HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 5A Medical Use of Marijuana
SPONSOR(S): Rodrigues
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Committee		Royal	Calamas

SUMMARY ANALYSIS

HB 5-A 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 8, 2016, Florida voters approved an amendment to the Florida Constitution (Fla. Const. art. X, s. 29) which allows the medical use of marijuana by patients with an enumerated debilitating medical condition. The amendment authorizes entities known as Medical Marijuana Treatment Centers (MMTCs) to be marijuana providers. 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, and the Florida Department of Law Enforcement. 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 federal government continues to limit scientific and clinical investigators' access to marijuana for research.[10]

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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*.
[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.

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 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

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[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.
[23] *Id*.

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]

Marijuana is the most widely used illicit drug during pregnancy.[26] According to data from the National Survey of Drug Use and Health, 3.85%of pregnant women between the ages of 18 and 44 years reported past-month marijuana use in 2014, compared with 2.37% in 2002.[27] A recent review and meta-analysis found that infants of women who used marijuana during pregnancy were more likely to be anemic, have lower birth weight, and require placement in neonatal intensive care than infants of mothers who did not use marijuana.[28] Studies have also shown links between prenatal marijuana exposure and impaired higher-order executive functions such as impulse control visual memory, and attention during the school years.[29]

Federal Regulation of Cannabis

Criminal Laws and Enforcement

The Federal Controlled Substances Act[30] 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.[31] The Federal Controlled Substances Act imposes penalties on those who possess, sell, distribute, dispense, and use cannabis.[32] 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.[33] Selling and cultivating cannabis are subject to even greater penalties.[34]

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."[35] 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."[36]

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

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[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] Nora D. Volkow, MD1; Wilson M. Compton, MD, MPE1; Eric M. Wargo, PhD. The Risks of Marijuana Use During Pregnancy. JAMA. 2017;317(2):129-130.Available at: https://jamanetwork.com/journals/jama/article-abstract/2594400.
[27] Id.
[28] J K L Gunn, C B Rosales, K E Center, A Nuñez,S J Gibson, C Christ, and J E Ehiri. Prenatal exposure to cannabis and maternal and child health outcomes: a systematic review and meta-analysis. BMJ open. 2016; 6(4): e009986. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4823436/.
[29] Chia-Shan Wu, Christopher P Jew, and Hui-Chen Lu. Lasting impacts of prenatal cannabis exposure and the role of endogenous cannabinoids in the developing brain. Future Neurol. 2011 Jul 1; 6(4): 459–480. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3252200/.
[30] 21 U.S.C. ss. 801-971.
[31] 21 U.S.C. s. 812.
[32] 21 U.S.C. ss. 841-65.
[33] 21 U.S.C. s. 844.
[34] 21 U.S.C. ss. 841-65.
[35] 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).
[36] *Id*.

the federal government's cannabis-related offense enforcement policies.[37] 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.[38]

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 preventing cannabis being grown, possessed or used on public lands.[39] 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.[40]

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.[41] 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.[42] Congress recently re-enacted the prohibition in section 542 of the Consolidated Appropriations Act of 2016.[43]

Federal Financial Transaction Laws and Enforcement[44]

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.[45] Financial institutions providing services to marijuana-related

[37] 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).
[38] *Id*.
[39] *Id*.
[40] *Id*.
[41] Pub. L. 113-235 (2014).
[42] *U.S. v. Marin Alliance for Medical Marijuana*, 2015 WL 6123062 (N.D. Cal. Oct. 19, 2015).
[43] Pub. L. 114-113 (2015).
[44] Florida House of Representatives, Insurance and Banking Subcommittee, *Banking Services for Marijuana Businesses* (2016). On file with the Health Quality Subcommittee.

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[46] and the District of Columbia have laws that permit and regulate the use of cannabis for medicinal purposes.[47] While these laws vary widely, most specify the medical conditions a 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.[48] The chart below indicates the most common qualifying conditions.[49]

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

[45] 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).

[46] 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, 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).

[47] 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).

[48] 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.

[49] 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.

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.[50] Sixteen states require a physician to report the patient's diagnosis when 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.[51]
All states require proof of residency in order for a patient to use medical cannabis.[52] Twenty states require qualified patients to register with the state and obtain a registration ID card, usually from a state agency.[53]

Patient populations vary greatly by state, from 0.1 patients per 1,000 state residents to 19.8 patients per 1,000 state residents.[54] 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.[55] 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.[56]

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.[57]

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[58] and Colorado prohibits the caregiver from being the patient's physician.[59] 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.

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[50] 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.
[51] Arizona, Colorado, Delaware, Georgia, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington.
[52] 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).
[53] *Supra* note 46.
[54] 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).
[55] The Florida Office of Economic and Demographic Research*, Complete Initiative Financial Information Statement for the Use of Marijuana for Debilitating Medical Conditions (15-01).*
[56] 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.
[57] 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).
[58] 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).
[59] *See*, e.g., the definition of "primary caregiver" in C.R.S.A. § 25-1.5-106 (Colorado).

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[60] cannabis to 24 ounces of usable cannabis, depending on the state. Furthermore, 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.[61]

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.[62]

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.[63] Massachusetts also requires that labs be accredited to standards set by the International Organization or accredited or certified by an organization approved by the Massachusetts Department of Public Health.[64] Connecticut also prohibits laboratories from having a direct or indirect interest in any entity that cultivates processes or dispenses or in any certifying physician.[65]

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.[66]

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[60] "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).
[61] *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).
[62] 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.
[63] *See* Conn. Gen. Stat. Ch. 420f and Conn. Regs. §§ 21a-408-1 to 21a-408-70 (Connecticut)
[64] *See* 105 CMR 725.105(C)(2) (Massachusetts)
[65] *Supra*, note 63.
[66] *See* C.R.S.A. § 12-43.3-104(Colorado) and Haw. Admin. Rules (HAR) § 11-850-92 (Hawaii).

