The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Appropriations Subcommittee on Health and Human Services

BILL:	CS/SB 406
INTRODUCER:	Health Policy Committee and Senator Bradley and others
SUBJECT:	Compassionate Use of Low-THC Cannabis and Marijuana
DATE:	April 17, 2017
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.	Fournier/Loe	Williams	AHS	**Pre-meeting**
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 406 amends s. 381.986, F.S., to implement the provisions of article X, section 29 of the State Constitution, Medical Marijuana Production, Possession, and Use. The bill makes numerous changes to the section including:

- Adding legislative intent.
- Amending definitions to incorporate terms used in article X, section 29 of the State Constitution, and to add definitions for "chronic nonmalignant pain" and "close relative."
- Allowing allopathic[1] and osteopathic[2] physicians to certify the medical use of marijuana for patients with debilitating medical conditions and other specified patients, including certain patients from other states who meet Florida requirements.
- Establishing requirements that a physician must meet before certifying a patient and after certification.
- Reducing the required course a physician must take prior to certifying patients to a 4-hour course that must be taken only once.[3]
- Removing the three-month patient treatment prerequisite.
- Amending current criminal penalties to conform with other changes in the bill and establishing new criminal violations for patients and caregivers cultivating or purchasing

[1] Licensed under ch. 458, F.S.
[2] Licensed under ch. 459, F.S.
[3] Section 381.986(4)(a), F.S., requires that physicians take an 8-hour course annually.

marijuana from a source other than a medical marijuana treatment center (MMTC) or who violate other provisions of the act.
- Prohibiting unlicensed activity and providing for criminal and financial penalties.
- Establishing requirements for caregivers including limiting a patient to one caregiver and a caregiver to one patient with certain exceptions, and requiring that caregivers pass a Level 2 background screening with certain exceptions for a caregiver who is a close relative.
- Requiring the Department of Health (DOH) to begin issuing identification cards to patients and caregivers by October 3, 2017.
- Requiring the DOH to establish requirements for the licensure and certification of independent testing laboratories (ITL), a marijuana quality control program, and a seed-to-sale tracking program for marijuana.
- Grandfathering in existing dispensing organizations as MMTCs,[4] adding five MMTCs by October 3, 2017, and increasing the overall number of MMTCs that may be registered when certain numbers of patients are registered on the compassionate use registry.
- Requiring MMTCs to maintain compliance with the representations made in their applications for registration and allowing the DOH to grant variances in certain circumstances.
- Authorizing emergency rulemaking for implementation and timeframes for initiating nonemergency rulemaking.

The bill also creates s. 1004.4351, F.S., to establish the "Medical Marijuana Research and Education Act" and the Coalition for Medical Marijuana Research and Education within the H. Lee Moffitt Cancer Center and Research Institute, Inc.

The bill also makes other conforming and technical changes to ss. 381.986, 381.987, 385.211, 499.0295, and 1004.411, F.S.

The fiscal impact of the bill is indeterminate. On April 7, 2017, the Revenue Estimating Conference estimated the bill has an indeterminate positive fiscal impact on state revenues.[5] The increased costs incurred by the DOH and the Florida Department of Law Enforcement (FDLE) should be offset by fees and fines authorized in the bill.

The bill is effective upon becoming a law.

II. Present Situation:

Treatment of Marijuana in Florida

Florida law defines cannabis 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,"[6] and places it, along with other sources of tetrahydrocannabinol (THC), on the list of Schedule I

[4] Including dispensing organizations that are currently in litigation but would qualify under ch. 2016-1236, L.O.F.
[5] Office of Economic and Demographic Research, *Revenue Estimating Impact Conference results for CS/SB 406, (April 7, 2017)* available at http://edr.state.fl.us/Content/conferences/revenueimpact/archives/2017/_pdf/Impact0407.pdf, pages 527-531 (last visited April 16, 2017).
[6] Section 893.02(3), F.S.

controlled substances.[7] The definition excludes "low-THC cannabis" as defined in s. 381.986, F.S., if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed in conformance with that section.

Schedule I controlled substances are substances that have a high potential for abuse and no currently accepted medical use in the United States.[8] As a Schedule I controlled substance, possession and trafficking of cannabis carry criminal penalties that vary from a first-degree misdemeanor[9] up to a first-degree felony with a mandatory minimum sentence of 15 years in state prison and a $200,000 fine.[10] Paraphernalia[11] that is sold, manufactured, used, or possessed with the intent to be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance, is also prohibited and carries criminal penalties ranging from a first degree misdemeanor to a third degree felony.[12]

Medical Marijuana in Florida: the Compassionate Medical Cannabis Act of 2014

Patient Treatment with Low-THC Cannabis

The Compassionate Medical Cannabis Act of 2014[13] (act) legalized a low tetrahydrocannabinol (THC) and high cannabidiol (CBD) form of cannabis (low-THC cannabis)[14] for medical use[15] by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms. The act provides that a Florida licensed allopathic or osteopathic physician who has completed the required training[16] and has examined and is treating such a patient may order low-THC cannabis for that patient to treat such disease, disorder, or condition or to alleviate its symptoms, if no other satisfactory alternative treatment options exist for that patient. In order for a physician to order low-THC cannabis for a patient, all of the following conditions must apply:

- The patient is a permanent resident of Florida;

[7] Section 893.03(1)(c)7. and 37., F.S.
[8] Section 893.03(1), F.S.
[9] This penalty is applicable to possession or delivery of less than 20 grams of cannabis. *See* s. 893.13(3) and (6)(b), F.S.
[10] Trafficking in more than 25 pounds, or 300 plants, of cannabis is a first-degree felony with a mandatory minimum sentence that varies from three to 15 years in state prison depending on the quantity of the cannabis possessed, sold, etc. *See* s. 893.135(1)(a), F.S.
[11] Section 893.145, F.S.
[12] Section 893.147, F.S.
[13] Chapter 2014-157, Laws of Fla., codified in s. 381.986, F.S.
[14] Section 381.986(b), F.S., 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.
[15] Section 381.986(1)(c), F.S., defines "medical use" as administration of the ordered amount of low-THC cannabis; and the term does not include the possession, use, or administration by smoking, or 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. 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.
[16] 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 that 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.

- The physician has treated the patient for at least 3 months immediately preceding the patient's registration and has determined that the risks of ordering low-THC cannabis are reasonable in light of the potential benefit for that patient;[17]
- The physician registers as the orderer of low-THC cannabis for the patient on the compassionate use registry (registry) maintained by the DOH and updates the registry to reflect the contents of the order;
- The physician maintains a patient treatment plan that includes the dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of tolerance or reaction to the low-THC cannabis;
- The physician submits the patient treatment plan quarterly to the University of Florida, College of Pharmacy (UFCP) for research on the safety and efficacy of low-THC cannabis on patients; and
- The physician obtains the voluntary informed consent of the patient or the patient's legal guardian to treatment with low-THC cannabis after sufficiently explaining the current state of knowledge in the medical community about the effectiveness of treatment of the patient's condition with low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects.[18]

The act creates exceptions to existing law to allow qualified patients[19] and their legal representatives to purchase, acquire, and possess low-THC cannabis – up to the amount ordered – for that patient's medical use; and to allow dispensing organizations (DO) and their owners, managers, and employees to acquire, possess, cultivate, and dispose of excess product in reasonable quantities to produce low-THC cannabis and to possess, process, and dispense low-THC cannabis. The DOs and their owners, managers, and employees are not subject to licensure and regulation under ch. 465, F.S., relating to pharmacies.[20]

Patient Treatment with Medical Cannabis

Chapter 2016-123, Laws of Florida, amended the act to expand the regulatory structure relating to dispensing low-THC cannabis and authorized approved dispensing organizations to cultivate and dispense medical cannabis to eligible patients as defined under the Right to Try Act (RTTA).[21] In conjunction with s. 381.986, F.S., the RTTA allows physicians to treat eligible patients with terminal conditions with medical cannabis by including medical cannabis[22] within the definition of an investigational drug, biological product, or device. Physicians must order the use of medical cannabis for those patients pursuant to the provisions of s. 381.986, F.S.

