest are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is a mind-altering chemical that increases appetite and reduces nausea and may also decrease pain, inflammation, and muscle control problems. CBD is a chemical that does not affect the mind or behavior, but may be useful in reducing pain and inflammation, controlling epileptic seizures, and possibly treating mental illness and addictions.[4]

The THC potency of illicit cannabis has consistently increased over time from 4% in 1995 to 12% in 2014. The CBD content has decreased from .28% in 2001 to .15% in 2014. In 1995, the level of THC was 14 times higher than its CBD level. In 2014, the THC level was 80 times the CBD level.[5]

Research on the Medical Use of Cannabis

During the course of drug development, a typical compound is found to have some medical benefit and then extensive tests are undertaken to determine its safety and proper dosage for medical use.[6] In contrast, marijuana has been widely used in the United States for decades. In 2014, just over 49% of the U.S. population over 12 years old had tried marijuana or hashish at least once and just over 10% were current users.[7] The data on the adverse effects of marijuana are more extensive than the data on its effectiveness.[8] Clinical studies of marijuana are difficult to conduct as researchers interested in clinical studies of marijuana face a series of barriers, research funds are limited, and there is a daunting thicket of federal and state regulations to be negotiated.[9] In fact, recently, there has been an exponential rise in the use of marijuana compared to the rise in scientific knowledge of its benefits or adverse effects because some states have allowed the public or patients to access marijuana while the

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[1] U.S. Department of Health & Human Services, National Center for Complementary and Integrative Health, *Medical Marijuana, available at* https://nccih.nih.gov/health/marijuana (last visited on February 12, 2016).
[2] U.S. Department of Health & Human Services, National Center for Complementary and Integrative Health, *What is medical marijuana?, available at* http://www.drugabuse.gov/publications/drugfacts/marijuana-medicine (last visited on February 12, 2016).
[3] *Id.*
[4] *Id.*
[5] ElSohly, M.A., Mehmedic, Z., Foster, S., Gon, C., Chandra, S. and Church, J.C. *Changes in Cannabis Potency Over the Last 2 Decades (1995-2014): Analysis of Current Data in the United States.*. Biological Psychiatry. April 1, 2016; 79:613-619.
[6] Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base*, The National Academies Press, 1999, available at http://www.nap.edu/catalog/6376/marijuana-and-medicine-assessing-the-science-base (last visited on February 12, 2016).
[7] Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, *Results from the 2014 National Survey on Drug Use and Health: Detailed Tables, available at* http://www.samhsa.gov/data/population-data-nsduh/reports (last visited on February 12, 2016).
[8] *Supra,* note 6.
[9] *Id.*

federal government continues to limit scientific and clinical investigators' access to marijuana for research.[10]

In 1999, the Institute of Medicine published a study based on a comprehensive review of existing scientific data and clinical studies pertaining to the medical value of marijuana.[11] The study concluded that there is potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of nausea and vomiting, and appetite stimulation.[12] Recent comprehensive reviews of studies regarding the health effects of marijuana published by the Journal of the American Medical Association and the National Academies of Sciences, Engineering, and Medicine concluded that there is moderate-quality evidence that the use of cannabis or cannabinoids for the treatment of chronic pain, spasticity symptoms in patients with MS, and nausea and vomiting due to chemotherapy.[13] There is limited evidence suggesting that cannabis or cannabinoids are associated with improvements increasing appetite and weight gain in HIV infected patients, sleep disorders, anxiety, Post-Traumatic Stress Disorder and Tourette syndrome.[14] There is inconclusive evidence that cannabis or cannabinoids are effective or ineffective in the treatment of cancer, epilepsy, ALS, Huntington's disease, Parkinson's, or spasticity symptoms in patients with spinal cord injuries.[15]

There is also research that suggests the combination of THC and CBD increases the efficacy of treatment while reducing adverse reactions.[16] CBD may offset the negative effects of THC including intoxication, sedation, and increased heartrate. CBD may also relive pain, nausea, and vomiting and contain anti-carcinogenic properties.

The 1999 Institute of Medicine study also concluded that smoked marijuana is a crude THC delivery system that delivers harmful substances.[17] The Institute of Medicine's study, which warned that smoking marijuana is harmful, was corroborated by a study published in the New England Journal of Medicine in 2014.[18] Smoking marijuana is associated with worse respiratory symptoms such as coughing, wheezing, and chest tightness and more frequent episodes of chronic bronchitis.[19] Marijuana smoke contains many of the same toxins as tobacco smoke, including those that cause cardiovascular disease.[20] A recent study found that one minute of exposure to second hand marijuana smoke diminishes blood vessel function to the same extent as second hand tobacco smoke, but the harmful cardiovascular effects last three times longer.[21]

The New England Journal of Medicine 2014 study further warned that long-term marijuana use can lead to addiction and that adolescents have an increased vulnerability to adverse long-term outcomes from marijuana use.[22] Specifically, the study found that, as compared with persons who begin to use

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[10] Friedman, D., M.D., Devinsky, O., M.D., *Cannabinoids in the Treatment of Epilepsy*, NEW ENG. J. MED., September 10, 2015, on file with the Health Quality Subcommittee.
[11] *Supra* note 6.
[12] *Id.*
[13] Whiting, P.F., et. al., *Cannabinoids for Medical Use: A Systematic Review and Meta-analysis*, JAMA (June 2015) and The National Academies of Sciences, Engineering, and Medicine, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research* (2017) available at: https://www.nap.edu/catalog/24625/the-health-effects-of-cannabis-and-cannabinoids-the-current-state (last visited on March 3, 2017).
[14] *Id.*
[15] The National Academies of Sciences, Engineering, and Medicine, *The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research* (2017) available at: https://www.nap.edu/catalog/24625/the-health-effects-of-cannabis-and-cannabinoids-the-current-state (last visited on March 3, 2017).
[16] Russo, E., Guy, G.W., *A tale of two cannabinoids:The therapeutic rationale for combining tetrahydrocannabinol and cannabidiol.* (2006) Med Hypotheses 66(2):234-46.
[17] *Supra note 6*
[18] Volkow, N.D., Baler, R.D., Compton, W.M. and Weiss, S.R., *Adverse Health Effects of Marijuana Use*, NEW ENG. J. MED., June 5, 2014, *available at* dfaf.org/assets/docs/Adverse%20health%20effects.pdf (last visited on February 12, 2016).
[19] *Supra*, note 15.
[20] Wang, X., Derakhshandeh, R., Liu, J., Narayan, S., Nabavizadeh, P., Le, S.,Springer, M. L. (2016). *One Minute of Marijuana Secondhand Smoke Exposure Substantially Impairs Vascular Endothelial Function.* Journal of the American Heart Association: Cardiovascular and Cerebrovascular Disease, 5(8), e003858. http://doi.org/10.1161/JAHA.116.003858
[21] *Id.*
[22] *Supra,* note 18.

marijuana in adulthood, those who begin in adolescence are approximately 2 to 4 times as likely to have symptoms of cannabis dependence within 2 years after first use.[23] The study also found that cannabis-based treatment with THC may have irreversible effects on brain development in adolescents as the brain's endocannabinoid system undergoes development in childhood and adolescence.[24] Heavy use of marijuana by adolescents is associated with impairments in attention, learning, memory, poor grades, high drop rates and I.Q. reduction.[25]

Federal Regulation of Cannabis

Criminal Laws and Enforcement

The Federal Controlled Substances Act[26] lists cannabis as a Schedule I drug, meaning it has a high potential for abuse, has no currently accepted medical use, and has a lack of accepted safety for use under medical supervision.[27] The Federal Controlled Substances Act imposes penalties on those who possess, sell, distribute, dispense, and use cannabis.[28] A first misdemeanor offense for possession of cannabis in any amount can result in a $1,000 fine and up to a year in prison, climbing for subsequent offenses to as much as $5,000 and three years.[29] Selling and cultivating cannabis are subject to even greater penalties.[30]

In August of 2013, the United States Department of Justice (USDOJ) issued a publication entitled "Smart on Crime: Reforming the Criminal Justice System for the 21st Century."[31] This document details the federal government's changing stance on low-level drug crimes announcing a "change in Department of Justice charging policies so that certain people who have committed low-level, nonviolent drug offenses, who have no ties to large-scale organizations, gangs, or cartels will no longer be charged with offenses that impose draconian mandatory minimum sentences. Under the revised policy, these people would instead receive sentences better suited to their individual conduct rather than excessive prison terms more appropriate for violent criminals or drug kingpins."[32]

On August 29, 2013, United States Deputy Attorney General James Cole issued a memorandum to federal attorneys that provided guidance to states that have legalized cannabis in some form regarding the federal government's cannabis-related offense enforcement policies.[33] The memo stated that the USDOJ was committed to using its limited investigative and prosecutorial resources to address the most significant threats in the most effective, consistent, and rational ways, and outlined eight areas of enforcement priorities.[34]

These enforcement priorities include preventing cannabis from being distributed to minors, preventing cannabis sale revenues going to criminal gangs or other similar organizations, preventing the diversion of cannabis from states where it is legal under state law in some form to other states, preventing state-authorized cannabis activity from being used as a cover or pretext for trafficking of other illegal drugs or illegal activity, preventing violence and the use of firearms in the cultivation and distribution of cannabis, preventing drugged driving and the exacerbation of other adverse public health consequences, and

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[23] *Id.*
[24] *Id.*
[25] Bertha K. Madras, PhD., Dept. of Psychiatry, McLean Hospital, Harvard Medical School, *Marijuana: Risks and Consequences,* prepared for Florida Legislature, February 2016 and *Presentation to the Health Quality Subcommittee on January 11, 2017.* On file with the Health Quality Subcommittee.
[26] 21 U.S.C. ss. 801-971.
[27] 21 U.S.C. s. 812.
[28] 21 U.S.C. ss. 841-65.
[29] 21 U.S.C. s. 844.
[30] 21 U.S.C. ss. 841-65.
[31] U.S. Department of Justice, *Smart on Crime: Reforming the Criminal Justice System for the 21st Century.* Available at: http://www.justice.gov/ag/smart-on-crime.pdf. (last visited on March 26, 2017).
[32] *Id.*
[33] U.S. Department of Justice, *Guidance Regarding Marijuana Enforcement*, August 29, 2014. Available at: http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf (last visited on March 26, 2017).
[34] *Id.*

preventing cannabis being grown, possessed or used on public lands.[35] The memo indicated that outside of the listed enforcement priorities, the federal government would not enforce federal cannabis-related laws in states that have legalized the drug and that have a robust regulatory scheme in place with effective enforcement procedures that address the enforcement priorities of the federal government listed above.[36]

In 2014, Congress enacted the Consolidated and Further Continuing Appropriations Act of 2015 (Appropriations Act of 2015). Section 538 of the Appropriations Act of 2015 prohibits the USDOJ from expending any funds in connection with the enforcement of any law that interferes with a state's ability to implement its own state law that authorizes the use, distribution, possession, or cultivation of medical marijuana.[37] Despite this prohibition in the Appropriations Act of 2015, the USDOJ has continued to take some enforcement measures against dispensaries of cannabis for medical use. However, in October 2015, the United States District Court for the Northern District of California held that section 538 plainly on its face prohibits the Department of Justice from taking such action.[38] Congress recently re-enacted the prohibition in section 542 of the Consolidated Appropriations Act of 2016.[39]

Federal Financial Transaction Laws and Enforcement[40]

Under the U.S. dual banking system, financial institutions are chartered under either federal or state law. All financial institutions, regardless whether they are federally or state-chartered, must comply with the federal Bank Secrecy Act and anti-money laundering laws and regulations ("BSA/AML"). The BSA/AML contains a broad set of programmatic requirements, enforced by the Financial Crimes Enforcement Network (FinCEN), to safeguard the U.S. financial system from illicit use, to combat money laundering, and to promote national security through the collection, analysis, and dissemination of financial intelligence. The BSA/AML requires all financial institutions to assist U.S. law enforcement by keeping records of cash purchases of negotiable instruments, filing reports of cash transactions exceeding $10,000, and filing suspicious activity reports if the financial institutions suspect money laundering, tax evasion, or other criminal activities. The BSA/AML also requires financial institutions to implement robust customer identification programs/"know your customer" verification procedures for new account holders.

In 2014, FinCEN issued guidance for financial institutions regarding the provision of banking services to marijuana-related businesses.[41] Financial institutions providing services to marijuana-related businesses must file marijuana-specific suspicious activity reports for all of its marijuana-related businesses. The type of marijuana-specific suspicious activity report that must be filed is based on whether or not the financial institution reasonably believes, based on its due diligence, that the marijuana-related business is violating one of the Cole Memo priorities or state law. The guidance requires heightened due diligence and reporting requirements by financial institutions but does not provide immunity and is discretionary for prosecutors to follow.

State Regulation of Cannabis for Medical Use

Currently, 27 states[42] and the District of Columbia have laws that permit and regulate the use of cannabis for medicinal purposes.[43] While these laws vary widely, most specify the medical conditions a

[35] *Id.*
[36] *Id.*
[37] Pub. L. 113-235 (2014).
[38] *U.S. v. Marin Alliance for Medical Marijuana*, 2015 WL 6123062 (N.D. Cal. Oct. 19, 2015).
[39] Pub. L. 114-113 (2015).
[40] Florida House of Representatives, Insurance and Banking Subcommittee, *Banking Services for Marijuana Businesses* (2016). On file with the Health Quality Subcommittee.
[41] United States Department of Treasury, Financial Crimes Enforcement Unit, *BSA Expectations Regarding Marijuana-Related Businesses.* (February 2014) Available at: https://www.fincen.gov/resources/statutes-regulations/guidance/bsa-expectations-regarding-marijuana-related-businesses (last visited March 26, 2017).
[42] These states include: Alaska, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island,

patient must be diagnosed with to be eligible to use cannabis for treatment, allow a caregiver to assist with such treatment, require the registration of the patient and caregiver and a registration ID card to be issued to the patient and caregiver, restrict where cannabis can be used, and provide standards pertaining to the growing, processing, packaging, transport, and dispensing of cannabis for medical use.

Medical Use of Cannabis

Of the 27 states that allow medical use of cannabis, most have a statutory list of medical conditions for which the patient may be treated with cannabis for medical use, the particular conditions vary from state to state. Twenty three states also provide a mechanism for the list of qualifying medical conditions to be expanded, mostly by allowing the public to petition a state agency or a board to add qualifying medical conditions to the list or by providing a physician with some discretion in determining whether such treatment would benefit the patient.[44] The chart below indicates the most common qualifying conditions.[45]

Medical Condition	Number of States
Cancer	27
HIV/AIDS	27
Multiple Sclerosis	26
Epilepsy	26
Glaucoma	25
Chronic Pain	24
Chron's Disease	17
Amyotrophic Lateral Sclerosis (ALS)	14
Hepatitis C	12
Alzheimer's Disease	11

Five states include terminal illness with a probable life expectancy of one year or less as a qualifying condition (Delaware, Minnesota, New Jersey, New York and Pennsylvania).

Twenty-one states require a physician to certify that the patient has a qualifying condition. Some states require physicians to have certain qualifications to be able to order cannabis for medical use for qualified patients.[46] Sixteen states require a physician to report the patient's diagnosis when

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Vermont, and Washington. California was the first to establish a medical marijuana program in 1996 and Ohio and Pennsylvania were the most recent state to pass medical marijuana legislation which took effect in 2016. National Conference of State Legislatures, *State Medical Marijuana Laws, available at* http://www.ncsl.org/issues-research/health/state-medical-marijuana-laws.aspx (last visited on February 24, 2017).

[43] According to the National Conference of State Legislatures, 17 other states allow the use of low-THC cannabis for medical use or allow a legal defense for such use, including Florida. National Conference of State Legislatures, *State Medical Marijuana Laws, available at* http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (last visited on February 15, 2017).

[44] For example, see the following state laws allowing an agency to approve other conditions: AS § 17.37.070 (Alaska), A.R.S. § 36-2801 (Arizona), C.R.S.A. Const. Art. 18, § 14 (Colorado), C.G.S.A. § 21a-408 (Connecticut), 16 Del.C. § 4902A (Delaware), HRS § 329-121 (Hawaii), 410 ILCS 130/10 (Illinois), M.C.L.A. 333.26423 (Michigan), M.S.A. §152.22 (Minnesota), N.R.S. 453A.050 (Nevada), N.H. Rev. Stat. §126-X:1 (New Hampshire), N.J.S.A. 24:6I-3 (New Jersey), N.M.S.A. 1978, § 26-2B-3 (New Mexico), O.R.S. § 475.302 (Oregon), and Gen. Laws 1956, § 21-28.6-3 (Rhode Island). For examples of states allowing for physician discretion in treating other conditions with the medical use of cannabis, see M.G.L.A. 94C App. §1-2.

[45] These are conditions specified in states' statutes or state constitutional amendments. Many also include symptoms or conditions that could apply to several other conditions, such as cachexia or wasting syndrome, severe pain, severe nausea, seizures, or muscle spasms.

[46] For example, the following states require the ordering physician to be a neurologist: Iowa (I.C.A. § 124D.3), Missouri (V.A.M.S. 192.945), Utah (U.C.A. 1953 § 26-56-103), and Wyoming (W.S.1977 § 35-7-1902). Additionally, Vermont requires a physician to establish a bona fide relationship with the patient for not less than 6 months before ordering such treatment. *See* 18 V.S.A. § 4472.

recommending or certifying medical marijuana, usually on a form certifying the patient has a qualifying condition that is submitted to the state agency that regulates the medical use of marijuana.[47]
All states require proof of residency in order for a patient to use medical cannabis.[48] Twenty states require qualified patients to register with the state and obtain a registration ID card, usually from a state agency.[49]

Patient populations vary greatly by state, from 0.1 patients per 1,000 state residents to 19.8 patients per 1,000 state residents.[50] The Florida Office of Economic and Demographic Research estimated that the number of potential users of medical marijuana in Florida upon full implementation of the 2014 constitutional amendment allowing use of marijuana for the treatment of debilitating medical conditions would be approximately 450,000 persons per year.[51] However, calculating the expected patient population and rate of increase is difficult. In Colorado, the patient population grew exponentially after 2009 when retail dispensaries were established and the caregiver limit of 5 patients per caregiver was eliminated. The Colorado patient population increased from roughly 5,000 in 2009 to just over 100,000 patients in 2010. The Colorado patient population has remained steady since 2010. Other states have experienced slower and steadier increases in patients.[52]

Most states place restrictions on where cannabis for medical use may be used by patients. Typically, cannabis for medical use may not be used in public places, such as parks and on buses, or in areas where there are more stringent restrictions placed on the use of drugs, such as in or around schools or in prisons.[53]

Caregivers

Twenty-three states allow caregivers to purchase or grow cannabis for the patient, possess a specified quantity of cannabis, and aid the patient in using cannabis, but prohibit them from using cannabis themselves. Eleven states also require the caregiver to be at least 21[54] and Colorado prohibits the caregiver from being the patient's physician.[55] Like the patient receiving treatment, the caregiver is usually required to be registered and have a registration ID card, typically issued by a state agency.

Regulatory Framework

There are two general methods by which patients can obtain cannabis for medical use. They may either self-cultivate the cannabis in their homes, or buy commercially-produced cannabis from specified points of sale or dispensaries. Sixteen states allow patients and/or their caregivers to cultivate cannabis. Regulations governing the amount of cannabis for medical use that may be grown or dispensed vary widely. For example, the amount of cannabis for medical use patients are allowed to have ranges from 1 ounce of usable[56] cannabis to 24 ounces of usable cannabis, depending on the state. Furthermore,

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[47] Arizona, Colorado, Delaware, Georgia, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington.
[48] Procon.org, *28 Legal Medical Marijuana States and DC: Laws, Fees, and Possession Limits*. Available at: http://medicalmarijuana.procon.org/view.resource.php?resourceID=005889 (last visited on February 24, 2017).
[49] *Supra* note 42.
[50] Procong.org, *Number of Legal Medical Marijuana Patients*. Available at: http://medicalmarijuana.procon.org/view.resource.php?resourceID=005889 (last visited on February 24, 2017).
[51] The Florida Office of Economic and Demographic Research, *Complete Initiative Financial Information Statement for the Use of Marijuana for Debilitating Medical Conditions (15-01)*.
[52] For example Arizona saw an increase from 34,699 in 2012 to 43,148 in 2013, 65,547 in 2014, 92,838 in 2015 and a slight decrease to 89,405 in 2016.
[53] For example, see N.R.S. 453A.322 (Nevada), N.J.S.A. 18A:40-12.22 (New Jersey), 5 CCR 1006-2:12 (Colorado), and West's Ann.Cal.Health & Safety Code § 11362.768 (California).
[54] See, for example, 22 M.R.S.A. § 2423-A (Maine), 105 CMR 725.020 (Massachusetts), and Gen.Laws 1956, § 44-67-2 (Rhode Island).
[55] *See*, e.g., the definition of "primary caregiver" in C.R.S.A. § 25-1.5-106 (Colorado).
[56] "Usable cannabis" generally means the seeds, leaves, buds, and flowers of the cannabis plant and any mixture or preparation thereof, but does not include the stalks and roots of the plant or the weight of any non-cannabis ingredients combined with cannabis. For example, see 410 ILCS 130/10 (Illinois) and OAR 333-008-0010 (Oregon).

the number of cannabis plants that patients are allowed to grow ranges from 2 mature marijuana plants to 18 seedling marijuana plants. At least 10 states limit the amount of cannabis for medical use that may be ordered by specifying the number of days or months of a supply a physician may order.[57]

States regulations vary for the commercial production of marijuana for medical use. A state may require vertical integration, in which a single entity engages in the entire enterprise of manufacturing and distribution. Or a state may allow horizontal integration, in which separate entities form a drug manufacturing/distribution chain, regulated by a single state agency or multiple state agencies. Ten states require vertical integration in which a single licensed entity cultivates, processes, and dispenses medical marijuana. Four of states require such entities to operate as non-profits. Colorado requires vertical integration for medical but requires horizontal integration for recreational. Colorado found that horizontal integration has more of a tendency towards monopolization or consolidation than vertical integration, especially among growers.[58]

Quality and Safety Standards

Most states with cannabis laws require entities that cultivate and process medical cannabis to meet certain standards to ensure the quality, safety and security of medical cannabis.

For example, 22 states require marijuana cultivated and process for medical use be laboratory tested for potency, mold, toxins, contaminants, and pesticides. Six states require laboratories that test medical marijuana be licensed or registered by the state. Oregon requires that laboratories that test medical cannabis be accredited and licensed through the state's Environmental Lab Accreditation Program. The accreditation program ensures that laboratories meet the standards adopted by the National Environmental Laboratory Accreditation Program and ensures the accuracy and reliability of their test results. Connecticut requires laboratories to be accredited to standards set by the International Organization for Standardization and licensed as a controlled substance laboratory.[59] Connecticut also prohibits laboratories from having a direct or indirect interest in any entity that cultivates processes or dispenses or in any certifying physician.[60]

States also require certain packaging and labeling standards for cannabis for medical use, including the requirement for packaging to meet the standards under the United States Poison Prevention Packaging Act which requires child-resistant packaging.[61]

Security and Diversion Standards

Some states have experienced diversion of medical cannabis into the black market. An estimated 75 percent of the medical marijuana in the State of Oregon is diverted to the black market.[62] About 60 to 80 percent of the black-market cannabis consumed nationally is from California.[63] In Colorado, patients and caregivers are allowed to cultivate up to 99 plants without any state or local regulation, which has resulted in criminal enterprises operating under the guise of patients or caregivers.[64] During 2009-2012,

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[57] *See* C.G.S.A. §21a-4089 (Connecticut), 410 ILCS 130/10 (Illinois), MD Code, Health-General, § 13-3301 (Maryland), M.G.L.A. 94C App. §1-2 (Massachusetts), M.S.A. § 152.29 (Minnesota), N.R.S. 453A.200 (Nevada), N.H. Rev. Stat. § 126-X:8 (New Hampshire), N.J.S.A. 24:6I-10 (New Jersey), N.M.S.A. 1978, § 26-2B-3 (New Mexico), and McKinney's Public Health Law § 3362 (New York).
[58] Andrew Freedman, Former Director of Marijuana Coordination in Colorado, *Presentation to the Health Quality Subcommittee on January 25, 2017*. On file with the Health Quality Subcommittee.
[59] *See* Conn. Gen. Stat. Ch. 420f and Conn. Regs. §§ 21a-408-1 to 21a-408-70 (Connecticut)
[60] *Id.*
[61] *See* C.R.S.A. § 12-43.3-104(Colorado) and Haw. Admin. Rules (HAR) § 11-850-92 (Hawaii).
[62] Rob Patridge, chairman of the Oregon Liquor Control Commission, quoted at: http://www.oregonlive.com/mapes/index.ssf/2015/03/medical_marijuana_growers_may.html
[63]Hezekiah Allen, Executive Director of the California Growers Association, quoted at: http://www.laweekly.com/news/how-will-marijuana-legalization-affect-californias-black-market-exports-7660623
[64] Colorado Office of the Governor, *Marijuana Grey Market Report (2016)*. Available at: https://www.colorado.gov/pacific/sites/default/files/16Marijuana0817Marijuana%20Grey%20Market.pdf

the yearly average number of interdiction seizures of Colorado marijuana increased 357% from 53 to 242 per year.[65]

To prevent diversion, some states require facilities that grow, process, transport, and dispense cannabis for medical use to implement an inventory tracking system that tracks the cannabis from "seed-to-sale."[66] Nine states require one statewide approved "seed-to-sale" tracking program be used by all facilities that grow, process, transport, and dispense cannabis for medical use.[67] Colorado's requirement for licensees to use one "seed-to-sale" tracking system established by the state has been successful in preventing diversion from commercial production into the black market and preventing access by youth. [68]

Medical Marijuana Products

Some states allow for the production of only certain forms of medical marijuana. Minnesota only allows marijuana in liquid, oil, pill, or vapor form for medical use.[69] Several states ban smoking of marijuana for medical use.[70] New York only allows production of five "brands" of medical marijuana, one of which must be low-THC and one that must have an equal THC to CBD ratio.[71]

Fifteen states allow patients to consume cannabis-infused food products known as "edibles." However some states have faced difficulties in ensuring the safety and quality of edible products. The effects of THC are typically delayed 1-3 hours after ingestion. Users that feel no immediate effect after ingestion may consume more than the suggested serving size, leading to overdose which can cause psychosis.[72] In Colorado, edibles were implicated in three deaths.[73] Calls to poison-control centers for unintentional marijuana exposure in children under the age of 9 occur at higher rates in states where medical marijuana is legal, [74] and at a children's hospital and a regional poison control center in Colorado edibles were responsible for over half of the accidental marijuana ingestions by children.[75]

Colorado and Oregon recently implemented new regulations regarding edibles.[76] Colorado prohibits edibles in the shape or likeness of humans, animals, or fruit. Colorado and Oregon require that edibles be marked with a universal symbol and labeled with the serving size and amount of THC. Both cap the amount of THC per edible at 100 mg. The efficacy of these regulations in preventing overdose or accidental ingestion by children is unknown at this point.

