HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 307 Experimental Treatments for Terminal Conditions
SPONSOR(S): Health Care Appropriations Subcommittee; Criminal Justice Subcommittee; Gaetz; Edwards and others
TIED BILLS: None **IDEN./SIM. BILLS:** SB 460

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Criminal Justice Subcommittee	9 Y, 4 N, As CS	White	White
2) Health Care Appropriations Subcommittee	9 Y, 2 N, As CS	Garner	Pridgeon
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Under the Florida Comprehensive Drug Abuse Prevention and Control Act, cannabis is a Schedule I controlled substance and, as such, criminal penalties ranging from first degree misdemeanors to second degree felonies apply to the unlawful possession, use, sale, purchase, manufacture, delivery, transport, or trafficking of cannabis. Currently, the only statutorily-allowed use of cannabis in this state is set forth in the Compassionate Medical Cannabis Act of 2014 (CMCA), which authorizes dispensing organizations 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 physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms.

In 2015, the Legislature adopted the Right to Try Act (RTTA). The RTTA authorizes an eligible patient with a "terminal condition," meaning that the patient will die within one year if the condition runs its normal course, to receive an "investigational drug, biological product, or device," meaning a drug, 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.

The bill amends the definition of "investigational drug, biological product, or device" set forth in the RTTA to include cannabis that is manufactured and sold by a licensed dispensing organization under the CMCA. The bill further specifies that, notwithstanding the state's laws criminalizing the non-medical use of cannabis, eligible patients under the RTTA or their legal representatives may purchase and possess cannabis for the patient's medical use and dispensing organizations may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of cannabis.

The bill does not have a fiscal impact on state or local governments; current budget authority and revenues are adequate to absorb any additional workload the bill may cause.

The bill takes effect July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Florida's Cannabis Laws

Non-Medical Use of Cannabis

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).[1] The Drug Control Act classifies controlled substances into five categories, ranging from Schedule I to Schedule V.[2] Cannabis is currently a Schedule I controlled substance,[3] 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.[4] 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.[5]

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

- Section 893.13, F.S., makes it a crime to sell, manufacture, deliver, purchase, or possess cannabis. The penalties for these offenses range from first degree misdemeanors to second degree felonies.[6]
- Section 893.135(1)(a), F.S., makes it a first degree felony[7] 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.[8]
- Section 893.147, F.S., makes it a crime to possess, use, deliver, manufacture, transport, or sell drug paraphernalia.[9] The penalties for these offenses range from first degree misdemeanors to second degree felonies.[10]

[1] s. 893.01, F.S.
[2] s. 893.03, F.S.
[3] s. 893.03(1)(c)7., F.S.
[4] s. 893.03(1), F.S.
[5] s. 893.02(3), F.S.
[6] 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.
[7] 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.
[8] s. 893.13(1)(a), F.S.
[9] 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.

[10] s. 893.147, F.S.

Florida's 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.[11]

In *Jenks v. State,*[12] 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.[13] 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 Jenks met the criteria for the medical necessity defense.[14] The court ordered the Jenks to be acquitted.[15]

Seven years after the *Jenks* decision, the First District Court of Appeal again recognized the medical necessity defense in *Sowell v. State*.[16] 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.[17]

Compassionate Medical Cannabis Act of 2014

The Compassionate Medical Cannabis Act of 2014[18] (CMCA) legalized a low tetrahydrocannabinol (THC) and high cannabidiol (CBD) form of cannabis (low-THC cannabis)[19] for the medical use[20] 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[21] 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

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[11] *Jenks v. State*, 582 So.2d 676, 679 (Fla. 1st DCA 1991), *rev. denied,* 589 So.2d 292 (Fla.1991).
[12] 582 So.2d 676 (Fla. 1st DCA 1991).
[13] *Id*.
[14] *Id*.
[15] *Id*.
[16] 739 So.2d 333 (Fla. 1st DCA 1998).
[17] *Interdepartmental Memorandum*, State Attorney's Office for the Twelfth Judicial Circuit of Florida, SAO Case # 13CF007016AM, April 2, 2013 (on file with Judiciary Committee staff).
[18] *See* ch. 2014-157, L.O.F., and s. 381.986, F.S.
[19] The act defined "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. Eleven states allow limited access to marijuana products (low-THC and/or high CBD-cannabidiol): Alabama, Florida, Iowa, Kentucky, Mississippi, Missouri, North Carolina, South Carolina, Tennessee, Utah, and Wisconsin. Twenty-three states, the District of Columbia, and Guam have laws that permit the use of marijuana for medicinal purposes. See infra note 28. *See* http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (Tables 1 and 2), (last visited on March 27, 2015).
[20] 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."
[21] 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

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.[22]
- 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.[23]

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.[24] 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.[25]

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.[26] Thereafter, the rules took effect on June 17, 2015.[27]

The application process to become a dispensing organization closed on July 8, 2015, with 28 applications received by DOH. As of November 13, 2015, DOH is continuing to conduct its review process to select the five approved dispensing organizations as directed by statute.[28]

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.[29]

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

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[22] 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.
[23] s. 381.986(2), F.S.
[24] s. 381.986(5)(b), F.S.
[25] *Id.*
[26] *Baywood v.Nurseries Co., Inc. v. Department of Health,* Case No. 15-1694RP (Fla. DOAH May 27, 2015).
[27] Rule Chapter 64-4, F.A.C.
[28] Telephone call with staff of the Department of Health (November 13, 2015).
[29] s. 381.986(3), F.S.