[17] 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.
[18] Section 381.986(2), F.S.
[19] Section 381.986(1)(d), F.S., defines a "qualified patient" as a Florida resident who has been added by a physician licensed under ch. 458 or 459, F.S., to the compassionate use registry to receive low-THC cannabis from a DO.
[20] Section 381.986(7), F.S.
[21] Section 499.0295, F.S.
[22] "Medical cannabis" means 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, sale, derivative, mixture, or preparation of the plant or its seeds or resin that is dispensed only from a DO for medical use by an eligible patient as defined in the Right to Try Act.

Dispensing Organizations under the Act

Section 381.986, F.S., requires that the DOH approve five DOs, one in each of five regions throughout the state. In order to be approved as a DO, an applicant must possess a certificate of registration issued by the Department of Agriculture and Consumer Services (DACS) 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. DOs must be vertically integrated, meaning the DO performs all stages in the production, processing, marketing, and retailing of low-THC and medical cannabis. Applicants are required to demonstrate:

- The technical and technological ability to cultivate and produce low-THC cannabis;
- The ability to secure the premises, resources, and personnel necessary to operate as a DO;
- 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 the DOH;
- The financial ability to maintain operations for the duration of the two year approval cycle, including the provision of certified financials to the DOH;
- That all owners and managers have been fingerprinted and have successfully passed a Level 2 background screening pursuant to s. 435.04, F.S; and
- The employment of a medical director, who must be a physician[23] and successfully completed a course and examination that encompasses appropriate safety procedures and knowledge of low-THC cannabis.[24]

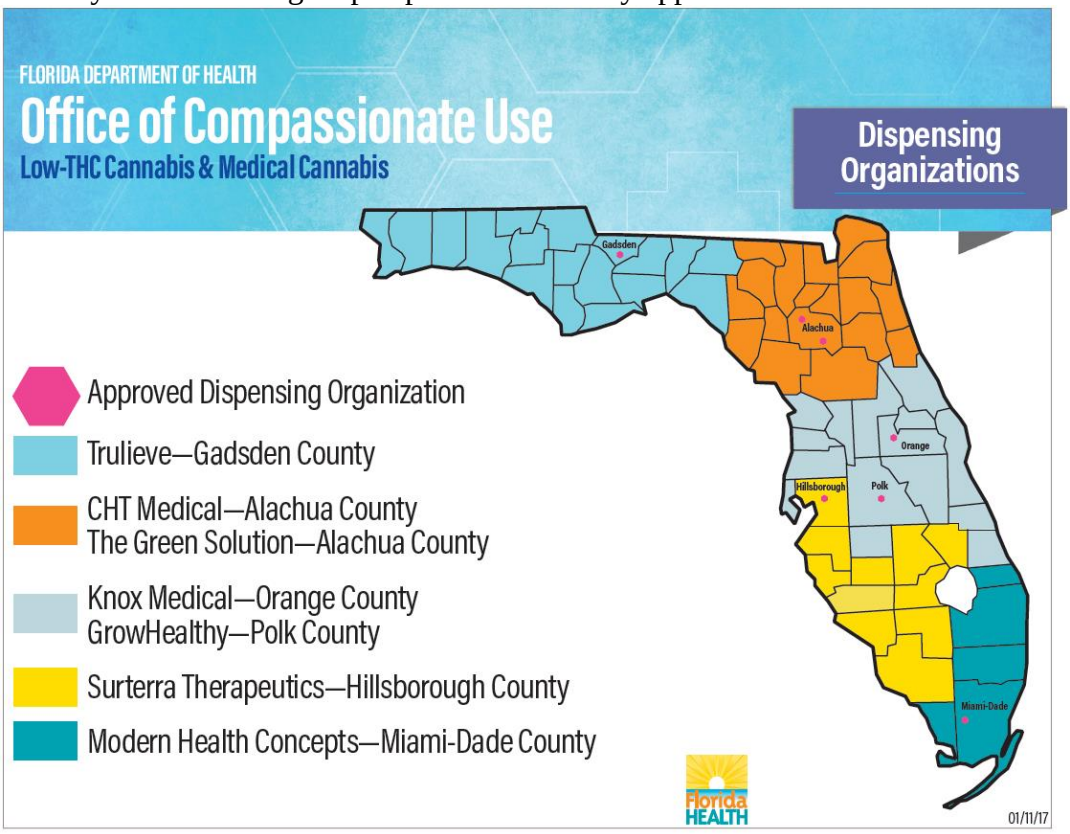
An approved DO must post a $5 million performance bond within 10 business days of approval. The DOH is authorized to charge an initial application fee and a licensure renewal fee, but is not authorized to charge an initial licensure fee.[25] An approved DO must maintain all approval criteria at all times.[26]

Beginning on July 7, 2014, the DOH held several rule workshops[27] to write and adopt rules implementing the provisions of s. 381.986, F.S., and the DOH put forward a proposed rule on September 9, 2014.[28] This proposed rule was challenged by multiple organizations involved in the rulemaking workshops and was found to be an invalid exercise of delegated legislative authority by an administrative law judge on November 14, 2014.[29] Afterward, the DOH held a negotiated rulemaking workshop in February of 2015, which resulted in a new proposed rule being published on February 6, 2015.[30] The new proposed rule was also challenged on, among other things, the DOH's statement of estimated regulatory costs and the DOH's conclusion that

[23] Licensed under ch. 458 or 459, F.S.
[24] *Id.*
[25] *Id.*
[26] Section 381.986(6), F.S.
[27] Audio recordings of the rule development workshops are available on the DOH website at: http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/resources/rulemaking/index.html (last visited Mar. 20, 2017).
[28] Proposed Rule ch. 64-4, F.A.C., ID 14941024, (Aug. 14, 2014) and changed, ID 15040352, (Sept. 9, 2014).
[29] Tornello Landscape Corp. v. DOH, Case No. 14-4547RP; Fl. Medical Cannabis Assoc. v. DOH, Case No. 14-4517RP; Plants of Ruskin, Inc. v. DOH, Case No. 14-4299RP; Costa Farms, LLC v. DOH, Case No. 14-4296RP (Fla. DOAH 2014). A copy of each Final Order is available on the Division of Administrative Hearings website.
[30] Proposed Rule ch. 64-4, F.A.C., ID 15645147, (Feb. 2, 2015).

the rule will not require legislative ratification. Hearings were held on April 23 and 24, 2015, and a final order was issued on May 27, 2015, which found the rule to be valid.[31] The rule took effect June 17, 2015, and the DOH held an application period for DO approval which ended on July 8, 2015. Twenty-eight applications were submitted.[32]

On November 23, 2015, the DOH approved a DO in each of the following five regions as required by the act: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida.[33] Numerous petitions were filed challenging the DOH's selection process. In order to allow the approved DOs to begin dispensing products, the 2016 Legislature required the DOH to approve as a DO applicants that received the highest aggregate score through the DOH's evaluation process, notwithstanding any prior determination by the DOH that the applicant failed to meet the requirements of s. 381.986, F.S. The Legislature also provided that if the Division of Administrative Hearings, the DOH, or a court of competent jurisdiction makes a final determination that an applicant was entitled to be a DO, that both this DO and currently approved DOs may operate in the same region.[34] Currently, in addition to the five DOs originally approved, the DOH has since approved The Green Solution in Alachua County and Grow Health in Polk County. The following map depicts the currently approved DOs.



