HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	CS for CS/CS/HB 307 & HB 1313	**FINAL HOUSE FLOOR ACTION:**	
SPONSOR(S):	Health & Human Services Committee; Health Care Appropriations Subcommittee; Criminal Justice Subcommittee; Gaetz; Brodeur; Edwards and others	99 **Y's**	16 **N's**
COMPANION BILLS:	CS/SB 460	**GOVERNOR'S ACTION:**	Approved

SUMMARY ANALYSIS

CS for CS/CS/HB 307 & HB 1313 passed the House on March 3, 2016, and subsequently passed the Senate on March 7, 2016.

In 2014, the Legislature enacted the Compassionate Medical Cannabis Act (CMCA), which authorizes dispensing organizations (DO) approved by the Department of Health (DOH) to manufacture, possess, sell, and dispense low-THC cannabis for medical use by patients suffering from cancer or a condition that chronically produces symptoms of seizures or severe and persistent muscle spasms. In 2015, the Legislature enacted the Right to Try Act (RTTA), which authorizes an eligible patient with a terminal condition to receive an investigational drug, biological product, or device, but which did not address cannabis.

The bill allows a patient with a terminal condition to use "medical cannabis" under the RTTA. The bill defines medical cannabis as the whole cannabis plant without THC limits or cannabinoid composition requirements. The bill allows physicians to order and DOs approved under the CMCA to cultivate, process, transport, and dispense medical cannabis for RTTA patients. The bill adds medical cannabis to the regulatory structure of the CMCA.

The bill amends the CMCA to increase regulatory oversight by DOH. The bill creates stricter criteria ordering physicians must meet before ordering low-THC or medical cannabis (cannabis), including establishing a patient relationship for a certain length of time, new education requirements, informed consent, a prohibition on being a medical director employed by a DO, and an order limit of a 45-day supply at a time. The bill also includes penalties for receiving compensation from a DO related to the ordering of cannabis. The bill creates new standards for DOs, including standards for growing, processing, testing, packaging, labeling, dispensing, distributing, and transporting of cannabis. The bill also authorizes independent testing laboratories to possess, test, transport, and lawfully dispose of cannabis.

The bill prohibits the use and administration of cannabis under certain circumstances and creates criminal penalties for violations.

The bill allows DOH to approve 3 additional DOs, to include an applicant that is a member of a specified class, when a certain number of active registrations in the compassionate use registry has been reached.

The bill requires DOH to grant authorization to cultivate and operate to DOs that meet certain criteria for the full term of their original approval and all subsequent renewals. The bill also provides that the additional approval of other DOs does not affect the approval and authorization of these DOs. Finally, the bill authorizes DOH to enforce the inspection requirements on these additional DOs.

The bill was approved by the Governor on March 25, 2016, ch. 2016-123, L.O.F., and became effective on that date.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF 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]

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.[5] 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.[6] The data on the adverse effects of marijuana are more extensive than the data on its effectiveness.[7] 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.[8] 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.[9]

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.[10] The study concluded that there is potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of

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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] 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).
[6] 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).
[7] *Supra* note 5 at 137.
[8] *Id*.
[9] Friedman, Daniel, M.D., Devinsky, Orrin, M.D., *Cannabinoids in the Treatment of Epilepsy*, NEW ENG. J. MED., September 10, 2015, on file with the Health Quality Subcommittee.
[10] *Supra* note 5 at 179.

nausea and vomiting, and appetite stimulation.[11] The study reports that smoked marijuana, however, is a crude THC delivery system that also delivers harmful substances.[12]

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.[13] The 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.[14] 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.[15] The study also found that cannabis-based treatment with THC may have irreversible effects on brain development in adolescents as the brain's endocannabinoid system undergoes development in childhood and adolescence.[16]

More recently, a study published in 2015 in the Journal of the American Medical Association found that there is moderate-quality evidence to support the use of cannabinoids for the treatment of chronic pain and spasticity and that there is low-quality evidence suggesting that cannabinoids are associated with improvements in nausea and vomiting due to chemotherapy, weight gain in HIV infection, sleep disorders, and Tourette syndrome.[17]

Despite the uncertainty of the efficacy of marijuana on various medical conditions, there has recently been much interest in the use of marijuana, especially the compound CBD, to treat epilepsy.[18] A few factors contributing to the interest of the public, media, and researchers in such treatment are that new anti-seizure drugs have not substantially reduced the proportion of patients with medically refractory seizures, the side effects of such drugs continue to have negative side effects to the central nervous system and affect quality of life, and there appears to be some evidence-based efficacy of such treatment based on case stories and limited preclinical and clinical studies.[19]