- Qualified patients[30] 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.[31]

The Compassionate Use Registry

The CMCA requires DOH to create a secure, electronic, and online registry for the registration of physicians and patients.[32] 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.[33] 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.[34]

Medical Cannabis Laws in Other States

Currently, 23 states[35] and the District of Columbia have laws that permit the use of cannabis for medicinal purposes. While these laws vary widely, most include the following:

- A list of medical conditions for which a practitioner may order medical cannabis for a patient.
    - While nearly every state has a list of medical conditions, the particular conditions vary from state to state. Most states also include a way to expand the list either by allowing a state agency or board to add medical conditions to the list or by including a "catch-all" phrase. Most states require that the patient receive certification from at least one, but often two, physicians designating that the patient has a qualifying condition.
- Provisions allowing the patient to designate one or more caregivers who can possess the medical cannabis and assist the patient in preparing and using the medical cannabis.
- Provisions specifying the number of caregivers allowed and the qualifications to become a caregiver. Most states allow one or two caregivers, require that they be at least 21, and prohibit the caregiver from being the patient's physician. Caregivers are generally allowed to purchase or grow cannabis for the patient, be in possession of a specified quantity of cannabis, and aid the patient in using cannabis, but are strictly prohibited from using cannabis themselves.
- A requirement that the patient or caregiver have an ID card, typically issued by a state agency.
- The creation of a registry of people who have been issued an identification card.
- A method for registered patients and caregivers to obtain medical cannabis.
    - There are two general methods by which patients can obtain medical cannabis. They must either self-cultivate the cannabis in their homes, or buy cannabis from specified points of sale or dispensaries. Regulations governing such dispensaries vary widely.
- General restrictions on where medical cannabis may be used.
    - Typically, medical cannabis 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.

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[30] 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.
[31] s. 381.986(7), F.S.
[32] s. 381.985(5)(a), F.S.
[33] s. 381.986(2)(c), F.S.
[34] s. 381.985(5)(a), F.S.
[35] 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. http://www.ncsl.org/issues-research/health/state-medical-marijuana-laws.aspx (last visited on Nov. 18, 2016).

Interaction of State Medical Marijuana Laws with Federal Law

The Federal Controlled Substances Act[36] lists cannabis as a Schedule 1 drug with no accepted medical uses.[37] Like the Florida's Drug Control Act, the Federal Controlled Substances Act imposes penalties on those who possess, sell, distribute, etc. cannabis.[38] A first misdemeanor offense for possession of cannabis in any amount can result in a $1,000 fine and up to year in prison, climbing for subsequent offenses to as much as $5,000 and three years.[39] Selling and cultivating cannabis are subject to even greater penalties.[40]

Although state medical cannabis laws protect patients from prosecution for the legitimate use of cannabis under the guidelines established in that state, such laws do not protect individuals from prosecution under federal law should the federal government choose to enforce those laws. in recent years, however, the federal government appears to have softened its stance on cannabis.

In August of 2013, the United States Justice Department (USDOJ) issued a publication entitled "Smart on Crime: Reforming the Criminal Justice System for the 21st Century." [41] This document details the federal government's changing stance on low-level drug crimes announcing a "change in Department of Justice charging policies so that certain people who have committed low-level, nonviolent drug offenses, who have no ties to large-scale organizations, gangs, or cartels will no longer be charged with offenses that impose draconian mandatory minimum sentences. Under the revised policy, these people would instead receive sentences better suited to their individual conduct rather than excessive prison terms more appropriate for violent criminals or drug kingpins."[42]

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.[43] 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.[44] 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.[45] 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.[46]

[36] 21 U.S.C. ss. 801-971.
[37] 21 U.S.C. s. 812.
[38] 21 U.S.C. ss. 841-65.
[39] 21 U.S.C. s. 844.
[40] 21 U.S.C. ss. 841-65.
[41] USDOJ, *Smart on Crime: Reforming the Criminal Justice System for the 21st Century*, http://www.justice.gov/ag/smart-on-crime.pdf. (last visited on Nov. 15, 2015).
[42] *Id*.
[43] *See* USDOJ memo on "Guidance Regarding Marijuana Enforcement," August 29, 2014, http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf (last visited on Nov. 15, 2015).
[44] *Id*.
[45] *Id*.
[46] *Id*.