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.[67] About 60 to 80 percent of the black-market cannabis consumed nationally is from California.[68] 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.[69] During 2009-2012, the yearly average number of interdiction seizures of Colorado marijuana increased 357% from 53 to 242 per year.[70]

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."[71] 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.[72] 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. [73]

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.[74] Several states ban smoking of marijuana for medical use.[75] 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.[76]

Washington prohibits product names that include wording commonly associated with products marketed to and by children.[77] Banned product names include Candyland, Cinderella, and Girl Scout Cookies.[78]

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.[79] In Colorado, edibles were implicated in three deaths.[80] Calls to poison-control centers for unintentional

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[67] 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.
[68] 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.
[69] Colorado Office of the Governor, *Marijuana Grey Market Report (2016)*. Available at: https://www.colorado.gov/pacific/sites/default/files/16Marijuana0817Marijuana%20Grey%20Market.pdf.
[70] 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.
[71] *See* C.R.S.A. § 35-61-105.5 (Colorado), OAR 333-064-0100 (Oregon), and West's RCWA 69.51A.250 (Washington).
[72] 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.
[73] 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.
[74] *See* Minn. Stat. § 152.22 (Minnesota)
[75] Minnesota, New York, Ohio and Pennsylvania ban the smoking of marijuana for medical use.
[76] *See* NYCRR 1000.4 (New York)
[77] Oregon Liquor Control Commission, Clarification on Marijuana Products Attractiveness to Children and Strain Names. Available at: https://www.oregon.gov/olcc/marijuana/Documents/Packaging_Labeling/Strain_Name_Attractiveness_Children.pdf (Last visited on April 21, 2017).
[78] Id.
[79] Bertha K. Madras, PhD., *Marijuana: Risks and Consequences*, prepared for Florida Legislature, February 2016. On file with the Health Quality Subcommittee.
[80] *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.

marijuana exposure in children under the age of 9 occur at higher rates in states where medical marijuana is legal, [81] 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.[82]

Research has shown that children are attracted to foods that are colorful and novel in shape.[83] Children prefer sweet, fruity, or candy-like odors.[84] Marketing and branding have a significant impact on children's decision to consume certain foods. Promotional characters, such as cartoons, influence children's food preferences.[85] States have enacted various regulations of edibles and edible packaging to discourage consumption by children. Colorado prohibits medical marijuana edibles in the shape of a human, animal, or fruit or any shape that bears the likeness or contains characteristics of realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.[86] Massachusetts prohibits medical marijuana edibles from bearing a reasonable resemblance to any commercially available candy product.[87] Nine states requires edibles be packaged in opaque or light-resistant and child-resistant containers. Six states prohibit packaging that is attractive to children, such as cartoons or bright colors. Oregon and Massachusetts prohibit any images other than the licensee's logo. Oregon prohibits the licensee's logo on the packaging if it contains a cartoon.[88]

Colorado and Oregon recently implemented new regulations regarding edibles.[89] 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 product 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.[90] 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 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.[91]

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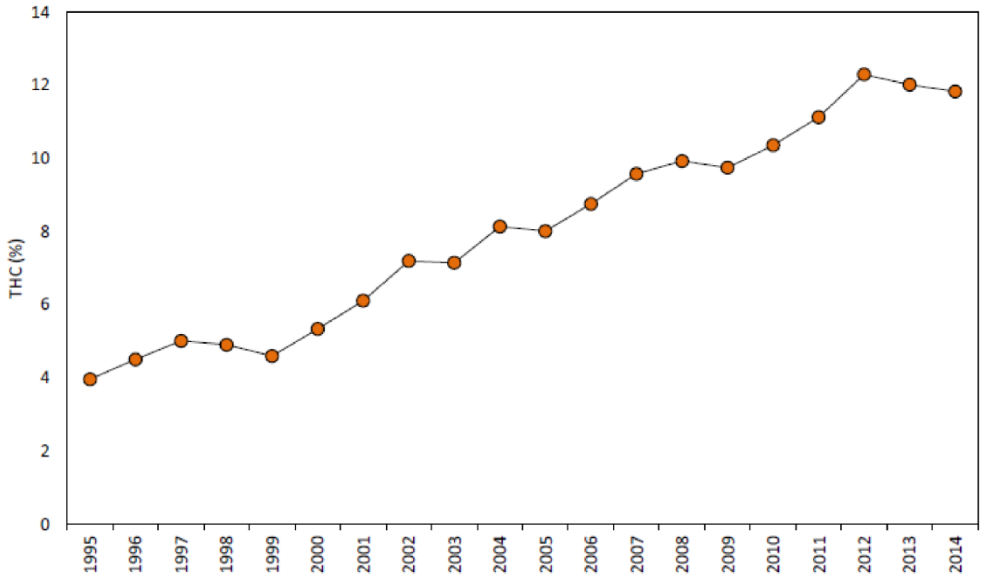
[81] Wang GS., Roosevelt G., Le Lait MC., et al. *Association of Unintentional Pediatric Exposures with Decriminalization of Marijuana in the United States*. Ann Emerg Med 2014; 63:684-689.
[82] Wang GS, et. al., *Pediatric Marijuana Exposures in a Medical Marijuana State*. JAMA Pediatr 2013;167:630-633.
[83] Cannabis Law & Policy Project. Univesity of Washington School of Law. Concerning Cannabis-Infused Edibles: Factors That Attract Children to Foods. June 28, 2016. Available at: http://lcb.wa.gov/publications/Marijuana/Concerning-MJ-Infused-Edibles-Factors-That-Attract-Children.pdf
[84] *Id*.
[85] *Id.*
[86] See 1 CCR 212-1 (Colorado).
[87] See 105 CMR 725.000 (Massachusetts).
[88] OAR 333-008-1225 (Oregon).
[89] See 1 CCR 212-1 (Colorado) and OAR 333-007-0220 (Oregon).
[90] 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.
[91] *Supra*, note 5.



