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 Committee on Fiscal Policy

BILL:	SB 460
INTRODUCER:	Senators Bradley and Soto
SUBJECT:	Experimental Treatments for Terminal Conditions
DATE:	January 19, 2016
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Favorable**
2.	Clodfelter	Sadberry	ACJ	**Recommend: Favorable**
3.	Pace	Hrdlicka	FP	**Pre-meeting**

I. Summary:

SB 460 amends the Right to Try Act to include cannabis that is sold and manufactured by an approved dispensing organization in the definition of "investigational drug, biological product, or device."

Under the bill, an eligible patient and the eligible patient's legal representative may purchase and possess cannabis for the patient's medical use and an approved DO and its owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of cannabis so long as the requirements of the Right to Try Act are met. Such persons are exempt from criminal penalties under ch. 893, F.S., and other laws. Further, an approved DO is exempt from the requirements of s. 381.986, F.S., and the DO and its owners, managers, and employees are not subject to licensure or regulation under ch. 465, F.S.

An eligible patient and his or her legal representative may only obtain the cannabis from a DO approved under s. 381.986, F.S. The bill provides that the Right to Try Act does not impair the license of an approved DO under s. 381.986, F.S.

The bill may result in increased sales tax revenue from new sales of medical cannabis that would be generated under the provisions of the bill. However, it is likely that the fiscal impact would be insignificant due to eligibility restrictions in the Right to Try Act.

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,"[1] and places it, along with other sources of THC, on the list of Schedule I controlled substances.[2] 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.[3] As a Schedule I controlled substance, possession and trafficking of cannabis carry criminal penalties that vary from a first degree misdemeanor[4] up to a first degree felony with a mandatory minimum sentence of 15 years in state prison and a $200,000 fine.[5] Paraphernalia[6] 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.[7]

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

Patient Treatment with Low-THC Cannabis

The Compassionate Medical Cannabis Act of 2014[8] (act) legalized a low tetrahydrocannabinol (THC) and high cannabidiol (CBD) form of cannabis (low-THC cannabis)[9] for medical use[10] 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[11] 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

[1] Section 893.02(3), F.S.
[2] Section 893.03(1)(c)7. and 37., F.S.
[3] Section 893.03(1), F.S.
[4] 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.
[5] Trafficking in more than 25 pounds, or 300 plants, of cannabis is a first degree felony with a mandatory minimum sentence that varies from 3 to 15 years in state prison depending on the quantity of the cannabis possessed, sold, etc. *See* s. 893.135(1)(a), F.S.
[6] Section 893.145, F.S.
[7] Section 893.147, F.S.
[8] Chapter 2014-157, L.O.F., and s. 381.986, F.S.
[9] 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.
[10] 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.
[11] 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.

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;
- The physician determines that the risks of ordering low-THC cannabis are reasonable in light of the potential benefit for that patient;[12]
- 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.[13]

The act creates exceptions to existing law to allow qualified patients[14] 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. DOs and their owners, managers, and employees are not subject to licensure and regulation under ch. 465, F.S., relating to pharmacies.[15]

Dispensing Organizations under the Act

On November 23, 2015, the Department of Health (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.[16] 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 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. Applicants are also required to demonstrate:

- The technical and technological ability to cultivate and produce low-THC cannabis;

[12] 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.
[13] Section 381.986(2), F.S.
[14] 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, F.S., or ch. 459, F.S., to the compassionate use registry to receive low-THC cannabis from a DO.
[15] Section 381.986(7), F.S.
[16] 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/_media/ocu/compassionate-dispensing-org-map.pdf (last visited Jan. 14, 2016).

- 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 department;
- The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department;
- 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 and have successfully completed a course and examination that encompasses appropriate safety procedures and knowledge of low-THC cannabis.[17]

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.[18] An approved DO must maintain all approval criteria at all times.[19]

Beginning on July 7, 2014, the DOH held several rule workshops[20] 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.[21] 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.[22] 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.[23] 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 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.[24] The rules took effect June 17, 2015, and the DOH held an application period for DO approval which ended on July 8, 2015. The five approved DOs were selected from 28 applications that were submitted.[25]

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[17] *Id.*
[18] *Id.*
[19] Section 381.986(6), F.S.
[20] An audio recording of the rule development workshops is available on the DOH website at: http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/rulemaking/index.html (last visited Jan. 14, 2016).
[21] Proposed Rule ch. 64-4, F.A.C., ID 14941024, (Aug. 14, 2014) and changed, ID 15040352, (Sept. 9, 2014).
[22] 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.
[23] Proposed Rule ch. 64-4, ID 15645147, (Feb. 2, 2015).
[24] Baywood Nurseries Co., Inc. v. DOH, Case No. 15-1694RP (Fla. DOAH 2015).
[25] Information about the applications and the approved DOs is available on the DOH, Office of Compassionate Use, Resources website, available at: http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/resources/index.html (last visited Jan. 18, 2016).