Labeling of the doses of THC and CBD in edibles has been found to be unreliable.[77] Tests of edibles purchased in California and Washington found that only 17% were accurately labeled for THC. On average, the tested edibles delivered a dose of THC 28 times higher than labeled. Sixty percent of the products that were tested had at least 10 percent less THC than labeled. Fifty-nine percent had

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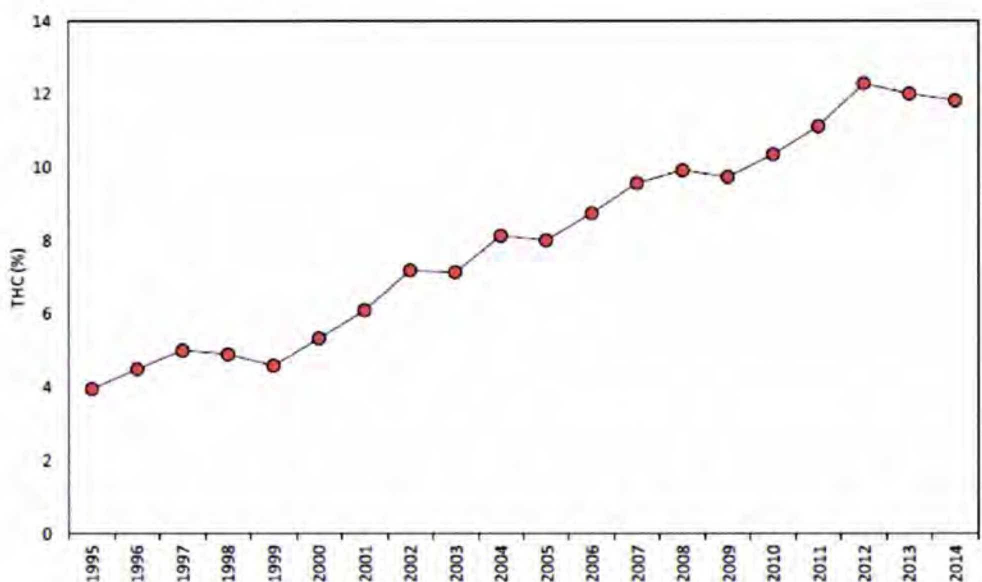
[65] Rocky Mountain High Intensity Drug Trafficking Area Program, *The impact of Legalization of Marijuana in Colorado, Vol. 4 (2016),* available at http://www.rmhidta.org
[66] *See* C.R.S.A. § 35-61-105.5 (Colorado), OAR 333-064-0100 (Oregon), and West's RCWA 69.51A.250 (Washington).
[67] Alaska, Colorado, Hawaii, Illinois, Nevada, New Mexico, New York, Oregon and Washington require the use of one seed-to-sale tracking program established by the state.
[68] Andrew Freedman, Former Director of Marijuana Coordination in Colorado, *Presentation to the Health Quality Subcommittee on January 25, 2017.* On file with the Health Quality Subcommittee.
[69] *See* Minn. Stat. § 152.22 (Minnesota)
[70] Minnesota, New York, Ohio and Pennsylvania ban the smoking of marijuana for medical use.
[71] *See* NYCRR 1000.4 (New York)
[72] Bertha K. Madras, PhD., *Marijuana: Risks and Consequences*, prepared for Florida Legislature, February 2016. On file with the Health Quality Subcommittee.
[73] *See* http://www.newsweek.com/deaths-prompt-colorado-crackdown-pot-infused-food-251833; http://denver.cbslocal.com/2015/03/25/marijuana-edibles-blamed-for-keystone-death/; and https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6428a6.htm?s_cid=mm6428a6_x
[74] Wang GS., Roosevelt G., Le Lait MC., et al. *Association of Unintentional Pediatric Exposures with Decriminalization of Marijuana in the United States.* Ann Emerg Med 2014; 63:684-689.
[75] Wang GS, et. al., *Pediatric Marijuana Exposures in a Medical Marijuana State.* JAMA Pediatr 2013;167:630-633.
[76] See 1 CCR 212-1 (Colorado) and OAR 333-007-0220 (Oregon).
[77] Vandrey, R., Raber, J., Raber M., Douglass B., Miller C, Bonn-Miller M., *Cannabinoid Dose and Label Accuracy in Edible Medical Cannabis Products*, JAMA 2015; 2491-2493.

detectable levels of CBD, but only 13 of those products had CBD labeled. The average ratio of THC to CBD was 36:1 and only one product had a 1:1 ratio. Inconsistent dosing poses a problem for patients who may experience adverse effects and less effective treatment.

Marijuana potency has increased in recent decades. One study examined samples from illicit marijuana seized by the U.S. Drug Enforcement Administration 1995-2014. It documents a rise from 4% THC to over 12% THC in that time.[78]



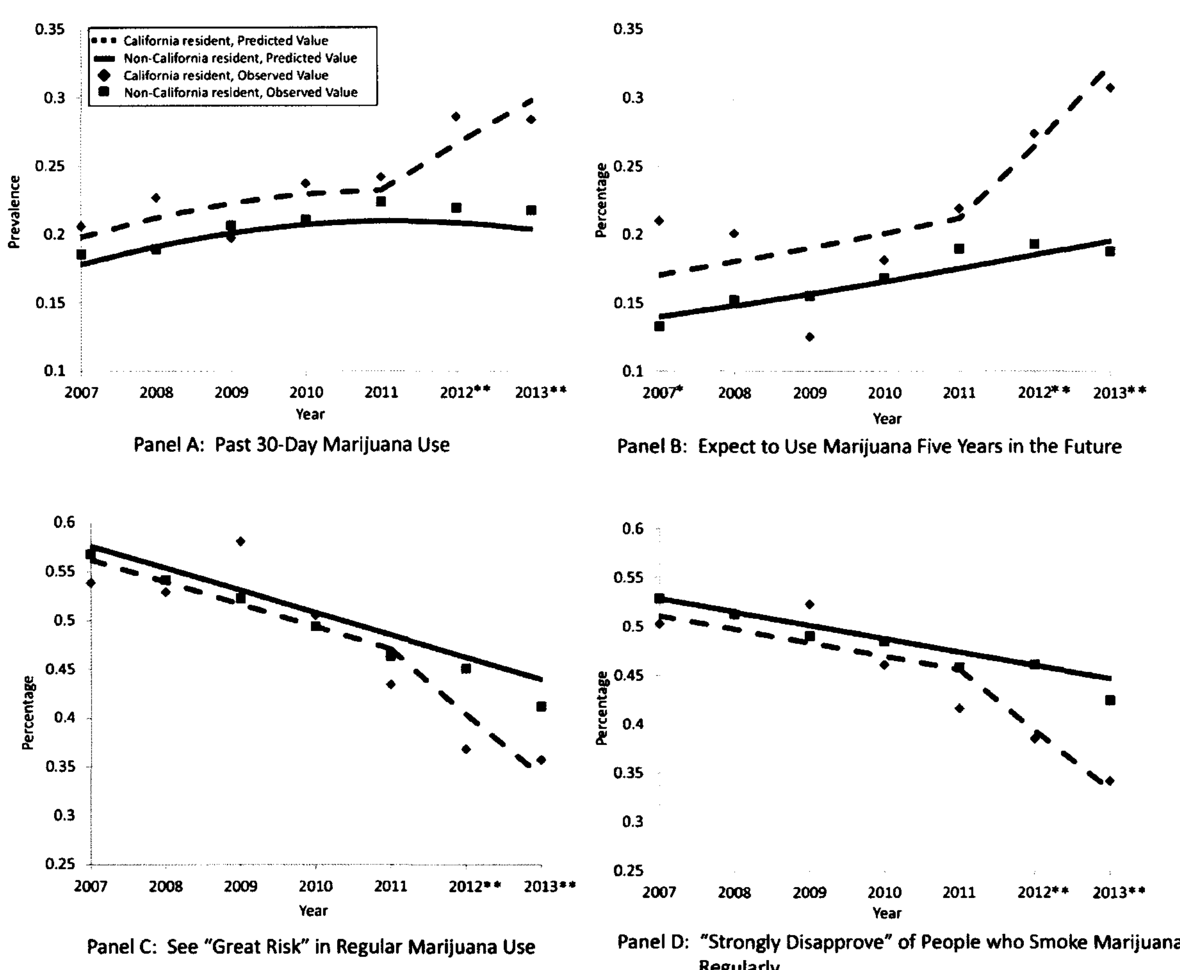
An analysis by a marijuana testing laboratory in Colorado found THC levels of close to 30%, and many samples with little or no CBD.[79]

Youth Education and Prevention

Recent research has found that a one percentage point increase in the amount of adults registered as medical marijuana patients within a state increases the prevalence of past month use by youth by 5-6%.[80] Studies have also found that medical marijuana laws reduce the perception of harm among adolescents.[81] A 2016 study in California found reduced perception of harm by youth after legalization, and increased youth use.[82]

[78] *Supra*, note 5.
[79] American Chemical Society, March 23, 2015, available at https://www.acs.org/content/acs/en/pressroom/newsreleases/2015/march/legalizing-marijuana-and-the-new-science-of-weed-video.html (last viewed March 25, 2017). The analysis also found high levels of contaminants.
[80] Rosalie Pacula, PhD, RAND Drug Policy Research Center, *Presentation to the Health Quality Subcommittee on January 25, 2017.* On file with the Health Quality Subcommittee.
[81] *Id.*
[82] Miech, R., Johnston, L., O'Malley, P, Bachman, J., Schulenberg, J., Patrick, M., *Trends in use of marijuana and attitudes toward marijuana among youth before and after decriminalization: The case of California 2007–2013*, International Journal of Drug Policy; vol. 26:4; 336-344 (April 2015).

Marijuana Use and Attitudes among California 12th Graders by Year[83]



In Colorado, there was a 26% increase in youth monthly marijuana use in the three years after medical marijuana retail dispensaries were established in 2009.[84] A study of adolescents in outpatient substance treatment in Denver, CO, found that 48.8% reported obtaining marijuana from someone with a medical marijuana license.[85]

Colorado and Washington have implemented youth education and prevention campaigns.[86] Colorado performed a survey of youth in 2014 to determine baseline knowledge among youth of marijuana laws and perceptions of harm and risk. The survey found that youth were less familiar with marijuana laws and perceived the use of marijuana as less harmful.[87] Colorado launched its education campaign in mid-2015 with the focus on the health and legal consequences of marijuana use for youth and has had a positive effect on youth education.[88] Washington's program included providing grants to prevention

[83] *Id.*
[84] Rocky Mountain High Intensity Drug Trafficking Area Program, *The impact of Legalization of Marijuana in Colorado, Vol. 2 (2014)*, available at http://www.rmhidta.org
[85] Thurstone,C. Lieberman, S., Schmiege, S, *Medical marijuana diversion and associated problems in adolescent substance treatment. Drug Alcohol Depend.* 2011 Nov 1; 118(2-3): 489–492.
[86] *See* http://protectwhatsnext.com/ (Colorado) and http://www.doh.wa.gov/YouandYourFamily/Marijuana (Washington)
[87] https://www.colorado.gov/pacific/sites/default/files/MJ_RMEP_baseline-analysis_Youth-Findings.pdf
[88] Andrew Freedman, Former Director of Marijuana Coordination in Colorado, *Presentation to the Health Quality Subcommittee on January 25, 2017.* On file with the Health Quality Subcommittee.

and treatment programs. Evaluation of the 21 programs receiving grants found that 18 of the programs produced benefits that outweighed the costs of funding.[89]

Advertising

Greater exposure to medical marijuana advertisements at an early age is associated with higher marijuana use by adolescents.[90] Colorado recently enacted legislation to regulate medical marijuana advertising that has a high likelihood of reaching youth. The new law also prohibits health or physical benefit claims, pop up advertising, banner ads on mass market websites, marketing directing toward location-based devices, and opt-in marketing that does not permit an easy and permanent and opt-out feature.[91] Colorado restricts retail advertising aimed at people under the age of 21 and restricts advertising across various mediums unless there is reliable evidence that no more than 30% of the viewing audience is reasonably expected to be under the age of 21.[92] Outdoor advertising is generally prohibited in Colorado except for signage identifying location of a retail dispensary.

Florida's Cannabis Laws

Criminal Law and Medical Necessity Defense

Florida's drug control laws are set forth in ch. 893, F.S., entitled the Florida Comprehensive Drug Abuse Prevention and Control Act (Drug Control Act).[93] The Drug Control Act classifies controlled substances into five categories, ranging from Schedule I to Schedule V.[94] Cannabis is currently a Schedule I controlled substance,[95] which means it has a high potential for abuse, it has no currently accepted medical use in treatment in the United States, and its use under medical supervision does not meet accepted safety standards.[96] Cannabis is defined as:

> All parts of any plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. The term does not include "low-THC cannabis," as defined in s. 381.986, if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed, in conformance with s. 381.986.[97]

The Drug Control Act contains a variety of provisions criminalizing behavior related to cannabis:

- Section 893.13, F.S., makes it a crime to sell, manufacture, deliver, purchase, or possess cannabis. The penalties for these offenses range from first degree misdemeanors to second degree felonies.[98]
- Section 893.135(1)(a), F.S., makes it a first degree felony[99] to traffic in cannabis, i.e., to possess, sell, purchase, manufacture, deliver, or import more than 25 pounds of cannabis or 300 or more cannabis plants. Depending on the amount of cannabis or cannabis plants

[89] Washington State Institute for Public Policy, *Preventing and Treating Youth Marijuana Use: An Updated Review of the Evidence.* Available at http://www.wsipp.wa.gov/ReportFile/1571/Wsipp_Preventing-and-Treating-Youth-Marijuana-Use-An-Updated-Review-of-the-Evidence_Report.pdf
[90] *Supra*, note 80.
[91] *See* C.R.S.A. §12-43.3-202 (Colorado).
[92] *See* 1 CCR 212-2 (Colorado)
[93] Section 893.01, F.S.
[94] Section 893.03, F.S.
[95] Section 893.03(1)(c)7., F.S.
[96] Section 893.03(1), F.S.
[97] Section 893.02(3), F.S.
[98] A first degree misdemeanor is punishable by up to one year in county jail and a $1,000 fine; a third degree felony is punishable by up to five years imprisonment and a $5,000 fine; and a second degree felony is punishable by up to 15 years imprisonment and a $10,000 fine. ss. 775.082 and 775.083, F.S.
[99] A first degree felony is punishable by up to 30 years imprisonment and a $10,000 fine. ss. 775.082 and 775.083, F.S.

trafficked, mandatory minimum sentences of three to 15 years and fines of $25,000 to $200,000 apply to a conviction.[100]

- Section 893.147, F.S., makes it a crime to possess, use, deliver, manufacture, transport, or sell drug paraphernalia.[101] The penalties for these offenses range from first degree misdemeanors to second degree felonies.[102]

Florida courts have held that persons charged with offenses based on the possession, use, or manufacture of marijuana may use the medical necessity defense, which requires a defendant to prove that:

- He or she did not intentionally bring about the circumstance which precipitated the unlawful act;
- He or she could not accomplish the same objective using a less offensive alternative; and
- The evil sought to be avoided was more heinous than the unlawful act.[103]

In *Jenks v. State,*[104] the defendants, a married couple, suffered from uncontrollable nausea due to AIDS treatment and had testimony from their physician that they could find no effective alternative treatment. The defendants tried cannabis, and after finding that it successfully treated their symptoms, decided to grow two cannabis plants.[105] They were subsequently charged with manufacturing and possession of drug paraphernalia. Under these facts, the First District Court of Appeal found that "section 893.03 does not preclude the defense of medical necessity" and that the defendants met the criteria for the medical necessity defense.[106] The court ordered the defendants to be acquitted.[107]

Seven years after the *Jenks* decision, the First District Court of Appeal again recognized the medical necessity defense in *Sowell v. State.*[108] More recently, the State Attorney's Office in the Twelfth Judicial Circuit cited the medical necessity defense as the rationale for not prosecuting a person arrested for cultivating a small amount of cannabis in his home for his wife's medical use.[109]

Compassionate Medical Cannabis Act

The Compassionate Medical Cannabis Act (CMCA) was enacted in 2014.[110] The CMCA legalized a low-THC and high-CBD form of low-THC cannabis[111] for medical use[112] 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.[113]

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[100] Section 893.13(1)(a), F.S.
[101] Drug paraphernalia is defined in s. 893.145, F.S., as: All equipment, products, and materials of any kind which are used, intended for use, or designed for use in the planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, transporting, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of ch. 893, F.S., or s. 877.111, F.S.
[102] Section 893.147, F.S.
[103] *Jenks v. State*, 582 So.2d 676, 679 (Fla. 1st DCA 1991), *rev. denied,* 589 So.2d 292 (Fla. 1991).
[104] 582 So.2d 676 (Fla. 1st DCA 1991).
[105] *Id.*
[106] *Id.*
[107] *Id.*
[108] 739 So.2d 333 (Fla. 1st DCA 1998).
[109] *Interdepartmental Memorandum*, State Attorney's Office for the Twelfth Judicial Circuit of Florida, SAO Case # 13CF007016AM, April 2, 2013, on file with the Health Quality Subcommittee.
[110] *See* ch. 2014-157, L.O.F., ch. 2016-123, L.O.F. and s. 381.986, F.S.
[111] 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.
[112] 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."
[113] Section 499.0295, F.S.

Dispensing Organizations

Under the CMCA, 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. DOH was also authorized to impose an initial application and biennial renewal fee that is sufficient to cover the costs of regulating the program.[114] To be approved as a dispensing organization, an applicant must:

- Possess a certificate of registration issued by the Department of Agriculture and Consumer Services for the cultivation of more than 400,000 plants;
- Be operated by a nurseryman;
- Have been operating as a registered nursery in this state for at least 30 continuous years;
- Have the technical and technological ability to cultivate and produce low-THC cannabis;
- Have the ability to secure the premises, resources, and personnel necessary to operate as a dispensing organization.
- Have the ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances.
- Have an infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department.
- Have the financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department. Upon approval, the applicant must post a $5 million performance bond.
- Have all owners and managers fingerprinted and all owners and managers must have successfully passed a level 2 background screening pursuant to s. 435.04.
- Employ a medical director, who must be a Florida-licensed allopathic physician or osteopathic physician and have successfully completed a course and examination that encompasses appropriate safety procedures and knowledge of low-THC cannabis.

Implementation by DOH of the dispensing organization approval process was delayed due to litigation challenging proposed rules that addressed the initial application requirements for dispensing organizations, revocation of dispensing organization approval, and inspection and cultivation authorization procedures for dispensing organizations. The litigation was resolved on May 27, 2015, with an order entered by the Division of Administrative Hearings holding that the challenged rules do not constitute an invalid exercise of delegated legislative authority.[115] Thereafter, the rules took effect on June 17, 2015.[116]

The application process to become a dispensing organization closed on July 8, 2015, with 28 applications received by DOH. Each application was evaluated and complete applications that met the minimum statutory requirements were then scored by three reviewers using a scorecard.[117] The scorecards of each reviewer were combined to generate an aggregate score for each application. The applicant with the highest aggregate score in each region was to be awarded a license.

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[114] Section 381.986(5)(b), F.S.
[115] *Baywood v.Nurseries Co., Inc. v. Dep't of Health,* Case No. 15-1694RP (Fla. DOAH May 27, 2015).
[116] Rule Chapter 64-4, F.A.C.
[117] Rule 64-4.002, F.A.C.

2014 Dispensing Organizations Applications:
Aggregate Score and Regional Rank

Applicant	Region	Reviewer 1	Reviewer 2	Reviewer 3	Final Rank	Regional Rank
3 Boys	Southwest	2.6875	3.1000	4.6125	3.4667	4
Alpha	Southwest	4.8750	3.5000	3.9375	4.1042	5
Perkins	Southwest	1.3750	2.0375	2.9375	2.1167	1
Plants of Ruskin	Southwest	2.7625	2.3375	2.8375	2.6458	2
Sun Bulb	Southwest	3.3000	4.0250	2.1500	3.1583	3
Bill's	Southeast	2.1125	1.1500	1.3875	1.5500	1
Costa	Southeast	4.2750	4.2375	4.6875	4.4000	5
Keith's St. Germain	Southeast	2.4125	4.1250	3.1000	3.2125	4
Nature's Way	Southeast	2.4500	3.4875	2.7125	2.8833	2
Redland	Southeast	3.7500	2.0000	3.7750	3.1750	3
Deleon	Central	1.8375	2.8875	1.0000	1.9083	1
Dewar	Central	4.7500	4.5750	2.5375	3.9542	3
Knox	Central	4.1750	6.5875	5.8750	5.5458	7
McCrory's	Central	5.4125	4.6875	6.5250	5.5417	6
Redland	Central	6.4000	2.3375	4.5500	4.4292	4
Spring Oak	Central	1.4375	1.3750	3.3125	2.0417	2
Treadwell	Central	3.9875	5.4375	4.2750	4.5667	5
Bill's	Northeast	1.2500	1.4250	1.0000	1.2250	1
Chestnut Hill	Northeast	4.7250	3.6500	3.0000	3.7917	4
Hart's	Northeast	3.2375	2.0750	2.0000	2.4375	2
Loop's	Northeast	2.7250	3.9875	4.0000	3.5708	3
San Felasco	Northeast	3.0625	3.8625	5.0000	3.9750	5
Alpha	Northwest	3.3125	2.9000	2.0000	2.7375	3
Hackney	Northwest	3.6125	3.4500	4.0000	3.6875	4
Hart's	Northwest	1.7250	1.9250	3.0000	2.2167	2
Tree King	Northwest	1.3500	1.7250	1.0000	1.3583	1

On November 23, 2015, DOH announced the five approved dispensing organizations: Hackney Nursery in the northwest region, Chestnut Hill Tree Farm in the northeast region, Knox Nursery in the central region, Costa Nursery Farms in the southeast region, and Alpha Foliage in the southwest region. Thirteen applicants that were denied a license filed petitions contesting their licensure denial and DOH's approval of these five dispensing organizations.[118] As of February 20, 2017, all but two of the petitions have been resolved. DOH awarded additional licenses to two of the petitioners, McCrory's and San Felasco, bringing the total number of dispensing organizations to seven. Loop's Nursery lost its challenge[119] and two more petitioners, 3 Boys and Plants of Ruskin, are awaiting final order from the Division of Administrative Hearings.[120] The remaining petitions were voluntarily dismissed.

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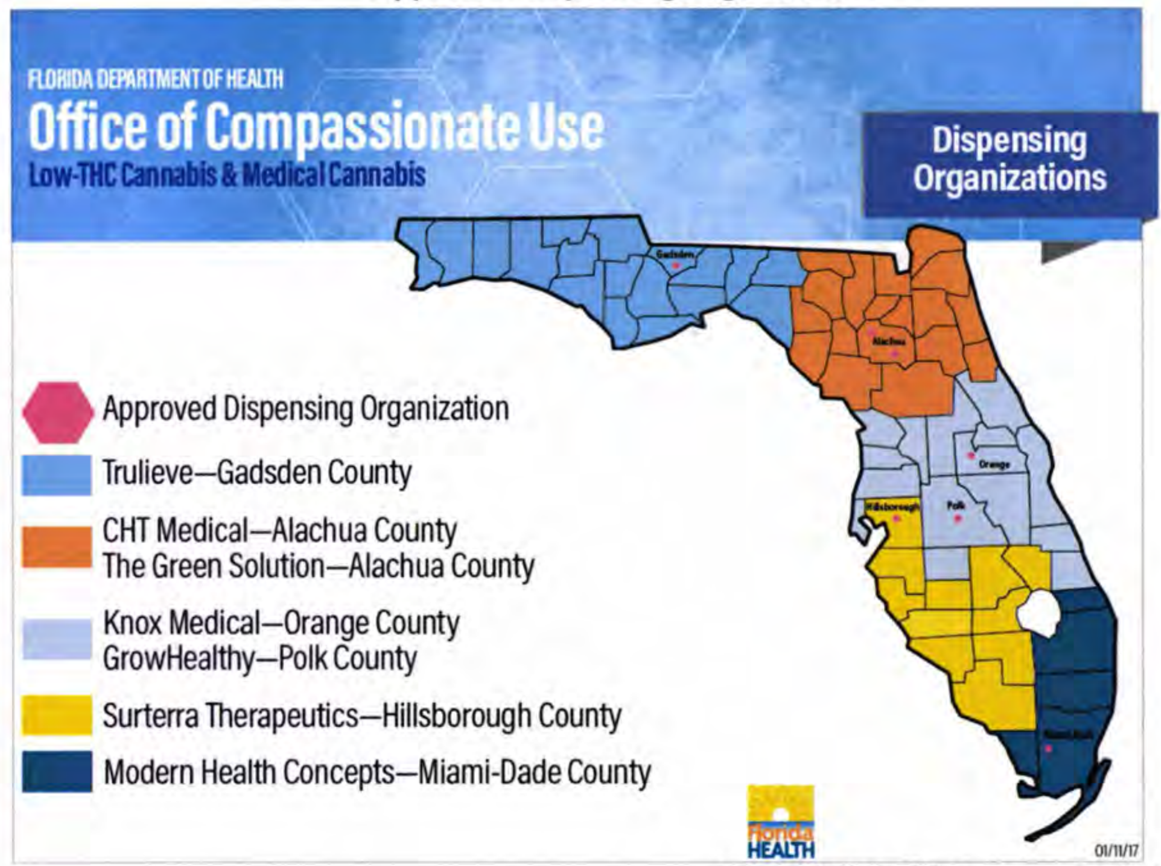
[118] A copy of each petition is available at http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/dispensing-organizations/dispensing-application-process/index.html (last visited on February 20, 2016).
[119] *Loop's Nursery and Greenhouses, Inc. v. Dep't of Health*. Case No. 15-7274 (Fla. DOAH October 7, 2016).
[120] *Plants of Ruskin and 3 Boys v. Dep't of Health*, DOAH Case Nos. 17-0116, 17-0117.