[31] Baywood Nurseries Co., Inc. v. DOH, Case No. 15-1694RP (Fla. DOAH 2015).
[32] Information about the applications and the approved DOs is available on the DOH, Office of Compassionate Use, website, available at: http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/dispensing-organizations/dispensing-application-process/index.html (last visited Mar. 20, 2017).
[33] Section 381.986(5)(b), F.S. A map of the dispensing regions and approved dispensing organizations is available on the DOH website at: http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/_documents/ocu-dispensing-map.pdf (last visited Mar. 20, 2017).
[34] Chapter 2016-123, Laws of Fla.

In addition to the currently approved DOs, s. 381.986(5)(c), F.S., requires the DOH to approve three additional DOs upon the registration of 250,000 active qualified patients in the compassionate use registry. At least one of the newly approved DOs must be an applicant that is a recognized class member of Pigford v. Glickman, 185 F.R.D. 82 (D.D.C. 1999), or In Re Black Farmers Litig., 856 F. Supp. 2d 1 (D.D.C. 2011), and a member of the Black Farmers and Agriculturalists Association. These additional applicants are not required to meet the requirement to possess a certificate of registration issued by the DACS for the cultivation of more than 400,000 plants, be operated by a nurseryman, and have been operating as a registered nursery in Florida for at least 30 continuous years.

The Compassionate Use Registry

The act requires the DOH to create a secure, electronic, and online registry for the registration of physicians and patients and for the verification of patient orders by DOs, which is accessible to law enforcement.[35] The registry must allow DOs to record the dispensing of low-THC cannabis, and must prevent an active registration of a patient by multiple physicians. Physicians must register qualified patients with the registry and DOs are required to verify that the patient has an active registration in the registry, that the order presented matches the order contents as recorded in the registry, and that the order has not already been filled before dispensing any low-THC cannabis. The DOs are also required to record in the registry the date, time, quantity, and form of low-THC cannabis dispensed.[36] The Compassionate Use Registry became operational on July 11, 2016.[37] As of the end of February 2017, there were 4,079 patients registered with the Compassionate Use Registry.[38]

The Office of Compassionate Use and Research on Low-THC Cannabis

The DOH was required to establish the Office of Compassionate Use under the direction of the deputy state health officer to administer the act.[39, 40]

The act includes several provisions related to research on low-THC cannabis and cannabidiol including:

- Requiring physicians to submit quarterly patient treatment plans to the UFCP for research on the safety and efficacy of low-THC cannabis;[41]

[35] Section 381.986(5)(a), F.S.
[36] Section 381.986(6), F.S.
[37] Office of Compassionate Use, *Implementation Timeline* (October 2016) *available at* http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/_documents/ocu-timeline.pdf, (last visited Mar. 21, 2017).
[38] Revenue Estimating Conference, *Use of Marijuana for Debilitating Medical Conditions* (March 2, 2017), p. 3, (on file with the Senate Committee on Health Policy).
[39] Section 385.212, F.S.
[40] The Office of Compassionate Use is authorized to enhance access to investigational new drugs for Florida patients through approved clinical treatment plans or studies by: creating a network of state universities and medical centers recognized for demonstrating excellence in patient-centered coordinated care for persons undergoing cancer treatment and therapy in this state; making any necessary application to the U.S. Food and Drug Administration (FDA) or a pharmaceutical manufacturer to facilitate enhanced access to compassionate use for Florida patients; and entering into agreements necessary to facilitate enhanced access to compassionate use for Florida patients. *See* ss. 381.925 and 385.212, F.S.
[41] Section 381.986(2)(e), F.S.

- Authorizing state universities to perform research on cannabidiol and low-THC cannabis and exempting them from the provisions in ch. 893, F.S., for the purposes of such research;[42] and
- Appropriating $1 million to the James and Esther King Biomedical Research Program for research on cannabidiol and its effects on intractable childhood epilepsy.[43]

Medical Marijuana in Florida: Amendment 2 (2016)

On November 4, 2016, Amendment 2 was voted into law and established article X, section 29 of the State Constitution. This section of the constitution became effective on January 3, 2017, and creates several exemptions from criminal and civil liability for:

- Qualifying patients medically using marijuana in compliance with the amendment;
- Physicians, solely for issuing physician certifications with reasonable care and in compliance with the amendment; and
- Medical Marijuana Treatment Centers (MMTCs), their agents, and employees for actions or conduct under the amendment and in compliance with DOH rules.

The constitution defines multiple terms including:

- "Qualifying patient" to mean a person who:
  - Has been diagnosed with a "debilitating medical condition;"
  - Has a "physician certification;" and
  - Has a valid qualifying patient identification card issued by the DOH.
  - In the case of a minor patient, must also have the consent of a parent or legal guardian prior to both obtaining a physician certification and obtaining an identification card from the DOH.[44]
- "Debilitating Medical Condition" to mean:
  - Cancer;
  - Epilepsy;
  - Glaucoma;
  - HIV/AIDS;
  - Post-Traumatic Stress Disorder (PTSD);
  - Amyotrophic lateral sclerosis (ALS);
  - Crohn's Disease;
  - Parkinson's Disease;
  - Multiple Sclerosis; or
  - Another debilitating medical condition of the same kind or class as, or comparable to, the enumerated conditions.
  - Additionally, a physician must believe that the medical use of marijuana would likely outweigh the potential health risks for the patient.
- "Marijuana" to have the meaning given to cannabis in section 893.02(3), F.S. (2014), and, in addition, "low-THC cannabis" as defined in section 381.986(1)(b), F.S. (2014), shall also be included in the meaning of the term "marijuana."

[42] Section 385.211, F.S.
[43] Chapter 2014-157, Laws of Fla. The DOH and the University of Florida executed a contract (ID 5EP01) on June 5, 2015, and $483,334 of the $1 million grant award has been spent. Florida Accountability Contract Tracking System (FACTS). *Available at:* https://facts.fldfs.com/Search/ContractDetail.aspx?AgencyId=640000&ContractId=5EP01. (last visited April 16, 2017).
[44] This provision is included in the definition of "physician certification."