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.[26] 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. DOs are also required to record in the registry the date, time, quantity, and form of low-THC cannabis dispensed.[27] The DOH has indicated that the registry is built and ready to move to the operational phase.[28]

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.[29] 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;[30]
- Making any necessary application to the United States 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.[31]

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;[32]
- 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;[33] and
- Appropriating $1 million to the James and Esther King Biomedical Research Program for research on cannabidiol and its effects on intractable childhood epilepsy.[34]

[26] Section 381.986(5)(a), F.S.
[27] Section 381.986(6), F.S.
[28] Conversation of Health Policy Committee staff with Jennifer Tschetter, Chief of Staff (DOH) (March 20, 2015).
[29] Section 385.212, F.S.
[30] *See* s. 381.925, F.S.
[31] Section 385.212, F.S.
[32] Section 381.986(2)(e), F.S.
[33] Section 385.211, F.S.
[34] Chapter 2014-157, L.O.F.

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 that "section 893.03 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.[35]

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, 23 states, the District of Columbia, and Guam have some form of law that permits the use of marijuana for medicinal purposes.[36] These laws vary widely in detail but most are similar in that they touch on several recurring themes. 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.[37]

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 law-THC cannabis differs from state to state. The THC level allowed range from as high as below 5 percent to less than 0.3 percent; most states restrict the level of THC to below 1 percent. CBD levels are generally required to be high, with most states requiring at least 10 percent.[38]

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

[36] 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 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*, (Jan. 8, 2016), available at: http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (last visited Jan. 13, 2016).

[37] Analysis by Senate Health Policy committee staff of s*upra* note 36.

[38] *Supra* note 36.

Interaction with the Federal Government

The Federal Controlled Substances Act lists marijuana as a Schedule 1 drug and provides no exceptions for medical uses.[39] Possession, manufacture, and distribution of marijuana is a crime under federal law.[40] Although a state's medical marijuana laws protect patients from prosecution for the legitimate use of marijuana under state law, state medical marijuana laws do not protect individuals from prosecution under federal law.

In 2013, the United States 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…"[41] 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.[42] 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.[43]

The Florida Right to Try Act

Section 499.0295, F.S., creates the Right to Try Act which allows drug manufacturers to make investigational drugs, biological products, or devices[44] (experimental treatment) available to an eligible patient (with or without compensation). The Right to Try Act defines an "eligible patient" as a person who meets all of the following requirements:

- Has a terminal condition[45] attested to by that patient's physician and confirmed by a second independent specialist physician;

[39] 21 U.S.C. s. 812

[40] 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.

[41] 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 Jan. 13, 2016).

[42] USDOJ Memorandum for all U.S. Attorneys, *"Guidance Regarding Marijuana Enforcement,"* (August 29, 2013), available at: http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf (last visited Jan. 13, 2016).

[43] *See* s. 542, Pub. L. No. 114-113 (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 Jan. 13, 2016).

[44] Section 499.0295(2)(b), F.S. defines "investigational drug, biological product, or device" as a drug, biological product, or device that has successfully completed phase 1 of a clinical trial but has not been approved for general use by the FDA and remains under investigation in a clinical trial approved by the FDA.

[45] Section 499.0295(2)(c), F.S. defines "terminal condition" 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

- Has considered all other treatment options for that condition currently approved by the FDA;
- Has given written informed consent for the use of an experimental treatment, which must include:
  - An explanation of the currently approved products and treatment for the patient's condition;
  - An attestation that the patient concurs 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 experimental treatment the patient is seeking to use;
  - A realistic description of the most likely outcomes of using the experimental treatment;
  - A statement that the patient's health plan or third-party administrator and physician are not obligated to pay for care or treatment consequent to the use of the experimental treatment unless required to do so by law or contract;
  - A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins such treatment and that hospice care may be reinstated once the treatment ends if the patient meets hospice eligibility requirements; and
  - A statement that the patient understands that he or she is liable for all expenses consequent to the use of the experimental treatment and that the liability extends to the patient's estate unless otherwise stated in the contract;[46]
- Has documentation from his or her treating physician that the patient meets the above requirements.[47]