Approved Dispensing Organizations



Source: Office of Compassionate Use

Future New Dispensing Organization Approvals

Current law requires DOH to approve three additional dispensing organizations upon the registration of 250,000 active qualified patients in the compassionate use registry.[121] One of these additional dispensing organizations must be a recognized class member of certain class-action cases[122] and a member of the Black Farmers and Agriculturalists Association. The applicants for such approval must meet all of the criteria for dispensing organizations except for the requirements to possess a certificate of registration issued by the Department of Agriculture and Consumer Services for the cultivation of more than 400,000 plants, be operated by a nurseryman and have been operating as a registered nursery in this state for at least 30 continuous years.

Growing Low-THC Cannabis and Medical Cannabis

The CMCA sets standards growing low-THC cannabis or medical cannabis. Dispensing organizations must:

- Grow low-THC cannabis and medical cannabis within an enclosed structure and in a room separate from any other plant;
- Inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state, notify the Department of Agriculture and Consumer Services within 10 calendar days of a determination that a plant is infested or infected by such plant pest, and implement and maintain phytosanitary policies and procedures; and
- Perform fumigation or treatment of plants or the removal and destruction of infested or infected plants in accordance with ch. 581, F.S., or any rules adopted thereunder.

[121] Section 381.986(5)(c), F.S.

[122] *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).

A dispensing organization may also use pesticides determined by DOH to be safely applied to plants intended for human consumption.

Processing Low-THC Cannabis and Medical Cannabis

The CMCA sets standards processing low-THC cannabis or medical cannabis. Dispensing organizations must:

- Process the low-THC cannabis or medical cannabis in an enclosure separate from other plants or products;
- Reserve two processed samples per each batch, retain such samples for at least 9 months, and make those samples available for testing when an audit is being conducted by an independent testing laboratory.

Testing Low-THC Cannabis and Medical Cannabis

Under the CMCA, each dispensing organization must contract with an independent testing laboratory[123] to perform audits on the dispensing organization's standard operating procedures, testing records, and samples and provide the results to DOH to confirm the low-THC cannabis and medical cannabis meet the requirements of the CMCA and that the medical cannabis and low-THC cannabis is safe for human consumption. Dispensing organizations have contracted with testing laboratories upon DOH approval. However there is no regulatory oversight of the laboratories beyond DOH's initial approval, resulting in a lack of true independence between the dispensing organization and testing laboratory.

Current law also creates an exemption from criminal law for the independent testing laboratories and their employees, allowing the laboratories and laboratory employees to possess, test, transport, and lawfully dispose of low-THC cannabis and medical cannabis.

Packaging and Labeling Low-THC Cannabis and Medical Cannabis

The CMCA requires dispensing organizations to package low-THC cannabis and medical cannabis in compliance with the U.S. Poison Prevention Act which requires child-resistant packaging. Dispensing organizations must also firmly affix to the package a legible label that includes the following information:

- A statement that the low-THC cannabis meets certain composition requirements, and that the low-THC cannabis and medical cannabis are safe for human consumption and are free from contaminants that are unsafe for human consumption.
- The name of the dispensing organization where the medical cannabis or low-THC cannabis originates; and
- The batch number and harvest number from which the medical cannabis or low-THC cannabis originates.

Dispensing Low-THC Cannabis and Medical Cannabis

Under the CMCA a dispensing organization may not dispense more than a 45-day supply of low-THC cannabis or medical cannabis to a patient or the patient's legal representative[124] or sell any products other than the physician ordered low-THC cannabis, medical cannabis, or a cannabis delivery device.

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[123] "Independent testing laboratory" is defined by the bill to mean a laboratory, including the managers, employees, or contractors of the laboratory, which has no direct or indirect interest in a dispensing organization.

[124] Section 381.986(1)(d), F.S. defines "legal representative" means the qualified patient's parent, legal guardian acting pursuant to a court's authorization as required under s. 744.3215(4), health care surrogate acting pursuant to the qualified patient's written consent or a court's authorization as required under s. 765.113, or an individual who is authorized under a power of attorney to make health care decisions on behalf of the qualified patient.

However, DOH allows two orders to be entered into the compassionate use registry so that a patient may obtain a refill.
When dispensing low-THC cannabis or medical cannabis, a dispensing organization employee must use the compassionate use registry created by DOH to:

- Enter his or her name or unique employee identifier;
- Verify that a physician has ordered low-THC cannabis, medical cannabis, or a specific type of cannabis delivery device for the patient;
- Verify the patient or patient's legal representative holds a valid and active registration card; and
- Record the date, time, quantity, and form dispensed and type of cannabis delivery device dispensed.

Products and Routes of Administration

The CMCA prohibits smoking marijuana for medical use. Vaping of low-THC marijuana is not prohibited. Current law allows patients to use a physician-recommended cannabis delivery device[125] which is defined as an object used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing low-THC cannabis or medical cannabis into the human body.

Safety and Security Measures

Current law requires a dispensing organization to:

- Maintain a fully operational security alarm system or a video surveillance system that records continuously 24 hours per day and meets certain minimum criteria;
- Ensure that the outdoor premises of the dispensing organization has sufficient lighting from dusk until dawn;
- Not dispense low-THC cannabis, medical cannabis, or cannabis delivery devices between the hours of 9 p.m. and 7 a.m., but allows the dispensing organization to perform all other operations and deliveries of its product 24 hours per day;
- Establish and maintain a tracking system approved by DOH that traces the low-THC cannabis and medical cannabis from seed to sale, including key notification of events as determined by DOH;
- Store low-THC cannabis and medical cannabis in secured, locked rooms or a vault;
- Have at least 2 employees of the dispensing organization or of a contracted security agency be on the dispensing organization premises at all times;
- Have all employees wear a photo identification badge at all times while on the premises;
- Have visitors wear a visitor's pass at all times while on the premises;
- Implement an alcohol and drug free workplace policy; and
- Report to local law enforcement within 24 hours of the dispensing organization being notified or becoming aware of the theft, diversion, or loss of low-THC cannabis or medical cannabis.

Transportation

To ensure the safe transport of low-THC cannabis or medical cannabis to dispensing organization facilities, laboratories, or patients, dispensing organizations must:

- Maintain a transportation manifest, which must be retained for at least one year;
- Ensure only vehicles in good-working order are used to transport low-THC cannabis or medical cannabis;
- Lock low-THC cannabis or medical cannabis in a separate compartment or container within the vehicle;

[125] Section 381.986(1)(a), F.S.

- Have at least two persons in a vehicle transporting low-THC cannabis or medical cannabis and at least one person remain in the vehicle while the low-THC cannabis or medical cannabis is being delivered; and
- Provide specific safety and security training to those employees transporting low-THC cannabis or medical cannabis.

Inspections

Current law authorizes DOH to conduct inspections. DOH:

- May conduct announced or unannounced inspections of dispensing organizations to determine compliance with the law;
- Must inspect a dispensing organization upon complaint or notice provided to DOH that the dispensing organization has dispensed low-THC cannabis or medical cannabis containing any mold, bacteria, or other contaminant that may cause or has caused an adverse effect to human health or the environment;
- Must conduct at least a biennial inspection to evaluate dispensing organization records, personnel, equipment, processes, security measures, sanitation practices, and quality assurance practices;

DOH may enter into interagency agreements with the Department of Agriculture and Consumer Services, the Department of Business and Professional Regulation, the Department of Transportation, the Department of Highway Safety and Motor Vehicles, and the Agency for Health Care Administration, and such agencies are authorized to enter into an interagency agreement with DOH, to conduct inspections or perform other responsibilities assigned to DOH under the CMCA.

Penalties and Exceptions

DOH may impose reasonable fines not to exceed $10,000 on a dispensing organization for certain delineated violations and may suspend, revoke, or refuse to renew the approval of a dispensing organization for committing any of those violations.

The CMCA exempts from criminal prosecution under ch. 893, F.S.,[126] approved dispensing organizations and their owners, managers, and employees for manufacturing, possessing, selling, delivering, distributing, dispensing, and lawfully disposing of reasonable quantities, as established by DOH rule, of low-THC cannabis and medical cannabis in accordance with the CMCA and the RTTA. Such dispensing organizations and their owners, managers, and employees are not subject to licensure or regulation under ch. 465, F.S., relating to pharmacies.[127]

Preemption of Regulations

The CMCA preempts to the state all matters regarding the regulation of the cultivation and processing of medical cannabis or low-THC cannabis by dispensing organizations. Pertaining to dispensing, a municipality may determine by ordinance the criteria for and the number and location of, and other permitting requirements that do not conflict with state law or rule for, dispensing facilities of dispensing organizations located within its municipal boundaries. A county has the same authority for dispensing facilities located within the unincorporated areas of that county.

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[126] Section 893.13, F.S., makes it a crime to sell, manufacture, deliver, purchase, or possess cannabis. The penalties for these offenses range from first degree misdemeanors to second degree felonies; Section 893.135(1)(a), F.S., makes it a first degree felony to traffic in cannabis, i.e., to possess, sell, purchase, manufacture, deliver, or import more than 25 pounds of cannabis or 300 or more cannabis plants. Depending on the amount of cannabis or cannabis plants trafficked, mandatory minimum sentences of three to 15 years and fines of $25,000 to $200,000 apply to a conviction; Section 893.147, F.S., makes it a crime to possess, use, deliver, manufacture, transport, or sell drug paraphernalia. The penalties for these offenses range from first degree misdemeanors to second degree felonies.
[127] Section 381.986(7), F.S.

Registry and ID Cards

The CMCA requires DOH to create a secure, electronic, and online registry for the registration of physicians and patients.[128] A physician must register as the orderer of low-THC cannabis or medical cannabis for a named patient on the registry and must update the registry to reflect the contents of the order.[129] The registry must prevent an active registration of a patient by multiple physicians and must be accessible to law enforcement agencies and to dispensing organizations to verify patient authorization for low-THC cannabis or medical cannabis and to record the low-THC cannabis or medical cannabis dispensed.[130]

The CMCA authorizes DOH to establish a registration card system for patients and their legal representatives, establish the circumstances under which the cards may be revoked by or must be returned to DOH, and establish fees to implement such system. The registration cards must, at a minimum:

- State the name, address, and date of birth of the patient or legal representative;
- Have a full-face, passport-style photograph of the patient or legal representative that has been taken within 90 days prior to registration;
- Identify whether the cardholder is a patient or legal representative;
- List a unique numerical identifier for the patient or legal representative that is matched to the identifier used for such person in DOH's compassionate use registry;
- Provide the expiration date, which shall be from one year from the physician's initial order of low-THC cannabis or medical cannabis;
- For the legal representative, provide the name and unique numerical identifier of the patient the legal representative is assisting; and
- Be resistant to counterfeiting or tampering.

Physicians

Only a Florida licensed allopathic or osteopathic physician who has completed an 8-hour course and examination offered by the Florida Medical Association[131] may order low-THC cannabis or medical cannabis for a qualified patient. To meet the requirements of the CMCA, each of the following conditions must be satisfied:

- The physician must have treated the patient for three months immediately preceding the patient's registration in the compassionate use registry.
- The physician must determine that the risks of ordering low-THC cannabis or medical cannabis are reasonable in light of the potential benefit for that patient.[132]
- The physician must obtain the voluntary informed consent of the patient or the patient's legal guardian to treatment with low-THC cannabis or medical cannabis.[133]
- The physician must register as the orderer of low-THC cannabis or medical cannabis for the patient on the compassionate use registry (registry) and must update the registry to reflect the contents of the order.
- The physician must update the registry within 7 days after any change is made to the original order.

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[128] Section 381.985(5)(a), F.S.
[129] Section 381.986(2)(c), F.S.
[130] Section 381.986(5)(a), F.S.
[131] Section 381.986(4), F.S., requires such physicians to successfully complete an 8-hour course and examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association which encompasses the clinical indications for the appropriate use of low-THC cannabis, appropriate delivery mechanisms, contraindications for such use, and the state and federal laws governing its ordering, dispensing, and processing.
[132] If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must be documented in the patient's medical record. s. 381.986(2)(b), F.S.
[133] Section 381.986(2), F.S.

- The physician must deactivate the registration of a patient and the patient's legal representative when treatment is discontinued.
- The physician must maintain a patient treatment plan that includes the dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indications of the patient's tolerance or reaction to low-THC cannabis or medical cannabis.
- The physician must submit the treatment plan quarterly to the University Of Florida College Of Pharmacy for research.

The University Of Florida College Of Pharmacy has been unable to perform research on the data collected from the treatment plans due to lack of funding.[134]

The CMCA requires DOH to publish a list of qualified ordering physicians on its website.

The CMCA prohibits a physician ordering low-THC cannabis or medical cannabis from being employed as a medical director of a dispensing organization. A physician who orders low-THC cannabis or medical cannabis and receives compensation from a dispensing organization related to the ordering of such, is subject to disciplinary action, including suspension or revocation of license, restriction of practice and administrative fines.

The CMCA makes it a first degree misdemeanor for a physician to order low-THC cannabis or medical cannabis for a patient without a reasonable belief that the patient is suffering from a required condition.

Patients

For a qualified patient to receive low-THC or medical cannabis from a dispensing organization, the patient must be a Florida resident who has been added to the compassionate use registry by a physician.[135] The CMCA exempts from criminal prosecution under Ch. 893, F.S.[136] qualified patients and their legal representatives that purchase and possess low-THC cannabis or medical cannabis up to the amount ordered for the patient's medical use in accordance with the requirements of the CMCA.

The CMCA makes it a first degree misdemeanor for:
- Any person to fraudulently represent that he or she has a required condition to a physician for the purpose of being ordered low-THC cannabis or medical cannabis.[137]
- An eligible patient under the RTTA to use medical cannabis in plain view or in a place open to the general public, on the grounds of a school, or in a school bus, vehicle, aircraft, or motorboat.
- A legal representative of an eligible patient under the RTTA to administer medical cannabis in plain view or in a place open to the general public, on the grounds of a school, or in a school bus, vehicle, aircraft, or motorboat.

Low-THC cannabis and medical cannabis cannot be used or administered:
- On any form of public transportation;
- In any public place;
- In a qualified patient's place of work, if restricted by his or her employer;
- In a state correctional institution, as defined in s. 944.02, F.S., or a correctional institution, as defined in s. 944.241, F.S.;
- On the grounds of any preschool, primary school, or secondary school; and
- On a school bus or in a vehicle, aircraft, or motorboat.

[134] Almut Winterstein, PhD., University of Florida College of Pharmacy, *Presentation to the Health Quality Subcommittee on January 25, 2017*. On file with the Health Quality Subcommittee.
[135] Section 381.986(1)(h), F.S.
[136] See supra note 119.
[137] Section 381.986(3), F.S.

Amendment 2: Use of Marijuana for Debilitating Medical Conditions (Fla Const. art. X, s. 29)

On November 7, 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 a debilitating medical condition to obtain medical marijuana.

Medical Marijuana Treatment Center (MMTC)

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 does not address what types of marijuana products a MMTC can produce. The amendment does state that it does not require the accommodation of smoking in a public place.

The amendment also does not address the authority of local governments to regulate MMTCs.

The bill exempts actions and conduct by MMTCs registered with DOH, or its agents or employees, in compliance with the amendment and DOH regulations, from criminal or civil liability or sanctions under Florida law.

Identification Cards

The amendment requires DOH to establish procedures for the issuance and annual renewal of identification cards for qualified patients and caregivers. The amendment requires DOH obtain written consent from a minor's parent or legal guardian before issuing a card to a minor patient.

Physicians

The amendment allows a physician licensed to practice medicine in Florida to certify patients for the medical use of marijuana. The amendment requires the physician conduct a physical examination and a full assessment of a patient's medical history prior to issuing a physician's certification. The amendment requires the physician to issue a "physician certification" signed by the physician, stating the patient has a debilitating medical condition and that the benefits of marijuana to treat the condition outweigh the risks associated with using marijuana. It must also specify how long the patient is recommended to use marijuana.

The amendment also requires DOH to establish the amount of marijuana that could reasonably be presumed to be an adequate supply for a qualified patients' medical use. The presumption may be overcome with evidence of a particular qualified patient's appropriate medical use.
A physician that issues a physician certification with reasonable care to a person diagnosed with a debilitating medical condition in compliance with Amendment 2 shall not be subject to criminal or civil liability or sanctions under Florida law.

Patients

The amendment allows a "qualified patient" who has been diagnosed with a debilitating medical condition and has a physician's certification and a valid patient identification card to obtain medical marijuana from a MMTC. The amendment defines "debilitating medical condition" as cancer, epilepsy,

glaucoma, HIV/AIDS, Post-Traumatic Stress Disorder (PTSD), Amyotrophic Lateral Sclerosis (ALS/Lou Gehrig's disease), Crohn's disease, Parkinson's disease, multiple sclerosis, or other medical conditions of the same kind or class as or comparable to the preceding conditions that the patient's physician finds to be debilitating.

The amendment exempts the medical use[138] of marijuana by a qualified patient in compliance with the amendment from criminal or civil liability or sanctions under Florida law.

The amendment states that it does not require accommodation of medical use of marijuana in the workplace.

Caregivers

The amendment allows caregivers to assist qualified patients with the medical use of marijuana. The amendment requires a caregiver to be at least twenty-one years old and meet qualifications established by DOH. A caregiver must also obtain a caregiver identification card from DOH. The amendment prohibits caregivers from consuming medical marijuana and authorizes DOH to limit the number of patients a caregiver may assist and the number of caregivers a qualified patient may have. The amendment exempts the acquisition, possession, or administration of marijuana by a caregiver in compliance with the amendment from criminal or civil liability or sanctions under Florida law.

Implementation/Rulemaking

The amendment requires DOH to adopt rules by July 3, 2017 for:

- Patient and caregiver ID cards;
- Caregivers' qualifications;
- MMTC registration process and operational regulations; and
- The amount of marijuana reasonably presumed to be an adequate supply for medical use by a patient, based on best available evidence.

The amendment requires DOH to begin registering MMTCs and issuing patient and caregiver ID cards by October 3, 2017.

If a constitutional provision is self-executing, legislative action is not required to implement the provision. A constitutional provision is self-executing if it "lays down a sufficient rule by means of which the right or purpose which it gives or is intended to accomplish may be determined, enjoyed, or protected without the aid of legislative enactment."[139] Even though the provision may be self-executing, the provision may be supplemented by legislation.[140]

The amendment states that the legislature may enact laws consistent with the amendment. Amendment 2 presents a unique situation as it does not require action to be taken by the legislature to implement it. However, it is not self-executing since it requires DOH to adopt rules in order to implement the amendment.

Cause of Action

The amendment allows any "Florida citizen" to bring a private cause of action to compel DOH rule-making, MMTC registration or issuance of ID cards, if DOH fails to meet the 6 or 9 month deadlines.

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[138] Medical use means the acquisition, possession, use, delivery, transfer, or administration of an amount of marijuana not in conflict with DOH rules, or of related supplies by a qualifying patient or caregiver for the use by the caregiver's designated qualifying patient for the treatment of a debilitating medical condition.
[139] Gray v. Bryant, 125 So.2d 846, 851 (Fla. 1960).
[140] *Id.*

The amendment does not specify the kind of cause of action, the remedy, or the venue for such cause of action.

HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects personal health information. Privacy rules were initially issued in 2000 by the U.S. Department of Health and Human Services and later modified in 2002.[141] These rules address the use and disclosure of an individual's personal health information as well as create standards for information security.
Only certain entities are subject to HIPAA's provisions. These "covered entities" include[142]:

- Health plans;
- Health care providers;
- Health care clearinghouses; and
- Business associates of any of the above.

HIPAA allows the disclosure of protected health information by a covered entity to a health oversight agency[143] for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of the health care system and entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards.[144] A health oversight agency includes an agency of a state that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

DOH is a health oversight agency for the purposes of administering the CMCA, Fla. Const. art. X s. 29, and the medical practice acts.

Patient Referrals, Kickbacks, and Patient Brokering

Section 456.053, F.S. prohibits a health care provider from referring a patient for clinical laboratory services, physical therapy services, comprehensive rehabilitative services, diagnostic-imaging services, and radiation therapy services to an entity in which the health care provider is an investor or has an investment interest unless certain exceptions apply. A violation of 456.053, F.S. constitutes grounds for disciplinary action to be taken by the applicable board.

Section 466.054, F.S. prohibits "kickbacks" which mean payments or renumberation made by a health care provider to another as an incentive or inducement to refer patients. A violation of 456.054, F.S. is considered patient brokering and is a third degree felony punishable under s. 817.505, F.S.

Section 817.505, F.S. prohibits patient brokering. It is a third degree felony for any person to offer or pay another to induce the referral of patients, solicit or receive compensation in return for referring patients, solicit or receive compensation in return for the acceptance or acknowledgement of treatment from a healthcare provider or facility and to aid, abet, advise or otherwise participate in such conduct.

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[141] *The Privacy Rule*, U.S. Department of Health and Human Services. http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/ (last visited on February 24, 2017).
[142] *For Covered Entities and Business Associates*, U.S. Department of Health and Human Services. http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/ (last visited on February 24, 2017).
[143] *See The Privacy Rule*, U.S. Department of Health and Human Services. http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/ (last visited on February 24, 2017).
[144] The Privacy Rule, U.S. Department of Health and Human Services. http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/ (last visited on February 24, 2017).

EFFECTS OF PROPOSED CHANGES

The bill implements Fla Const. art. X, s. 29 by significantly amending the CMCA.

The bill amends the CMCA to remove the requirement that only terminally ill patients under the RTTA may use a form of marijuana with no THC limit or CBD mandate. The bill amends the CMCA to allow patients with debilitating medical conditions, including terminal illnesses, to obtain marijuana, which is defined by the bill as all parts of any plant of the genus Cannabis whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt sale, derivative, mixture, or preparation of the plant or its seeds or resin, including low-THC cannabis, that is dispensed only from a medical marijuana treatment center for medical use by a qualified patient.

Medical Marijuana Treatment Centers (MMTCs)

The bill maintains the vertically integrated regulatory structure of the CMCA and authorizes MMTCs licensed by DOH to acquire, cultivate, possess process, transfer, transport, sell, distribute, dispense, or administer marijuana or marijuana delivery devices for medical use to qualified patients.

The bill requires DOH to grant MMTC licenses to dispensing organizations currently registered under the CMCA. The bill also requires DOH to grant MMTC licenses to dispensing organization applicants that were denied registration as a dispensing organization in each region that had the next highest score to the applicants that have been awarded licenses in that region. The bill also requires DOH to grant an MMTC license 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 member of the Black Farmers and Agriculturalists Association. The bill requires DOH to grant MMTC licenses to 5 additional applicants when the patient population reaches 200,000 and 3 additional MMTC licenses for every additional 100,000 patients.

The bill maintains the qualifications under the CMCA for applicants seeking licensure as an MMTC, however; it amends the requirement for an applicant to have been operating as a registered nursery in Florida from at least 30 continuous years to 5 continuous years.

Growing Medical Marijuana

The bill retains the current law under the CMCA for growing standards.

Processing and Testing Medical Marijuana

The bill retains current law under the CMCA for processing standards but also adds a prohibition on the use of hydrocarbon based solvents, such as butane, hexane or propane.

The bill requires MMTCs to contract with a certified marijuana testing laboratory to perform testing of its processed marijuana before it is dispensed. The bill allows MMTCs to contract with a laboratory that is not certified until at least one laboratory becomes certified. The bill requires DOH to establish a certification program for marijuana testing laboratories and lays out the requirements a laboratory must meet to receive certification, which includes accreditation by an accreditation body of the National Environmental Laboratory Accreditation Program. Florida is an accrediting body and the accreditation program is currently administered through DOH. The bill also authorizes DOH to establish regulatory standards for marijuana testing laboratories.

Packaging and Labeling Medical Marijuana

The bill increases the packaging and labeling requirements under current law. In addition to the CMCA requirement to comply with the US Poison Prevention Act, the bill requires MMTCs to include a package insert with the following information:

- Clinical pharmacology
- Indications and use
- Dosage and administration
- Contraindications
- Warnings and precautions
- Adverse reactions

The bill requires the label on the package to include:

- Statement that cannabis meets testing and safety requirements
- Name of MMTC
- Batch number and harvest number of origin
- Recommend dose
- Name of physician who issued certification
- Name of patient
- Product name, if applicable,
- Dosage form
- Concentration of THC and CBD
- Warning transfer to another person is illegal
- Medical Marijuana Universal Symbol developed by DOH

<u>Dispensing Medical Marijuana</u>

The bill requires an employee of a MMTC who dispenses marijuana for medical use to perform the following when dispensing marijuana for medical use:

- Enter the employee's name or unique employee identifier into the medical marijuana registry
- Verify in the medical marijuana registry physician has issued certification
- Verify patient has active registration in registry
- Verify the qualified patient or caregiver has valid and active marijuana registry identification card
- Verify the amount and type of marijuana dispensed matches the contents of the certification in the medical marijuana registry
- Verify that the physician certification has not already been filled
- Record in the medical marijuana registry the quantity and form dispensed and the type of marijuana delivery device dispensed
- Record in registry the name and registry ID number of the qualified patient or caregiver to whom the marijuana or delivery device was dispensed
- Dispense only cannabis delivery devices specified in certification.
- Dispense no more than a 90 day supply.