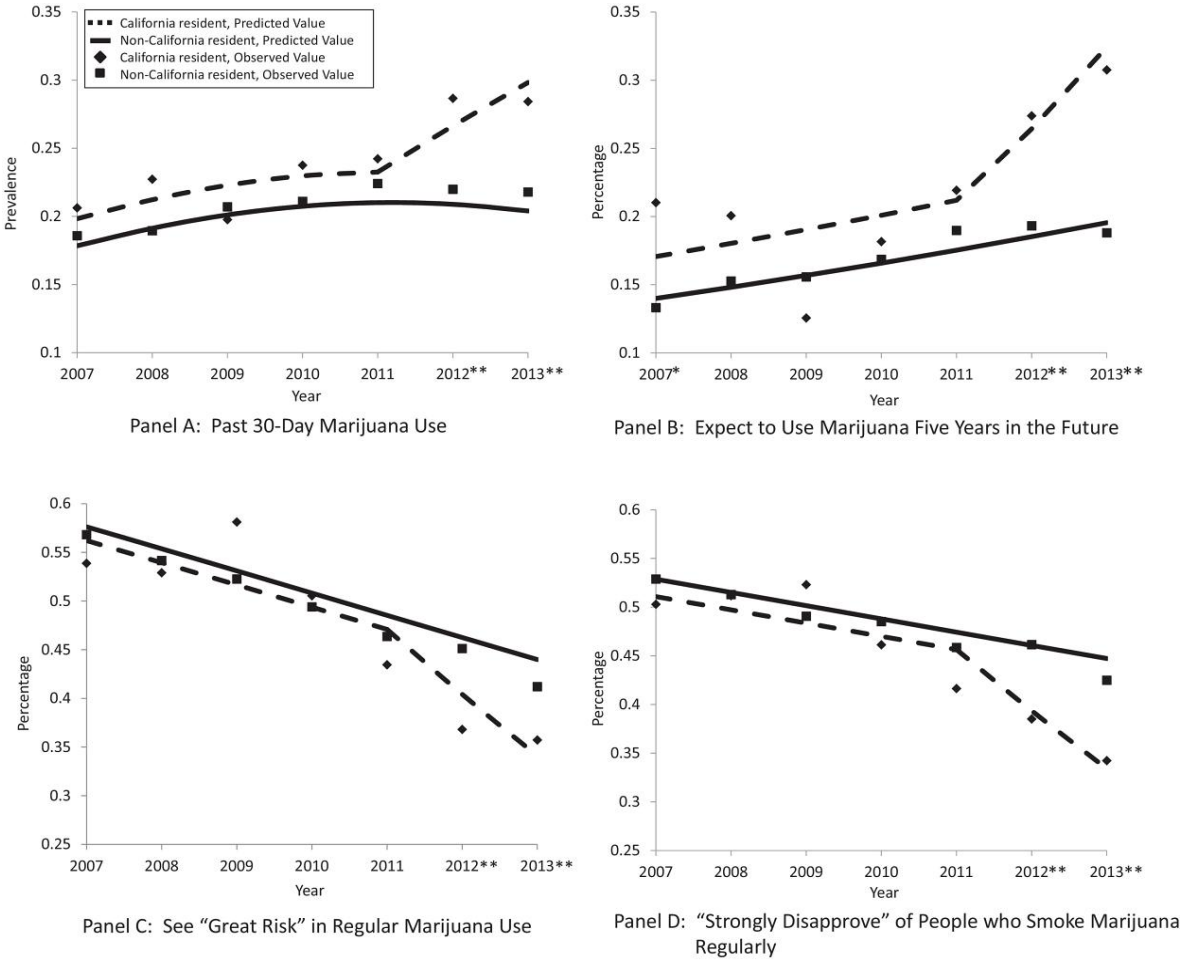
An analysis by a marijuana testing laboratory in Colorado found THC levels of close to 30%, and many samples with little or no CBD.[92]

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%.[93] Studies have also found that medical marijuana laws reduce the perception of harm among adolescents.[94] A 2016 study in California found reduced perception of harm by youth after legalization, and increased youth use.[95]

[92] 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.
[93] 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.
[94] *Id.*
[95] 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[96]



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.[97] 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.[98]

Colorado and Washington have implemented youth education and prevention campaigns.[99] 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.[100] 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.[101] Washington's program included providing grants to prevention

[96] *Id.*
[97] 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
[98] 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.
[99] *See* http://protectwhatsnext.com/ (Colorado) and http://www.doh.wa.gov/YouandYourFamily/Marijuana (Washington)
[100] https://www.colorado.gov/pacific/sites/default/files/MJ_RMEP_baseline-analysis_Youth-Findings.pdf
[101] 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.[102]

Advertising

Greater exposure to medical marijuana advertisements at an early age is associated with higher marijuana use by adolescents.[103] 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.[104] 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.[105] 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).[106] The Drug Control Act classifies controlled substances into five categories, ranging from Schedule I to Schedule V.[107] Cannabis is currently a Schedule I controlled substance,[108] 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.[109] 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.[110]

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.[111]
- Section 893.135(1)(a), F.S., makes it a first degree felony[112] 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.[113]

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[102] 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
[103] *Supra*, note 93.
[104] *See* C.R.S.A. §12-43.3-202 (Colorado).
[105] *See* 1 CCR 212-2 (Colorado)
[106] Section 893.01, F.S.
[107] Section 893.03, F.S.
[108] Section 893.03(1)(c)7., F.S.
[109] Section 893.03(1), F.S.
[110] Section 893.02(3), F.S.
[111] 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.
[112] 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.
[113] Section 893.13(1)(a), F.S.

- Section 893.147, F.S., makes it a crime to possess, use, deliver, manufacture, transport, or sell drug paraphernalia.[114] The penalties for these offenses range from first degree misdemeanors to second degree felonies.[115]

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.[116]

In *Jenks v. State,*[117] 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.[118] 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.[119] The court ordered the defendants to be acquitted.[120]

Seven years after the *Jenks* decision, the First District Court of Appeal again recognized the medical necessity defense in *Sowell v. State*.[121] 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.[122]

Compassionate Medical Cannabis Act

The Compassionate Medical Cannabis Act (CMCA) was enacted in 2014.[123] The CMCA legalized a low-THC and high-CBD form of low-THC cannabis[124] for medical use[125] 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.[126]

Dispensing Organizations

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[114] 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.
[115] Section 893.147, F.S.
[116] *Jenks v. State*, 582 So.2d 676, 679 (Fla. 1st DCA 1991), *rev. denied,* 589 So.2d 292 (Fla. 1991).
[117] 582 So.2d 676 (Fla. 1st DCA 1991).
[118] *Id*.
[119] *Id*.
[120] *Id*.
[121] 739 So.2d 333 (Fla. 1st DCA 1998).
[122] *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.
[123] *See* ch. 2014-157, L.O.F., ch. 2016-123, L.O.F. and s. 381.986, F.S.
[124] 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.
[125] 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."
[126] Section 499.0295, F.S.

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.[127] 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.[128] Thereafter, the rules took effect on June 17, 2015.[129]

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.[130] 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.