- "Medical Marijuana Treatment Center" or "MMTC" to mean an entity that acquires, cultivates, possesses, processes (including development of related products such as food, tinctures, aerosols, oils, or ointments), transfers, transports, sells, distributes, dispenses, or administers marijuana, products containing marijuana, related supplies, or educational materials to qualifying patients or their caregivers and is registered by the DOH.
- "Medical use" to mean 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 use by the caregiver's designated qualifying patient for the treatment of a debilitating medical condition.
- "Physician Certification" to mean a written document signed by a person who is "licensed to practice medicine" in Florida stating:
  - The physician has conducted a medical examination of the patient and a full assessment of the patient's medical history;
  - That, in the physician's professional opinion, the patient has a debilitating medical condition;
  - That, in the physician's professional opinion, the medical use of marijuana will outweigh the health risks for the patient; and
  - For how long the physician recommends the medical use of marijuana for the patient.

Once certified, a patient may designate one or more caregivers to assist him or her with the medical use of marijuana. The amendment defines a "caregiver" as a person who is at least 21 years of age who has agreed to assist with a qualifying patient's medical use of marijuana and has qualified for and obtained a caregiver identification card issued by the DOH. Caregivers:

- Are prohibited from consuming medical marijuana;
- Must obtain an ID card from the DOH;
- Are subject to standards and qualifications established by the DOH including:
  - Background checks;
  - Procedures for issuing ID cards; and
  - Limitations on the number of caregivers per patient and the number of patients per caregiver.

The DOH is required to register MMTCs that will be authorized to acquire, cultivate, possess, process, transfer, transport, sell, distribute, dispense, or administer medical marijuana, related supplies, or educational materials to patients and caregivers. The DOH is required to adopt rules regarding MMTCs including:

- Procedures to register as an MMTC;
- Procedures for the issuance, renewal, suspension, and revocation of MMTC registrations; and
- Standards to ensure proper security, record keeping, testing, labeling, inspection, and safety.

The amendment requires the DOH to adopt rules no later than July 3, 2017, six months after its effective date. The stated purpose of the rules is to ensure the availability and safe use of medical marijuana by qualifying patients. Currently, the DOH has begun the rulemaking process to implement article X, section 29 of the State Constitution and has held several workshops around Florida.[45] The DOH is required to adopt rules for:

[45] Rule 64-4.012, F.A.C., rule notice published on Jan. 17, 2017, *available at* https://www.flrules.org/gateway/ruleNo.asp?id=64-4.012, (last visited on Mar. 20, 2017).

- Issuing patient and caregiver ID cards;[46]
- Procedures for establishing caregiver qualifications;
- Procedures for registering MMTCs; and
- A regulation that defines the amount of marijuana that could reasonably be presumed to be an adequate supply, based on the best available medical evidence. This presumption can be overcome on an individual patient basis.

If the DOH does not adopt rules by the deadline, the amendment creates a cause of action for any Florida citizen to seek judicial relief to compel the DOH's compliance.

Additionally, the DOH is required to begin registering MMTCs and issuing patient and caregiver ID cards by October 3, 2017, nine months after the amendment's effective date. If the DOH does not comply with this requirement, the amendment states that a physician certification is sufficient for a person to become a qualifying patient without being issued an ID card from the DOH.

The amendment also creates a number of specific restrictions on its exemption from liability, and its grants of authority, including specifically:

- Not repealing or allowing violations of other laws related to the non-medical use of marijuana;
- Not permitting the operation of any vehicle under the influence of marijuana;
- Not requiring the accommodation of the use of marijuana in specific areas or in any public place;
- Not requiring any health insurance provider to cover the medical use of marijuana; and
- Not affecting laws related to negligence or malpractice on the part of any patient, caregiver, physician, or MMTC agent or employee.

The State Constitution authorizes the Legislature to enact laws consistent with the constitution's language, and provides for severability so that if any clause, sentence, paragraph or section of the amendment, or an application thereof, is found to be invalid by a court of competent jurisdiction, other provisions shall continue to be in effect to the fullest extent possible.

The Revenue Estimating Conference has estimated that under Amendment 2 and the proposed DOH rules, sales tax revenue from medical marijuana sales will be $2.6 million in Fiscal Year 2017-2018 and will increase to $24.3 million in Fiscal Year 2021-2022.

Medical Marijuana in Florida: The Necessity Defense

Despite the fact that the use, possession, and sale of marijuana are prohibited by state law, Florida courts have found that circumstances can necessitate medical use of marijuana and circumvent the application of criminal penalties. The necessity defense was successfully applied in a marijuana possession case in *Jenks v. State* where the First District Court of Appeal found

[46] On Feb. 18, 2017, the DOH adopted Rule 64-4.011, F.A.C., addressing the issuance of Compassionate Use Registry Identification Cards. This rule may bring the DOH into compliance with the requirement to adopt rules for issuing ID cards by July 3, 2017; however, the rule may need requiring amending to comply with constitutional terms and to comply with changes to s. 381.986, F.S., provided in this bill.

that s. 893.03, F.S., does not preclude the defense of medical necessity for the use of marijuana if the defendant:

- Did not intentionally bring about the circumstance which precipitated the unlawful act;
- Could not accomplish the same objective using a less offensive alternative available; and
- The evil sought to be avoided was more heinous than the unlawful act.[47]

In the cited case, the defendants, a married couple, were suffering from uncontrollable nausea due to AIDS treatment and had testimony from their physician that he could find no effective alternative treatment. Under these facts, the court found that the defendants met the criteria to qualify for the necessity defense and ordered an acquittal of the charges of cultivating cannabis and possession of drug paraphernalia.

Medical Marijuana Laws in Other States

Currently, 28 states, the District of Columbia, and Guam have some form of law that permits the use of marijuana for medicinal purposes.[48] These laws vary widely in detail but most share certain features. For example, most state laws require an identification card and registry for patients and caregivers to use medical marijuana; require the patient to receive certification from up to two physicians that the patient has a qualifying condition before the patient may use medical marijuana; allow a patient to designate a caregiver who can possess the medical marijuana and assist the patient in using the medical marijuana; and provide general restrictions on how medical marijuana can be obtained (self-cultivated or from a dispensary) and where it can be used.[49]

Of the 17 states with low-THC cannabis laws similar to s. 381.986, F.S., most specify that the use of such low-THC cannabis is reserved for patients with epileptic or seizure disorders. Florida allows the treatment of cancer and Georgia allows the treatment of end stage cancer and other specified conditions. Additionally, the definition of low-THC cannabis differs from state to state. The THC level allowed ranges from a high of below five percent to less than 0.3 percent; most states restrict the level of THC to below one percent. CBD levels are generally required to be high, with most states requiring at least 10 percent.[50]

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

[48] These states include: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oregon, Pennsylvania, 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 in June 2014. Seventeen states allow limited access to marijuana products (low-THC and/or high CBD-cannabidiol). Alabama, Florida, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming. National Conference of State Legislatures, *State Medical Marijuana Laws*, (Mar. 16, 2017), *available at* http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (last visited Mar. 20, 2017).

[49] Analysis by Senate Health Policy committee staff of s*upra* note 49.

[50] *Supra* note 49.

Interaction with the Federal Government

The federal Controlled Substances Act lists marijuana as a Schedule 1 drug and provides no exceptions for medical uses.[51] Possession, manufacture, and distribution of marijuana is a crime under federal law.[52] Although a state's medical marijuana laws protect patients from prosecution for the legitimate use of marijuana under state law, state medical marijuana laws, or Constitutional provisions, do not protect individuals from prosecution under federal law.