<u>Products and Routes of Administration</u>

The bill prohibits certain forms of marijuana for medical use. The bill prohibits smoking of marijuana for medical use. The bill also prohibits vaping of marijuana for medical use but provides an exception for terminally ill patients. The bill also prohibits edibles which are defined as commercially produces food items made with cannabis or cannabis oil. The bill allows for marijuana delivery devices recommended by a qualified physician. The bill requires MMTCs produce at least one low-THC marijuana product.

<u>MMTC Safety and Security Measures</u>

The bill requires that employees of MMTCs must be over the age of 21, pass a level 2 background screening, and receive training on the legal requirements to dispense marijuana for medical use.

The bill maintains the current law requirement to employ a medical director who is Florida-licensed allopathic physician or osteopathic physician with an active, unrestricted license and has passed an initial 2 hour board-approved course and examination.

The bill retains the current law's prohibition on hours of operation. The bill also retains the security requirements under current law, but requires that MMTCs use one seed to sale tracking program established by DOH. The bill also adds the requirement that MMTCs maintain all of their business banking accounts with a single bank.

Transportation

The bill increases the requirements for the maintenance of the transportation manifest that must be kept in any vehicle transporting marijuana. The bill requires the transportation manifest be maintained by the MMTC and testing laboratory for at least five years and include:

- Departure date and time of departure
- Name, address, license number of originating MMTC
- Name and address of recipient
- Quantity and form or marijuana or device being delivered
- Arrival date and estimated time of arrival
- Delivery vehicle make, model, license plate number
- Name and signature of MMTC employees delivering product

The bill requires the MMTC or marijuana testing laboratory to provide a copy of the transportation manifest to each individual, MMTC or marijuana testing laboratory that receives delivery and requires the receiving individual to sign a copy of the manifest acknowledging receipt.

The bill also requires each MMTC employee to possess his or her employee ID at all times when transporting and present a copy of the transportation manifest and his or her employee ID to law enforcement upon request. The bill makes the failure or refusal to present a transportation manifest upon request of a law enforcement officer a misdemeanor of the second degree, punishable as provided in s. 775.082, F.S. or s. 775.083, F.S.[145]

Advertising

The bill restricts advertising by MMTCs. The bill prohibits MMTCs from engaging in advertising that is visible to members of the public from any street, sidewalk, park or other public place. However, a dispensing location may have a sign with the licensee's business name or DOH-approved trade name affixed to the outside of the building or in a window.

The bill also restricts advertising via the internet. The bill requires DOH to approve all internet advertisements by a MMTC, prohibits internet advertising that targets individuals under 18, which includes but is not limited to cartoon characters or similar images. The bill prohibits pop-up ads and requires that opt-in marketing must have an easy and permanent opt-out feature.

The bill requires an MMTC to publish on its website each marijuana product and delivery device available for purchase along with the price for a 30 day supply. The bill also requires the MMTC publish on its website any discounts offered and the eligibility requirements to receive such discounts.

Inspections

The bill requires DOH to conduct announced or unannounced inspections of MMTC facilities and retains the current law authorization for DOH to enter into interagency agreements to conduct

[145] A second degree misdemeanor is punishable by imprisonment up 60 days and a fine up to $500.00.

inspections. The bill retains current law requiring biennial license renewal inspections and inspections upon complaint.

Penalties

The bill retains the current law's authorization for DOH to impose reasonable fines not to exceed $10,000 on a MMTC for certain delineated violations and to suspend, revoke, or refuse to renew the approval of a dispensing organization for committing any of those violations.

The bill authorizes DOH to discipline unlicensed activity by any person or entity that is not registered or licensed with DOH. The bill allows DOH to issue cease and desist orders or impose an administrative penalty up to $5000 or a civil penalty from $5000 to $10,000. The bill also requires DOH to notify law enforcement of any unlicensed activity.

The bill retains the exceptions from criminal prosecution under Ch. 893, F.S. for manufacturing, possessing, selling, delivering, distributing, dispensing, and lawfully disposing of marijuana by MMTCs.

Preemption of Regulation of MMTCs

The bill preempts to the state the regulation of cultivation, processing and delivery of marijuana. The bill prohibits cultivation and processing facilities from being within 500 feet of a private or public elementary, middle or secondary school.

The bill authorizes local ordinances that determine number and location of, and other permitting requirements not in conflict with state law or department rule for dispensing. The bill prohibits dispensing facilities within 500 feet of a private or public elementary, middle or secondary school. However, the bill allows a municipality or county to approve a dispensing facility location within 500 feet if the municipality or county approves the location as promoting the public health, safety, and general welfare of the community. The bill prohibits a municipality or county from enacting ordinances determining the location of dispensing facilities that are less restrictive than ordinances determining the location of entities licensed to sell alcoholic beverages.

The bill prohibits a municipality or county from charging a MMTC a license or permit fee that is higher than the fees charged to pharmacies.

Registry and Identification Cards

The bill requires DOH to maintain the registry established under the CMCA and requires additional information regarding patients and caregivers be entered into the registry.

The bill also requires DOH to register qualified patients and caregivers into the registry and issue identification cards to qualified patients and caregivers who meet the requirements of the bill. Patients and caregivers must be permanent residents of the state. Adult patients and caregivers must document permanent residency by providing DOH with a copy of his or her Florida driver's license or Florida identification card and a copy of one of the following:

- Proof of voter registration in this state;
- A utility bill in the individual's name including a Florida address which matches the address on the individual's Florida driver's license or Florida identification card; or
- The address as listed on federal income tax returns filed by the individual seeking to prove residency which matches the address on the individual's Florida driver's license or Florida identification card.

A minor patient must provide DOH a certified copy of the minor's birth certificate or current record of registration from a Florida K-12 school and must have a parent or legal guardian who is not a qualified physician and does not have an economic interest in a MMTC or marijuana testing laboratory.

The bill establishes conditions for suspension or revocation of the registration of a qualified patient or caregiver by DOH.

Physicians

The bill allows only a qualified physician to certify a patient for medical use of marijuana. The bill defines a qualified physician as a Florida-licensed allopathic physician or osteopathic physician, who holds an active, unrestricted license and has completed a board-approved 2-hour educational course and exam. The bill prohibits a qualified physician from being employed as a medical director of a MMTC and from having a financial interest in a MMTC or a certified marijuana testing laboratory.

The bill requires a qualified physician to have treated a qualified patient for at least 3 months before certifying the patient for medical use of marijuana, unless the qualified patient has a terminal condition. Terminal condition is defined by the bill as a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible without the administration of life-sustaining procedures, and will result in death within 1 year after diagnosis if the condition runs its normal course.

To certify a patient for medical use of marijuana, a qualified physician must:

- Determine that the qualified patient suffers from at least one the debilitating medical conditions listed in Amendment 2 or has a terminal condition.
- Provide documentation to the applicable board supporting the physician's determination that a qualified patient suffers from a debilitating medical condition that is of the same kind or class as the conditions listed in Fla. Const. art. X s. 29.
- Perform in in-person physical exam and full medical history
- Determine that medical marijuana would likely outweigh the health risks to patient
- Develop a treatment plan and submit the plan to the University of Florida College of Pharmacy
- Review the registry and confirm that the patient does not have a valid certification from another qualified physician.
- Register as the issuer of the certification in the registry.
- Enter into the registry the patient's qualifying condition, marijuana dosage and form, delivery device if needed, and the supply amount (up to 90 days).

In addition, the qualified physician must obtain informed written consent of a patient on a form adopted by the applicable board each time the qualified physician certifies the patient for medical use of marijuana,[146] which must document the:

- Federal government's classification of cannabis as Schedule I controlled substance;
- Approval and oversight status of cannabis by the FDA;
- Current state of research on efficacy;
- Potential for addiction;
- Potential effect on coordination, motor skills, and cognition;
- Potential side effects; and
- Risks, benefits, and drug interactions of cannabis

The bill requires the qualified physician to update the registry within 7 days if any change made to the certification, and to deactivate the qualified patient's registration if treatment is stopped.

[146] If the patient is a minor, the parent or legal guardian must consent.

The bill prohibits a qualified physician from issuing a certification for more than a 90-day supply. Pursuant to Fla. Const. art. X s. 29(d)(1)d, the bill allows a qualified physician to request an exception from DOH from the 90-day supply limit. If DOH fails to approve or deny the request within 30 days, the requested amount is deemed approved. The bill requires a qualified physician to submit the following to DOH:

- The qualified patient's qualifying medical condition.
- The dosage and route of administration that was insufficient to provide relief to the qualified patient.
- A description of how the patient will benefit from an increased supply.
- The minimum supply of marijuana that would be sufficient for the treatment of the qualified patient's qualifying medical condition.
- The qualified patient's records, upon the request of the department.

The bill retains the current law's criminal violation that makes it a first degree misdemeanor for a qualified physician to order marijuana for a patient without a reasonable belief that the patient is suffering from a qualifying medical condition. The bill also retains the current law's provision that subjects a qualified physician who issues a physician certification for marijuana or a marijuana delivery device and receives compensation from a medical marijuana treatment center related to the issuance of a physician certification to disciplinary action, including suspension or revocation of license, restriction of practice and administrative fines.

In addition, the patient referral, anti-kickback and patient brokering prohibitions set forth in ss. 456.053, 456.054 and 817.505, F.S. are applicable to qualified physicians.

Physician Certification Pattern Review Panel

The bill requires the Board of Medicine and Board of Osteopathic Medicine to jointly establish a physician certification pattern review panel. The panel must review all physician certifications submitted to the medical marijuana use registry and issue a yearly report to the Governor, President of the Senate and Speaker of the House. The report must include the number of physician certifications and the qualifying medical conditions, dosage, supply amount, and form of marijuana certified. The panel shall report the data both by individual qualified physician and in the aggregate, by county and statewide.

Patients

The bill defines a qualified patient as a permanent resident of Florida who has been added to the medical marijuana registry by a qualified physician to receive marijuana for medical use. A qualified patient must obtain a marijuana registry identification card and must possess the card when in possession of marijuana or a delivery device. The bill requires a qualified patient to present the card to law enforcement upon request.

Until DOH begins issuing the identification cards, the bill allows all patients with an order issued under the CMCA and registered in the registry to be considered qualified patients.

The bill requires each district school board to enact a policy and procedure for the medical use of marijuana by a student who is a qualified patient and exempts school personnel from prosecution for possession when acting pursuant to the policy and procedure. The bill specifically allows an employer to enforce a drug-free workplace.

The bill retains current law exemptions from criminal prosecution and prohibitions on the use or administration of marijuana but allows for use on the grounds of a school if in accordance with a policy

and procedure adopted by the district school board for medical use by a student who is a qualified patient.

The bill makes it a second degree misdemeanor for a qualified patient to fail or refuse to present his or her marijuana use registry identification card upon requires of law enforcement. The bill also makes it a criminal violation of 893.13[147] for a qualified patient who cultivates marijuana or who acquires, possesses, or delivers marijuana from any person or entity other than a medical marijuana treatment center.

Caregivers

The bill allows a qualified patient to designate only one caregiver. The bill requires caregivers to be permanent Florida residents over the age of 21 years. The bill requires a caregiver to agree in writing to assist a qualified patient, pass a level 2 background screening, pass a caregiver certification course and exam, be registered in the medical marijuana registry and acquire a medical marijuana registry identification card from DOH. The bill requires a caregiver to possess the card when in possession of marijuana or delivery device and present the card to law enforcement upon request.

The bill prohibits caregivers from receiving compensation for assisting a qualified patient except for payment of fees associated with the certification course and exam.

The bill prohibits a caregiver from assisting more than one patient unless:

- The caregiver is a parent of more than one minor child who is a qualified patient or more than one adult child
- All qualified patients are receiving hospice services or are residents in the same nursing home and the caregiver is an employee of the hospice or nursing home and the caregiver provides personal care or services directly to clients of the hospice or nursing home as part of his or her employment duties.

The bill exempts caregivers from criminal prosecution under Ch. 893, F.S.[148] for assisting qualified patients in accordance with the requirements of the bill. The bill makes it is a first degree misdemeanor for a caregiver to administer marijuana in plain view of or in a place open to the general public, on the grounds of a school, unless in accordance with a policy and procedure adopted by the district school board for medical use by a student who is a qualified patient, or in a school bus, vehicle, aircraft, or boat. The bill makes it a second degree misdemeanor for a caregiver to fail or refuse to present his or her medical marijuana use registry identification card upon the request of law enforcement. The bill makes it a criminal violation of 893.13[149] for a caregiver to cultivate marijuana or acquire, possess, or deliver marijuana from any person or entity other than a medical marijuana treatment center.

Education and Prevention

The bill requires DOH to implement a statewide marijuana education and use prevention campaign regarding the health effects of marijuana use, particularly on minors and young adults, the legal requirements for legal use and possession of marijuana and the safe use of marijuana, including preventing access by minors and those who are not qualified patients. DOH must annually evaluate the campaign for impact and efficacy.

The bill requires DHSMV to implement a statewide marijuana impaired driving education campaign to raise awareness of and prevent marijuana impaired driving.

[147] See supra note 119.
[148] See supra note 119.
[149] See supra note 119.

Implementation/Rulemaking

The bill grants DOH and the applicable boards limited emergency rulemaking authority in order for DOH to meet the rulemaking deadlines imposed by Fla Const. Art. X sec. 29. The bill allows DOH and the applicable boards to adopt emergency rules necessary to implement the bill. The bill allows DOH and the applicable boards to adopt emergency rules to replace any emergency rules that were held to be an invalid delegation of legislative authority or unconstitutional. However, the bill prohibits DOH and the applicable boards from adopting emergency rules to replace those emergency rules if they are also held to be an invalid delegation of legislative authority or unconstitutional. The bill requires DOH and the applicable boards to begin replacing the emergency rules by January 1, 2017.

The bill also exempts DOH and the applicable boards from the statement of regulatory costs requirements and the emergency rulemaking requirement that there is an immediate danger to the public health, safety, or welfare which requires emergency action. The bill also exempts the emergency rules from the 90 day effective date and allows the emergency rules to remain in effect until replaced through non-emergency rulemaking procedures by DOH and the applicable boards.

Cause of Action

The bill also establishes the Circuit Court in and for Leon County as the venue[150] for any cause of action brought under Fla. Const. art.X s.29 due to DOH's failure to meet the rulemaking deadlines imposed by Fla. Const. art. X s.29. The bill specifies that the judicial relief for such cause of action shall be an action for a declaratory judgment pursuant to ch. 86, F.S.[151] The bill also provides affirmative defenses to DOH for a cause of action brought under Fla. Const. art.X. s.29 due to DOH's failure to meet the rulemaking deadlines.

Taxation

The bill exempts marijuana for medical use by a qualified patient from sales tax.

Conforming changes

The bill makes the necessary conforming changes to the following statutes ss. 385.211, 499.0295, 893.02, and 1004.441, F.S.

B. SECTION DIRECTORY:

Section 1: Amends s.212.08, F.S., relating to sales tax exemptions.
Section 2: Amends s.381.986, F.S., relating to the medical use of marijuana.
Section 3: Amends s.458.331, F.S., relating to grounds for disciplinary action.
Section 4: Amends s.459.015, F.S., relating to grounds for disciplinary action.
Section 5: Creates s.381.988, F.S., relating to marijuana testing laboratories.
Section 6: Creates s.381.989, F.S., relating to public education campaigns.
Section 7: Amends s.385.211, F.S., relating to refractory and intractable epilepsy treatment and research at recognized medical centers.
Section 8: Amends s.499.0295, F.S., relating to experimental treatment for terminal conditions.

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[150] "It has long been the established common law of Florida that venue in civil actions brought against the state or one of its agencies or subdivisions, absent waiver or exception, properly lies in the county where the state, agency, or subdivision, maintains its principal headquarters." *Carlile v. Game & Fresh Water Fish Com., 354 So. 2d 362, 363-364 (Fla. 1977).*

[151] "Generally, the Legislature is empowered to enact substantive law while this Court has the authority to enact procedural law... Substantive law has been defined as that part of the law which creates, defines, and regulates rights, or that part of the law which courts are established to administer. It includes those rules and principles which fix and declare the primary rights of individuals with respect towards their persons and property. On the other hand, practice and procedure 'encompass the course, form, manner, means, method, mode, order, process or steps by which a party enforces substantive rights or obtains redress for their invasion. 'Practice and procedure' may be described as the machinery of the judicial process as opposed to the product thereof." It is the method of conducting litigation involving rights and corresponding defenses." *Massey v. David, 979 So. 2d 931, 936-937 (Fla. 2008).*

Section 9: Amends s.893.02, F.S., relating to the definition of cannabis.
Section 10: Amends s.1004.441, F.S. relating to refractory and intractable epilepsy treatment and research.
Section 11: Amends s.1006.062, F.S. relating to the administration of medication and provision of medical services by district school board personnel.
Section 12: Creates an unnumbered section relating to rulemaking authority and a cause of action.
Section 13: Creates an unnumbered section relating to appropriation of funds.
Section 14: Provides the bill will take effect upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill requires DOH to set fees for licensure and licensure renewal of MMTCs and certification of marijuana testing laboratories. The bill also requires DOH to set fees for issuing and renewing qualified patient and caregiver identification cards. The bill authorizes DOH to set fees to cover the costs of administering these programs.

DOH may also generate revenue from any fines assessed against MMTCs in violation of the bill, which would also positively affect revenues.

The bill exempts marijuana for medical use by qualified patients from sales tax. On March 24, 2017, the revenue estimating conference met to estimate the impact of the sales tax exemption in the bill. The conference agreed that the bill will result in a revenue loss to General Revenue of -$2.3 million in FY 2017-18, but is expected to grow to a recurring annual impact of -$21.5 million in five years.[152]

2. Expenditures:

DOH will likely incur costs associated with licensing additional MMTCs, certification of marijuana testing laboratories and registering and issuing identification cards to qualified patients and caregivers. However, the bill authorizes DOH to set fees to cover the costs of administering these programs.

DOH may have to alter the medical marijuana use registry to accommodate the additional information required by the bill and registration of caregivers. DOH may incur costs associated with any such system change. DOH may also incur costs associated with rulemaking and any potential challenges to those rules.

The bill appropriates $1,008,463 in nonrecurring funds from the General Revenue Fund to DOH to implement the requirements of the bill. The bill also appropriates $2,050,000 in nonrecurring funds from the General Revenue Fund to DOH for contracted consultant services, information technology improvements for the marijuana use registry and litigation costs for the purpose of implementing the requirements of the act.

DOH will also incur expenditures associated with the implementation of the statewide marijuana education and use prevention campaign. The bill appropriates $1,000,000 in recurring and $2,000,000 in nonrecurring funds from the General Revenue Fund to the DOH to implement the statewide marijuana education and use prevention campaign.

DHSMV will incur expenditures associated with the implementation of the statewide marijuana impaired driving education campaign. The bill appropriates $1,000,000 in recurring and $1,000,000

[152] The Florida Office of Economic and Demographic Research. Document will be available soon at: http://edr.state.fl.us/Content/

in nonrecurring funds from the General Revenue Fund to DHSMV to implement the impaired driving education campaign.

DHSMV will likely incur expenses associated with training law enforcement officers to recognize marijuana impaired driving. The bill appropriates $100,000 in recurring funds from the Highway Safety Operating Trust Fund to DHSMV for the purpose of training additional law enforcement officers as drug recognition experts.

The University of Florida College of Pharmacy will incur costs associated with research on the safety and efficacy of marijuana on patients based on the submission of the treatment plans. The bill appropriates $1,000,000 in nonrecurring funds from the General Revenue Fund to the University of Florida College of Pharmacy to meet the research requirements.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   The bill exempts marijuana for medical use by qualified patients from sales tax, thereby eliminating local governments' ability to impose a local sales tax. On March 24, 2017, the revenue estimating conference met to estimate the impact of the sales tax exemption in the bill. The conference agreed that the bill will result in a revenue loss of local government revenues of -$0.5 million in FY 2017-18, but is expected to grow to a recurring annual impact of -$5.5.5 million in five years.[153]

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

MMTCs will likely incur costs associated with licensure and meeting the regulatory standards required by the bill. Marijuana testing laboratories may incur additional costs to become certified by DOH.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   None.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The bill authorizes DOH or the applicable board to adopt rules to implement the requirements set forth in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

[153] Id.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

1 A bill to be entitled
2 An act relating to medical use of marijuana; amending
3 s. 212.08, F.S.; providing an exemption from the state
4 tax on sales, use, and other transactions for
5 marijuana used for medical purposes; amending s.
6 381.986, F.S.; providing, revising, and deleting
7 definitions; providing qualifying medical conditions
8 for a patient to be eligible to receive marijuana or a
9 marijuana delivery device; providing requirements for
10 designating a qualified physician; providing criteria
11 for certification of a patient for medical marijuana
12 treatment by a qualified physician; providing for
13 certain patients registered with the compassionate use
14 registry to be deemed qualified; requiring the
15 Department of Health to monitor physician registration
16 and certifications in the medical marijuana use
17 registry; requiring the Board of Medicine and the
18 Board of Osteopathic Medicine to create a physician
19 certification pattern review panel; providing
20 rulemaking authority to the department and the boards;
21 requiring the department to establish a medical
22 marijuana use registry; specifying entities and
23 persons who have access to the registry; providing
24 requirements for registration of, and maintenance of
25 registered status by, qualified patients and

26 caregivers; authorizing the department to revoke the
27 registration of a patient or caregiver under certain
28 circumstances; providing requirements for the issuance
29 of medical marijuana use registry identification
30 cards; requiring the department to issue licenses to a
31 certain number of medical marijuana treatment centers;
32 providing for license renewal and revocation;
33 providing for continuance of certain entities
34 authorized to dispense low-THC cannabis, medical
35 cannabis, and cannabis delivery devices; requiring
36 background screening of owners, officers, board
37 members, and managers of medical marijuana treatment
38 centers; requiring the department to establish,
39 maintain, and control a computer seed-to-sale
40 marijuana tracking system; requiring the department to
41 establish protocols and procedures for operation,
42 conduct periodic inspections, and restrict location of
43 medical marijuana treatment centers; providing a limit
44 on county and municipal permit fees; providing
45 penalties; authorizing the department to impose
46 sanctions on persons or entities engaging in
47 unlicensed activities; providing that a person is not
48 exempt from prosecution for certain offenses and is
49 not relieved from certain requirements of law under
50 certain circumstances; providing for certain school

51 personnel to possess marijuana pursuant to certain
52 established policies and procedures; amending ss.
53 458.331 and 459.015, F.S.; providing additional acts
54 by a physician or an osteopathic physician which
55 constitute grounds for denial of a license or
56 disciplinary action to which penalties apply; creating
57 s. 381.988, F.S.; providing for the establishment of
58 medical marijuana testing laboratories; requiring the
59 Department of Health, in collaboration with the
60 Department of Agriculture and Consumer Services and
61 the Department of Environmental Protection, to develop
62 certification standards and rules; creating s.
63 381.989, F.S.; directing the department to institute
64 public education campaigns relating to cannabis and
65 marijuana and impaired driving; authorizing the
66 department to contract with vendors to implement and
67 evaluate the campaigns; amending ss. 385.211,
68 499.0295, and 893.02, F.S.; conforming provisions to
69 changes made by the act; amending s. 1004.441, F.S.;
70 revising a definition; amending s. 1006.062, F.S.;
71 requiring district school boards to adopt policies and
72 procedures for access to medical marijuana by
73 qualified patients who are students; providing
74 emergency rulemaking authority; providing for venue
75 for a cause of action against the department;

76 providing for defense against certain causes of
77 action; providing appropriations; providing an
78 effective date.
79
80 Be It Enacted by the Legislature of the State of Florida:
81
82 Section 1. Paragraph (l) of subsection (2) of section
83 212.08, Florida Statutes, is redesignated as paragraph (m), and
84 a new paragraph (l) is added to that subsection, to read:
85 212.08 Sales, rental, use, consumption, distribution, and
86 storage tax; specified exemptions.—The sale at retail, the
87 rental, the use, the consumption, the distribution, and the
88 storage to be used or consumed in this state of the following
89 are hereby specifically exempt from the tax imposed by this
90 chapter.
91 (2) EXEMPTIONS; MEDICAL.—
92 (l) Marijuana, as defined in s. 381.986, is exempt from
93 the taxes imposed under this chapter.
94 Section 2. Section 381.986, Florida Statutes, is amended
95 to read:
96 (Substantial rewording of section. See
97 s. 381.986, F.S., for present text.)
98 381.986 Medical use of marijuana.—
99 (1) DEFINITIONS.—As used in this section, the term:
100 (a) "Caregiver" means a permanent resident of this state

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

101 who has agreed to assist with a qualified patient's medical use
102 of marijuana, has a caregiver identification card, and meets the
103 requirements of subsection (6).
104 (b) "Low-THC cannabis" means a plant of the genus
105 Cannabis, the dried flowers of which contain 0.8 percent or less
106 of tetrahydrocannabinol and more than 10 percent of cannabidiol
107 weight for weight; the seeds thereof; the resin extracted from
108 any part of such plant; or any compound, manufacture, salt,
109 derivative, mixture, or preparation of such plant or its seeds
110 or resin that is dispensed only from a medical marijuana
111 treatment center.
112 (c) "Marijuana" means all parts of any plant of the genus
113 Cannabis, whether growing or not; the seeds thereof; the resin
114 extracted from any part of the plant; and every compound,
115 manufacture, salt, derivative, mixture, or preparation of the
116 plant or its seeds or resin, including low-THC cannabis which
117 are dispensed only from a medical marijuana treatment center for
118 medical use by a qualified patient.
119 (d) "Marijuana delivery device" means an object used,
120 intended for use, or designed for use in preparing, storing,
121 ingesting, inhaling, or otherwise introducing marijuana into the
122 human body.
123 (e) "Marijuana testing laboratory" means a facility that
124 collects and analyzes marijuana samples from a medical marijuana
125 treatment center and has been certified by the department

126 pursuant to s. 381.988.
127 (f) "Medical director" means a person who holds an active,
128 unrestricted license as an allopathic physician under chapter
129 458 or osteopathic physician under chapter 459 and is in
130 compliance with the requirements of paragraph (3)(a).
131 (g) "Medical use" means the acquisition, possession, use,
132 delivery, transfer, or administration of marijuana authorized by
133 a physician certification. The term does not include:
134 1. Possession, use, or administration of marijuana that
135 was not purchased or acquired from a medical marijuana treatment
136 center.
137 2. Possession, use, or administration of marijuana in a
138 form for smoking or vaping or in the form of commercially
139 produced food items made with marijuana or marijuana oils,
140 except for vapable forms possessed, used, or administered by or
141 for a qualified patient diagnosed with a terminal condition.
142 3. Use or administration of any form or amount of
143 marijuana in a manner that is inconsistent with the qualified
144 physician's directions or physician certification.
145 4. Transfer of marijuana to a person other than the
146 qualified patient for whom it was authorized or the qualified
147 patient's caregiver on behalf of the qualified patient.
148 5. Use or administration of marijuana in the following
149 locations:
150 a. On any form of public transportation.