Federal Regulation of Cannabis

The Federal Controlled Substances Act[20] lists cannabis as a Schedule 1 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.[21] The Federal Controlled Substances Act imposes penalties on those who possess, sell, distribute, dispense, and use cannabis.[22] 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.[23] Selling and cultivating cannabis are subject to even greater penalties.[24]

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."[25] This document details

[11] *Id.*
[12] *Id.*
[13] 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).
[14] *Id*. at 2219.
[15] *Id*. at 2220.
[16] *Id*. at 2219.
[17] American Medical Association, *Cannabinoids for Medical Use: A Systematic Review and Meta-analysis*, JAMA, June 2015, on file with the Health Quality Subcommittee.
[18] *Supra* note 9 at 1048.
[19] *Supra* note 9 at 1048, 1052-1053, and 1056.
[20] 21 U.S.C. ss. 801-971.
[21] 21 U.S.C. s. 812.
[22] 21 U.S.C. ss. 841-65.
[23] 21 U.S.C. s. 844.
[24] 21 U.S.C. ss. 841-65.
[25] 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 February 12, 2016).

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."[26]

On August 29, 2013, United States Deputy Attorney General James Cole issued a memorandum to federal attorneys that appeared to relax the federal government's cannabis-related offense enforcement policies.[27] 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.[28] These enforcement priorities focused on offenses that would result in cannabis being distributed to minors, cannabis sale revenues going to criminal gangs or other similar organizations, and cannabis being grown on public lands.[29] 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.[30]

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.[31] 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.[32] Congress recently re-enacted the prohibition in section 542 of the Consolidated Appropriations Act of 2016.[33]

Regulation of Cannabis for Medical Use in Other States

Currently, 23 states[34] and the District of Columbia have laws that permit and regulate the use of cannabis for medicinal purposes.[35] 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

[26] *Id*.
[27] U.S. Department of Justice, *Guidance Regarding Marijuana Enforcement*, August 29, 2014, *available at* http://www.justice.gov/iso/opa/resources/305201382913275685746 7.pdf (last visited on February 12, 2016).
[28] *Id*.
[29] *Id*.
[30] *Id*.
[31] Pub. L. 113-235 (2014).
[32] *U.S. v. Marin Alliance for Medical Marijuana*, 2015 WL 6123062 (N.D. Cal. Oct. 19, 2015).
[33] Pub. L. 114-113 (2015).
[34] 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 New York was the most recent state to pass medical marijuana legislation which took effect in July 2014. 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 12, 2016).
[35] 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 12, 2016).

Of the 23 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. Most states also provide a mechanism for the list of qualifying medical conditions to be expanded, usually by allowing 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.[36] The most common qualifying conditions[37] named are:[38]

- Cancer- 22 states
- HIV/AIDS- 22 states
- Multiple sclerosis- 20 states
- Epilepsy- 20 states
- Glaucoma- 19 states
- Crohn's disease- 12 states
- Amyotrophic lateral sclerosis- 10 states
- Hepatitis C- 8 states
- Alzheimer's disease- 8 states

Minnesota, New Jersey, and New York also include, as a qualifying condition a terminal illness causing the patient to have a probable life expectancy of one year or less.[39]

Most states require that at least one, or sometimes two, physicians 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 qualifying patients.[40] Many states require qualifying patients to register with the state and obtain a registration ID card, usually from a state agency.[41]

Most states place restrictions on where cannabis for medical use may be used. 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.[42]

There are two general methods by which patients can obtain cannabis for medical use. They must either self-cultivate the cannabis in their homes, or buy cannabis from specified points of sale or dispensaries. 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[43] 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

[36] 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.

[37] These are diseases specified in states' statutes. The state statutes also included symptoms or conditions of diseases that could apply to several other diseases, such as cachexia or wasting syndrome, severe pain, severe nausea, seizures, or muscle spasms.

[38] Information based on research performed by Health Quality Subcommittee staff. The laws of each state are on file with the subcommittee.

[39] M.S.A. § 152.22 (Minnesota), N.J.S.A. 24:6I-3 (New Jersey), and McKinney's Public Health Law § 3360 (New York).

[40] 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.

[41] *Supra* note 38.

[42] 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).