In 2013, the U.S. Department of Justice (USDOJ) issued statements indicating that the federal government would not pursue cases for low-level drug crimes, leaving such prosecutions largely up to state authorities. The U.S. Attorney General issued a statement that the USDOJ was changing policy such that individuals "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… [and] would instead receive sentences better suited to their individual conduct…"[53] Further, the USDOJ issued a memorandum clarifying that the department considers small-scale marijuana use to be a state matter which states may choose to punish, and certain operations adhering to state laws legalizing marijuana in conjunction with robust state regulatory systems would be far less likely to come under federal scrutiny.[54] In addition, a rider in recent appropriations acts and continuing resolutions has prohibited the USDOJ from using appropriated funds to prevent specified states (including Florida) from implementing the states' own medical marijuana laws.[55] It is worth noting that, with the election of President Trump and changes to the leadership of the USDOJ, the guidance issued by the USDOJ may be amended in the future; however, it would require an act of Congress to amend the rider preventing the USDOJ from using funds to prevent specified states from implementing medical marijuana laws.

III. Effect of Proposed Changes:

In addition to technical and conforming changes made by the bill to ss. 381.986, 381.987, 385.211, 499.0295, and 1004.441, the bill substantially amends s. 381.986, F.S.

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[51] 21 U.S.C. s. 812. Note: On August 11, 2016, the Federal Drug Enforcement Administration refused two petitions to reschedule marijuana under the Controlled Substances Act, see https://www.dea.gov/divisions/hq/2016/hq081116.shtml, (last visited on Mar. 20, 2017).

[52] The punishments vary depending on the amount of marijuana and the intent with which the marijuana is possessed. *See* 21 U.S.C ss. 841-865.

[53] USDOJ, *Smart on Crime: Reforming the Criminal Justice System for the 21st Century*, (Aug. 2013), p. 3, *available at* http://www.justice.gov/ag/smart-on-crime.pdf (last visited on Mar. 20, 2017).

[54] USDOJ Memorandum for all U.S. Attorneys from James M. Cole, Deputy Attorney General, *Guidance Regarding Marijuana Enforcement* (August 29, 2013), *available at* http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf (last visited Mar. 20, 2017).

[55] *See* Pub. Law No. 114-113, s. 542 (Consolidated Appropriations Act, 2016). A recent court order by the U.S. District Court for the Northern District of California recently held that a similar provision in the previous appropriations act (s. 538, Pub. L. No. 113-235) does not prohibit the USDOJ from enforcing violations of *federal* marijuana laws by individuals or businesses who are complying with state medical marijuana laws. U.S. v. Marin Alliance for Medical Marijuana and Shaw, Order re: Motion to Dissolve Permanent Injunction, No. C 98-00086 CB, (Oct. 19, 2015), available at http://www.scribd.com/doc/286089509/US-vs-Marin-Alliance-for-Medical-Marijuana#scribd (last visited Mar. 20, 2017).

Legislative Intent

The bill:

- Adds the legislative intent:
  - To implement s. 29, Art. X of the State Constitution by creating a unified regulatory structure for the acquisition, cultivation, possession, processing, transfer, transportation, sale, distribution, and dispensing of marijuana, marijuana products, related supplies, and educational materials;
  - That all rules adopted by the DOH to implement the section be adopted pursuant to ch. 120, F.S., and that the DOH may use emergency rulemaking procedures to adopt rules if necessary to meet any rulemaking deadlines established in s. 29, Art. X of the State Constitution; and
  - That all registrations for MMTC activities be issued solely in accordance with the requirements of this section and rules adopted under the section.

Definitions

The bill:

- Conforms the definitions for "caregiver," "debilitating medical condition," "marijuana," "medical marijuana treatment center" or "MMTC," to the definitions in article X section 29 of the State Constitution.
- Uses the constitutional definition for "medical use" but amends the definition to restrict:
  - Smoking;
  - The possession, use, or administration of marijuana not purchased from an MMTC;
  - The transfer of marijuana to anyone other than a qualifying patient or his or her caregiver;
  - The use or administration of any type or amount of marijuana not specified on a qualifying patient's physician certification; and
  - The use or administration of marijuana:
    - On any form of public transportation;
    - In any public place;
    - In a qualifying patient's place of employment if restricted by his or her employer;
    - In a state correctional institution;
    - On the grounds of a preschool, primary school, or secondary school; or
    - On a school bus or in a vehicle, aircraft, or motorboat.
- Uses the constitutional definition for "qualifying patient," but also includes "eligible patients" as defined in the Right to Try Act, patients suffering from a physical medical condition that produces symptoms of seizures or severe and persistent muscle spasms, and patients suffering from chronic nonmalignant pain.
- Adds definitions for:
  - "Chronic nonmalignant pain" to mean pain that is caused by a debilitating medical condition or that originates from a debilitating medical condition and persists beyond the usual course of that debilitating medical condition; and
  - "Close relative" to mean a spouse, parent, sibling, grandparent, child, or grandchild, whether related by whole or half-blood, by marriage, or by adoption.

Physician Certifications

The bill allows physicians to issue physician certifications to:

- A patient suffering from a debilitating medical condition;
- A patient suffering from a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms;[56]
  -
- A patient suffering from chronic nonmalignant pain, if the physician has diagnosed an underlying debilitating medical condition as the cause of the pain, which allows the patient to receive marijuana for the patient's medical use to alleviate the patient's pain;
- An eligible patient as defined in the Right to Try Act; or
- A patient who is not a Florida resident and who qualifies under one of the above listed conditions and who can lawfully receive marijuana in the state in which he or she resides.

Before certifying a patient the physician must:

- Be licensed under ch. 458 or 459, F.S.;
- Have successfully completed the required 4-hour course and exam administered by the Florida Medical Association or the Florida Osteopathic Medical Association;[57]
- Have conducted a full assessment of the patient's medical history;
- Have determined that, in the physician's professional opinion, the patient meets one of the criteria specified above;
- Have determined that the medical use of marijuana would likely outweigh the potential health risks to the patient; and
- Have obtained the voluntary written informed consent of the patient or, if the patient is a minor, the patient's parent or legal guardian, after having sufficiently explained the current state of knowledge in the medical community of the effectiveness of treatment of the patient's condition with marijuana and the potential risks and side effects.[58]

For patients under the age of 18, a second physician must concur with the treating physician's determination that the medical use of marijuana would likely outweigh the health risks for the patient. Additionally, patients under the age of 18 are restricted from purchasing marijuana and are required to have a parent, legal guardian, caregiver, or health care provider assist them in purchasing and administering marijuana.

The physician must also register as the treating physician with the compassionate use registry and maintain a patient treatment plan that must be submitted to the University of Florida College of Pharmacy on a quarterly basis. The bill increases the amount of marijuana a physician may certify a patient to receive from a 45-day supply to a 90-day supply and allows a physician to certify a patient for longer than the 90-day period if the physician believes that the patient will use the additional marijuana in a medically appropriate way. Patients must be recertified at least annually. A physician may not issue physician certifications if he or she is a medical director employed by an MMTC.