151 b. In any public place.
152 c. In a qualified patient's place of employment, except
153 when permitted by his or her employer.
154 d. In a state correctional institution, as defined in s.
155 944.02, or a correctional institution, as defined in s. 944.241.
156 e. On the grounds of a preschool, primary school, or
157 secondary school, except as provided in s. 1006.062.
158 f. In a school bus, a vehicle, an aircraft, or a
159 motorboat.
160 (h) "Physician certification" means a qualified
161 physician's authorization for a qualified patient to receive
162 marijuana and a marijuana delivery device from a medical
163 marijuana treatment center.
164 (i) "Qualified patient" means a resident of this state who
165 has been added to the medical marijuana use registry by a
166 qualified physician to receive marijuana or a marijuana delivery
167 device for a medical use and who has a qualified patient
168 identification card.
169 (j) "Qualified physician" means a person who holds an
170 active, unrestricted license as an allopathic physician under
171 chapter 458 or as an osteopathic physician under chapter 459 and
172 is in compliance with the physician education requirements of
173 subsection (3).
174 (k) "Smoking" means burning or igniting a substance and
175 inhaling the smoke.

176 (l) "Terminal condition" means a progressive disease or
177 medical or surgical condition that causes significant functional
178 impairment, is not considered by a treating physician to be
179 reversible without the administration of life-sustaining
180 procedures, and will result in death within 1 year after
181 diagnosis if the condition runs its normal course.
182 (2) QUALIFYING MEDICAL CONDITIONS.—A patient must be
183 diagnosed with at least one of the following conditions to
184 qualify to receive marijuana or a marijuana delivery device:
185 (a) Cancer.
186 (b) Epilepsy.
187 (c) Glaucoma.
188 (d) Positive status for human immunodeficiency virus.
189 (e) Acquired immune deficiency syndrome.
190 (f) Post-traumatic stress disorder.
191 (g) Amyotrophic lateral sclerosis.
192 (h) Crohn's disease.
193 (i) Parkinson's disease.
194 (j) Multiple sclerosis.
195 (k) Medical conditions of the same kind or class as or
196 comparable to those enumerated in paragraphs (a)-(j).
197 (l) A terminal condition diagnosed by a physician other
198 than the qualified physician issuing the physician
199 certification.
200 (3) QUALIFIED PHYSICIANS.-To be approved as a qualified

201 physician, as defined in paragraph (1)(j), a physician must:
202 (a) Successfully complete a 2-hour course and subsequent
203 examination approved by the applicable board which encompass the
204 requirements of this section and any rules adopted hereunder.
205 The course and examination shall be administered at least
206 annually and may be offered in a distance learning format,
207 including an electronic, online format that is available upon
208 request. A physician who has met the physician education
209 requirements of former s. 381.986(4), Florida Statutes 2016,
210 before the effective date of this section, shall be deemed to be
211 in compliance with this paragraph from the effective date of
212 this act until 90 days after the course and examination required
213 by this paragraph become available.
214 (b) Not be employed by, or have any direct or indirect
215 economic interest in, a medical marijuana treatment center or
216 marijuana testing laboratory.
217 (4) PHYSICIAN CERTIFICATION.—
218 (a) A qualified physician may issue a physician
219 certification only if the qualified physician:
220 1. Conducted a physical examination while physically
221 present in the same room as the patient and a full assessment of
222 the medical history of the patient.
223 2. Diagnosed the patient with at least one qualifying
224 medical condition, and, if the diagnosis is pursuant to
225 paragraph (2)(k), submits to the applicable board:

226 a. Documentation supporting the qualified physician's
227 opinion that the medical condition is of the same kind or class
228 as the conditions in paragraphs (2)(a)-(j).
229 b. Documentation that establishes the efficacy of
230 marijuana as treatment for the condition.
231 c. Documentation supporting the qualified physician's
232 opinion that medical use of marijuana would likely outweigh the
233 potential health risks for the patient.
234 d. Any other documentation requested by the board.
235 3. Treated the patient for at least 3 months immediately
236 preceding the patient's registration in the medical marijuana
237 use registry, except for a patient who has been diagnosed with a
238 terminal condition.
239 4. Determined that the medical use of marijuana would
240 likely outweigh the potential health risks for the patient. If a
241 patient is younger than 18 years of age, a second physician must
242 concur with this determination, and such determination must be
243 documented in the patient's medical record.
244 5. Reviewed the medical marijuana use registry and
245 confirmed that the patient does not have an active physician
246 certification from another qualified physician.
247 6. Registers as the issuer of the physician certification
248 for the named qualified patient on the medical marijuana use
249 registry in an electronic manner determined by the department,
250 and:

251 a. Enters into the registry the contents of the physician
252 certification, including the patient's qualifying condition and
253 the dosage, amount, and form of marijuana authorized for the
254 patient and any marijuana delivery device needed by the patient
255 for the medical use of marijuana.
256 b. Updates the registry within 7 days after any change is
257 made to the original physician certification to reflect such
258 change.
259 c. Deactivates the registration of the qualified patient
260 and the patient's caregiver when treatment is discontinued.
261 7. Maintains an individualized patient treatment plan that
262 includes the qualified patient's qualifying condition and the
263 dose, route of administration, planned duration, treatment
264 objectives, plan for assessing and monitoring the qualified
265 patient's risk of aberrant drug-related behavior, and plan for
266 monitoring the qualified patient's symptoms and other indicators
267 of tolerance or reaction to the marijuana.
268 8. Submits the patient treatment plan quarterly to the
269 University of Florida College of Pharmacy for research on the
270 safety and efficacy of marijuana.
271 9. Obtains the voluntary and informed written consent of
272 the patient to treatment with marijuana each time the qualified
273 physician issues a physician certification for the patient,
274 which shall be maintained in the patient's medical record. The
275 patient, or the patient's parent or legal guardian if the

276 patient is a minor, must sign the informed consent acknowledging
277 that the qualified physician has sufficiently explained its
278 content. The qualified physician must use a standardized
279 informed consent form adopted in rule by the Board of Medicine
280 and the Board of Osteopathic Medicine, which must include, at a
281 minimum, information related to:
282 a. The Federal Government's classification of marijuana as
283 a Schedule I controlled substance.
284 b. The approval and oversight status of marijuana by the
285 Food and Drug Administration.
286 c. The current state of research on the efficacy of
287 marijuana to treat the qualifying conditions set forth in this
288 section.
289 d. The potential for addiction.
290 e. The potential effect that marijuana may have on a
291 patient's coordination, motor skills, and cognition, including a
292 warning against operating heavy machinery, operating a motor
293 vehicle, or engaging in activities that require a person to be
294 alert or respond quickly.
295 f. The potential side effects of marijuana use.
296 g. The risks, benefits, and drug interactions of
297 marijuana.
298 (b) A qualified physician may not issue a physician
299 certification for more than a 90-day supply of marijuana. The
300 department shall quantify by rule a daily dose amount with

301 equivalent dose amounts for each allowable form of marijuana
302 dispensed by a medical marijuana treatment center. The
303 department shall use the daily dose amount to calculate the 90-
304 day supply.
305 1. A qualified physician may request an exception to the
306 90-day supply limit. The request shall be made electronically on
307 a form adopted by the department in rule and must include, at a
308 minimum:
309 a. The qualified patient's qualifying medical condition.
310 b. The dosage and route of administration that was
311 insufficient to provide relief to the qualified patient.
312 c. A description of how the patient will benefit from an
313 increased supply.
314 d. The minimum supply of marijuana that would be
315 sufficient for the treatment of the qualified patient's
316 qualifying medical condition.
317 2. A qualified physician must provide the qualified
318 patient's records upon the request of the department.
319 3. The department shall approve or disapprove the request
320 within 30 days after receipt of the complete documentation
321 required by this paragraph. The request shall be deemed approved
322 if the department fails to act within this time period.
323 (c) A qualified physician must evaluate an existing
324 patient at least once every 90 days to determine if the patient
325 still meets the requirements of paragraph (a).

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326 (d) An active order for low-THC cannabis or medical
327 cannabis issued pursuant to former s. 381.986, Florida Statutes
328 2016, and registered with the compassionate use registry before
329 the effective date of this section, is deemed a physician
330 certification, and all patients possessing such orders are
331 deemed qualified patients until the department begins issuing
332 medical marijuana use registry identification cards.
333 (e) The department shall monitor physician registration in
334 the medical marijuana use registry and the issuance of physician
335 certifications for practices that could facilitate unlawful
336 diversion or misuse of marijuana or a marijuana delivery device
337 and shall take disciplinary action as appropriate.
338 (f) The Board of Medicine and the Board of Osteopathic
339 Medicine shall jointly create a physician certification pattern
340 review panel that shall review all physician certifications
341 submitted to the medical marijuana use registry. The panel shall
342 track and report the number of physician certifications and the
343 qualifying medical conditions, dosage, supply amount, and form
344 of marijuana certified. The panel shall report the data both by
345 individual qualified physician and in the aggregate, by county,
346 and statewide. The physician certification pattern review panel
347 shall, beginning January 1, 2018, submit an annual report of its
348 findings and recommendations to the Governor, the President of
349 the Senate, and the Speaker of the House of Representatives.
350 (g) The department, the Board of Medicine, and the Board

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351 of Osteopathic Medicine may adopt rules pursuant to ss.
352 120.536(1) and 120.54 to implement this subsection.
353 (5) MEDICAL MARIJUANA USE REGISTRY.—
354 (a) The department shall create and maintain a secure,
355 electronic, and online medical marijuana use registry for
356 physicians, patients, and caregivers as provided under this
357 section. The medical marijuana use registry must be accessible
358 to law enforcement agencies, qualified physicians, and medical
359 marijuana treatment centers to verify the authorization of a
360 qualified patient or a caregiver to possess marijuana or a
361 marijuana delivery device and record the marijuana or marijuana
362 delivery device dispensed. The medical marijuana use registry
363 must prevent an active registration of a qualified patient by
364 multiple physicians.
365 (b) The department shall determine whether an individual
366 is a permanent resident of this state for the purpose of
367 registration of qualified patients and caregivers in the medical
368 marijuana use registry. To prove permanent residency:
369 1. An adult must provide the department with a copy of his
370 or her valid Florida driver license issued under s. 322.18 or a
371 valid Florida identification card issued under s. 322.051 and a
372 copy of one of the following documents:
373 a. Proof of voter registration in this state.
374 b. A utility bill in the individual's name including a
375 Florida address which matches the address on the individual's

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

376 Florida driver license or Florida identification card.
377 c. The address as listed on federal income tax returns
378 filed by the individual seeking to prove residency which matches
379 the address on the individual's Florida driver license or
380 Florida identification card.
381 2. A minor must provide the department with a certified
382 copy of a birth certificate or a current record of registration
383 from a Florida K-12 school and must have a parent or legal
384 guardian who meets the requirements of subparagraph (6)(b)1.
385 (c) The department may suspend the registration of a
386 qualified patient or caregiver if the qualified patient or
387 caregiver:
388 1. Provides misleading, incorrect, false, or fraudulent
389 information to the department;
390 2. Obtains a supply of marijuana in an amount greater than
391 the amount authorized by the physician certification;
392 3. Falsifies, alters, or otherwise modifies an
393 identification card;
394 4. Fails to timely notify the department of any changes to
395 his or her qualified patient status; or
396 5. Violates the requirements of this section or any rule
397 adopted under this section.
398 (d) The department shall immediately suspend the
399 registration of a qualified patient charged with a violation of
400 chapter 893 until final disposition of any alleged offense.

401 Thereafter, the department may extend the suspension, revoke the
402 registration, or reinstate the registration.
403 (e) The department shall immediately suspend the
404 registration of any caregiver charged with a violation of
405 chapter 893 until final disposition of any alleged offense. The
406 department shall revoke a caregiver registration if the
407 caregiver does not meet the requirements of subparagraph
408 (6)(b)6.
409 (f) The department may revoke the registration of a
410 qualified patient or caregiver who cultivates marijuana or who
411 acquires, possesses, or delivers marijuana from any person or
412 entity other than a medical marijuana treatment center.
413 (g) The department shall revoke the registration of a
414 qualified patient, and the patient's associated caregiver, upon
415 notification that the patient no longer meets the criteria of a
416 qualified patient.
417 (h) The department may adopt rules pursuant to ss.
418 120.536(1) and 120.54 to implement this subsection.
419 (6) CAREGIVERS.—
420 (a) The department must register an individual as a
421 caregiver on the medical marijuana use registry and issue a
422 caregiver identification card if an individual designated by a
423 qualified patient meets all of the requirements of this
424 subsection and department rule.
425 (b) A qualified patient may designate one caregiver to

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426 assist with the qualified patient's medical use of marijuana. A
427 caregiver must:
428 1. Not be a qualified physician and not be employed by or
429 have an economic interest in a medical marijuana treatment
430 center or a marijuana testing laboratory.
431 2. Be 21 years of age or older and a permanent resident of
432 this state.
433 3. Agree in writing to assist with the qualified patient's
434 medical use of marijuana.
435 4. Be registered in the medical marijuana use registry as
436 a caregiver for no more than one qualified patient, except as
437 provided in this paragraph.
438 5. Successfully complete a caregiver certification course
439 and subsequent examination developed and administered by the
440 department or its designee, which must be renewed biennially.
441 6. Successfully pass a level 2 background screening as
442 provided under chapter 435, which, in addition to the
443 disqualifying offenses provided in s. 435.04, shall exclude an
444 individual who has an arrest awaiting final disposition for, has
445 been found guilty of, regardless of adjudication, or has entered
446 a plea of nolo contendere or guilty to an offense under chapter
447 837, chapter 895, or chapter 896 or similar law of another
448 jurisdiction.
449 (c) A caregiver may be registered in the medical marijuana
450 use registry as a designated caregiver for no more than one

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451 qualified patient, unless:
452 1. The caregiver is a parent or legal guardian of more
453 than one minor child who is a qualified patient;
454 2. The caregiver is a parent or legal guardian of more
455 than one adult child who is a qualified patient and who has an
456 intellectual or developmental disability that prevents the adult
457 child from being able to protect or care for himself or herself
458 without assistance or supervision; or
459 3. All qualified patients the caregiver has agreed to
460 assist are admitted to a hospice program or are residents of the
461 same nursing facility and have requested the assistance of that
462 caregiver with the medical use of marijuana; the caregiver is an
463 employee of the hospice or nursing facility; and the caregiver
464 provides personal care or other services directly to clients of
465 the hospice or nursing facility in the scope of that employment.
466 (d) A caregiver may not receive compensation for any
467 services provided to the qualified patient but may recover
468 caregiver certification fees.
469 (e) A caregiver must be in immediate possession of his or
470 her medical marijuana use registry identification card at all
471 times when in possession of marijuana or a marijuana delivery
472 device and must present his or her medical marijuana use
473 registry identification card upon the request of a law
474 enforcement officer.
475 (f) The department may adopt rules pursuant to ss.

476 120.536(1) and 120.54 to implement this subsection.
477 (7) IDENTIFICATION CARDS.-
478 (a) The department shall issue medical marijuana use
479 registry identification cards for qualified patients and
480 caregivers who are permanent residents of this state, which must
481 be renewed annually. The identification cards must be resistant
482 to counterfeiting and tampering and must include, at a minimum,
483 the following:
484 1. The name, address, and date of birth of the qualified
485 patient or caregiver.
486 2. A full-face, passport-type, color photograph of the
487 qualified patient or caregiver taken within the 90 days
488 immediately preceding registration.
489 3. Identification as a qualified patient or a caregiver.
490 4. The unique numeric identifier used for the qualified
491 patient in the medical marijuana use registry.
492 5. For a caregiver, the name and unique numeric identifier
493 of the qualified patient or patients that the caregiver is
494 assisting.
495 6. The expiration date of the identification card.
496 (b) The department must receive written consent from a
497 qualified patient's parent or legal guardian before it may issue
498 an identification card to a qualified patient who is a minor.
499 (c) The department shall, by July 3, 2017, adopt rules
500 pursuant to ss. 120.536(1) and 120.54 establishing procedures

501 for the issuance, renewal, suspension, replacement, surrender,
502 and revocation of medical marijuana use registry identification
503 cards and shall begin issuing qualified patient identification
504 cards by October 3, 2017.
505 (d) Applications for identification cards must be
506 submitted on a form prescribed by the department. The department
507 may charge a reasonable fee associated with the issuance,
508 replacement, and renewal of identification cards. The department
509 may contract with a third party to issue identification cards.
510 (e) A qualified patient or caregiver must return his or
511 her identification card to the department within 5 business days
512 after revocation.
513 (8) MEDICAL MARIJUANA TREATMENT CENTERS.—
514 (a) The department shall license medical marijuana
515 treatment centers to ensure reasonable statewide accessibility
516 and availability as necessary for qualified patients registered
517 in the medical marijuana use registry and who are issued a
518 physician certification under this section.
519 1. The department shall license as a medical marijuana
520 treatment center any entity that holds an active, unrestricted
521 license to cultivate, process, transport, and dispense low-THC
522 cannabis, medical cannabis, and cannabis delivery devices, under
523 former s. 381.986 Florida Statutes 2016, before July 1, 2017,
524 and which meets the requirements of this section. In addition to
525 the authority granted under this section, these entities are

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526 authorized to dispense low-THC cannabis, medical cannabis, and
527 cannabis delivery devices ordered pursuant to former s. 381.986,
528 Florida Statutes 2016, which were entered into the compassionate
529 use registry before July 1, 2017. The department may grant
530 variances from the representations made in such an entity's
531 original application for approval under former s. 381.986,
532 Florida Statutes 2014, pursuant to paragraph (e).
533 2. The department shall also license as a medical
534 marijuana treatment center any applicant that was denied a
535 dispensing organization license by the department under former
536 s. 381.986, Florida Statutes 2014, if the applicant is awarded a
537 license pursuant to an administrative or legal challenge filed
538 prior to January 1, 2017, and meets the requirements of this
539 section.
540 3. Upon the registration of 150,000 active qualified
541 patients in the medical marijuana use registry, the department
542 shall also license as a medical marijuana treatment center one
543 applicant per region which was a dispensing organization
544 applicant under former s. 381.986, Florida Statutes 2014; was
545 the next-highest scoring applicant after the applicant or
546 applicants that were awarded a license for that region; and
547 meets the requirements of this section.
548 4. Upon the registration of 150,000 active qualified
549 patients in the medical marijuana use registry, the department
550 shall also license as a medical marijuana treatment center one

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551 applicant that is a recognized class member of Pigford v.
552 Glickman, 185 F.R.D. 82 (D.D.C. 1999), or In Re Black Farmers
553 Litig., 856 F. Supp. 2d 1 (D.D.C. 2011); is a member of the
554 Black Farmers and Agriculturalists Association; and meets the
555 requirements of this section.
556 5. Upon the registration of 200,000 active qualified
557 patients in the medical marijuana use registry, the department
558 shall license five additional medical marijuana treatment
559 centers that meet the requirements of this section. Thereafter,
560 the department shall license three medical marijuana treatment
561 centers upon the registration of each additional 100,000 active
562 qualified patients in the medical marijuana use registry who
563 meet the requirements of this section.
564 (b) An applicant for licensure as a medical marijuana
565 treatment center shall apply to the department on a form
566 prescribed by the department and adopted in rule. The department
567 shall adopt rules pursuant to ss. 120.536(1) and 120.54
568 establishing a procedure for the issuance and biennial renewal
569 of licenses, including initial application and biennial renewal
570 fees sufficient to cover the costs of administering this
571 licensure program. The department shall issue a license to an
572 applicant if the applicant meets the requirements of this
573 section and pays the initial application fee. The department
574 shall renew the licensure of a medical marijuana treatment
575 center biennially if the licensee meets the requirements of this

576 section and pays the biennial renewal fee. An applicant for
577 licensure as a medical marijuana treatment center must
578 demonstrate:
579 1. The technical and technological ability to cultivate
580 and produce marijuana, including, but not limited to, low-THC
581 cannabis. The applicant must possess a valid certificate of
582 registration issued by the Department of Agriculture and
583 Consumer Services pursuant to s. 581.131 which is issued for the
584 cultivation of more than 400,000 plants, be operated by a
585 nurseryman as defined in s. 581.011, and have operated as a
586 registered nursery in this state for at least 5 continuous
587 years.
588 2. The ability to secure the premises, resources, and
589 personnel necessary to operate as a medical marijuana treatment
590 center.
591 3. The ability to maintain accountability of all raw
592 materials, finished products, and any byproducts to prevent
593 diversion or unlawful access to or possession of these
594 substances.
595 4. An infrastructure reasonably located to dispense
596 marijuana to registered qualified patients statewide or
597 regionally as determined by the department.
598 5. The financial ability to maintain operations for the
599 duration of the 2-year approval cycle, including the provision
600 of certified financial statements to the department. Upon

601 approval, the applicant must post a $5 million performance bond.
602 However, a medical marijuana treatment center serving at least
603 1,000 qualified patients is only required to maintain a $2
604 million performance bond.
605 6. That all owners, officers, board members, and managers
606 have successfully passed a level 2 background screening as
607 provided under chapter 435, which, in addition to the
608 disqualifying offenses provided in s. 435.04, shall exclude an
609 individual that has an arrest awaiting final disposition for,
610 has been found guilty of, regardless of adjudication, or entered
611 a plea of nolo contendere or guilty to an offense under chapter
612 837, chapter 895, or chapter 896 or similar law of another
613 jurisdiction.
614 7. The employment of a medical director to supervise the
615 activities of the medical marijuana treatment center.
616 (c) A medical marijuana treatment center may make a
617 wholesale purchase of marijuana from, or a distribution of
618 marijuana to, another medical marijuana treatment center.
619 (d) The department shall establish, maintain, and control
620 a computer software tracking system that traces marijuana from
621 seed to sale and allows real-time, 24-hour access by the
622 department to data from all medical marijuana treatment centers
623 and marijuana testing laboratories. The tracking system must, at
624 a minimum, include notification of when marijuana seeds are
625 planted, when marijuana plants are harvested and destroyed, and

626 when marijuana is transported, sold, stolen, diverted, or lost.
627 Each medical marijuana treatment center shall use the seed-to-
628 sale tracking system selected by the department.
629 (e) A licensed medical marijuana treatment center must, at
630 all times, maintain compliance with the criteria demonstrated
631 and representations made in the initial application and the
632 criteria established in this subsection. Upon request, the
633 department may grant a medical marijuana treatment center a
634 variance from the representations made in the initial
635 application. Consideration of such a request shall be based upon
636 the individual facts and circumstances surrounding the request.
637 A variance may not be granted unless the requesting medical
638 marijuana treatment center can demonstrate to the department
639 that it has a proposed alternative to the specific
640 representation made in its application which fulfills the same
641 or a similar purpose as the specific representation in a way
642 that the department can reasonably determine will not be a lower
643 standard than the specific representation in the application.
644 1. A medical marijuana treatment center, and any
645 individual or entity who directly or indirectly owns, controls,
646 or holds with power to vote 25 percent or more of the voting
647 shares of a medical marijuana treatment center, may not acquire
648 direct or indirect ownership or control of more than 5 percent
649 of the voting shares or other form of ownership of any other
650 medical marijuana treatment center.