[43] "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).

for medical use that may be ordered by specifying the number of days or months of a supply a physician may order.[44]

Caregivers

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. Some states also require the caregiver to be at least 21[45] and prohibit the caregiver from being the patient's physician.[46] 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.[47]

Quality and Safety Standards

States vary in their regulations of entities that grow, process, transport, and dispense cannabis for medical use. However, most states with cannabis laws require such entities to meet certain standards to ensure the quality and safety of the medical use of cannabis and the security of the facilities possessing the cannabis. For example, some states require a state agency to establish and enforce standards for laboratory testing of cannabis for medical use.[48] 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.[49] 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."[50]

Florida's Cannabis Laws

Criminal Law

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).[51] The Drug Control Act classifies controlled substances into five categories, ranging from Schedule I to Schedule V.[52] Cannabis is currently a Schedule I controlled substance,[53] 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.[54] 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.[55]

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

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[44] *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).
[45] 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).
[46] *See*, e.g., the definition of "primary caregiver" in C.R.S.A. § 25-1.5-106 (Colorado).
[47] *Supra* note 38.
[48] *See* HRS § 329D-8 (Hawaii), N.R.S. 453A.368 (Nevada), and West's RCWA 69.50.348 (Washington).
[49] *See* C.R.S.A. § 12-43.3-104(Colorado) and Haw. Admin. Rules (HAR) § 11-850-92 (Hawaii).
[50] *See* C.R.S.A. § 35-61-105.5 (Colorado), OAR 333-064-0100 (Oregon), and West's RCWA 69.51A.250 (Washington- effective July 1, 2016).
[51] Section 893.01, F.S.
[52] Section 893.03, F.S.
[53] Section 893.03(1)(c)7., F.S.
[54] Section 893.03(1), F.S.
[55] Section 893.02(3), F.S.

- 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.[56]
- Section 893.135(1)(a), F.S., makes it a first degree felony[57] 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.[58]
- Section 893.147, F.S., makes it a crime to possess, use, deliver, manufacture, transport, or sell drug paraphernalia.[59] The penalties for these offenses range from first degree misdemeanors to second degree felonies.[60]

Medical Necessity Defense

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.[61]

In *Jenks v. State,*[62] 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.[63] 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.[64] The court ordered the defendants to be acquitted.[65]

Seven years after the *Jenks* decision, the First District Court of Appeal again recognized the medical necessity defense in *Sowell v. State*.[66] 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.[67]

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[56] 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.

[57] 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.

[58] Section 893.13(1)(a), F.S.

[59] 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.

[60] Section 893.147, F.S.

[61] *Jenks v. State*, 582 So.2d 676, 679 (Fla. 1st DCA 1991), *rev. denied,* 589 So.2d 292 (Fla. 1991).

[62] 582 So.2d 676 (Fla. 1st DCA 1991).

[63] *Id*.

[64] *Id*.

[65] *Id*.

[66] 739 So.2d 333 (Fla. 1st DCA 1998).

[67] *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.

Compassionate Medical Cannabis Act of 2014

The Compassionate Medical Cannabis Act of 2014[68] (CMCA) legalized a low-THC and high-CBD form of low-THC cannabis[69] for the medical use[70] by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms.

The CMCA provides that a Florida licensed allopathic or osteopathic physician who has completed certain training[71] and has examined and is treating such a patient may order low-THC cannabis for that patient to treat the disease, disorder, or condition or to alleviate its symptoms, if no other satisfactory alternative treatment options exist for the patient. To meet the requirements of the CMCA, each of the following conditions must be satisfied:

- The patient must be a permanent resident of Florida.
- The physician must determine that the risks of ordering low-THC cannabis are reasonable in light of the potential benefit for that patient.[72]
- The physician must register as the orderer of low-THC cannabis for the patient on the compassionate use registry (registry) maintained by the Department of Health (DOH) and must update the registry to reflect the contents of the order.
- The physician must maintain a patient treatment plan and must submit the plan quarterly to the University of Florida College of Pharmacy.
- The physician must obtain the voluntary informed consent of the patient or the patient's legal guardian to treatment with low-THC cannabis.[73]

Under the CMCA, DOH was required to approve five dispensing organizations by January 1, 2015, 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.[74] To be approved as a dispensing organization, an applicant must establish that it:

- Possesses a certificate of registration issued by the Department of Agriculture and Consumer Services for the cultivation of more than 400,000 plants;
- Is operated by a nurseryman;
- Has been operating as a registered nursery in this state for at least 30 continuous years;
- Has the technical and technological ability to cultivate and produce low-THC cannabis;
- Employs a medical director, who must be a physician and have successfully completed a course and examination that encompasses appropriate safety procedures and knowledge of low-THC cannabis; and
- Other specified requirements.[75]