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.[47] 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.[48]

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."[49] The eligible patient's treating 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.[50]

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.[51]

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.[52] The eligible patient may be required to pay the costs of, or associated with, the manufacture of the investigational drug, biological product, or device.[53] The RTTA allows, but does not require, a health plan, third-party administrator, or governmental agency to cover the cost of an

[47] s. 499.0295(1)-(3), F.S.
[48] s. 499.0295(3) and (7), F.S.
[49] s. 499.0295(2)(c), F.S.
[50] s. 499.0295(2)(a), F.S.
[51] s. 499.0295(2)(d), F.S.
[52] s. 499.0295(3), F.S.
[53] *Id.*

investigational drug, biological product, or device.[54] 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.[55]

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.[56]

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.[57]

Effect of Bill

The bill amends the definition of "investigational drug, biological product, or device" set forth in the RTTA to include cannabis that is manufactured and sold by a dispensing organization licensed under the CMCA.

The bill further specifies that, notwithstanding the state's laws criminalizing the non-medical use of cannabis:

- Eligible patients under the RTTA or their legal representatives may purchase cannabis from a dispensing organization and may possess such cannabis for the patient's medical use.
- Dispensing organizations and their owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of cannabis and are not subject to licensing and regulation by the Board of Pharmacy under ch. 465, F.S.

The bill specifies that the terms "manufacture,"[58] "possession,"[59] "deliver,"[60] "distribute,"[61] and "dispense"[62] are defined as provided in s. 893.02, F.S. The bill also specifies that the RTTA does not impair the license of an approved dispensing organization under the CMCA.

B. SECTION DIRECTORY:

Section 1. Amends s. 499.0295, F.S., relating to experimental treatments for terminal conditions.

Section 2. Provides an effective date of July 1, 2016.

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[54] s. 499.0295(4) and (9), F.S.
[55] s. 499.0295(6), F.S.
[56] s. 499.0295(7), F.S.
[57] s. 499.0295(8), F.S.
[58] Section 893.02(15)(a), F.S., provides that "manufacture" means "the production, preparation, propagation, compounding, cultivating, growing, conversion, or processing of a controlled substance, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation, compounding, packaging, or labeling of a controlled substance by: 1. A practitioner or pharmacist as an incident to his or her administering or delivering of a controlled substance in the course of his or her professional practice. 2. A practitioner, or by his or her authorized agent under the practitioner's supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis, and not for sale."
[59] Section 893.02(19), F.S., provides that "possession" includes "temporary possession for the purpose of verification or testing, irrespective of dominion or control."
[60] Section 893.02(6), F.S., provides that "deliver" or "delivery" means "the actual, constructive, or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship."
[61] Section 893.02(8), F.S., provides that "distribute" means "to deliver, other than by administering or dispensing, a controlled substance."
[62] Section 893.02(7), F.S., provides that "dispense" means "the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer thereof or to one who represents that it is his or her intention not to consume or use the same but to transfer the same to the ultimate consumer or user for consumption by the ultimate consumer or user."

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill does not have an impact on state government 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.[63] Current budget authority and revenues are adequate to absorb any additional workload the bill may cause.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

The bill does not have an impact on local government revenues.

2. Expenditures:

The bill does not have an impact on local government expenditures.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

None.

2. Other:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

[63] See Specific Appropriation 469A, pg. 101, Ch. 2015-232, Laws of Florida (2015).

B. RULE-MAKING AUTHORITY:

The bill does not provide rulemaking authority for DOH.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill refers to the licensure of dispensing organizations under the CMCA; however, the CMCA refers to the "approval," rather than "licensure," of dispensing organizations by the DOH.

The bill authorizes eligible patients to purchase "cannabis" from a dispensing organization licensed under the CMCA. Such dispensing organizations, however, are only authorized to manufacture, possess, sell, and dispense "low-THC cannabis." If the intent of the bill is to only authorize "low-thc cannabis" for "eligible patients" under the RTTA, the bill should be amended to use the term "low-thc cannabis." If the intent is to permit dispensing organizations to manufacture, possess, sell, and dispense any type of cannabis, it may be desirable for the bill to also amend provisions in the CMCA to ensure that dispensing organizations have the technical and technological ability to produce all forms of cannabis and that DOH is authorized to regulate such production and distribution by dispensing organizations.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On November 17, 2016, the Criminal Justice Subcommittee adopted a substitute amendment and reported the bill favorable as a committee substitute. This amendment defines the term "dispensing organization," requires DOH to approve 20 dispensing organizations by October 1, 2016, and authorizes DOH to adopt rules.

On February 8, 2016, the Health Care Appropriations Subcommittee adopted a strike-all amendment, which removed the approval of 20 new dispensing organizations and removed the authority for DOH to adopt rules.

The bill was reported favorably as a committee substitute. This analysis is drafted to the committee substitute as passed by the Health Care Appropriations Subcommittee.