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651 2. All employees of a medical marijuana treatment center
652 must be 21 years of age or older and have successfully passed a
653 level 2 background screening as provided under chapter 435,
654 which, in addition to the disqualifying offenses provided in s.
655 435.04, shall exclude an individual who has an arrest awaiting
656 final disposition for, has been found guilty of, regardless of
657 adjudication, or has entered a plea of nolo contendere or guilty
658 to an offense under chapter 837, chapter 895, or chapter 896 or
659 similar law of another jurisdiction.
660 3. Each medical marijuana treatment center must adopt and
661 enforce policies and procedures to ensure employees and
662 volunteers receive training on the legal requirements to
663 dispense marijuana to qualified patients.
664 4. When growing marijuana, a medical marijuana treatment
665 center:
666 a. May use pesticides determined by the department, after
667 consultation with the Department of Agriculture and Consumer
668 Services, to be safely applied to plants intended for human
669 consumption, but may not use pesticides designated as
670 restricted-use pesticides pursuant to s. 487.042.
671 b. Must grow marijuana within an enclosed structure and in
672 a room separate from any other plant.
673 c. Must inspect seeds and growing plants for plant pests
674 that endanger or threaten the horticultural and agricultural
675 interests of the state, notify the Department of Agriculture and

676 Consumer Services within 10 calendar days after a determination
677 that a plant is infested or infected by such plant pest, and
678 implement and maintain phytosanitary policies and procedures.
679 d. Must perform fumigation or treatment of plants, or
680 remove and destroy infested or infected plants, in accordance
681 with chapter 581 and any rules adopted thereunder.
682 5. Each medical marijuana treatment center must produce
683 and make available for purchase at least one low-THC cannabis
684 product, which must be available in all forms that a medical
685 marijuana treatment center produces for other products.
686 6. When processing marijuana, a medical marijuana
687 treatment center must:
688 a. Process the marijuana within an enclosed structure and
689 in a room separate from other plants or products.
690 b. Not use a hydrocarbon based solvent, such as butane,
691 hexane, or propane, to extract or separate resin from marijuana.
692 c. Test the processed marijuana using a medical marijuana
693 testing laboratory before it is dispensed. Results must be
694 verified and signed by two medical marijuana treatment center
695 employees. Before dispensing, the medical marijuana treatment
696 center must determine that the test results indicate that low-
697 THC cannabis meets the definition of low-THC cannabis and that
698 all marijuana is safe for human consumption and free from
699 contaminants that are unsafe for human consumption. The
700 Department of Health shall determine by rule which contaminants

701 must be tested for and the maximum levels of each contaminant
702 which are safe for human consumption. The medical marijuana
703 treatment center must retain records of all testing and samples
704 of each homogenous batch of marijuana for at least 9 months. The
705 medical marijuana treatment center must contract with a
706 marijuana testing laboratory to perform audits on the medical
707 marijuana treatment center's standard operating procedures,
708 testing records, and samples and provide the results to the
709 department to confirm that the marijuana or low-THC cannabis
710 meets the requirements of this section and that the marijuana or
711 low-THC cannabis is safe for human consumption. A medical
712 marijuana treatment center shall reserve two processed samples
713 from each batch and retain such samples for at least 9 months
714 for the purpose such audits. A medical marijuana treatment
715 center may use a laboratory that has not been certified by the
716 department under s. 381.988 until such time as at least one
717 laboratory holds the required certification, but in no event
718 later than July 1, 2018.
719 d. Package the marijuana in compliance with the United
720 States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss.
721 1471 et seq.
722 e. Package the marijuana in a receptacle that has a firmly
723 affixed and legible label stating the following information:
724 (I) The marijuana or low-THC cannabis meets the
725 requirements of sub-subparagraph c.

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726 (II) The name of the medical marijuana treatment center
727 from which the marijuana originates.
728 (III) The batch number and harvest number from which the
729 marijuana originates and the date dispensed.
730 (IV) The name of the physician who issued the physician
731 certification.
732 (V) The name of the patient;
733 (VI) The product name, if applicable, and dosage form,
734 including concentration of THC and CBD.
735 (VII) The recommended dose.
736 (VIII) A warning that it is illegal to transfer medical
737 marijuana to another person.
738 (IX) A marijuana universal symbol developed by the
739 department.
740 7. The medical marijuana treatment center shall include in
741 each package a patient package insert with information on the
742 specific product dispensed related to:
743 a. Clinical pharmacology.
744 b. Indications and use.
745 c. Dosage and administration.
746 d. Dosage forms and strengths.
747 e. Contraindications.
748 f. Warnings and precautions.
749 g. Adverse reactions.
750 8. When dispensing marijuana or a marijuana delivery

751 device, a medical marijuana treatment center:
752 a. May dispense any active, valid order for low-THC
753 cannabis, medical cannabis and cannabis delivery devices issued
754 pursuant to former s. 381.986 Florida Statutes 2016, which was
755 been entered into the medical marijuana use registry before July
756 1, 2017.
757 b. May not dispense more than a 90-day supply of marijuana
758 to a qualified patient or caregiver.
759 c. Must have the medical marijuana treatment center's
760 employee who dispenses the marijuana or a marijuana delivery
761 device enter into the medical marijuana use registry his or her
762 name or unique employee identifier.
763 d. Must verify that the qualified patient and the
764 caregiver, if applicable, both have an active and valid
765 compassionate use registry identification card and that the
766 amount and type of marijuana dispensed matches the physician's
767 certification in the medical marijuana use registry for that
768 qualified patient.
769 e. May not dispense or sell any other type of cannabis,
770 alcohol, or illicit drug-related product, including pipes,
771 bongs, or wrapping papers, other than a marijuana delivery
772 device required for the medical use of marijuana and which is
773 specified in a physician certification.
774 f. Must verify that the qualified patient has an active
775 registration in the medical marijuana use registry, the

776 qualified patient or caregiver holds a valid and active medical
777 marijuana use registry identification card, the physician
778 certification presented matches the physician certification
779 contents as recorded in the registry, and the physician
780 certification has not already been filled.
781 g. Must, upon dispensing the marijuana or marijuana
782 delivery device, record in the registry the date, time,
783 quantity, and form of marijuana dispensed; the type of marijuana
784 delivery device dispensed; and the name and medical marijuana
785 use registry identification number of the qualified patient or
786 caregiver to whom the marijuana delivery device was dispensed.
787 (f) To ensure the safety and security of its premises and
788 any off-site storage facilities, and to maintain adequate
789 controls against the diversion, theft, and loss of marijuana or
790 marijuana delivery devices, a medical marijuana treatment center
791 shall:
792 1.a. Maintain a fully operational security alarm system
793 that secures all entry points and perimeter windows and is
794 equipped with motion detectors; pressure switches; and duress,
795 panic, and hold-up alarms; or
796 b. Maintain a video surveillance system that records
797 continuously 24 hours a day and meets the following criteria:
798 (I) Cameras are fixed in a place that allows for the clear
799 identification of persons and activities in controlled areas of
800 the premises. Controlled areas include grow rooms, processing

801 rooms, storage rooms, disposal rooms or areas, and point-of-sale
802 rooms.
803 (II) Cameras are fixed in entrances and exits to the
804 premises, which shall record from both indoor and outdoor, or
805 ingress and egress, vantage points.
806 (III) Recorded images must clearly and accurately display
807 the time and date.
808 (IV) Retain video surveillance recordings for at least 45
809 days or longer upon the request of a law enforcement agency.
810 2. Ensure that the medical marijuana treatment center's
811 outdoor premises have sufficient lighting from dusk until dawn.
812 3. Not dispense from its premises marijuana or a marijuana
813 delivery device between the hours of 9 p.m. and 7 a.m., but may
814 perform all other operations and deliver marijuana to qualified
815 patients 24 hours a day.
816 4. Store marijuana in a secured, locked room or a vault.
817 5. Require at least two of its employees, or two employees
818 of a security agency with whom it contracts, to be on the
819 premises at all times.
820 6. Require each employee to wear a photo identification
821 badge at all times while on the premises.
822 7. Require each visitor to wear a visitor pass at all
823 times while on the premises.
824 8. Implement an alcohol and drug-free workplace policy.
825 9. Report to local law enforcement within 24 hours after

826 the treatment center is notified or becomes aware of the theft,
827 diversion, or loss of marijuana.
828 (g) If a medical marijuana treatment center uses a banking
829 institution, the treatment center must maintain all accounts
830 that are directly or indirectly associated with the business of
831 the medical marijuana treatment center at a single bank.
832 (h) To ensure the safe transport of marijuana to medical
833 marijuana treatment centers, marijuana testing laboratories, or
834 qualified patients, a medical marijuana treatment center must:
835 1. Maintain a marijuana transportation manifest in any
836 vehicle transporting marijuana. The marijuana transportation
837 manifest must be generated from a medical marijuana treatment
838 center's seed-to-sale tracking system and include the:
839 a. Departure date and approximate time of departure.
840 b. Name, location address, and license number of the
841 originating medical marijuana treatment center.
842 c. Name and address of the recipient of the delivery.
843 d. Quantity and form of any marijuana or marijuana
844 delivery device being transported.
845 e. Arrival date and estimated time of arrival.
846 f. Delivery vehicle make and model and license plate
847 number.
848 g. Name and signature of the medical marijuana treatment
849 center employees delivering the product.
850 (I) A copy of the marijuana transportation manifest must

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851 be provided to each individual, medical marijuana treatment
852 center, or marijuana testing laboratory that receives a
853 delivery. The individual, or a representative of the center or
854 laboratory, must sign a copy of the marijuana transportation
855 manifest acknowledging receipt.
856 (II) An individual transporting marijuana must present a
857 copy of the relevant marijuana transportation manifest and his
858 or her employee identification card to a law enforcement officer
859 upon request.
860 (III) Medical marijuana treatment centers and marijuana
861 testing laboratories must retain copies of all marijuana
862 transportation manifests for at least 5 years.
863 2. Ensure only vehicles in good working order are used to
864 transport marijuana.
865 3. Lock marijuana in a separate compartment or container
866 within the vehicle.
867 4. Require employees to have possession of their employee
868 identification card at all times when transporting marijuana.
869 5. Require at least two persons to be in a vehicle
870 transporting marijuana, and require at least one person to
871 remain in the vehicle while the marijuana is being delivered.
872 6. Provide specific safety and security training to
873 employees transporting or delivering marijuana.
874 (i) A medical marijuana treatment center may not engage in
875 advertising that is visible to members of the public from any

876 street, sidewalk, park, or other public place, except:
877 1. The dispensing location of a medical marijuana
878 treatment center may have a sign that is affixed to the outside
879 or hanging in the window of the premises which identifies the
880 dispensary by the licensee's business name or by a department-
881 approved trade name.
882 2. A medical marijuana treatment center may engage in
883 Internet advertising and marketing under the following
884 conditions:
885 a. All advertisements must be approved by the department.
886 b. An advertisement may not have any content that
887 specifically targets individuals under the age of 18, including
888 cartoon characters or similar images.
889 c. An advertisement may not be an unsolicited pop-up
890 advertisement.
891 d. Opt-in marketing must include an easy and permanent
892 opt-out feature.
893 (j) Each medical marijuana treatment center that dispenses
894 marijuana and marijuana delivery devices shall make available to
895 the public on its website:
896 1. Each marijuana and low-THC product available for
897 purchase, including the form, strain of marijuana from which it
898 was extracted, CBD content, THC content, dose unit, total number
899 of doses available, and the ratio of CBD to THC for each
900 product.

901 2. The price for a 30-day supply at a standard dose for
902 each marijuana and low-THC product available for purchase.
903 3. The price for each marijuana delivery device available
904 for purchase.
905 4. If applicable, any discount policies and eligibility
906 criteria for such discounts.
907 (k) Medical marijuana treatment centers are the sole
908 source from which a qualified patient may legally obtain
909 marijuana.
910 (l) The department may adopt rules pursuant to ss.
911 120.536(1) and 120.54 to implement this subsection.
912 (9) MEDICAL MARIJUANA TREATMENT CENTER INSPECTIONS;
913 ADMINISTRATIVE ACTIONS.—
914 (a) The department shall conduct announced or unannounced
915 inspections of medical marijuana treatment centers to determine
916 compliance with this section or rules adopted pursuant to this
917 section.
918 (b) The department shall inspect a medical marijuana
919 treatment center upon receiving a complaint or notice that the
920 medical marijuana treatment center has dispensed marijuana
921 containing mold, bacteria, or other contaminant that may cause
922 or has caused an adverse effect to human health or the
923 environment.
924 (c) The department shall conduct at least a biennial
925 inspection of each medical marijuana treatment center to

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926 evaluate the medical marijuana treatment center's records,
927 personnel, equipment, processes, security measures, sanitation
928 practices, and quality assurance practices.
929 (d) The department may enter into interagency agreements
930 with the Department of Agriculture and Consumer Services, the
931 Department of Business and Professional Regulation, the
932 Department of Transportation, the Department of Highway Safety
933 and Motor Vehicles, and the Agency for Health Care
934 Administration, and such agencies are authorized to enter into
935 an interagency agreement with the department to conduct
936 inspections or perform other responsibilities assigned to the
937 department under this section.
938 (e) The department shall publish a list of all approved
939 medical marijuana treatment centers, medical directors, and
940 qualified physicians on its website.
941 (f) The department may impose reasonable fines not to
942 exceed $10,000 on a medical marijuana treatment center for any
943 of the following violations:
944 1. Violating this section or department rule.
945 2. Failing to maintain qualifications for approval.
946 3. Endangering the health, safety, or security of a
947 qualified patient.
948 4. Improperly disclosing personal and confidential
949 information of the qualified patient.
950 5. Attempting to procure medical marijuana treatment

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951 center approval by bribery, fraudulent misrepresentation, or
952 extortion.
953 6. Being convicted or found guilty of, or entering a plea
954 of guilty or nolo contendere to, regardless of adjudication, a
955 crime in any jurisdiction which directly relates to the business
956 of a medical marijuana treatment center.
957 7. Making or filing a report or record that the medical
958 marijuana treatment center knows to be false.
959 8. Willfully failing to maintain a record required by this
960 section or department rule.
961 9. Willfully impeding or obstructing an employee or agent
962 of the department in the furtherance of his or her official
963 duties.
964 10. Engaging in fraud or deceit, negligence, incompetence,
965 or misconduct in the business practices of a medical marijuana
966 treatment center.
967 11. Making misleading, deceptive, or fraudulent
968 representations in or related to the business practices of a
969 medical marijuana treatment center.
970 12. Having a license or the authority to engage in any
971 regulated profession, occupation, or business that is related to
972 the business practices of a medical marijuana treatment center
973 suspended, revoked, or otherwise acted against by the licensing
974 authority of any jurisdiction, including its agencies or
975 subdivisions, for a violation that would constitute a violation

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976 under Florida law.
977 13. Violating a lawful order of the department or an
978 agency of the state, or failing to comply with a lawfully issued
979 subpoena of the department or an agency of the state.
980 (g) The department may suspend, revoke, or refuse to renew
981 a medical marijuana treatment center license if the treatment
982 center commits any of the violations in paragraph (f).
983 (h) The department shall renew the medical marijuana
984 treatment center license biennially if the treatment center
985 meets the requirements of this section and pays the biennial
986 renewal fee.
987 (i) The department may adopt rules pursuant to ss.
988 120.536(1) and 120.54 to implement this subsection.
989 (10) PREEMPTION.—Regulation of cultivation, processing,
990 and delivery of marijuana by medical marijuana treatment centers
991 is preempted to the state except as provided in this subsection.
992 (a) A medical marijuana treatment center cultivating or
993 processing facility may not be located within 500 feet of the
994 real property that comprises a public or private elementary
995 school, middle school, or secondary school.
996 (b) A municipality may determine by ordinance the criteria
997 for the number and location of, and other permitting
998 requirements that do not conflict with state law or department
999 rule for, medical marijuana treatment center dispensing
1000 facilities located within the boundaries of the municipality. A

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1001 county may determine by ordinance the criteria for the number
1002 and location of, and other permitting requirements that do not
1003 conflict with state law or department rule for, all such
1004 dispensing facilities located within the unincorporated areas of
1005 that county. However, a medical marijuana treatment center
1006 dispensing facility may not be located within 500 feet of the
1007 real property that comprises a public or private elementary
1008 school, middle school, or secondary school unless the county or
1009 municipality approves the location as promoting the public
1010 health, safety, and general welfare of the community under
1011 proceedings as provided in s. 125.66(4) for counties, and s.
1012 166.041(3)(c) for municipalities. A municipality or county may
1013 not enact ordinances determining the location of dispensing
1014 facilities which are less restrictive than the county's or
1015 municipality's ordinances determining the location of entities
1016 licensed to sell alcoholic beverages.
1017 (c) A municipality or county may not charge a medical
1018 marijuana treatment center a license or permit fee in an amount
1019 greater that the fee charged by such municipality or county to
1020 pharmacies.
1021 (11) PENALTIES.—
1022 (a) A qualified physician commits a misdemeanor of the
1023 first degree, punishable as provided in s. 775.082 or s.
1024 775.083, if the qualified physician orders marijuana for a
1025 patient without a reasonable belief that the patient is

1026 suffering from a qualifying medical condition.
1027 (b) A person who fraudulently represents that he or she
1028 has a qualifying medical condition to a qualified physician for
1029 the purpose of being issued a physician certification commits a
1030 misdemeanor of the first degree, punishable as provided in s.
1031 775.082 or s. 775.083.
1032 (c) A qualified patient's marijuana, and such patient's
1033 caregiver who administers marijuana, in plain view of or in a
1034 place open to the general public, in a school bus, a vehicle, an
1035 aircraft, or a boat, or on the grounds of a school except as
1036 provided in s. 1006.062, commits a misdemeanor of the first
1037 degree, punishable as provided in s. 775.082 or s. 775.083.
1038 (d) A qualified patient or caregiver who cultivates
1039 marijuana or who purchases or acquires marijuana from any person
1040 or entity other than a medical marijuana treatment center
1041 violates s. 893.13 and is subject to the penalties provided
1042 therein.
1043 (e) A qualified patient or caregiver in possession of
1044 marijuana or a marijuana delivery device who fails or refuses to
1045 present his or her marijuana use registry identification card
1046 upon the request of a law enforcement officer commits a
1047 misdemeanor of the second degree, punishable as provided in s.
1048 775.082 or s. 775.083.
1049 (f) A caregiver who violates any of the applicable
1050 provisions of this section or applicable department rules, for

1051 the first offense, commits a misdemeanor of the second degree,
1052 punishable as provided in s. 775.082 or s. 775.083 and, for a
1053 second or subsequent offense, commits a misdemeanor of the first
1054 degree, punishable as provided in s. 775.082 or s. 775.083.
1055 (g) A qualified physician who issues a physician
1056 certification for marijuana or a marijuana delivery device and
1057 receives compensation from a medical marijuana treatment center
1058 related to the issuance of a physician certification for
1059 marijuana or a marijuana delivery device is subject to
1060 disciplinary action under the applicable practice act and s.
1061 456.072(1)(n).
1062 (h) A person transporting marijuana or marijuana delivery
1063 devices on behalf of a medical marijuana treatment center or
1064 marijuana testing laboratory who fails or refuses to present a
1065 transportation manifest upon the request of a law enforcement
1066 officer commits a misdemeanor of the second degree, punishable
1067 as provided in s. 775.082 or s. 775.083.
1068 (i) Persons and entities conducting activities authorized
1069 and governed by this section and s. 381.988 are subject to the
1070 provisions of ss. 456.053, 456.054, and 817.505, as applicable.
1071 (12) UNLICENSED ACTIVITY.—
1072 (a) If the department has probable cause to believe that a
1073 person or entity that is not registered or licensed with the
1074 department has violated this section, s. 381.988, or any rule
1075 adopted pursuant to this section, the department may issue and

1076 deliver to such person or entity a notice to cease and desist
1077 from such violation. The department also may issue and deliver a
1078 notice to cease and desist to any person or entity who aids and
1079 abets such unlicensed activity. The issuance of a notice to
1080 cease and desist does not constitute agency action for which a
1081 hearing under s. 120.569 or s. 120.57 may be sought. For the
1082 purpose of enforcing a cease and desist order, the department
1083 may file a proceeding in the name of the state seeking issuance
1084 of an injunction or a writ of mandamus against any person or
1085 entity who violates any provisions of such order.
1086 (b) In addition to the remedies under paragraph (a), the
1087 department may impose by citation an administrative penalty not
1088 to exceed $5,000 per incident. The citation shall be issued to
1089 the subject and shall contain the subject's name and any other
1090 information the department determines to be necessary to
1091 identify the subject, a brief factual statement, the sections of
1092 the law allegedly violated, and the penalty imposed. If the
1093 subject does not dispute the matter in the citation with the
1094 department within 30 days after the citation is served, the
1095 citation shall become a final order of the department. The
1096 department may adopt rules pursuant to ss. 120.536(1) and 120.54
1097 to implement this section. Each day that the unlicensed activity
1098 continues after issuance of a notice to cease and desist
1099 constitutes a separate violation. The department shall be
1100 entitled to recover the costs of investigation and prosecution

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1101 in addition to the fine levied pursuant to the citation. Service
1102 of a citation may be made by personal service or by mail to the
1103 subject at the subject's last known address or place of
1104 practice. If the department is required to seek enforcement of
1105 the cease and desist or agency order, it shall be entitled to
1106 collect attorney fees and costs.
1107 (c) In addition to or in lieu of any other administrative
1108 remedy, the department may seek the imposition of a civil
1109 penalty through the circuit court for any violation for which
1110 the department may issue a notice to cease and desist. The civil
1111 penalty shall be no less than $5,000 and no more than $10,000
1112 for each offense. The court may also award to the prevailing
1113 party court costs and reasonable attorney fees and, in the event
1114 the department prevails, may also award reasonable costs of
1115 investigation and prosecution.
1116 (d) The department must notify local law enforcement of
1117 such unlicensed activity for a determination of any criminal
1118 violation of chapter 893.
1119 (13) EXCEPTIONS TO OTHER LAWS.—
1120 (a) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
1121 any other provision of law, but subject to the requirements of
1122 this section, a qualified patient and the qualified patient's
1123 caregiver may purchase from a medical marijuana treatment center
1124 for the patient's medical use a marijuana delivery device and up
1125 to the amount of marijuana authorized in the physician

1126 certification, but may not possess more than a 90-day supply of
1127 marijuana at any given time and all marijuana purchased must
1128 remain in its original packaging.
1129 (b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
1130 any other provision of law, but subject to the requirements of
1131 this section, an approved medical marijuana treatment center and
1132 its owners, managers, and employees may manufacture, possess,
1133 sell, deliver, distribute, dispense, and lawfully dispose of
1134 marijuana or a marijuana delivery device as provided in this
1135 section, s. 381.988, and by department rule. For purposes of
1136 this subsection, the terms "manufacture," "possession,"
1137 "deliver," "distribute," and "dispense" have the same meanings
1138 as provided in s. 893.02.
1139 (c) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
1140 any other provision of law, but subject to the requirements of
1141 this section, a certified marijuana testing laboratory,
1142 including an employee of a certified marijuana testing
1143 laboratory acting within the scope of his or her employment, may
1144 acquire, possess, test, transport, and lawfully dispose of
1145 marijuana as provided in this section, s. 381.988, and by
1146 department rule.
1147 (d) A licensed medical marijuana treatment center and its
1148 owners, managers, and employees are not subject to licensure or
1149 regulation under chapter 465 or chapter 499 for manufacturing,
1150 possessing, selling, delivering, distributing, dispensing, or

1151 lawfully disposing of marijuana or a marijuana delivery device,
1152 as provided in this section, s. 381.988, and by department rule.
1153 (e) This subsection does not exempt a person from
1154 prosecution for a criminal offense related to impairment or
1155 intoxication resulting from the medical use of marijuana or
1156 relieve a person from any requirement under law to submit to a
1157 breath, blood, urine, or other test to detect the presence of a
1158 controlled substance.
1159 (f) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
1160 any other provision of law, but subject to the requirements of
1161 this section and pursuant to policies and procedures established
1162 pursuant to s. 1006.62(8), school personnel may possess
1163 marijuana that is obtained for medical use pursuant to this
1164 section by a student who is a qualified patient.
1165 (14) APPLICABILITY.—This section does not limit the
1166 ability of an employer to establish, continue, or enforce a
1167 drug-free workplace program or policy.
1168 Section 3. Paragraph (uu) is added to subsection (1) of
1169 section 458.331, Florida Statutes, to read:
1170 458.331 Grounds for disciplinary action; action by the
1171 board and department.—
1172 (1) The following acts constitute grounds for denial of a
1173 license or disciplinary action, as specified in s. 456.072(2):
1174 (uu) Issuing a physician certification, as defined in s.
1175 381.986, in a manner out of compliance with the requirements of

1176 that section and rules adopted thereunder.
1177 Section 4. Paragraph (ww) is added to subsection (1) of
1178 section 459.015, Florida Statutes, to read:
1179 459.015 Grounds for disciplinary action; action by the
1180 board and department.—
1181 (1) The following acts constitute grounds for denial of a
1182 license or disciplinary action, as specified in s. 456.072(2):
1183 (ww) Issuing a physician certification, as defined in s.
1184 381.986, in a manner not in compliance with the requirements of
1185 that section and rules adopted thereunder.
1186 Section 5. Section 381.988, Florida Statutes, is created
1187 to read:
1188 381.988 Medical marijuana testing laboratories; marijuana
1189 tests conducted by a certified laboratory.—
1190 (1) A person or entity seeking to be a certified marijuana
1191 testing laboratory must:
1192 (a) Not be owned or controlled by a medical marijuana
1193 treatment center.
1194 (b) Submit a completed application accompanied by an
1195 application fee, as established by department rule.
1196 (c) Submit proof of accreditation issued by an
1197 accreditation body of the National Environmental Laboratory
1198 Accreditation Program.
1199 (d) Require all owners and managers to submit to and pass
1200 a level 2 background screening pursuant to s. 435.04 and shall

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1201 deny certification if the person or entity has been found guilty
1202 of, or has entered a plea of guilty or nolo contendere to,
1203 regardless of adjudication, any offense listed in chapter 837,
1204 chapter 895, or chapter 896 or similar law of another
1205 jurisdiction.
1206 (e) Demonstrate to the department the capability of
1207 meeting the standards for certification required by this
1208 subsection, and the testing requirements of s. 381.986 and this
1209 section and rules adopted thereunder.
1210 (2) The department shall adopt rules pursuant to ss.
1211 120.536(1) and 120.54 establishing a procedure for initial
1212 certification and biennial renewal, including initial
1213 application and biennial renewal fees sufficient to cover the
1214 costs of administering this certification program. The
1215 department shall renew the certification biennially if the
1216 laboratory meets the requirements of this section and pays the
1217 biennial renewal fee.
1218 (3) The department shall adopt rules pursuant to ss.
1219 120.536(1) and 120.54 establishing the standards for
1220 certification of marijuana testing laboratories under this
1221 section. The Department of Agriculture and Consumer Services and
1222 the Department of Environmental Protection shall assist the
1223 department in developing the rule, which must include, but is
1224 not limited to:
1225 (a) Security standards.