[56] Such patient may receive only low-THC cannabis if the patient does not meet any of the other qualifications.
[57] Current law requires an 8-hour course and exam which must be retaken annually.
[58] If the patient is an eligible patient, the physician must obtain written informed consent pursuant to s. 499.0295, F.S.

The bill also grandfathers in all orders for low-THC cannabis issued prior to the effective date of the act as physician certifications, and requires the DOH to consider patients with such orders as qualifying patients until the DOH begins issuing compassionate use registry identification cards.

Prohibited Acts

The bill:

- Conforms existing penalties to the changes made by the bill;
- Creates two new misdemeanors for a qualifying patient or caregiver who cultivates marijuana or who purchases or acquires marijuana from any person or entity other than an MMTC[59] and a caregiver who violates any of the applicable provisions of this section or applicable department rules;[60]
- Specifies that an MMTC may not advertise services that it is not registered to provide; and
- Prohibits any person or entity from offering or advertising services as an MMTC without being registered as an MMTC. The bill establishes penalties for unlicensed activity including fines of up to $10,000 per day, and that the DOH or any state attorney may bring action for an injunction of the activity until compliance has been established to the satisfaction of the DOH. The bill also allows the DOH to assess reasonable investigative and legal costs for a successful prosecution.

Caregivers

The bill allows a qualifying patient to designate a caregiver to assist him or her with the medical use of marijuana. The bill requires the DOH to register a caregiver and issue him or her a compassionate use registry identification card if designated by a qualifying patient, and the caregiver:

- Is 21 years of age or older, unless the patient is a close relative of the caregiver;
- Agrees in writing to be the qualifying patient's caregiver;
- Does not receive compensation, other than actual expenses incurred, for assisting the qualifying patient with the medical use of marijuana unless the caregiver is acting pursuant to employment in a licensed facility in accordance with subparagraph (c)2.; and
- Passes a Level 2 background screening pursuant to ch. 435, F.S., unless the patient is a close relative of the caregiver.

A qualifying patient may have only one designated caregiver at a time unless all of the patient's caregivers are his or her close relatives or legal representatives. A caregiver may assist only one patient at a time unless:

- All qualifying patients the caregiver is assisting are close relatives of each other and the caregiver is the legal representative of at least one of the patients; or
- All qualifying patients the caregiver is assisting are receiving hospice services, or are residents, in the same assisted living facility, nursing home, or other licensed facility and have requested the assistance of that caregiver with the medical use of marijuana; the caregiver is an employee of the hospice or licensed facility; and the caregiver provides

[59] A first degree misdemeanor.
[60] A second degree misdemeanor on the first offense and a first degree misdemeanor on subsequent offenses.

personal care or services directly to clients of the hospice or licensed facility as a part of his or her employment duties at the hospice or licensed facility.

Duties of the DOH

Compassionate Use Registry

The bill requires the DOH to expand access to the compassionate use registry to:

- Practitioners licensed under ch. 458 or 459, F.S., to ensure proper care for patients requesting physician certifications; and
- Practitioners licensed to prescribe prescription drugs, to ensure proper care for patients before prescribing medications that may interact with the medical use of marijuana;

The bill specifies that law enforcement agencies may check the registry to verify the authorization of a qualifying patient or a patient's caregiver to possess marijuana or a cannabis delivery device.

Compassionate Use Registry Identification Cards

By July 3, 2017, the bill requires the DOH to adopt rules establishing procedures for the issuance, annual renewal, suspension, and revocation of compassionate use registry identification cards for patients and caregivers who are residents of this state. The bill allows the DOH to charge a reasonable fee for issuing and renewal of identification cards. The bill requires that the DOH begin issuing identification cards to patients and caregivers by October 3, 2017. Minor patients must provide the DOH with written consent from a parent or a legal guardian before being issued an identification card. Identification cards may be issued to out-of-state patients after the DOH confirms they are able to receive marijuana legally in their state of residency through a medical marijuana program.

The bill specifies that the identification cards must be resistant to counterfeiting and tampering and at a minimum contain:

- The name, address, and date of birth of the patient or caregiver, as appropriate;
- A full-face, passport-type, color photograph of the patient or caregiver, as appropriate, taken within the 90 days immediately preceding registration;
- Designation of the cardholder as a patient or caregiver;
- A unique numeric identifier for the patient or caregiver which is matched to the identifier used for such person in the department's compassionate use registry. A caregiver's identification number and file in the compassionate use registry must be linked to the file of the patient or patients the caregiver is assisting so that the caregiver's status may be verified for each patient individually;
- The expiration date, which shall be one year after issuance or the date treatment ends as provided in the patient's physician certification, whichever occurs first; and
- For caregivers who are assisting three or fewer qualifying patients, the names and unique numeric identifiers of the qualifying patient or patients that the caregiver is assisting.

Dispensing Organization Grandfathering

The bill requires the DOH to grandfather in all existing DOs as MMTCs as soon as practicable.[61] The DOH may not charge the DOs a registration fee and the bill states that, for the purposes of the act, all DOs are deemed to be MMTCs on the effective date of the act. The bill requires that the DOs continue to comply with all representations made in their applications to be dispensing organizations after being registered as MMTCs and allows the DOH to grant variances to those representations.

Additional MMTCs

The bill requires that, by October 3, 2017, the DOH register five additional MMTCs with at least one applicant that is a recognized class member of Pigford v. Glickman, 185 F.R.D. 82 (D.D.C. 1999) or In re Black Farmers Litig., 856 F. Supp. 2d 1 (D.D.C. 2011) and a member of the Black Farmers and Agriculturalists Association. Additionally, within six months of each instance of the registration of 75,000 patients in the compassionate use registry, the DOH must register four additional MMTCs. The bill retains the requirement that MMTCs be vertically integrated, but eliminates the requirements that MMTCs possess a valid certificate of registration issued by the DACS pursuant to s. 581.131, F.S., that is issued for the cultivation of more than 400,000 plants, be operated by a nurseryman as defined in s. 581.011, F.S., and have been operated as a registered nursery in this state for at least 30 continuous years. The bill requires that all applicants must be registered to do business in Florida for at least five continuous years prior to applying. The bill also restricts the DOH from issuing more than one MMTC registration to a person or entity.

Independent Testing Laboratories

The bill authorizes the establishment of independent testing laboratories (ITLs) to collect and accept samples of, possess, store, transport, and test marijuana. All MMTCs are required to have their marijuana tested at an ITL to ensure that it meets DOH standards before it is dispensed. All ITLs must be licensed by the DOH except clinical laboratories licensed by the Agency for Health Care Administration (AHCA) which are exempt from this requirement. The DOH is required to adopt rules for ITL licensure requirements and a process for licensing ITLs including an application form, an initial application fee, and a biennial renewal fee.

In addition to licensure, the bill also requires that ITLs be certified by the DOH to perform all required tests. The DOH must issue a certification to an ITL that has been certified by a third-party laboratory certification body approved by the DOH. The DOH must adopt rules for certifying ITLs including rules for personnel qualifications, equipment and methodology, proficiency testing, tracking, sampling, chain of custody, record and sample retention, reporting, audit and inspection, and security.