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

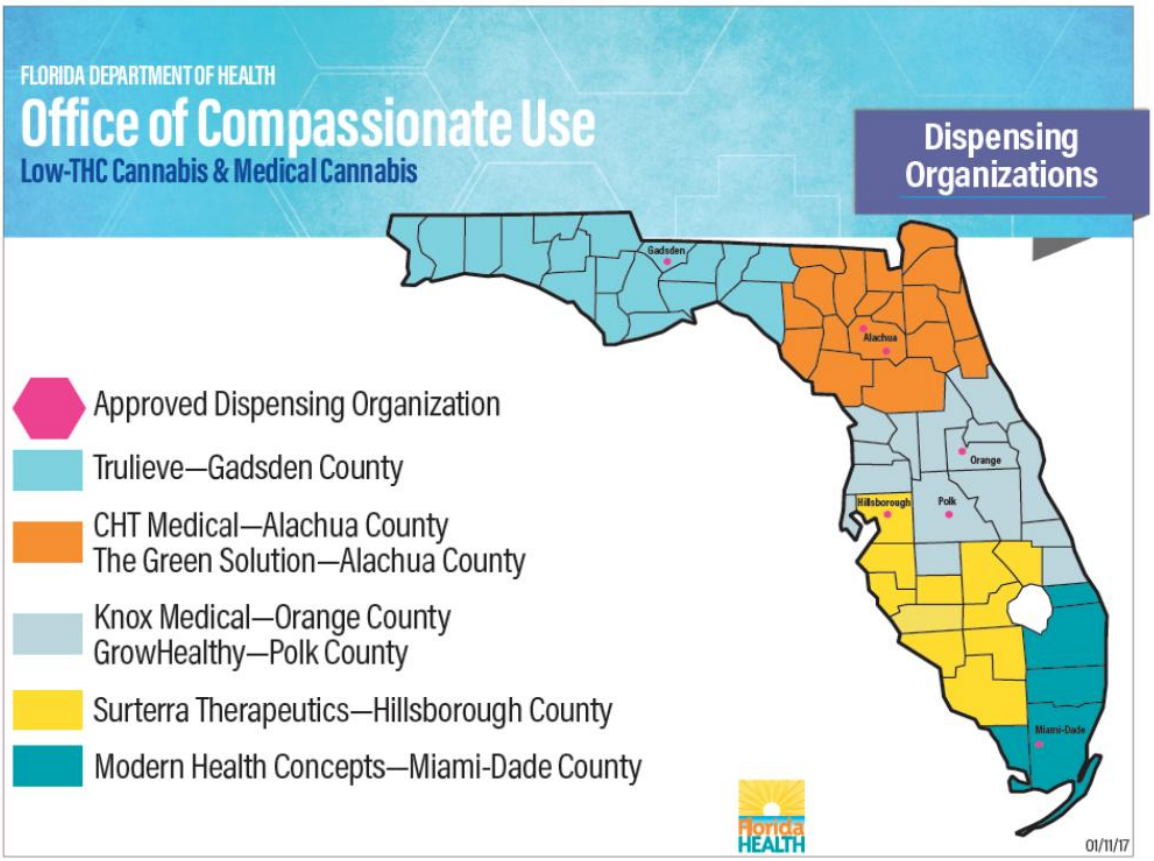
2014 Dispensing Organizations Applications:
Aggregate Score and Regional Rank

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.[131] 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[132] and two more petitioners, 3 Boys and Plants of Ruskin, are awaiting final order from the Division of Administrative Hearings.[133] The remaining petitions were voluntarily dismissed.

[131] 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).
[132] *Loop's Nursery and Greenhouses, Inc. v. Dep't of Health*. Case No. 15-7274 (Fla. DOAH October 7, 2016).
[133] *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.[134] One of these additional dispensing organizations must be a recognized class member of certain class-action cases[135] 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.

[134] Section 381.986(5)(c), F.S.
[135] *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[136] 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[137] or sell any products other than the physician ordered low-THC cannabis, medical cannabis, or a cannabis delivery device.

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[136] "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.

[137] 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.

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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[138] 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;

[138] 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.,[139] 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.[140]

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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[139] 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.
[140] 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.[141] 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.[142] 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.[143]

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[144] 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.[145]
- 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.[146]
- 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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[141] Section 381.985(5)(a), F.S.
[142] Section 381.986(2)(c), F.S.
[143] Section 381.986(5)(a), F.S.
[144] 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.
[145] 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.
[146] 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.[147]

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.[148] The CMCA exempts from criminal prosecution under Ch. 893, F.S.[149] 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.[150]
- 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.

[147] 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.
[148] Section 381.986(1)(h), F.S.
[149] *Supra,* note 136.
[150] Section 381.986(3), F.S.

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

On November 8, 2016, Florida voters approved Amendment 2, Use of Marijuana for Debilitating Medical Conditions as Art. X, Sec. 29 of the Florida Constitution. The amendment authorizes patients with 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[151] 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."[152] Even though the provision may be self-executing, the provision may be supplemented by legislation.[153]

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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[151] 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.
[152] Gray v. Bryant, 125 So.2d 846, 851 (Fla. 1960).
[153] *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.[154] 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[155]:

- 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[156] 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.[157] 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.

Prescription Drug Monitoring Program (PDMP)

Chapter 2009-197, Laws of Fla., established the Prescription Drug Monitoring Program (PDMP) within 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.[158] The PDMP database became operational in September of 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[159] Dispensers of controlled substances listed in Schedule II, III, or IV of the Florida Comprehensive Drug Abuse Prevention and Control Act must report certain information to the PDMP database, including the name of the prescriber, the date the prescription is filled and dispensed, and the name, address, and date of birth of the person to whom the controlled substance is dispensed.[160] Dispensers must report dispensing a specified controlled substance to the PDMP database within seven days.[161]

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[154] *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).
[155] *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).
[156] *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).
[157] 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).
[158] Section 893.055(2)(a), F.S.
[159] 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).
[160] Section 893.055(3), F.S.; controlled substances listed in Schedule II, III, or IV can be found in s. 893.03(2)-(4), F.S.
[161] Section 893.055(4), F.S.

Direct access to the PDMP database is presently limited by law to a pharmacy, prescriber, or dispenser.[162] A pharmacy, prescriber, or dispenser has access to information in the PDMP database that relates to a patient of that pharmacy, prescriber, or dispenser, as needed, for reviewing the patient's controlled substance prescription history.[163] The only prescribers authorized to access the PDMP database are Florida-licensed health care practitioners.[164]

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.