1226 (b) Minimum standards for personnel.
1227 (c) Sample collection method and process standards.
1228 (d) Proficiency testing.
1229 (e) Reporting content, format, and frequency.
1230 (f) Onsite inspections.
1231 (g) Quality assurance.
1232 (h) Any other standard the department deems necessary to
1233 ensure the health and safety of the public.
1234 (4) A marijuana testing laboratory may acquire marijuana
1235 only from a medical marijuana treatment center. A marijuana
1236 testing laboratory is prohibited from selling, distributing, or
1237 transferring marijuana received from a marijuana treatment
1238 center, except that a marijuana testing laboratory may transfer
1239 a sample to another marijuana testing laboratory in this state.
1240 (5) A marijuana testing laboratory must properly dispose
1241 of all samples it receives, unless transferred to another
1242 marijuana testing laboratory, after all necessary tests have
1243 been conducted and any required period of storage has elapsed,
1244 as established by department rule.
1245 (6) A marijuana testing laboratory shall use the computer
1246 software tracking system selected by the department under s.
1247 381.986.
1248 (7) The following acts constitute grounds for which
1249 disciplinary action specified in subsection (8) may be taken
1250 against a certified marijuana testing laboratory:

1251 (a) Permitting unauthorized persons to perform technical
1252 procedures or issue reports.
1253 (b) Demonstrating incompetence or making consistent errors
1254 in the performance of testing or erroneous reporting.
1255 (c) Performing a test and rendering a report thereon to a
1256 person or entity not authorized by law to receive such services.
1257 (d) Failing to file any report required under this section
1258 or s. 381.986 or the rules adopted thereunder.
1259 (e) Reporting a test result if the test was not performed.
1260 (f) Failing to correct deficiencies within the time
1261 required by the department.
1262 (g) Violating or aiding and abetting in the violation of
1263 any provision of s. 381.986 or this section or any rules adopted
1264 thereunder.
1265 (8) The department may refuse to issue or renew, or may
1266 suspend or revoke, the certification of a marijuana testing
1267 laboratory that is found to be in violation of this section or
1268 any rules adopted hereunder. The department may impose fines for
1269 violations of this section or rules adopted thereunder, based on
1270 a schedule adopted in rule. In determining the administrative
1271 action to be imposed for a violation, the department must
1272 consider the following factors:
1273 (a) The severity of the violation, including the
1274 probability of death or serious harm to the health or safety of
1275 any person that may result or has resulted; the severity or

1276 potential harm; and the extent to which the provisions of s.
1277 381.986 or this section were violated.
1278 (b) The actions taken by the marijuana testing laboratory
1279 to correct the violation or to remedy the complaint.
1280 (c) Any previous violation by the marijuana testing
1281 laboratory.
1282 (d) The financial benefit to the marijuana testing
1283 laboratory of committing or continuing the violation.
1284 (9) The department may adopt rules pursuant to ss.
1285 120.536(1) and 120.54 to implement this section.
1286 Section 6. Section 381.989, Florida Statutes, is created
1287 to read:
1288 381.989 Public education campaigns.—
1289 (1) DEFINITIONS.—As used in this section, the term:
1290 (a) "Cannabis" has the same meaning as in s. 893.02.
1291 (b) "Department" means the Department of Health.
1292 (c) "Marijuana" has the same meaning as in s. 381.986.
1293 (2) STATEWIDE CANNABIS AND MARIJUANA EDUCATION AND USE
1294 PREVENTION CAMPAIGN.—
1295 (a) The department shall implement a statewide cannabis
1296 and marijuana education and use prevention campaign to publicize
1297 accurate information regarding:
1298 1. The short-term and long-term health effects of cannabis
1299 and marijuana use, particularly on minors and young adults.
1300 2. The legal requirements for licit use and possession of

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1301 marijuana in this state.
1302 3. Safe use of marijuana, including preventing access by
1303 persons other than qualified patients as defined in s. 381.986,
1304 particularly children.
1305 4. Other cannabis-related and marijuana-related education
1306 determined by the department to be necessary to the public
1307 health and safety.
1308 (b) The department may use television messaging, radio
1309 broadcasts, print media, digital strategies, social media, and
1310 any other form of messaging deemed necessary and appropriate by
1311 the department to implement the campaign. The department may
1312 work with school districts, community organizations and
1313 businesses and business organizations and other entities to
1314 provide training and programming.
1315 (c) The department may contract with one or more vendors
1316 to implement the campaign.
1317 (d) The department shall contract with an independent
1318 entity to conduct annual evaluations of the campaign. The
1319 evaluations shall assess the reach and impact of the campaign,
1320 success in educating the citizens of the state regarding the
1321 legal parameters for marijuana use, success in preventing
1322 illicit access by adults and youth, and success in preventing
1323 negative health impacts from the legalization of marijuana. The
1324 first year of the program, the evaluator shall conduct surveys
1325 to establish baseline data on youth and adult cannabis use, the

1326 attitudes of youth and the general public toward cannabis and
1327 marijuana, and any other data deemed necessary for long-term
1328 analysis. By January 31 of each year, the department shall
1329 submit to the Governor, the President of the Senate, and the
1330 Speaker of the House of Representatives the annual evaluation of
1331 the campaign.
1332 (3) STATEWIDE IMPAIRED DRIVING EDUCATION CAMPAIGN.—The
1333 Department of Highway Safety and Motor Vehicles shall implement
1334 a statewide impaired driving education campaign to raise
1335 awareness and prevent marijuana-related and cannabis-related
1336 impaired driving and may contract with one or more vendors to
1337 implement the campaign. The Department of Highway Safety and
1338 Motor Vehicles may use television messaging, radio broadcasts,
1339 print media, digital strategies, social media, and any other
1340 form of messaging deemed necessary and appropriate by the
1341 department to implement the campaign.
1342 Section 7. Subsection (1) of section 385.211, Florida
1343 Statutes, is amended to read:
1344 385.211 Refractory and intractable epilepsy treatment and
1345 research at recognized medical centers.—
1346 (1) As used in this section, the term "low-THC cannabis"
1347 means "low-THC cannabis" as defined in s. 381.986 that is
1348 dispensed only from a dispensing organization as defined in
1349 former s. 381.986, Florida Statutes 2016, or a medical marijuana
1350 treatment center as defined in s. 381.986.

1351 Section 8. Paragraphs (b) through (e) of subsection (2) of
1352 section 499.0295, Florida Statutes, are redesignated as
1353 paragraphs (a) through (d), respectively, and present paragraphs
1354 (a) and (c) of that subsection, and subsection (3) of that
1355 section are amended to read:
1356 499.0295 Experimental treatments for terminal conditions.—
1357 (2) As used in this section, the term:
1358 ~~(a) "Dispensing organization" means an organization~~
1359 ~~approved by the Department of Health under s. 381.986(5) to~~
1360 ~~cultivate, process, transport, and dispense low-THC cannabis,~~
1361 ~~medical cannabis, and cannabis delivery devices.~~
1362 (b)~~(c)~~ "Investigational drug, biological product, or
1363 device" means~~:~~
1364 ~~1.~~ a drug, biological product, or device that has
1365 successfully completed phase 1 of a clinical trial but has not
1366 been approved for general use by the United States Food and Drug
1367 Administration and remains under investigation in a clinical
1368 trial approved by the United States Food and Drug
1369 Administration~~; or~~
1370 ~~2. Medical cannabis that is manufactured and sold by a~~
1371 ~~dispensing organization~~.
1372 (3) Upon the request of an eligible patient, a
1373 manufacturer may~~, or upon a physician's order pursuant to s.~~
1374 ~~381.986, a dispensing organization may~~:
1375 (a) Make its investigational drug, biological product, or

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1376 device available under this section.
1377 (b) Provide an investigational drug, biological product,
1378 or device~~, or cannabis delivery device as defined in s. 381.986~~
1379 to an eligible patient without receiving compensation.
1380 (c) Require an eligible patient to pay the costs of, or
1381 the costs associated with, the manufacture of the
1382 investigational drug, biological product, or device~~, or cannabis~~
1383 ~~delivery device as defined in s. 381.986~~.
1384 Section 9. Subsection (3) of section 893.02, Florida
1385 Statutes, is amended to read:
1386 893.02 Definitions.—The following words and phrases as
1387 used in this chapter shall have the following meanings, unless
1388 the context otherwise requires:
1389 (3) "Cannabis" means all parts of any plant of the genus
1390 Cannabis, whether growing or not; the seeds thereof; the resin
1391 extracted from any part of the plant; and every compound,
1392 manufacture, salt, derivative, mixture, or preparation of the
1393 plant or its seeds or resin. The term does not include
1394 "marijuana," ~~"low-THC cannabis,"~~ as defined in s. 381.986, if
1395 manufactured, possessed, sold, purchased, delivered,
1396 distributed, or dispensed, in conformance with s. 381.986.
1397 Section 10. Subsection (1) of section 1004.441, Florida
1398 Statutes, is amended to read:
1399 1004.441 Refractory and intractable epilepsy treatment and
1400 research.—

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1401 (1) As used in this section, the term "low-THC cannabis"
1402 means "low-THC cannabis" as defined in s. 381.986 that is
1403 dispensed only from a dispensing organization as defined in
1404 former s. 381.986, Florida Statutes 2016, or a medical marijuana
1405 treatment center as defined in s. 381.986.
1406 Section 11. Subsection (8) is added to section 1006.062,
1407 Florida Statutes, to read:
1408 1006.062 Administration of medication and provision of
1409 medical services by district school board personnel.—
1410 (8) Each district school board shall adopt a policy and a
1411 procedure for allowing a student who is a qualified patient, as
1412 defined in s. 381.986, to use marijuana obtained pursuant to
1413 that section. Such policy and procedure shall ensure access by
1414 the qualified patient; identify how the marijuana will be
1415 received, accounted for, and stored; and establish processes to
1416 prevent access by other students and school personnel
1417 unnecessary to the implementation of the policy.
1418 Section 12. Department of Health; authority to adopt
1419 rules; cause of action.—
1420 (1) EMERGENCY RULEMAKING.—
1421 (a) The Department of Health and the applicable boards
1422 shall adopt emergency rules pursuant to s. 120.54(4), Florida
1423 Statutes, and this subsection necessary to implement ss. 381.986
1424 and 381.988, Florida Statutes. If an emergency rule adopted
1425 under this subsection is held to be unconstitutional or an

1426 invalid exercise of delegated legislative authority, and becomes
1427 void, the department or the applicable boards may adopt an
1428 emergency rule to replace the rule that has become void. If the
1429 emergency rule adopted to replace the void emergency rule is
1430 also held to be unconstitutional or an invalid exercise of
1431 delegated legislative authority and becomes void, the department
1432 and the applicable boards must follow the nonemergency
1433 rulemaking procedures of the Administrative Procedures Act to
1434 replace the rule that has become void.
1435 (b) For emergency rules adopted under this section, the
1436 department and the applicable boards need not make the findings
1437 required by s. 120.54(4)(a), Florida Statutes. Emergency rules
1438 adopted under this section are exempt from ss. 120.54(3)(b) and
1439 120.541, Florida Statutes. The department and the applicable
1440 boards shall meet the procedural requirements in s. 120.54(a),
1441 Florida Statutes, if the department or the applicable boards
1442 have, prior to the effective date of this act, held any public
1443 workshops or hearings on the subject matter of the emergency
1444 rules adopted under this subsection. Challenges to emergency
1445 rules adopted under this subsection shall be subject to the time
1446 schedules provided in s. 120.56(5), Florida Statutes.
1447 (c) Emergency rules adopted under this section are exempt
1448 from s. 120.54(4)(c), Florida Statutes, and shall remain in
1449 effect until replaced by rules adopted under the nonemergency
1450 rulemaking procedures of the Administrative Procedures Act. By

1451 January 1, 2018, the department and the applicable boards shall
1452 initiate nonemergency rulemaking pursuant to the Administrative
1453 Procedures Act to replace all emergency rules adopted under this
1454 subsection by publishing a notice of rule development in the
1455 Florida Administrative Register. Except as provided in paragraph
1456 (a), after January 1, 2018, the department and applicable boards
1457 may not adopt rules pursuant to the emergency rulemaking
1458 procedures provided in this subsection.
1459 (2) CAUSE OF ACTION.—
1460 (a) As used in s. 29(d)(3), Art X, of the State
1461 Constitution, the term:
1462 1. "Issue regulations" means the filing by the department
1463 of a rule or emergency rule for adoption with the Department of
1464 State.
1465 2. "Judicial relief" means an action for declaratory
1466 judgment pursuant to chapter 86, Florida Statutes.
1467 (b) The venue for actions brought against the department
1468 pursuant to s. 29(d)(3), Art X, of the State Constitution shall
1469 be in the circuit court in and for Leon County.
1470 (c) If the department is not issuing patient and caregiver
1471 identification cards or licensing medical marijuana treatment
1472 centers by October 3, 2016, the following shall be a defense to
1473 a cause of action brought under s. 29(d)(3), Art X, of the State
1474 Constitution:
1475 1. The department is unable to issue patient and caregiver

1476 identification cards or license medical marijuana treatment
1477 centers due to litigation challenging a rule as an invalid
1478 exercise of delegated legislative authority or unconstitutional.
1479 2. The department is unable to issue patient or caregiver
1480 identification cards or license medical marijuana treatment
1481 centers due to a rule being held as an invalid exercise of
1482 delegated legislative authority or unconstitutional.
1483 Section 13. (1) For the 2017-2018 fiscal year, 10 full-
1484 time equivalent positions, with associated salary rate of
1485 411,811, are authorized and the sum of $1,008,463 in
1486 nonrecurring funds from the General Revenue Fund is appropriated
1487 to the Department of Health for the purpose of implementing the
1488 requirements of the act.
1489 (2) For the 2017-2018 fiscal year, the sum of $2,050,000
1490 in nonrecurring funds from the General Revenue Fund is
1491 appropriated to the Department of Health for contracted
1492 consultant services, information technology improvements for the
1493 medical marijuana use registry, and litigation costs for the
1494 purpose of implementing the requirements of the act.
1495 (3) For the 2017-2018 fiscal year, the sums of $1,000,000
1496 in recurring funds and $2,000,000 in nonrecurring funds from the
1497 General Revenue Fund are appropriated to the Department of
1498 Health to implement the statewide cannabis and marijuana
1499 education and use prevention campaign established under s.
1500 381.989, Florida Statutes.

1501 (4) For the 2017-2018 fiscal year, the sums of $1,000,000
1502 in recurring funds and $1,000,000 in nonrecurring funds from the
1503 General Revenue Fund are appropriated to the Department of
1504 Highway Safety and Motor Vehicles to implement the statewide
1505 impaired driving education campaign established under s.
1506 381.989, Florida Statutes.
1507 (5) For the 2017-2018 fiscal year, the sum of $1,000,000
1508 in nonrecurring funds from the General Revenue Fund is
1509 appropriated to the University of Florida College of Pharmacy to
1510 implement the requirements of s. 381.986(4)(a)8., Florida
1511 Statutes.
1512 (6) For the 2017-2018 fiscal year, the sum of $100,000 in
1513 recurring funds from the Highway Safety Operating Trust Fund is
1514 appropriated to the Department of Highway Safety and Motor
1515 Vehicles for the purpose of training additional law enforcement
1516 officers as drug recognition experts.
1517 Section 14. This act shall take effect upon becoming a
1518 law.

PCB HQS 17-03

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HQS 17-03 Pub. Rec./Medical Marijuana Use Registry
SPONSOR(S): Health Quality Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Quality Subcommittee		Royal	McElroy

SUMMARY ANALYSIS

The Compassionate Medical Cannabis Act (CMCA) (ss. 381.986, 499.0295 F.S.) legalized a low-THC and high-CBD form of cannabis for medical use by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms and legalized medical cannabis without any THC limit or CBD mandate for the terminally ill. The CMCA also allows the use of cannabis delivery devices by patients.

The CMCA required DOH to approve dispensing organizations to cultivate, process and dispense low-THC cannabis, medical cannabis, and cannabis delivery devices and provided regulatory standards for those activities. The CMCA also required DOH to create an online registry, the Compassionate Use Registry, to be used by physicians and dispensing organizations for the ordering and dispensing of low-THC cannabis, medical cannabis and cannabis delivery devices.

Section 381.987, F.S., makes the personal identifying information of physicians and patients contained within the Compassionate Use Registry confidential and exempt from public records. This information is available to certain individuals and entities, including law enforcement investigating a cannabis-related violation and dispensing organizations for the purposes of verifying a patient order when dispensing low-THC cannabis, medical cannabis and cannabis delivery devices.

On November 7, 2016, Florida voters approved an amendment to the Florida Constitution (Fla. Const. art. X, s. 29), which allows the medical use of marijuana without any THC limit by patients certified by physicians as having an enumerated debilitating medical condition. The amendment authorizes Medical Marijuana Treatment Centers (MMTCs) to be marijuana providers.

HB 1397 implements Fla. Const. art. X, s. 29 by amending the CMCA. HB 1397 renames the Compassionate Use Registry as the Medical Marijuana Use Registry and changes the requirements for its use.

PCB HQS 17-03 amends the current public records exemption in s. 381.987, F.S. to reflect the changes to the registry made by HB 1397. It makes confidential and exempt any personal identifying information in the registry of patients that obtain marijuana for medical use and the physicians that certify patients for medical use of marijuana.

The PCB also amends the current public records exemption to allow access by MMTCs to verify patients' certifications when dispensing marijuana or marijuana delivery devices.

The PCB does not have a fiscal impact on state or local governments.

The PCB takes effect on the same date that HB 1397 or similar legislation takes effect, if such legislation is adopted in the same legislative session.

Article I, s. 24(c) of the State Constitution requires a two-thirds vote of the members present and voting for final passage of a newly created public record or public meeting exemption. The bill creates public record and public meeting exemptions; thus, it appears to require a two-thirds vote for final passage.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Public Records and Open Meetings Requirements

The Florida Constitution provides that the public has the right to access government records and meetings. The public may inspect or copy any public record made or received in connection with the official business of any public body, officer, or employee of the state, or of persons acting on their behalf.[1] The public also has a right to notice and access to meetings of any collegial public body of the executive branch of state government or of any local government.[2] The Legislature's meetings must also be open and noticed to the public, unless there is an exception provided for by the Constitution.[3]

In addition to the Florida Constitution, the Florida Statutes specify conditions under which public access must be provided to government records and meetings. The Public Records Act[4] guarantees every person's right to inspect and copy any state or local government public record.[5] The Sunshine Law[6] requires all meetings of any board or commission of any state or local agency or authority at which official acts are to be taken be noticed and open to the public.[7]

The Legislature may create an exemption to public records or open meetings requirements.[8] An exemption must specifically state the public necessity justifying the exemption[9] and must be tailored to accomplish the stated purpose of the law.[10] There is a difference between records the Legislature has determined to be exempt from the Public Records Act and those which the Legislature has determined to be exempt from the Public Records Act and also confidential.

Exempt Records

If a record is exempt, the specified record or meeting, or portion thereof, is not subject to the access requirements of s. 119.07(1), F.S., s. 286.011, F.S., or article I, section 24 of the Florida Constitution. If records are only exempt from the Public Records Act and not confidential, the exemption does not

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[1] FLA. CONST., art. I, s. 24(a).
[2] FLA. CONST., art. I, s. 24(b).
[3] FLA. CONST., art. I, s. 24(b).
[4] Chapter 119, F.S.
[5] Section 119.011(12), F.S., defines "public record" as all documents, papers, letters, maps, books, tapes, photographs, films, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connection with the transaction of official business by any agency. Section 119.011(2), F.S. defines "agency" as any state, county, district, authority, or municipal officer, department, division, board, bureau, commission, or other separate unit of government created or established by law including, for the purposes of this chapter, the Commission on Ethics, the Public Service Commission, and the Office of Public Counsel, and any other public or private agency, person, partnership, corporation, or business entity acting on behalf of any public agency. The Public Records Act does not apply to legislative or judicial records, *Locke v. Hawkes*, 595 So. 2d 32 (Fla. 1992), however, the Legislature's records are public pursuant to section 11.0431, F.S.
[6] Section 286.011, F.S.
[7] Section 286.011(1)-(2), F.S. The Sunshine Law does not apply to the Legislature; rather, open meetings requirements for the Legislature are set out in the Florida Constitution. Article III, section 4(e) of the Florida Constitution provide that legislative committee meetings must be open and noticed to the public. In addition, prearranged gatherings, between more than two members of the Legislature, or between the Governor, the President of the Senate, or the Speaker of the House of Representatives, the purpose of which is to agree upon or to take formal legislative action, must be reasonably open to the public.
[8] FLA. CONST., art. I, s. 24(c).
[9] FLA. CONST., art. I, s. 24(c).
[10] FLA. CONST., art. I, s. 24(c).

prohibit the showing of such information, but simply exempts them from the mandatory disclosure requirements in s. 119.07(1)(a), F.S.[11]

Confidential Records

The term "confidential" is not defined in the Public Records Act; however, it is used in Article I, S. 24 of the Florida Constitution, which provides that every person has the right to inspect or copy any public record, except with respect to records exempted pursuant to this section or specifically made confidential by this Constitution. If information is made confidential in the statutes, the information is not subject to inspection by the public and may be released only to those persons and entities designated in the statute.[12]

Open Government Sunset Review Act

The Open Government Sunset Review Act (OGSR) prescribes a legislative review process for newly created or substantially amended public records or open meetings exemptions.[13] The OGSR provides that an exemption automatically repeals on October 2nd of the fifth year after creation or substantial amendment; in order to save an exemption from repeal, the Legislature must reenact the exemption.[14]

The OGSR provides that a public records or open meetings exemption may be created or maintained only if it serves an identifiable public purpose and is no broader than is necessary.[15] An exemption serves an identifiable purpose if it meets one of the following criteria:

- It allows the state or its political subdivision to effectively and efficiently administer a program, and administration would be significantly impaired without the exemption; or
- Releasing sensitive personal information would be defamatory or would jeopardize an individual's safety. If this public purpose is cited as the basis of an exemption, however, only personal identifying information is exempt; or
- It protects trade or business secrets.[16]

In addition, the Legislature must find that the identifiable public purpose is compelling enough to override Florida's open government public policy and that the purpose of the exemption cannot be accomplished without the exemption.[17]

The OGSR also requires specific questions to be considered during the review process.[18] In examining an exemption, the OGSR asks the Legislature to question the purpose and necessity of reenacting the exemption. If, in reenacting an exemption, the exemption is expanded, then a public necessity statement and a two-thirds vote for passage are required.[19] If the exemption is reenacted without

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[11] See, *Williams v. City of Minneola*, 575 So. 2d 683 (Fla. 5th DCA 1991), rev. denied, 589 So. 2d 289 (Fla. 1991), in which the court observed that pursuant to s. 119.07(3)(d), F.S, [now s. 119.071(2)(c), F.S.] "active criminal investigative information" was exempt from the requirement that public records be made available for public inspection. However, as stated by the court, "the exemption does not prohibit the showing of such information." Id. at 686.
[12] *WFTV, Inc. v. School Board of Seminole*, 874 So. 2d 48 (Fla. 5th DCA 2004), rev. denied, 892 So. 2d 1015 (Fla. 2004). See also, 04-09 Fla Op. Att'y Gen. (2004) and 86-97 Fla Op. Att'y Gen. (1986).
[13] Section 119.15, F.S. Section 119.15(4)(b), F.S., provides that an exemption is considered to be substantially amended if it expanded to include more information or to include meetings. The OGSR does not apply to an exemption that is required by federal law or that applies solely to the Legislature or the State Court System pursuant to s. 119.15(2), F.S.
[14] Section 119.15(3), F.S.
[15] Section 119.15(6)(b), F.S.
[16] *Id.*
[17] *Id.*
[18] Section 119.15(6)(a), F.S. The questions are: What specific records or meetings are affected by the exemption? Whom does the exemption uniquely affect, as opposed to the public? What is the identifiable public purpose or goal of the exemption? Can the information contained in the records or discussed in the meeting be readily obtained by alternative means? If so, how? Is the record or meeting protected by another exemption? Are there multiple exemptions for the same type of record or meeting that it would be appropriate to merge?
[19] FLA. CONST., art. I, s. 24(c).

substantive changes or if the exemption is narrowed, then a public necessity statement and a two-thirds vote for passage are *not* required. If the Legislature allows an exemption to sunset, the previously exempt records will retain their exempt status unless provided for by law.[20]

Compassionate Medical Cannabis Act

The Compassionate Medical Cannabis Act (CMCA) was enacted in 2014 and amended in 2016.[21] The CMCA legalized a low-THC and high-CBD form of low-THC cannabis[22] for medical use[23] 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.[24]

Under the CMCA, a physician who is authorized to order low-THC or medical cannabis must register as the patient's physician and enter the patient and the contents of the patient's order for low-THC cannabis, medical cannabis, or a cannabis delivery device into the Compassionate Use Registry.

Under the CMCA, entities known as dispensing organizations are authorized to cultivate, process, transport and dispense low-THC cannabis, medical cannabis, and cannabis delivery devices. Dispensing organizations are required to verify the patient's order before dispensing low-THC cannabis, medical cannabis or a cannabis delivery device. Dispensing organizations must also enter into the registry the date, time, quantity, and form dispensed and type of cannabis delivery device dispensed to the patient.

CMCA Public Records Exemption

Section 381.987, F.S., makes the personal identifying information of physicians and patients contained within the Compassionate Use Registry confidential and exempt from public records. Information relating to the patient's name, address, telephone number, government issued identification number and all information pertaining to the physician's order for low-THC cannabis and the dispensing thereof is confidential and exempt from public records requirements. The physician's name, address, telephone number, government issued identification number and Drug Enforcement Administration number are confidential and exempt from public records requirements.

This information is available to certain individuals and entities, including law enforcement investigating a cannabis-related violation, dispensing organizations for the purposes of verifying a patient order when dispensing low-THC cannabis, medical cannabis and cannabis delivery devices, physicians for the purposes of ordering low-THC cannabis, medical cannabis or cannabis delivery devices, a DOH employee for purposes of maintaining the registry, DOH's relevant health care regulatory boards for purposes of investigation a possible violation of the CMCA by a physician, and a person engaged in bona fide research under certain conditions.