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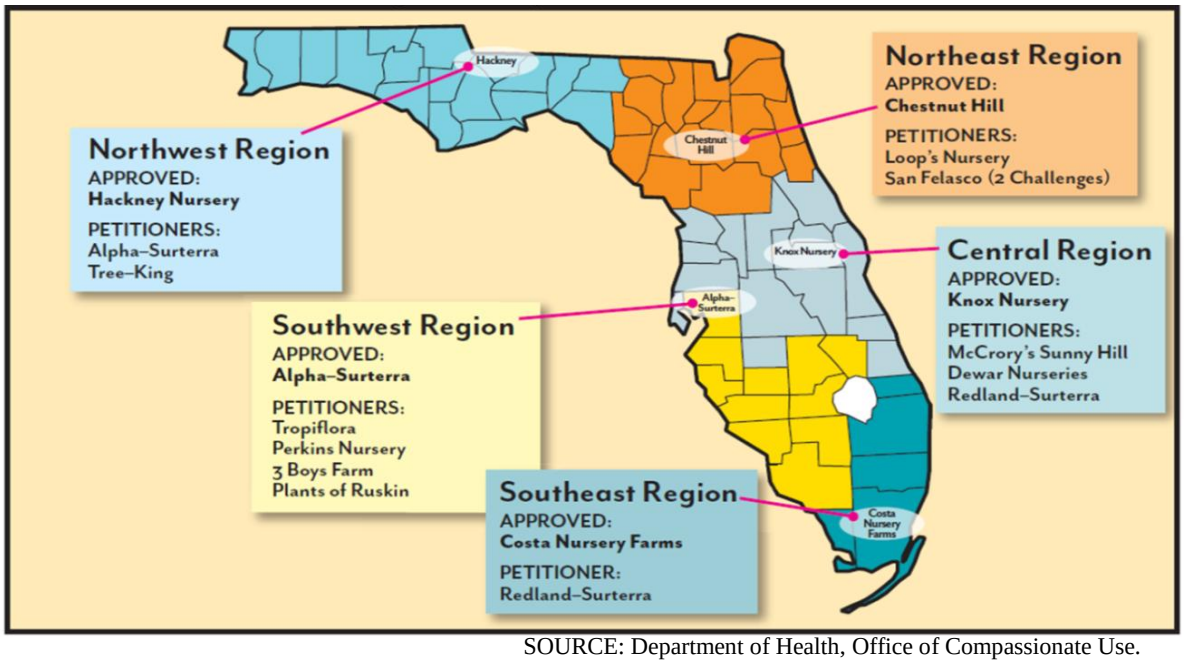
[68] *See* ch. 2014-157, L.O.F., and s. 381.986, F.S.
[69] The act defines "low-THC cannabis," as the dried flowers of the plant *Cannabis* which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight, or the seeds, resin, or any compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. *See* s. 381.986(1)(b), F.S.
[70] 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."
[71] 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.
[72] 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.
[73] Section 381.986(2), F.S.
[74] Section 381.986(5)(b), F.S.
[75] *Id.*

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. Such 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.[76] Thereafter, the rules took effect on June 17, 2015.[77]

The application process to become a dispensing organization closed on July 8, 2015, with 28 applications received by DOH. 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 petitions[78] were filed contesting DOH's approval of these five dispensing organizations.[79] However, the petition contesting the approval of Costa Nursery Farms in the southeast region was voluntarily dismissed.[80]

[76] *Baywood v.Nurseries Co., Inc. v. Dep't of Health,* Case No. 15-1694RP (Fla. DOAH May 27, 2015).
[77] Rule Chapter 64-4, F.A.C.
[78] A copy of each petition is available at http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/resources/index.html (last visited on February 12, 2016).
[79] Chestnut Hill Tree Farm also filed a counter-petition to San Felasco Nurseries' challenge to the Chestnut Hill Tree Farm being approved as the northeast region dispensing organization. *Chestnut Hill Tree Farm, LLC v. San Felasco Nurseries, Inc.*, Case. No. 15-007276, (Fla. DOAH, Dec. 18, 2015).
[80] *Redland Nursery, Inc., v. Dep't of Health*, Case No. 15-7277 (Fla. DOAH January 11, 2016).

APPROVED DISPENSING ORGANIZATIONS AND PENDING CHALLENGES



SOURCE: Department of Health, Office of Compassionate Use.