Regulation of Florida Nurseries

Florida nurseries[165] are regulated by the Department of Agriculture and Consumer Services (DACS)[166] and must obtain a certificate of registration[167] from DACS before selling or distributing any nursery stock[168] in the state.[169] Among the powers and duties granted to DACS for regulation of nurseries, DACS has the authority to inspect plants or plant products for pests or noxious weeds.[170] DACS also has the authority to supervise or cause the fumigation or treatment of plants and plant products that are infested or infected by pests.[171] If DACS identifies plants or plant products that are infested or infected with pests or noxious weeds, DACS must notify the nursery and the plants or plant products must be treated or removed or destroyed if it cannot be successfully treated within 10 days of the notice.[172]

EFFECTS OF PROPOSED CHANGES

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

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[162] Section 893.055(7)(b), F.S.
[163] *Id*.
[164] Section 893.055(1)(d), F.S., defines health care practitioner for the purpose of the PDMP program as those practitioners who are subject to licensure or regulation by DOH under ch. 458, F.S., (Medicine), ch. 459, F.S., (Osteopathic Medicine), ch. 461, F.S., (Podiatric Medicine), ch. 462, F.S., (Naturopath), ch. 463, F.S., (Optometry), ch. 464, F.S., (Nursing), ch. 465, F.S., (Pharmacy), or ch. 466, F.S., (Dentistry).
[165] "Nursery" means any grounds or premises on or in which nursery stock is grown, propagated, or held for sale or distribution, except where aquatic plant species are tended for harvest in the natural environment Section 581.011(20), F.S.
[166] Ch. 581, F.S., Rule 5B-2, F.A.C., and Rule 5B-3, F.A.C.
[167] "Certificate of registration" means an official document issued by the division to nurseries, stock dealers, agents, and plant brokers as evidence of being properly registered with the division in compliance with the requirements of this chapter and of any of the rules promulgated hereunder. Section 581.011(6), F.S.
[168] "Nursery stock" means all plants, trees, shrubs, vines, bulbs, cuttings, grafts, scions, or buds grown or kept for or capable of propagation or distribution, unless specifically excluded by the rules of the department. Section 581.011(22),F.S.
[169] Section 581.131, F.S.
[170] Section 581.031, F.S.
[171] Section 581.161, F.S.
[172] Section 581.181, F.S.

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 from a medical marijuana treatment center for medical use by a qualified patient.

The bill amends the name of the DOH Office of Compassionate Use in s. 385.212, F.S., to be the Office of Medical Marijuana Use, and expressly authorizes that office to administer and enforce the provisions of s. 381.986.

Medical Marijuana Treatment Centers (MMTCs)

The bill maintains the vertically integrated regulatory structure of the CMCA and requires MMTCs licensed by DOH to cultivate, process, transport and dispense 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 by July 3, 2017, and authorizes those licensees to begin dispensing marijuana under the bill on July 3, 2017.

The bill also requires DOH to grant ten additional MMTC licenses. Among theses, licenses must be awarded by August 1, 2017, to any denied dispensing organization applicant whose application was scored by DOH and had one or more administrative or legal challenges pending as of January 1, 2017, or had a final ranking within one point of the highest final ranking applicant in its region, and proves to DOH that it has the infrastructure and ability to begin cultivating marijuana within 30 days after registration as a MMTC.

DOH must award the remaining licenses by October 3, 2017, one of which must be awarded to an applicant that is a recognized class member of Pigford v. Glickman, 185 F.R.D. 82 (D.D.C. 1999), or In Re Black Farmers Litig., 856 F. Supp. 2d 1 (D.D.C. 2011), and a Florida member of the Black Farmers and Agriculturalists Association.

The bill also requires DOH to give preference to up to two applicants that own one or more citrus processing facilities and that will use or convert those facilities for processing marijuana.

The bill requires DOH to grant 4 additional MMTC licenses when the patient population reaches 100,000 and 4 additional MMTC licenses for every additional 100,000 patients thereafter.

The bill limits the number of dispensing facilities that a MMTC may operate to twenty-five for the entire state. Upon the registration of each additional 100,000 patients, each MMTC may operate 5 additional dispensing facilities. The bill also limits the number of dispensing facilities that a MMTC may operate within 5 designated regions of the state. The bill requires DOH to determine the maximum number of dispensing facilities per region by multiplying the percentage of the state population in the region times the statewide maximum number of dispensing facilities. A MMTC may sell unused dispensing facility slots to another MMTC, but the dispensing facility slot must remain in the region to which it was assigned prior to the sale. The sale of a dispensing facility slot reduces the seller's statewide and regional maximums by one and increases the purchaser's statewide and regional maximums by one. The limitation on the number of statewide and regional dispensing facilities per MMTC expires April 1, 2020.The bill also provides a severability clause for the limitation on the number of dispensing facilities per MMTC.

The bill maintains the qualifications under the CMCA for applicants seeking licensure as an MMTC, however; it removes the requirement for an applicant to have been operating as a registered nursery in

Florida from at least 30 continuous years. The bill requires applicants to have been operating as a Florida business for at least 5 consecutive years prior to application. The bill also requires an applicant to possess a nursery certificate from DACS. The bill exempts the 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 from the requirements for an applicant to have been operating as a Florida business for at least 5 consecutive years prior to application and possess a nursery certificate from DACS.

The bill requires MMTCs to have diversity plans that promote and ensure the involvement of minorities, minority business enterprises, and veteran business enterprises in ownership, management, and employment. The bill requires DOH identify applicants for licensure with strong diversity plans.

The bill prohibits an individual from being an applicant, owner, officer, board member or manager on more than one application for licensure as a MMTC. The bill also prohibits an individual or entity from being awarded more than one license.

The bill also prohibits a MMTC, or any individual or entity who directly or indicted owns, controls, or holds with power to vote 5% or more of the voting shares of the MMTC, from acquiring direct or indirect ownership or control of any voting shares or other form of ownership of any other MMTC.
The bill allows a MMTC to transfer ownership to an individual or entity that meets the requirements for licensure. The bill requires a MMTC seeking to transfer ownership to notify DOH in writing 60 days prior to any proposed transfer of ownership. An individual or entity seeking ownership must submit an application to DOH 60 days prior any proposed transfer of ownership. DOH must approve or deny the transfer of ownership within 30 days of receiving a complete application. The bill does not prohibit a publicly traded corporation or publicly traded company that meets the requirements for licensure from MMTC ownership.

The bill amends the requirement under the CMCA for a MMTC to post a $5 million dollar performance bond at approval or a $2 million dollar bond if serving 1,000 patients to allow the MMTC to deposit cash or an irrevocable letter of credit with DOH in lieu of obtaining the performance bond. The bill also requires the MMTC use an authorized surety insurance company rated in one of the three highest rating categories by a nationally recognized rating service if they opt to obtain the performance bond.