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[20] S. 119.15(7), F.S.
[21] *See* ch. 2014-157, L.O.F., ch. 2016-123, L.O.F. and s. 381.986, F.S.
[22] 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.
[23] 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."
[24] Section 499.0295, F.S.

Amendment 2: Use of Marijuana for Debilitating Medical Conditions

On November 7, 2016, Florida voters approved an amendment to the Florida Constitution (Fla. Const. art. X, s. 29), which allows the medical use of marijuana without any THC limit by patients who are certified by physicians with an enumerated debilitating medical condition. The amendment authorizes entities known as Medical Marijuana Treatment Centers (MMTCs) to be marijuana providers.

HB 1397

HB 1397 implements Fla. Const. art. X, s. 29 by amending the CMCA. HB 1397 renames the Compassionate Use Registry as the Medical Marijuana Use Registry and changes the requirements for its use. The Medical Marijuana Use Registry will be used by physicians to certify patients and by MMTCs to dispense marijuana under Fla. Const. art. X s.29. Physicians must enter the contents of the patient's certification for marijuana into the registry, including the patient's debilitating medical condition. MMTCs must use the registry to verify the patient's certification before dispensing marijuana to the patient and must enter certain information regarding the dispensing of the marijuana to the patient.

Effect of Proposed Changes

PCB HQS 17-03 amends the current public records exemption in s. 381.987, F.S. to reflect the changes to the registry made by HB 1397. It makes confidential and exempt any personal identifying information in the registry of patients that obtain marijuana for medical use and the physicians that certify patients for medical use of marijuana.

The PCB also amends the current public records exemption to allow access to MMTCs to verify patients' certifications when dispensing marijuana or marijuana delivery devices.

The PCB provides a public necessity statement as required by the State Constitution, which states that the exemption is necessary to protect the privacy rights of physicians and patients, including protecting patients' personal health information.

The PCB takes effect on the same date that HB 1397 or similar legislation takes effect, if such legislation is adopted in the same legislative session.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.987, relating to public records exemption for personal identifying information in the compassionate use registry.
Section 2: Creates an unnumbered section of law relating to the public necessity for making exempt and confidential the person identifying information in the Medical Marijuana Use Registry.
Section 3: Provides a contingent effective date.

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. The bill does not appear to affect county or municipal governments.

2. Other:

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

1 A bill to be entitled
2 An act relating to public records; amending s.
3 381.987, F.S.; exempting from public records
4 requirements personal identifying information of
5 patients and physicians held by the Department of
6 Health in the medical marijuana use registry and
7 information related to the physician's certification
8 for marijuana and the dispensing thereof; authorizing
9 specified persons and entities access to the exempt
10 information; requiring that information released from
11 the registry remain confidential and exempt; providing
12 a criminal penalty; providing for future legislative
13 review and repeal of the exemption; providing a
14 statement of public necessity; providing an effective
15 date.
16
17 Be It Enacted by the Legislature of the State of Florida:
18
19 Section 1. Section 381.987, Florida Statutes, is amended
20 to read:
21 381.987 Public records exemption for personal identifying
22 information in the medical marijuana ~~compassionate~~ use
23 registry.—
24 (1) A patient's personal identifying information held by
25 the department in the medical marijuana ~~compassionate~~ use

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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26 registry established under s. 381.986, ~~including, but not~~
27 ~~limited to, the patient's name, address, telephone number, and~~
28 ~~government-issued identification number,~~ and all information
29 pertaining to the physician's certification ~~order~~ for marijuana
30 ~~low-THC cannabis~~ and the dispensing thereof, are confidential
31 and exempt from s. 119.07(1) and s. 24(a), Art. I of the State
32 Constitution.
33 (2) A physician's personal identifying information and
34 Drug Enforcement Administration number held by the department in
35 the medical marijuana ~~compassionate~~ use registry established
36 under s. 381.986, ~~including, but not limited to, the physician's~~
37 ~~name, address, telephone number, government-issued~~
38 ~~identification number, and Drug Enforcement Administration~~
39 ~~number,~~ and all information pertaining to the physician's
40 certification ~~order~~ for marijuana ~~low-THC cannabis~~ and the
41 dispensing thereof, are confidential and exempt from s.
42 119.07(1) and s. 24(a), Art. I of the State Constitution.
43 (3) The department shall allow access to the confidential
44 and exempt information in the medical marijuana use registry~~,~~
45 ~~including access to confidential and exempt information,~~ to:
46 (a) A law enforcement agency that is investigating a
47 violation of law regarding marijuana ~~cannabis~~ in which the
48 subject of the investigation claims an exception established
49 under s. 381.986.
50 (b) A medical marijuana treatment center ~~dispensing~~

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

51 ~~organization~~ approved by the department pursuant to s. 381.986
52 which is attempting to verify the authenticity of a physician's
53 certification ~~order~~ for marijuana ~~low-THC cannabis~~, including
54 whether the certification ~~order~~ had been previously filled and
55 whether the certification ~~order~~ was issued ~~written~~ for the
56 person attempting to have it filled.
57 (c) A physician who has issued a certification for
58 marijuana ~~written an order for low-THC cannabis~~ for the purpose
59 of monitoring the patient's use of such marijuana ~~cannabis~~ or
60 for the purpose of determining, before issuing a certification
61 for marijuana ~~an order for low-THC cannabis~~, whether another
62 physician has issued a certification for ~~ordered~~ the patient's
63 use of marijuana ~~low-THC cannabis~~. The physician may access the
64 confidential and exempt information only for the patient for
65 whom he or she has issued a certification ~~ordered~~ or is
66 determining whether to issue a certification for ~~order~~ the use
67 of marijuana ~~low-THC cannabis~~ pursuant to s. 381.986.
68 (d) An employee of the department for the purposes of
69 maintaining the registry and periodic reporting or disclosure of
70 information that has been redacted to exclude personal
71 identifying information.
72 (e) The department's relevant health care regulatory
73 boards responsible for the licensure, regulation, or discipline
74 of a physician if he or she is involved in a specific
75 investigation of a violation of s. 381.986. If a health care

76 regulatory board's investigation reveals potential criminal
77 activity, the board may provide any relevant information to the
78 appropriate law enforcement agency.
79 (f) A person engaged in bona fide research if the person
80 agrees:
81 1. To submit a research plan to the department which
82 specifies the exact nature of the information requested and the
83 intended use of the information;
84 2. To maintain the confidentiality of the records or
85 information if personal identifying information is made
86 available to the researcher;
87 3. To destroy any confidential and exempt records or
88 information obtained after the research is concluded; and
89 4. Not to contact, directly or indirectly, for any
90 purpose, a patient or physician whose information is in the
91 registry.
92 (4) All information released from the registry under
93 subsection (3) remains confidential and exempt, and a person who
94 receives access to such information must maintain the
95 confidential and exempt status of the information received.
96 (5) A person who willfully and knowingly violates this
97 section commits a felony of the third degree, punishable as
98 provided in s. 775.082 or~~,~~ s. 775.083~~, or s. 775.084~~.
99 (6) This section is subject to the Open Government Sunset
100 Review Act in accordance with s. 119.15 and shall stand repealed

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101 on October 2, 2022 ~~2019~~, unless reviewed and saved from repeal
102 through reenactment by the Legislature.
103 Section 2. The Legislature finds that it is a public
104 necessity that identifying information of patients and
105 physicians held by the Department of Health in the medical
106 marijuana use registry established under s. 381.986, Florida
107 Statutes, be made confidential and exempt from s. 119.07(1),
108 Florida Statutes, and s. 24(a), Article I of the State
109 Constitution. The Legislature further finds that it is a public
110 necessity to make confidential and exempt from s. 119.07(1),
111 Florida Statutes, and s. 24(a), Article I of the State
112 Constitution all information held in the medical marijuana use
113 registry that pertains to a physician's certification for
114 marijuana and the dispensing thereof pursuant to s. 381.986,
115 Florida Statutes. The choice made by a physician to certify and
116 his or her patient to use marijuana to treat the patient's
117 medical condition or symptoms is a personal and private matter
118 between those two parties. The availability of such information
119 could make the public aware of both the patient's use of
120 marijuana and the patient's diseases or other medical conditions
121 for which the patient is using marijuana. The knowledge of the
122 patient's use of marijuana, the knowledge that the physician
123 certified the use of marijuana, and the knowledge of the
124 patient's diseases or other medical conditions could be used to
125 embarrass, humiliate, harass, or discriminate against the

126 patient and the physician. This information could be used as a
127 discriminatory tool by an employer who disapproves of the
128 patient's use of marijuana or of the physician's certification
129 of such use. However, despite the potential hazards of
130 collecting such information, maintaining the medical marijuana
131 use registry established under s. 381.986, Florida Statutes, is
132 necessary to prevent the diversion and nonmedical use of
133 marijuana as well as to aid and improve research done on the
134 efficacy of marijuana. Therefore, the Legislature finds that it
135 is a public necessity to make confidential and exempt from
136 public records requirements the identifying information of
137 patients and physicians held by the Department of Health in the
138 medical marijuana use registry established under s. 381.986,
139 Florida Statutes, and all information held in the registry that
140 pertains to a physician's certification for marijuana and the
141 dispensing thereof pursuant to s. 381.986, Florida Statutes.
142 Section 3. This act shall take effect on the same date
143 that HB 1397 or similar legislation takes effect, if such
144 legislation is adopted in the same legislative session or an
145 extension thereof and becomes a law, if such legislation is
146 adopted in the same legislative session or an extension thereof
147 and becomes a law.

PCB HQS 17-04

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HQS 17-04 Direct Support Organization of the Prescription Drug Monitoring Program
SPONSOR(S): Health Quality Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Quality Subcommittee		Siples	McElroy

SUMMARY ANALYSIS

Citizen support and direct-support organizations (CSOs and DSOs) are statutorily created entities that are generally required to be non-profit corporations and are authorized to carry out specific tasks in support of public entities or public causes. The functions and purposes of CSOs and DSOs are prescribed by their enacting statutes and, for most, by a written contract with the agency the CSO or DSO was created to support.

In 2009, the Florida PDMP Foundation, Inc. (Foundation), was established as a DSO for the prescription drug monitoring program (PDMP). The PDMP is an electronic database that tracks prescribing and dispensing of certain controlled substance prescription drugs to patients. The PDMP is designed to monitor this information for suspected abuse or diversion and provide prescribers and pharmacists with a patient's controlled substance prescription history. State law requires the Department of Health (DOH) to acquire federal and private funds to operate the PDMP, which requires approximately $600,000 annually to maintain.

The mission of the Foundation is to raise funds for the benefit of the PDMP, in order to reduce prescription drug abuse and diversion. Since its inception, the Foundation has acquired almost $3 million in funds to support the PDMP, including a $1.9 million donation from the Office of the Attorney General in 2014. Other donations have come from law enforcement agencies and other health care-affiliated entities, such as drug testing laboratories and medical technology providers.

The statutory authority for the Foundation is scheduled to repeal on October 1, 2017, unless reviewed and saved from repeal by the Legislature.

PCB HQS 17-04 extends the scheduled repeal of the law authorizing the PDMP DSO to October 1, 2027.

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

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Citizen Support Organizations and Direct-support Organizations

Citizen support and direct-support organizations (CSOs and DSOs) are statutorily created entities that are generally required to be non-profit corporations and are authorized to carry out specific tasks in support of public entities or public causes. The functions and purposes of CSOs and DSOs are prescribed by their enacting statutes and, for most, by a written contract with the agency the CSO or DSO was created to support.

Prior to 2014, there was no formal review process in law to determine whether a CSO or DSO was established pursuant to such authorization, or whether the rationale for the authorization remained applicable. However, Chapter 2014-96, Laws of Florida,[1] established reporting and transparency requirements for each CSO and DSO created or authorized pursuant to law or executive order and created, approved, or administered by a state agency. The CSO or DSO must report information related to its organization, mission, and finances to the agency it was created to support by August 1 of each year.[2] Specifically, a CSO or DSO must provide:

- The name, mailing address, telephone number, and website address of the organization;
- The statutory authority or executive order that created the DSO;
- A brief description of the mission of, and results obtained by, the organization;
- A brief description of the organization's plans for the next three fiscal years;
- A copy of the organization's code of ethics; and
- A copy of the organization's most recent federal Internal Revenue Service Return of Organization Exempt from Income Tax form (Form 990).[3]

Each agency receiving the above information must make the information available to the public through the agency's website. If the CSO or DSO maintains a website, the agency's website must provide a link to the website of the CSO or DSO.[4] Additionally, any contract between an agency and a CSO or DSO must be contingent upon the CSO or DSO submitting and posting the information.[5] If a CSO or DSO fails to submit the required information for two consecutive years, the agency must terminate its contract with the CSO or DSO.[6]

By August 15 of each year, each agency must report to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the Office of Program Policy Analysis and Government Accountability the information provided by the CSO or DSO. The report must also include a recommendation by the agency, with supporting rationale, to continue, terminate, or modify the agency's association with each organization.[7]

Lastly, a law creating or authorizing the creation of a CSO or DSO must state that the creation of or authorization for the CSO or DSO is repealed on October 1 of the 5th year after enactment, unless

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[1] Codified at s. 20.058, F.S.
[2] Section 20.058(1), F.S.
[3] Section 20.058(1)(a)-(f), F.S
[4] Section 20.058(2), F.S
[5] Section 20.058(4), F.S.
[6] Id.
[7] Section 20.058(3), F.S.

reviewed and saved from repeal through reenactment by the Legislature. CSOs or DSOs in existence on July 1, 2014, must be reviewed by the Legislature by July 1, 2019.[8]

CSO and DSO Audit Requirements

CSOs or DSOs with annual expenditures in excess of $100,000 and that are created, approved, or administered by a state agency are statutorily-required to provide for an annual financial audit of accounts and records to be conducted by an independent certified public accountant, with certain exceptions.[9] The audit report must be submitted within nine months after the end of the fiscal year to the Auditor General and to the state agency responsible for its creation, administration, or approval of the CSO or DSO.

Additionally, the Auditor General may, pursuant to his or her own authority, or at the direction of the Legislative Auditing Committee, conduct audits or other engagements of the accounts and records of the CSO or DSO.[10] The Auditor General is authorized to require and receive any records from the CSO or DSO, or from its independent auditor.[11]

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.[12] PDMPs are designed to monitor this information for suspected abuse or diversion and provide prescribers and pharmacists with critical information regarding a patient's controlled substance prescription history.[13] As of September 2015, 49 states either had an operational PDMP database.[14]

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.[15] The PDMP database became operational in September 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[16]

Funding for the PDMP

Current law restricts how DOH may fund implementation and operation of the PDMP.. Section 893.055(10), F.S., prohibits DOH from using state funds and any money received directly or indirectly from prescription drug manufacturers to implement the PDMP.[17] Since 2010, the PDMP has spent $3,615,939 for system and database infrastructure, personnel, and facility expenses.[18] Funding for the PDMP comes from three funding sources: federal and private grants, state appropriations, and donations procured by its DSO, the Florida PDMP Foundation, Inc. (Foundation).

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[8] Section 20.058(5), F.S.
[9] Section 215.981(1), F.S. This subsection does not apply to a CSO or DSO of a university, district board of trustees of a community college, district school board, Department of Environmental Protection, or Department of Agriculture and Consumer Services.
[10] Section 11.45(3), F.S.
[11] Id.
[12] Centers for Disease Control and Prevention, *Prescription Drug Monitoring Programs*, available at http://www.cdc.gov/drugoverdose/pdmp/ (last visited March 17, 2017).
[13] Id.
[14] National Alliance for Model State Drug Laws, *2015 Annual Review of Prescription Monitoring Programs*, (September 2015), available at http://www.namsdl.org/IssuesandEvents/2015%20Annual%20Review%20of%20Prescription%20Monitoring%20Programs.pdf (last visited March 20, 2017). Missouri is the only state without a PDMP. Legislation was filed in December 2016 to establish a program. *See http://www.senate.mo.gov/17info/BTS_Web/Bill.aspx?SessionType=R&BillID=57095432* (last visited March 17, 2017).
[15] Section 893.055(2)(a), F.S.
[16] Florida Department of Health, *Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2015-2016 Prescription Drug Monitoring Program Annual Report*, (December 1, 2016), available at http://www.floridahealth.gov/statistics-and-data/e-forcse/_documents/2016PDMPAnnualReport.pdf (last visited March 17, 2017).
[17] Section 893.055(10) and (11)(c), F.S.
[18] *Supra* note 16.

Federal and Private Grants

Since its inception, DOH applied for and was awarded several grants for the implementation and enhancement of the PDMP. DOH has been awarded a total of $2,443,471 in federal grants.[19] The federal grants and the purpose of each are as follows:

Grant	Grant Amount	Grant Purpose	Project End Date
U.S. Department of Justice Harold Rogers PDMP Implementation Grant	$400,000	Implementation of the PDMP system.	August 31, 2012
U.S. DOJ Harold Rogers PDMP Enhancement Grant	$400,000	Performance of system enhancements.	March 31, 2013
U.S. DOJ Harold Rogers PDMP Enhancement Grant	$399,300	To enhance of collaborations with law enforcement; enhance the PDMP's ability to analyze data to identify drug abuse trends; and increase the number of PDMP users.	September 30, 2014
U.S. Substance Abuse and Mental Health Services Administration Grant	$240,105	To integrate PDMP data into existing clinical workflow and technology and to expand operability.	March 31, 2015
U.S. DOJ Harold Rogers PDMP Enhancement Grant	$399,950	To form multidisciplinary and multijurisdictional groups to identify areas of greatest risk of drug abuse and diversion and create data-driven responses at the local level.	March 31, 2017
U.S. DOJ Harold Rogers PDMP Enhancement Grant	$499,991	To enhance proactive reporting efforts to health care practitioners and law enforcement and analysis of impact on prescriber behavior and law enforcement efforts.	September 30, 2017
DCF Partnership for Success	$86,625	To ensure the PDMP includes additional alert features and computer based training, to encourage safer prescribing and reduce drug abuse and diversion.	September 30, 2017
UF Harold Rogers PDMP: Data Driven Responses to Prescription Drug Abuse	$17,500	To link de-identified PDMP data with other key data sources to improve care coordination.	September 30, 2019

The National Association of State Controlled Substance Authorities has awarded three private grants to DOH, totaling $49,952. These funds were used to create a website and to purchase office equipment and promotional items.[20]

State Appropriations

Although s. 893.055(1), F.S., makes the PDMP contingent on nonstate funding, and restricts funding to only federal grants and private donations, the Legislature has, on three separate occasions, appropriated state funds for the operation of the PDMP:

- In 2013, the Legislature appropriated $500,000 to DOH for fiscal year 2013-2014, for the general administration of the PDMP;[21]

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[19] Id.

[20] DOH, *E-Forcse Funding*, available at http://www.floridahealth.gov/statistics-and-data/e-forcse/funding/index.html (last visited March 24, 2017).

[21] Chapter 2013-153, Laws of Fla.

- In 2015, the Legislature appropriated $500,000 to DOH to administer the PDMP for fiscal year 2015-2016, and prohibited DOH or the Office of the Attorney General (OAG) from using funds received as a part of a settlement agreement to administer the PDMP;[22] and
- In 2016, the Legislature appropriated $500,000 to DOH to administer the PDMP for fiscal year 2016-2017, and prohibited DOH and the OAG from using funds received as a part of a settlement agreement to administer the PDMP.[23]

PDMP funding is now a recurring appropriation of $500,000 from the General Revenue Fund, in the base budget.

Funding from the Foundation

The Foundation has provided $1,010,513 to fund the PDMP.[24] With the funds held by the Foundation, the PDMP has sustainable funding through fiscal year 2019-2020.[25] Please see below for more information about the fundraising activities of the Foundation.

<u>The Florida PMDP Foundation</u>

In 2009, the Legislature authorized DOH to establish a DSO to provide assistance, funding, and promotional support for the activities authorized for the PDMP.[26] The Foundation was founded in 2009 as a nonprofit organization under the laws of this state 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, real or personal; and
- Make expenditures or provide funding to or for the direct or indirect benefit of DOH in furtherance of the PDMP.[27]

The PDMP has an executive director and a board of directors who are appointed by the Surgeon General. The Foundation's board currently consists of 10 members and includes health care practitioners, representatives of the pharmaceutical and insurance industries, and a consumer advocate.[28] The Surgeon General provides guidance to board of directors to ensure that the DSO does not receive funds from inappropriate sources, which include funds from donors, grantors, persons, or organizations that may monetarily or substantively benefit from the purchase of goods or services by DOH in furtherance of the PDMP.[29]

The Foundation has two major goals. The first goal is to raise funds for the operation of the PDMP and the second is to educate law enforcement and licensed health care practitioners about the database and its uses.[30] The Foundation has collaborated with the PDMP, Florida Hospital Association, and

[22] Chapter 2015-522, Laws of Fla.
[23] Chapter 2016-62, Laws of Fla.
[24] *Supra* note 16.
[25] Id.
[26] Chapter 2009-197, Laws of Fla., codified at 893.055(10), F.S.
[27] Articles of Incorporation of the Florida PDMP Foundation, Inc., dated Dec. 30, 2009, *available at* http://search.sunbiz.org/Inquiry/CorporationSearch/ConvertTiffToPDF?storagePath=COR%5C2010%5C0126%5C63623995.Tif&documentNumber=N10000000221 (last visited March 24, 2017). *See also* s. 893.055(10), F.S.
[28] E-mail correspondence with DOH, dated March 24, 2017 (on file with the Health Quality Subcommittee). The appointment of a member of law enforcement is also pending. *See also* Florida PDMP Foundation, *About Us*, available at http://www.flpdmpfoundation.com/about/ (last visited March 25, 2017).
[29] Section 893.055(11), F.S.
[30] Florida PDMP Foundation, *Goals*, available at http://www.flpdmpfoundation.com/goals/ (last visited March 25, 2017).

Florida Nurse Practitioner Network to develop a three-hour continuing education course regarding controlled substances.[31]

The Foundation operates under a written contract with DOH, which requires the Foundation to:

- Raise funds, request and receive grants, gifts, and bequests of money, acquire and otherwise act in accordance with the goals of the PDMP and in the best interest of the state;
- Obtain written approval from DOH for any activities in support of the PDMP before undertaking those activities;
- Submit an annual budget to DOH by May 15 of each year for review and approval. The budget must detail the Foundation's fundraising plan to support the spending plan for the PDMP; and
- Annually certify that it is complying with the terms of the contract.

The Foundation may also collect, expend and provide funds to DOH to develop, implement and operate the PDMP.

Since its inception, the Foundation has acquired almost $3 million in funds to support the PDMP. The majority of its revenues is from a $1.973 million donation from the Office of the Attorney General (OAG) in 2014. These funds were from a settlement of a fraud case against CVS/Caremark. At the time of the contribution, the Foundation entered into Memorandum of Understanding (MOU) with the OAG that restricts use of the funds for the sole operation of the PDMP which does not exceed $500,000 in any one state fiscal year. The MOU authorizes the Foundation to PDMP to invest the funds in FDIC-protected products, such as certificates of deposit. In Fiscal Year 2014-2015, the Foundation disbursed $500,000 of the OAG donation to DOH for the PDMP. However, in Fiscal Years 2015-2016 and 2016-2017, the Implementing Bills for the General Appropriations Acts prohibited use of the settlement funds for the PDMP.[32] The current prohibition expires July 1, 2017, unless reenacted. The Foundation invested the remainder of the donation, pending a change in law.

The other Foundation's fundraising efforts, as well as expenditures, are detailed below.[33] In the Fiscal Year 2014-2015 and Fiscal Year 2015-2016, the Foundation's expenses exceeded its revenues.

Fiscal Year	Donations	Expenses	Provided to DOH for PDMP
2009-2010	$125,000	N/A	$39,108
2010-2011	*$339,443	$39,134	$201,552
2011-2012	$120,010	$4,570	$96,758
2012-2013	$73,910	$4,147	$205,308
2013-2014	†$2,161,881	$46,080	$0
2014-2015	$35,650	$75,130	$500,000
2015-2016	$26,050	$76,325	$7,811
Totals	**$2,881,944**	**$245,386**	**$1,050,537**

*A portion of the funds donated were specified for expenses related to legal services and government fees.
† Includes a donation of $1,973,156 from the OAG, and $179,675 in other donations.

As of January 2017, the Foundation had assets of almost $1.6 million, of which $1.35 million is invested.[34] The annual cost to maintain the PDMP is $600,000.[35] With these funds, the PDMP has sustainable funding through Fiscal Year 2019-2020.

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[31] 30DOH, *E-FORCSE: 2015-2016 PDMP Annual Report,* (Dec. 1, 2016), available at http://www.floridahealth.gov/statistics-and-data/e-forcse/_documents/2016PDMPAnnualReport.pdf (last visited March 25, 2017).
[32] Sections 893.055(17), F.S. (2015, 2016).
[33] Based on information received from DOH and the Foundation (on file with the Health Quality Subcommittee).
[34] E-mail correspondence with DOH, dated January 30, 2017, (on file with the Health Quality Subcommittee).
[35] *Supra* note

Effect of Proposed Changes

The bill extends the scheduled repeal of the PDMP DSO to October 1, 2027.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 893.055, F.S.; relating to prescription drug monitoring program.
Section 2: Provides an effective date of July 1, 2017.

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. The 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 the direct support organization of the prescription drug monitoring program; amending s. 893.055, F.S.; providing for future repeal of such provisions; providing an effective date.

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

Section 1. Paragraph (k) of subsection (11) of section 893.055, Florida Statutes, is amended to read:

893.055 Prescription drug monitoring program.—

(11) The department may establish a direct-support organization that has a board consisting of at least five members to provide assistance, funding, and promotional support for the activities authorized for the prescription drug monitoring program.

(k) This subsection is repealed October 1, 2027 ~~2017~~, unless reviewed and saved from repeal by the Legislature.

Section 2. This act shall take effect July 1, 2017.

V