The CMCA provides that it is a first degree misdemeanor for:

- A physician to order low-THC cannabis for a patient without a reasonable belief that the patient is suffering from a required condition; or
- 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.[81]

The CMCA specifies that notwithstanding ss. 893.13, 893.135, or 893.147, F.S., or any other law that:

- Qualified patients[82] and their legal representatives may purchase and possess low-THC cannabis up to the amount ordered for the patient's medical use.
- Approved dispensing organizations and their owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by DOH rule, of low-THC cannabis. Such dispensing organizations and their owners, managers, and employees are not subject to licensure or regulation under ch. 465, F.S., relating to pharmacies.[83]

[81] Section 381.986(3), F.S.
[82] Section 381.986(1)(d), F.S., provides that a "qualified patient" is a Florida resident who has been added by a physician licensed under ch. 458, F.S. or ch. 459, F.S., to the compassionate use registry to receive low-THC cannabis from a dispensing organization.
[83] Section 381.986(7), F.S.

The CMCA requires DOH to create a secure, electronic, and online registry for the registration of physicians and patients.[84] Physicians must register as the orderer of low-THC cannabis for a named patient on the registry and must update the registry to reflect the contents of the order.[85] The registry must prevent an active registration of a patient by multiple physicians and must be accessible to law enforcement agencies and to a dispensing organization to verify patient authorization for low-THC cannabis and to record the low-THC cannabis dispensed.[86]

Low-THC Cannabis Research

The CMCA also allows medical centers that are recipients of a Cancer Center of Excellence Award pursuant to s. 381.925, F.S., and state universities with both medical and agricultural research programs, to conduct research on cannabidiol and low-THC cannabis, including research pertaining to agricultural development, production, clinical research, and use of liquid medical derivatives of cannabidiol and low-THC cannabis for the treatment for refractory or intractable epilepsy.[87]

In Fiscal Year 2014-2015, $1 million in nonrecurring general revenue was appropriated to DOH for the James and Esther King Biomedical Research Program to be deposited into the Biomedical Research Trust Fund. These funds are reserved for research of cannabidiol and its effect on intractable childhood epilepsy[88] and were awarded to the University of Florida to perform such research,[89] which is pursuing research on Epidiolex. Epidiolex is produced by GW Pharmaceuticals, and has recently announced successful results in the reduction of epileptic seizures in its first major clinical trial.[90]

Right to Try Act

During the 2015 Regular Session, the Legislature enacted the "Right to Try Act" (RTTA), which authorizes a manufacturer to provide an eligible patient with an investigational drug, biological product, or device that has successfully completed phase 1 of a clinical trial, but that has not been approved for general use by the United States Food and Drug Administration (FDA), and that remains under investigation in a clinical trial approved by the FDA.[91] The RTTA allows manufacturers to contract with and dispense investigational drugs directly to patients without licensure or regulation under chapter 465, F.S., by the Board of Pharmacy.[92]

To be eligible to access such drugs, products, or devices, a patient must have a "terminal condition," which is defined as "a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible even with the administration of available treatment options currently approved by the United States Food and Drug Administration, and, without the administration of life-sustaining procedures, will result in death within one year after diagnosis if the condition runs its normal course."[93] The eligible patient's treating

[84] Section 381.985(5)(a), F.S.
[85] Section 381.986(2)(c), F.S.
[86] Section 381.985(5)(a), F.S.
[87] Section 385.211, F.S.
[88] Chapter 2014-157, L.O.F.
[89] A description of the research to be performed at the University of Florida is available in a letter to the Chairman of the Health Quality Subcommittee, dated October 7, 2015, which may be accessed at http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=13&ved=0ahUKEwio8Nar28XLAhWBWx4KHW9kByc4ChAWCCcwAg&url=http%3A%2F%2Fwww.floridahealth.gov%2F_documents%2Fhouse-heallth-quality-letter.pdf&usg=AFQjCNEokpCnIfNYPqOg8DC4S84Yj7YGkw&sig2=xL9EUYzrBM1Py4tM_UXucg&bvm=bv.116954456,d.dmo (last visited on March 16, 2016).
[90] GW Pharmaceuticals is also expecting the results of another trial for Dravet syndrome later this year, and the results of two trials in another form of epilepsy, Lennox-Gastaut. Andrew Pollack, *Marijuana-Based Drug Found to reduce Epileptic Seizures*, The New York Times, March 14, 2016, http://www.nytimes.com/2016/03/15/business/marijuana-based-drug-found-to-reduce-epileptic-seizures.html (last visited March 22, 2016).
[91] Section 499.0295(1)-(3), F.S.
[92] Section 499.0295(3) and (7), F.S.
[93] Section 499.0295(2)(c), F.S.

physician must attest to the terminal condition, such condition must be confirmed by a second evaluation by a board-certified physician in an appropriate specialty, and the patient must have considered all other approved treatments.[94]

The RTTA also requires the patient, a parent of a minor patient, a court-appointed guardian for the patient, or a health care surrogate designated by the patient to provide written informed consent prior to accessing an investigational drug, biological product, or device. The written informed consent must include:

- An explanation of the currently approved products and treatments for the patient's terminal condition.
- An attestation that the patient agrees with his or her physician in believing that all currently approved products and treatments are unlikely to prolong the patient's life.
- Identification of the specific name of the investigational drug, biological product, or device.
- A realistic description of the most likely outcome, detailing the possibility of unanticipated or worse symptoms.
- A statement that death could be hastened by use of the investigational drug, biologic product, or device.
- A statement that the patient's health plan or third-party administrator and physician are not obligated to pay for treatment consequent to the use of the investigational drug, biological product, or device, unless required to do so by law.
- A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins treatment, and that hospice care may be reinstated if treatment ends and the patient meets hospice eligibility requirements.
- A statement that the patient understands he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device and that liability extends to the patient's estate, unless negotiated otherwise.[95]

The RTTA specifies that there is no obligation on the part of any manufacturer to provide a requested investigational drug, biologic product, or device, but that a manufacturer may do so with or without compensation.[96] The eligible patient may be required to pay the costs of, or associated with, the manufacture of the investigational drug, biological product, or device.[97] The RTTA allows, but does not require, a health plan, third-party administrator, or governmental agency to cover the cost of an investigational drug, biological product, or device.[98] The RTTA exempts a patient's heirs from any outstanding debt associated with the patient's use of the investigational drug, biological product, or device.[99]

The RTTA prohibits the Board of Medicine or Board of Osteopathic Medicine from revoking, suspending, or denying renewal of a physician's license based solely on the physician's recommendation to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device. It also prohibits action against a physician's Medicare certification for the same reason.[100]

The RTTA provides liability protection for a manufacturer, person, or entity involved in the use of an investigational drug, biological product, or device in good faith compliance with the provisions of the bill and exercising reasonable care.[101]

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[94] Section 499.0295(2)(a), F.S.
[95] Section 499.0295(2)(d), F.S.
[96] Section 499.0295(3), F.S.
[97] *Id.*
[98] Section 499.0295(4) and (9), F.S.
[99] Section 499.0295(6), F.S.
[100] Section 499.0295(7), F.S.
[101] Section 499.0295(8), F.S.

Effect of Proposed Changes

The bill authorizes dispensing organizations to cultivate, process, transport, and dispense medical cannabis in addition to low-THC cannabis. Medical cannabis is defined to include the whole cannabis plant and does not require a certain composition of cannabinoids. However, the bill allows dispensing organizations to dispense, and physicians to order, medical cannabis only for qualified patients who have been diagnosed with a terminal condition under the RTTA. A terminal condition under the RTTA is a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible even with the administration of available treatment options, and, without the administration of life-sustaining procedures, will result in death within 1 year after diagnosis if the condition runs its normal course.

This bill also creates additional regulatory standards under the CMCA for dispensing organizations approved by DOH to grow, process, transport, distribute, and dispense low-THC cannabis and medical cannabis. Additionally, the bill strengthens the criteria for physicians to be able to order low-THC cannabis or medical cannabis, the criteria for physicians to become medical directors of dispensing organizations, and DOH's responsibilities under the CMCA. The bill includes other measures to increase the accountability of those who have access to low-THC cannabis or medical cannabis, to increase the safety and quality of the low-THC cannabis and medical cannabis being dispensed, and to increase the security of premises and personnel in possession of low-THC cannabis or medical cannabis.

Dispensing Organizations

Current Dispensing Organization Approvals

The bill requires DOH to grant cultivation authorization and permit operation as a dispensing organization for the full term of its original approval and all subsequent renewals for any dispensing organization approved under Rule 64-4.002, F.A.C., which has posted the performance bond, met certain rule requirements, and spent at least $100,000 in order to fulfill its legal obligations as a dispensing organization. The bill also requires DOH to grant an applicant with the highest aggregate score, through DOH's evaluation process, cultivation authorization and permit it to operate as a dispensing organization.

These authorizations will be issued notwithstanding any act by DOH, the Division of Administrative Hearings (DOAH), or a court with jurisdiction, that has the effect of approving another dispensing organization. Any dispensing organization approved through an act by DOH, DOAH, or a court with jurisdiction may operate in the same region as a previously approved dispensing organization. During such operation, DOH may enforce Rule 64-4.005, F.A.C.,[102] as filed June 17, 2015.

The bill expressly authorizes DOH to renew the approval of a dispensing organization biennially if the dispensing organization meets the requirements under the CMCA, pays the biennial renewal fee, and, if applicable, cures any violation it has committed under the CMCA. The bill requires DOH to publish a list of all approved dispensing organizations and their medical directors on its website.