The bill allows DOH to grant variances to MMTCs from representations made in its application if the MMTC can demonstrate that its proposed alternative fulfills the same or similar purpose as the representation made in the application and will not be of a lower standard. The bill prohibits DOH from granting variances to the requirements that the MMTC be a Florida business for at least 5 continuous years and possess a nursery certificate from DACS and the prohibition on the ownership of more than one MMTC license.

The bill prohibits MMTCs from subcontracting for services directly related to cultivating, processing and dispensing but allows existing dispensing organizations to continue subcontracting with a single entity to cultivate, process, transport and dispense marijuana.

Growing Medical Marijuana

The bill retains current law under the CMCA for growing standards and clarifies that MMTCs must comply with ch. 581 and DACS rules for inspection and treatment of pests.

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 that marijuana products be tested for contaminants that are harmful for human consumption and THC and CBD potency. DOH must adopt rules determining what contaminants must be tested for and at what levels such contaminants are unsafe for human consumption. The bill requires DACS to assist DOH in developing rules for testing edibles. The bill also requires DOH to adopt rules for treatment of marijuana products that fail the safety and potency requirements.

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. To qualify, a laboratory must have a DOH-approved accreditation or certification by a DOH-approved accreditation or certification body, and must meet additional requirements specific to marijuana testing established by DOH in rule.

Marijuana Products and Routes of Administration

The bill prohibits certain forms of marijuana for medical use: smoking and marijuana seeds and flower, except for flower in a tamper-proof sealed receptacle for vaping. The bill allows vaping and edibles, which are defined by the bill as commercially produced food items made with cannabis oil that are produced and dispensed by a MMTC. The bill allows marijuana delivery devices recommended by a qualified physician. The bill requires MMTCs to produce at least one low-THC marijuana product.

The bill prohibits edibles that are attractive to children, in the shape of humans, animals, or cartoon characters. The bill also prohibits edibles from resembling commercially available candy. The bill requires DOH to adopt rules on the appearance and ingredients of edibles to discourage consumption by children. MMTCs may not begin producing edibles until DOH has adopted rules. DOH must also adopt sanitation rules for the display and storage of edibles.
MMTCs must also obtain a food establishment permit from DACS before producing edibles and must comply with the Florida Food Safety Act. The bill limits the amount of THC in each edible product and each serving size. Edibles may only contain 200 mg of THC in the total product and 10 mg of THC per serving. The bill prohibits a potency variance for edibles greater than 15%. The bill authorizes DOH to select random samples of edible products available for purchase for testing to determine whether the THC and CBD potency on the label is accurate and whether the edible is safe for human consumption. The bill requires edibles that fail to meet the safety and potency requirements must be recalled along with all edibles made from the same batch of marijuana.

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

The bill prohibits product names that contain wording commonly associated with products marketed by or to children.

In addition to the packaging and labeling requirements for all marijuana products, the bill requires edibles be packaged in a plain, white receptacle with no images other than the MMTC's DOH approved logo and the Medical Marijuana Universal Symbol. The bill requires edible packaging contain a list of the ingredients, storage instructions, an expiration date, a prominent and legible warning to keep away from children and pets, and a warning that the edible has not been produced or inspected pursuant to federal food safety laws.

Each edible must also be individually sealed in plain, opaque wrapping that displays the Medical Marijuana Universal Symbol. Where practical, edibles must be stamped with the Medical Marijuana Universal Symbol.

Dispensing Medical Marijuana

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 70 day supply.
- Ensure that patient records are not visible to anyone other than the patient, caregiver, or authorized staff.

The bill requires dispensing facilities to have a waiting area and private consultation area. The bill prohibits MMTCs from displaying products in the waiting area.

MMTC Safety and Security Measures

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 course and examination offered by the Florida Medical Association (FMA) or the Florida

Osteopathic Medical Association (FOMA). The bill requires the course to be taken at every biennial licensure renewal and caps the price of the course at $500.

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 have both a security system and video surveillance system and removes the requirement that two employees or security contractors be on the premises of dispensing facilities at all times.

The bill requires MMTCs use one seed-to-sale tracking system established by DOH. The bill requires the seed-to-sale tracking system established by DOH allow for integration of other seed-to-sale tracking systems used by MMTCs. MMTCs must either use the system established by DOH or integrate their system with the system established by DOH. The bill allows MMTCs to use their own seed-to-sale tracking systems until DOH has established one. The bill requires DOH to select a vendor for the seed-to-sale tracking system which does not have a direct or indirect financial interest in a MMTC or marijuana testing laboratory or any other contractual relationships with DOH.

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 three 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.[173]

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, DOH-approved trade name or DOH-approved logo affixed to the outside of the building or in a window. The trade name or logo may not contain wording or images commonly associated with marketing targeted toward children or that promotes recreational use of marijuana.

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.

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

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, 50 day, and 70 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. The bill retains current law requiring biennial license renewal inspections and inspections upon complaint. The bill requires DOH and DACS to enter into an interagency agreement to ensure cooperation and coordination in the performance of their obligations under the bill and their respective authorizing statutes. The bill also allows DOH to enter into interagency agreements with DHSMV and FDLE.

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 authorizes DOH or the state attorney to seek an injunction to enjoin unlicensed activity. The bill 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.

The bill makes cultivating, processing, distributing, selling, or dispensing low-THC cannabis or marijuana without a medical marijuana treatment center license a violation of 893.13.[174]

The bill makes it a third degree felony for a person to manufacture, distribute, sell, give or possess with the intent to manufacture, distribute, sell or give marijuana or marijuana delivery devices that he or she holds out to have originated from a MMTC but are counterfeit. The bill defines counterfeit as marijuana, a marijuana delivery device, or a marijuana or marijuana delivery device container, seal, or label which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a licensed medical marijuana treatment center and which thereby falsely purports or is represented to be the product of, or to have been distributed by, that licensed medical marijuana treatment facility

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 allows counties or municipalities to ban dispensing facilities from being located within its boundaries. The bill prohibits counties or municipalities that allow dispensing facilities to place limits on the number of dispensing facilities that may be located within its boundaries. The bill authorizes local ordinances for determining the location of dispensing facilities and other permitting requirements not in conflict with state law or DOH rule. The bill prohibits a municipality or county from enacting ordinances for permitting or determining the location of dispensing facilities that are more restrictive than those for

[174] *Supra,* note 136.

pharmacies, except that dispensing facilities may not be located within 500 feet of a private or public elementary, middle or secondary school, unless municipality or county approves a dispensing facility location within 500 feet of a school as promoting the public health, safety, and general welfare of the community. The bill also exempts dispensing facility locations already approved by municipalities or counties pursuant to the current CMCA from the location requirements.
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.