The bill specifies that an ITL may accept samples only from a sample source approved by the DOH which, at a minimum, must include an MMTC, a researcher affiliated with an accredited university or research hospital, a qualifying patient, or a caregiver.

[61] Including DOs that become MMTCs pursuant to the results of litigation (see present situation for details).

Quality Control Program

The bill requires the DOH to establish a marijuana quality control program that must require MMTCs to submit samples from each batch or lot of marijuana harvested or manufactured to an ITL to ensure that, at a minimum, labeling of the potency of THC and other marketed cannabinoids or terpenes is accurate and that it is safe for human consumption. The MMTC is required to maintain records of all tests conducted including the results and any other information required by the DOH. The DOH is required to adopt rules to create and oversee the program which must, at a minimum, include:

- Permissible levels of variation in potency labeling and standards requiring THC be consistently distributed throughout edible marijuana products;
- Permissible levels of contaminants and mandatory testing for contaminants including, but not limited to, testing for microbiological impurity, residual solvents, and pesticide residues;
- The destruction of marijuana determined to be inaccurately labeled or unsafe for human consumption after the MMTC has an opportunity to take remedial action;
- The collection, storage, handling, recording, and destruction of samples of marijuana by ITLs; and
- Security, inventory tracking, and record retention.

The bill also requires the DOH to reduce or suspend any testing requirement in its quality control program if the number of licensed and certified ITLs is insufficient to process the tests necessary to meet patient demand.

Seed-to-Sale Tracking System

The bill requires the DOH to establish, maintain, and control a computer software tracking system that traces marijuana from seed to sale. The tracking system must allow real-time, 24-hour access by the DOH to data from all MMTCs and ITLs and must, at a minimum, include notification of when marijuana seeds are planted, when marijuana plants are harvested and destroyed, and when marijuana is transported, sold, stolen, diverted, or lost. Each MMTC must use the seed-to-sale tracking system selected by the DOH.

MMTC Requirements

The requirements for MMTCs are substantially similar to the requirements for DOs in current law. The bill amends requirements for MMTCs so that:

- MMTCs are required to maintain compliance with all the representations made to the DOH in the MMTC's application for registration.
  - Upon request, the DOH may grant an MMTC one or more variances from the representations made in the MMTC's application.
  - Consideration of such a variance shall be based upon the individual facts and circumstances surrounding the request.
  - A variance may not be granted unless the requesting MMTC can demonstrate to the department that it has a proposed alternative to the specific representation made in its application which fulfills the same or a similar purpose as the specific representation in a way that the DOH can reasonably determine will not be a lower standard than the specific representation in the application.

- MMTCs are required to label all marijuana with the concentration of THC and CBD in the product and with the recommended dose for the qualifying patient receiving it.
- MMTCs are allowed to produce edible products, but may not produce such items that are designed to be attractive to children. Additionally, MMTCs must meet all food safety standards established in state and federal law, including, but not limited to, the identification of the serving size and the amount of THC in each serving.
- When transporting marijuana, a copy of the transportation manifest must be in the vehicle at all times.

The bill also requires the DOH to adopt by rule a process for approving MMTC changes in ownership and changes in an MMTC owner's investment interest.

Rulemaking

The bill requires the DOH to adopt emergency rules pursuant to s. 120.54(4), F.S., as necessary to implement the section. The bill states that if an emergency rule adopted under this section is voided due to being held unconstitutional or an invalid exercise of delegated legislative authority, the DOH and any applicable boards may adopt an emergency rule to replace the voided rule. However, if the second emergency rule is voided, the DOH and the applicable boards must adopt rules based on standard procedures.

The bill exempts emergency rules from the requirement to make findings pursuant to s. 120.54(4)(a), F.S.;[62] from ss. 120.54(3)(b),[63] 120.541,[64] and 120.54(4)(c), F.S.[65] The DOH and applicable boards must meet the procedural requirements in s. 120.54(2)(a), F.S.,[66] if the DOH or the applicable boards have, before the effective date of the act, held any public workshops or hearings on the subject matter of the emergency rules. Additionally, challenges to emergency rules adopted under this section are subject to the time schedules provided in s. 120.56(5), F.S.[67] Emergency rules adopted under this section remain in effect until they are replaced by rules adopted through normal procedures. The DOH must begin nonemergency rulemaking by January 1, 2018, and may not use emergency rulemaking procedures after that date, unless replacing emergency rules deemed invalid.

Miscellaneous Provisions

The bill:

- Specifies that nothing in the act limits the ability of an employer to establish, continue, or enforce a drug-free workplace program or policy and that an employer is not required to

[62] Section 120.54(a)3., F.S., requires the agency publishing emergency rules to also publish in writing at the time of, or prior to, its action the specific facts and reasons for finding an immediate danger to the public health, safety, or welfare and its reasons for concluding that the procedure used is fair under the circumstances.
[63] The requirement to prepare a statement of estimated regulatory cost (SERC) and to consider the impact of rules on small business, small counties, and small cities.
[64] Detailing the requirements of a SERC.
[65] Restricting an emergency rule from being effective for more than 90 days with some exceptions.
[66] Requiring notice of rule development be published prior to filing for rule adoption.
[67] The DOAH has seven days to assign an administrative law judge who must conduct the hearing within 14 total days (including the days used in assigning the judge). The judge then has 14 days after the hearing to render a decision.

accommodate the use of marijuana in the workplace or any employee working while under the influence of the marijuana.
- Specifies that nothing in the section creates a cause of action against an employer for wrongful discharge or discrimination.
- Creates an additional exemption from criminal penalties related to marijuana for research institutions established by a public postsecondary educational institution, such as the H. Lee Moffitt Cancer Center and Research Institute, and for state universities that have achieved preeminent state research university designation.[68]

The Medical Marijuana Research and Education Act

The bill creates s. 1004.4351, F.S., to create the Medical Marijuana Research and Education Act. The act:
- Establishes the Coalition for Medicinal Cannabis Research and Education (Coalition) within the H. Lee Moffitt Cancer Center and Research Institute, Inc. (MCCRI) and provides that the Coalition's purpose is to conduct rigorous scientific research, provide education, disseminate research, and to guide policy development for the adoption of a statewide policy on ordering and dosing practices for the medicinal use of cannabis.
- Creates the Medicinal Cannabis Research and Education Board (Board) to direct the Coalition's operations. Additionally, the bill specifies Board membership requirements and requires the Board to:
  - Advise the Board of Governors, the State Surgeon General, the Governor, and the Legislature with respect to medicinal cannabis research and education in Florida.
  - Explore methods of implementing and enforcing medicinal cannabis laws in relation to cancer control, research, treatment, and education.
  - Annually adopt a plan for medicinal cannabis research, known as the Medicinal Cannabis Research and Education Plan (Plan) in accordance with state law, and must include recommendations for the coordination and integration of medical, nursing, paramedical, community, and other resources connected with the treatment of debilitating medical conditions, research related to the treatment of such conditions, and education.
  - Issue an annual report, by February 15, to the Governor, the President of the Senate, and the Speaker of the House Representatives on research projects, community outreach initiatives, and future plans for the Coalition.
- Provides that the Coalition must be administered by a director who, subject to Board approval, must:
  - Propose a budget.
  - Foster the collaboration of scientists, researchers, and other appropriate personnel.
  - Identify and prioritize the Coalition's research.
  - Prepare the Plan for submission to the Board.
  - Apply for grants to obtain funding for the Coalition's research.
  - Perform other Board specified duties.
- Requires the MCCRI to allocate staff, information, and assistance to assist the Board.