Additional Dispensing Organization Approvals

The bill allows 3 additional dispensing organizations to be approved by DOH upon the registration of 250,000 active qualified patients in the compassionate use registry. One of these additional dispensing organizations must be a recognized class member of certain class-action cases[103] and a member of the Black Farmers and Agriculturalists Association. The applicants for such approval must meet the following requirements:

[102] Permits entry by DOH at any reasonable time into any dispensing organization facility to inspect any portion of the facility, review any required records, and identify samples of cannabis or derivative product for laboratory analysis.
[103] *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).

- The ability to secure the premises, resources, and personnel necessary to operate as a dispensing organization.
- 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.
- An infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by DOH.
- The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to DOH. Upon approval, the applicant must post a $5 million performance bond. However, upon a dispensing organization serving at least 1,000 qualified patients, the dispensing organization is only required to maintain a $2 million performance bond.
- That all owners and managers have been fingerprinted and have successfully passed a level 2 background screening.
- The employment of a medical director who is a physician licensed under chapter 458 or chapter 459, F.S., to supervise the activities of the dispensing organization.

Growing Low-THC Cannabis and Medical Cannabis

Current law requires approved dispensing organizations to maintain compliance with certain criteria required to be met prior to their selection, but it does not provide standards specifically relating to the quality or safety of their products, or the security of their buildings or the transport of their products. The bill establishes new quality and safety standards for growing, processing, transporting, and dispensing low-THC cannabis and medical cannabis, and security standards for those entities performing such acts.

When growing low-THC cannabis or medical cannabis, the bill provides that a dispensing organization may use pesticides determined by DOH to be safely applied to plants intended for human consumption and requires the dispensing organization to:

- Grow and process 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.

Processing Low-THC Cannabis and Medical Cannabis

When processing low-THC cannabis or medical cannabis, a dispensing organization must:

- Process the low-THC cannabis or medical cannabis in an enclosure separate from other plants or products;
- Package the low-THC cannabis or medical cannabis in compliance with the United States Poison Prevention Packaging Act (15 U.S.C. §§1471-1477);[104]
- Package the low-THC cannabis or medical cannabis in a receptacle that has a firmly affixed and legible label stating the following information:

[104] The Poison Prevention Packaging Act requires packaging to be designed or constructed in a manner to make it significantly difficult for children under five years of age to open within a reasonable time, and not difficult for normal adults to use properly. *See* U.S. Consumer Product Safety Commission*, Poison Prevention Packaging A*ct, available at http://www.cpsc.gov/en/Regulations-Laws--Standards/Statutes/Poison-Prevention-Packaging-Act/ (last visited on December 29, 2015).

    - 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.
- 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.

Dispensing Low-THC Cannabis and Medical Cannabis

The bill prohibits a dispensing organization from dispensing more than a 45-day supply of low-THC cannabis or medical cannabis to a patient or the patient's legal representative or selling certain products other than the physician ordered low-THC cannabis, medical cannabis, or a cannabis delivery device.[105] The bill also requires the dispensing organization to:

- Have the dispensing organization employee dispensing the low-THC cannabis or medical cannabis enter into the compassionate use registry his or her name or unique employee identifier;
- Verify in the compassionate use registry 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 in the compassionate use registry the cannabis delivery device dispensed, if any, in addition to the other information required under current law to be recorded in the registry.

Safety and Security Measures

The bill also requires the dispensing organization to implement and maintain certain safety and security measures relating to its facilities and certain safety and quality measures for low-THC cannabis and medical cannabis dispensed or transported by the dispensing organization. Specifically, the bill requires the dispensing organization to:

- Maintain a:
    - Fully operational security alarm system; or
    - 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 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

[105] The bill defines "cannabis delivery device" 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.

- 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.

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

- 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;
- 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

The bill 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;
- 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; and
- 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.

Testing Laboratories

Current law does not require the testing of low-THC cannabis by laboratories to ensure the composition of the low-THC cannabis to be dispensed complies with law or to ensure that it is safe. The bill requires a dispensing organization to contract with an independent testing laboratory[106] 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.

The bill 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.

[106] "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.

Physicians

Current law requires a physician to meet certain criteria, including additional training and education, to be qualified to order low-THC cannabis. The bill increases the physician ordering qualification criteria and allows the physician to order cannabis delivery devices for the administration of low-THC cannabis and medical cannabis. An ordering physician must have treated the patient at least 3 months immediately preceding the patient's registration in the compassionate use registry. The physician must also record in the registry the ordered amount of low-THC cannabis that will provide the patient with not more than a 45-day supply and any cannabis delivery device needed by the patient for the medical use of low-THC cannabis or medical cannabis.