The bill also expressly allows local governments to enforce compliance by the MMTCs with the Florida Building Code and Florida Fire Prevention Code.

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 requires that the registry be accessible to:

- Qualified physicians for the purpose of certifying the patient for medical use of marijuana;
- MMTCs for dispensing marijuana for medical use;
- Practitioners licensed to prescribe prescription drugs to ensure proper care of patients before prescribing medications that may interact with the medical use of marijuana; and
- Law enforcement to verify the authorization of a qualified patient or a caregiver to possess marijuana or a marijuana delivery device.

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. DOH must allocate $10 of every identification card fee to the Division of Research at Florida Agricultural and Mechanical University for the purpose of educating minorities about the medical use of marijuana and the impact of unlawful use on minority communities. The bill allows DOH to contract with a vendor for the issuance of the identification cards. The vendor must have experience performing similar functions for other state agencies.

Patients and caregivers must be residents of the state. An adult patient or caregiver must document residency by providing DOH with a copy of his or her Florida driver's license or Florida identification card. Seasonal residents that temporarily reside in Florida for at least 31 consecutive days but retain primary residency in another state may prove Florida residency by providing DOH with two of the following documents proving temporary residency in Florida:

- A deed, mortgage, monthly mortgage statement, mortgage payment booklet or residential rental or lease agreement.
- One proof of residential address from the seasonal resident's parent, step-parent, legal guardian or other person with whom the seasonal resident resides and a statement from the person with whom the seasonal resident resides stating that the seasonal resident does reside with him or her.
- A utility hook up or work order dated within 60 days prior to registration in the medical use registry.
- A utility bill, not more than 2 months old.
- Mail from a financial institution, including checking, savings, or investment account statements, not more than 2 months old.
- Mail from a federal, state, county, or municipal government agency, not more than 2 months old.
- Any other documentation that provides proof of residential address as determined by department rule.

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.

The bill makes it a third degree felony for any person to possess or manufacture a blank, forged, stolen, fictitious, fraudulent, counterfeit, or otherwise unlawfully issued medical marijuana identification card.

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 2-hour educational course and exam offered by the Florida Medical Association (FMA) or the Florida Osteopathic Medical Association (FOMA). The bill requires the course to be taken at every biennial licensure renewal and caps the price of the course at $500. 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.

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

- Determine that the qualified patient suffers from at least one the qualifying medical conditions listed in Amendment 2 or has a terminal condition[175] or chronic nonmalignant pain[176];
- Perform in in-person physical exam and full medical history;
- Determine that medical marijuana would likely outweigh the health risks to patient;
- Determine that the patient is not pregnant. The bill prohibits a physician from issuing a certification to a pregnant patient, except for low-THC cannabis;
- Review the patient's controlled drug prescription history in the PDMP;
- 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; and
- Enter into the registry the patient's qualifying condition, dose not to exceed the daily dose amount determined by DOH, forms of marijuana authorized for the patient, types of delivery devices if needed, and the supply amount (up to three 70 day supply amounts).
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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,[177] 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;
- Risks, benefits, and drug interactions of cannabis; and

[175] 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.
[176] Chronic non-malignant pain is defined by the bill as pain that is caused by a qualifying medical condition or that originates from a qualifying medical condition and persists beyond the usual course of that qualifying medical condition.
[177] If the patient is a minor, the parent or legal guardian must consent.

- Possible use of the patient's de-identified health information in the registry, treatment plan, or certification for research.

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.

The bill also requires a physician who issues a certification for qualifying medical condition that is of the same kind or class as the conditions enumerated in in Fla. Const. art. X s. 29 to 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 within 14 days after issuing the certification. The bill requires DOH to submit the documentation to the Coalition for Medical Marijuana Research and Education created by the bill.

The bill requires the physician to recertify the patient every 30 weeks. At each recertification, the physician must document whether the patient experience an adverse drug reaction or reduction in the use of opioids and submit such documentation to DOH, which must submit the findings to the Coalition for Medical Marijuana Research and Education created by the bill.

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 daily dose amount limit. If DOH fails to approve or deny the request within 14 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 daily dose amount.
- The minimum daily dose amount 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 DOH.

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 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 does not require an employer to accommodate the medical use of marijuana in the workplace or any employee working while under the influence or create a cause of action against an employer for wrongful discharge or discrimination. The bill also states that marijuana is not reimbursable under the Workers Compensation Law.

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 also allows for use and administration of low-THC cannabis in public.

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, unless it can be determined through the registry that the person is authorized to possess marijuana or a marijuana delivery device. A qualified patient charged with failure or refusal to present his or her identification card may not be convicted if prior to the court or hearing appearance, the patient produces his identification card to the court or clerk. The patient may have to pay a $5 fee for dismissal of the case.

The bill also makes it a criminal violation of 893.13[178] 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 requires caregivers to be 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 unless the caregiver is a close relative[179] of the patient, complete a caregiver certification course, 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 actual expenses incurred.

The bill allows a qualified patient to designate only one caregiver unless:

- The qualified patient is a minor child and the designated caregivers are parents or legal guardians of the patient;
- The qualified patient is an adult who has an intellectual or developmental disability that prevents the adult from being able to protect or care for himself or herself without assistance or supervision and the designated caregivers are parents or legal guardians of the patient; or
- The qualified patient is admitted to a hospice program.

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

[178] *Supra,* note 136.
[179] Close relative is defined by the bill as a spouse, parent, sibling, grandparent, child or grandchild.

- The caregiver is a parent of more than one minor child who is a qualified patient or more than one adult child.
- The caregiver is a parent or legal guardian of more than one adult child who is a qualified patient and who has an intellectual or developmental disability that prevents the adult child from being able to protect or care for himself or herself without assistance or supervision.
- All the caregiver's qualified patients are admitted to hospice, the caregiver is an employee of the hospice, and the caregiver provides personal care or services directly to clients of the hospice as part of his or her employment duties.

If a qualified patient is a minor, only the caregiver may purchase or administer marijuana for medical use by the qualified patient.

The bill exempts caregivers from criminal prosecution under Ch. 893, F.S.[180] 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, not including low-THC cannabis, 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, unless it can be determined through the registry that the person is authorized to possess marijuana or a marijuana delivery device. A caregiver charged with failure or refusal to present his or her identification card may not be convicted if prior to the court or hearing appearance, the caregiver produces his or her identification card to the court or clerk. The caregiver may have to pay a $5 fee for dismissal of the case.