The bill is effective upon becoming law.

[68] Pursuant to s. 1001.7065, F.S.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

Article X, section 29 of the State Constitution is a unique provision in that it directs a state agency, the DOH, to implement its provisions without requiring implementing legislation. However, article X, section 29(4)(e) of the State Constitution, does provide that nothing in that section shall limit the Legislature from enacting laws consistent with the section. Given the novelty of the constitutional provision, it is unclear how the courts will interpret its provisions as well as the interaction between its provisions and implementing legislation and rules.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The Revenue Estimating Conference estimates that the bill has a positive but indeterminate fiscal impact on state revenues.

B. Private Sector Impact:

The bill will create opportunities for new MMTCs that are called for under its provisions, and for independent testing laboratories. Existing DOs may face a more competitive marketplace due to the increase in the number of allowed suppliers of marijuana, but the number of patients using their services is also expected to grow.

Patients and caregivers will be required to pay for identification cards, and caregivers and employees of MMTCs must pay for background screening.

C. Government Sector Impact:

The bill has an indeterminate fiscal impact on the DOH due to the cost of increased regulatory activity required by the bill, which should be offset by fees and fines the DOH is allowed to assess. The DOH estimates that fees and fines may generate between $6.1

million and $8.6 million while total expenditures may be between $6 million and $8.9 million.[69]

The FDLE estimates that revenues derived from the bill for the FDLE may range from $9 million to $18 million generated by fees for criminal history records checks.[70] The FDLE analysis indicates that implementation of the bill will require 16 FTEs to perform criminal history background checks, two additional toxicology analysts, and two additional fingerprint analysts. Cost estimates provided by the FDLE for the additional staff are $1,278,157 in Fiscal Year 2017-2018, and $1,197,237 on a recurring basis; however, fees for criminal history records checks should offset these costs.[71]

The bill may have an indeterminate fiscal impact on local governments. Local governments may see a positive fiscal impact from fees associated with licensing and inspecting additional MMTC facilities as permitted by current law and may derive additional tax revenue from the sale of marijuana. Local governments may see a negative fiscal impact due to the expenses associated with implementing ordinances and undertaking regulatory activities required by such ordinances.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Although the bill allows MMTCs to use contractors in general, it is unclear from the text of the bill what limits are placed on how an MMTC may use a contractor. The bill should be clarified to specify the duties a contractor may perform for an MMTC.

The FDLE notes that entering results obtained from a state or criminal history record check into a registry, as the bill appears to require DOH to do with information it receives from physicians, patients and caregivers, is prohibited by Public Law 92-544. Similarly, the provision in the bill that the application form for registration as an MMTC must demonstrate that all owners and managers have been fingerprinted and have successfully passed a level 2 background screening is also prohibited by Public Law 92-544.[72]

The bill provides circumstances under which a physician may lawfully issue a physician certification to a patient who is not a resident of this state or under which DOH may issue a compassionate use registry identification card to a patient who is not a resident of this state, but never explicitly states that a patient must otherwise be a resident of this state.[73]

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[69] The DOH states that expenditures are highly dependent on the number of qualifying patients. See DOH, *Senate Bill 406 Analysis* (Feb. 14, 2017) (on file with the Senate Committee on Health Policy).
[70] The fee depends on whether or not caregivers are intended to be entered into the clearinghouse. See FDLE, *Senate Bill 406 Analysis* (Feb. 15, 2017) (on file with the Senate Committee on Health Policy).
[71] FDLE, *Senate Bill 406 Analysis* (Feb 15, 2017) (on file with the Senate Appropriations Subcommittee on Finance and Tax).
[72] FDLE, *Senate Bill 406 Analysis* (Feb 15, 2017) (on file with the Senate Appropriations Subcommittee on Finance and Tax).
[73] Amendment 2 provides that a "qualifying patient" means a person (not a Florida resident) who meets certain criteria.

The bill allows a physician to certify an amount greater than a 90-day supply of marijuana if he or she has reasonable belief that the patient will use the additional marijuana in a medically appropriate way; however, the bill does not apply the exception to the 90-day supply limit of marijuana to the exemptions from criminal penalties contained in chapter 893, F.S. The bill should be clarified to apply the exception to the 90-day supply limit of marijuana consistently throughout the bill.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 381.986, 381.987, 385.211, 499.0295, and 1004.441.

The bill creates section 1004.4351 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on April 3, 2017:
The CS amends SB 406 to:

- Add legislative intent.
- Reinstate the requirement that a second physician confirm a diagnosis when certifying a person under the age of 18 and require a parent, legal guardian, caregiver, or health care provider to purchase marijuana for qualifying patients under the age of 18.
- Allow a physician to certify out of state patients that meet Florida requirements for treatment with marijuana.
- Allow a physician to certify a patient for greater than a 90-day supply if the physician believes the patient will use the marijuana appropriately.
- Specify that MMTCs may not advertise services that they are not registered to provide.
- Prohibit any person or entity from offering or advertising services as an MMTC without being registered as an MMTC and provide penalties for unlicensed activity.
- Require the DOH to register five additional MMTCs by October 3, 2017, including one that is a member of the Black Farmers and Agriculturalists Association.
- Require the Department of Health to add four new MMTCs within six months after the registration of each instance of 75,000 patients in the Compassionate Use Registry.
- Require that all MMTC applicants be registered to do business in Florida for at least five consecutive years prior to submitting their application.
- Prohibit any person or entity from being issued more than one MMTC registration.
- Require the DOH to license ITLs (clinical laboratories licensed by the AHCA are exempt from this requirement). ITLs must also be certified by the DOH to perform all required tests. The DOH must certify an ITL that has third-party accreditation from

an accrediting body approved by the DOH. The DOH must adopt rules for licensure and certification of ITLs.

- Require the DOH to establish a quality control program for the testing of marijuana. The program must require MMTCs to submit samples of marijuana to an ITL to ensure minimum standards are met. The DOH must adopt rules to create and oversee the program.
- Require the DOH to establish, maintain, and control a seed-to-sale tracking system.
- Authorize an employer to deny accommodation for the ingestion of marijuana in the workplace or for any employee working while under the influence of marijuana.
- Specify that the section does not create a cause of action for wrongful discharge or discrimination.
- Incorporate an exemption from criminal laws for research institutions performing research on marijuana.
- Require the DOH to abide by the provisions of ch. 120, F.S., when adopting rules to implement this section and allows the department to use emergency rulemaking procedures.
- Establish the "Medical Marijuana Research and Education Act" to:
  - Create the Coalition for Medical Marijuana Research and Education within the H. Lee Moffitt Cancer Center and Research Institute, Inc.;
  - Task the coalition with conducting rigorous scientific research, providing education, disseminating research, and guiding policy for the adoption of a statewide policy on ordering and dosing practices for medical marijuana;
  - Specify the make-up of the coalition including the duties of the director of the coalition;
  - Require the coalition to annually adopt a research plan; and
  - Require the coalition to annually report to the Governor and the Legislature on research projects, community outreach, and future plans.

B. Amendments:

None.