The bill prohibits a physician ordering low-THC cannabis or medical cannabis from being employed as a medical director of a dispensing organization and provides that a physician who orders low-THC cannabis or medical cannabis and receives compensation from a dispensing organization related to the ordering of such may be subject to disciplinary action under the applicable practice act and under s. 456.072(1)(n), F.S. The bill requires DOH to publish a list of qualified ordering physicians on its website.

Patients

The bill 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.

Preemption of Regulations

The bill provides that all matters regarding the regulation of the cultivation and processing of medical cannabis or low-THC cannabis by dispensing organizations are preempted to the state. Pertaining to the dispensing or low-THC cannabis or medical cannabis, the bill authorizes a municipality to 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. Furthermore, the bill allows a county to determine by ordinance the criteria for the number, location, and other permitting requirements that do not conflict with state law or rule for, all dispensing facilities located within the unincorporated areas of that county.

Prohibited Uses and Penalties

The bill prohibits low-THC cannabis and medical cannabis from being smoked, and 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.

The bill provides that a physician commits a misdemeanor of the first degree, if the physician orders medical cannabis for a patient without a reasonable belief that the patient has a terminal condition, as defined under the RTTA. The bill also adds to the current criminal penalty for any person fraudulently representing he or she has a certain medical condition to be ordered low-THC cannabis, and adds a criminal penalty for fraudulently representing the person has a terminal condition to be ordered medical cannabis. The penalty for such act, a misdemeanor of the first degree, remains unchanged.

The bill also provides that an eligible patient, as defined under the RTTA as a person diagnosed with a terminal condition, who uses medical cannabis, and a legal representative of the patient who administers medical cannabis, in plain view of or in a place open to the general public, on the grounds of a school, or in a school bus, vehicle, aircraft, or motorboat commits a misdemeanor of the first degree.

The bill provides that certain exceptions to criminal law for the possession, sale, delivery, distribution, dispensing, or disposing of low-THC cannabis or medical cannabis does not preclude a person from being prosecuted for a criminal offense related to impairment or intoxication resulting from the medical use of low-THC cannabis or medical cannabis or relieve a person from any requirement under law to submit to a breath, blood, urine, or other test to detect the presence of a controlled substance.

Presumptions Concerning Approved Dispensing Organizations

The bill provides that an approved dispensing organization, which continues to meet the requirements for such approval, is presumed to be registered with DOH and to meet the regulations adopted by DOH or its successor agency for the purpose of dispensing medical cannabis or low-THC cannabis under all laws of the state. The bill also states that the authority provided to a dispensing organization in the RTTA does not impair the approval of a dispensing organization.

Cannabis Research

The bill creates an unnumbered section of law that authorizes any college or university in the state with a college of agriculture to conduct cannabis research in accordance with state and federal law. This permits research on whole plant cannabis, without the requirement of a certain composition of cannabinoids, at facilities other than the one currently authorized to research low-THC cannabis (the University of Florida).

The bill becomes effective upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Section 381.986, F.S., authorizes DOH to impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering the CMCA. This bill also authorizes DOH to establish fees to implement the registration card system should DOH create such a system.

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

2. Expenditures:

The Office of Compassionate Use (OCU) was required to approve five dispensing organizations by January 1, 2015, upon the passage of the CMCA. In order to implement the CMCA, DOH was appropriated three full time equivalent positions and $380,472 from the Grants and Donations Trust Fund.[107] However, DOH will likely incur additional costs associated with the regulatory standards for the operation, security, and safety of dispensing organizations or the growing, processing, testing, packaging, labeling, dispensing, or transportation of low-THC cannabis and medical cannabis. If there are at least 250,000 registered patients in the state, DOH may also incur costs associated with approving an additional 3 dispensing organizations.

DOH will also incur expenditures associated with implementation of the registration card system; however implementation of this system is permissive and the bill authorizes DOH to establish fees to implement the system.

DOH may have to alter the compassionate use registry and may incur costs associated with any such change. DOH may also incur costs associated with rulemaking and any potential challenges to those rules.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Dispensing organizations may incur costs associated with meeting the bill's new quality, safety, and security standards unless they already meet such standards. Dispensing organizations will also incur costs associated with contracting with testing laboratories. The contract cost is indeterminate and may vary within each dispensing organization.

D. FISCAL COMMENTS:

None.

[107] *See* Specific Appropriation 469A, pg. 101, Ch. 2015-232, L.O.F. (2015).