The bill makes it a criminal violation of 893.13[181] 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 illicit 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 also requires DOH to provide education materials regarding the eligibility of patients with a terminal condition for medical use of marijuana to individuals that provide palliative care or hospice services.

The bill also requires DOH implement diversity training and education to enable minorities, minority business enterprises, and veteran business enterprises to compete for MMTC licensure and contracts.

The bill requires DHSMV to implement a statewide marijuana impaired driving education campaign to raise awareness of and prevent marijuana impaired driving. DHSMV must annually evaluate the campaign's efficacy.

[180] *Supra*, note 136.
[181] *Supra,* note 136.

The bill also requires the Department of Law Enforcement to develop training available to all law enforcement agencies that covers the legal parameters of marijuana-related activities by qualified patients, caregivers, MMTCs, and medical marijuana testing labs.

Coalition for Medical Marijuana Research and Education

The bill creates the Coalition for Medical Research and Education (Coalition) at the H. Lee Moffitt Cancer Center and Research Institute, Inc. for the purpose of conducting research and providing education regarding the medical use of marijuana. The Coalition must annually adopt a plan for medical marijuana research and must issue a report by February 15th of each year to the Governor, President of the Senate, and Speaker of the House on research projects, community outreach initiatives, and future plans for the coalition. Beginning January 15, 2018, DOH must submit to the Coalition a data set that includes, for each patient in the registry, the patient's qualifying medical condition, the daily dose amount and forms of marijuana certified for the patient.

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[182] 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.[183] 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 and marijuana delivery devices for medical use by a qualified patient from sales tax.

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[182] "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).*

[183] "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).*

Legislative Intent and Sunset Provision

The bill specifies that the intent of the legislature is to implement s. 29, Art. X, Fla. Const. by creating a unified regulatory structure and if s. 29, Art. X, Fla. Const. is amended or another constitutional amendment related to cannabis or marijuana is adopted, the act shall expire 6 months after the effective date of such amendment.

Conforming Changes

The bill makes the necessary conforming changes to 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.
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. DOH may also generate revenue from any fines assessed against MMTCs in violation of the bill, which would also positively affect revenues.

Revenues received are highly dependent on the number of patients in the registry. At full market adoption, the Revenue Estimating Conference estimates 105,305 patients to be in the registry.[184]

The following provides a potential scenario of what revenues may be for Fiscal Year 2017-2018. For estimating purposes, current fees[185] charged by the DOH for identification cards and MMTC licenses is utilized, it is estimated 33% of patients will need a caregiver, and an estimated application fee for laboratories is used.

[184] The Florida Office of Economic and Demographic Research. Revenue Estimating Conference. Available at http://edr.state.fl.us/Content/conferences/revenueimpact/archives/2017/_pdf/Impact0324.pdf.
[185] Rule 64-4.002 and 64-4.011, F.A.C.

Estimated Revenues for Fiscal Year 17-18

Source	Fee	Number	Revenue
Patient ID card	$75	22,500	$1,687,500
Caregiver ID card	$75	7,425	$556,875
MMTC license	$60,063	7	$420,441
Laboratory application	$1,000	2	$2,000
			$2,666,816

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.[186] On April 7, 2017, the Revenue Estimating Conference met to estimate the impact of the marijuana delivery device sales tax exemption in the bill. The conference agreed that the bill will result in a negative insignificant loss to General Revenue.[187]

2. Expenditures:

DOH will incur costs associated with licensing additional MMTCs, certification of marijuana testing laboratories, registering and issuing identification cards to qualified patients and caregivers, responding to program inquiries, conducting field inspections of MMTC facilities, and maintaining the physician certifications review panel.

DOH estimates at full implementation 55 FTEs and $8,793,440 in spending authority will be required to fully implement the program:

Estimated Implementation Staffing Needs

Program	FTE	Functions
Administration	10	Promulgating rules, processing MMTC applications/renewals, monitoring MMTC operational requirements
Card Program	1	Contract manager to serve as point of contact for patient and caregiver card applications/renewals, which will likely be contracted with a third party
Customer Service	3	Answer emails and calls from patients, caregivers, physicians, MMTC employees, and law enforcement about the program
Field	31	Field staff to conduct required inspection of MMTC facilities
Medical Quality Assurance	10	Staff to review, track, and report physician certifications submitted to the registry on qualifying medical condition, dosage, supply amount, and form of marijuana certified
	55	

It is estimated full market adoption may not be realized during the first year of implementation, therefore 27 FTE and associated spending authority should be held in reserve pending a justified need and revenue to support. The bill authorizes DOH to set fees to cover the costs of administering these programs; however, DOH will need startup dollars until sufficient fees are received.

[186] *Supra,* note 181.
[187] The Florida Office of Economic and Demographic Research. Revenue Estimating Conference. Available at http://edr.state.fl.us/Content/conferences/revenueimpact/archives/2017/_pdf/Impact0407.pdf.

The bill appropriates $3,500,000 in nonrecurring funds from the General Revenue Fund and $4,055,292 in recurring and $1,238,148 in nonrecurring funds from the Grants and Donations Trust Fund to the DOH for the purpose of implementing the requirements of this act. Of these funds, $3,158,572 in recurring and $1,238,148 in nonrecurring funds from the Grants and Donations Trust Fund and 27 full-time equivalent positions are placed in reserve. The DOH may submit a budget amendment requesting release of these funds contingent upon need and demonstrating fee collections to support the budget authority.

DOH will incur expenditures associated with the implementation of the statewide marijuana education and illicit use prevention campaign. The bill appropriates $500,000 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 $5,000,000 in nonrecurring funds from the Highway Safety Operating Trust Fund to DHSMV to implement the impaired driving education campaign.

DHSMV will 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.

FDLE will incur costs associated with development of the training for law enforcement agencies. However, FDLE's current resources are adequate to absorb the costs.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

The bill exempts marijuana and marijuana delivery devices 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 marijuana 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 million in five years.[188] On April 7, 2017, the Revenue Estimating Conference met to estimate the impact of the marijuana delivery device sales tax exemption in the bill. The conference agreed that the exemption will result in a negative insignificant loss of local government revenues.[189]

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.

[188] *Supra,* note 181.
[189] *Supra,* note 184.

MMTCs and marijuana testing laboratories will incur costs associated with the required background screenings. The total cost for a state and national criminal history record check with fingerprint retention for five years by FDLE is $60.[190]

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.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[190] Florida Department of Law Enforcement. *2017 Legislative Bill Analysis HB 1397*. March 15, 2017. On file with the Health and Human Services Committee.