The Right to Try Act prescribes how the eligible patient's use of the experimental treatment may impact certain third parties including that:

- A health plan, third party administrator, or governmental agency may, but is not required to, provide coverage for the costs of such treatment;[48]
- A hospital or health care facility is not required to provide new or additional services unless such services are approved by that hospital or health care facility;[49]
- The patient's heirs are not liable for any outstanding debt related to the patient's use of such treatment if the patient dies while undergoing such treatment;[50]
- A licensing board and a state entity responsible for Medicare certification may not revoke, fail to renew, suspend, or take other action against a physician's license based solely on the physician's recommendations to an eligible patient regarding access to treatment under the Right to Try Act;[51] and
- The Right to Try Act does not create a private cause of action:
  - Against the manufacturer of the experimental treatment;
  - Against a person or entity involved in the care of an eligible patient who is using the experimental treatment; or

administration of available treatment options currently approved by FDA, and, without the administration of life-sustaining procedures, will result in death within 1 year after diagnosis if the condition runs its normal course.

[46] Section 499.0295(2)(d), F.S.
[47] Section 499.0295(2)(a), F.S.
[48] Section 499.0295(4), F.S.
[49] Section 499.029(5), F.S.
[50] Section 499.0295(6), F.S.
[51] Section 499.0295(7), F.S.

- For any harm to the patient that is the result of the use of the experimental treatment if the manufacturer or other person or entity complies in good faith with the terms of Right to Try Act and exercises reasonable care.[52]

III. Effect of Proposed Changes:

SB 460 amends the Right to Try Act to include cannabis that is sold and manufactured by an approved dispensing organization (DO) as defined in s. 381.986, F.S., in the definition of "investigational drug, biological product, or device."

Under the bill, an eligible patient and the eligible patient's legal representative may purchase and possess cannabis for the patient's medical use and an approved DO and its owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of cannabis so long as the requirements of the Right to Try Act are met. Such persons are exempt from criminal penalties under ch. 893, F.S., and other laws.[53] Further, an approved DO is exempt from the requirements of s. 381.986, F.S., and the DO and its owners, managers, and employees are not subject to licensure or regulation under ch. 465, F.S.[54]

An eligible patient and his or her legal representative may only obtain the cannabis from a DO approved under s. 381.986, F.S. The bill provides that the Right to Try Act does not impair the license of an approved DO under s. 381.986, F.S.

The bill takes effect on July 1, 2016.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

[52] Section 499.0295(8), F.S.
[53] Chapter 893, F.S., is the Florida Comprehensive Drug Abuse Prevention and Control Act. Specifically, the bill exempts patients from s. 893.13, F.S., related to unauthorized selling, purchasing, manufacturing, and possessing of controlled substances; s. 893.135, F.S., related to trafficking in controlled substances; and s. 893.147, F.S., related to the use, manufacture, possession, and sale of drug paraphernalia.
[54] Chapter 465, F.S., is the Florida Pharmacy Act.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The state may see increased sales tax revenue from new sales of medical cannabis that would be generated under the provisions of the bill. However, it is likely that the fiscal impact would be insignificant due to eligibility restrictions in the Right to Try Act.

B. Private Sector Impact:

SB 460 may have a positive fiscal impact on approved dispensing organizations that may see new sales generated by an increased number of patients to whom they may sell medical cannabis.

C. Government Sector Impact:

See Tax/Fee Issues.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill is silent on the regulatory authority of the DOH to develop rules to regulate activities of dispensing organizations for activities that are authorized under the bill. The regulatory framework created by the Compassionate Medical Cannabis Act under s. 381.986, F.S., may not be adequate to prevent or deter diversion of cannabis that is authorized to be manufactured by this bill.

Additionally, the bill exempts dispensing organizations from licensing and regulation under ch. 465, F.S., relating to pharmacy, but does not specifically exempt the dispensing organizations from regulation under ch. 499, F.S., related to the manufacturing of drugs, devices, and cosmetics. Since the bill makes changes in ch. 499, F.S., it may be advisable to also specifically exempt dispensing organizations from regulation under that chapter.

VIII. Statutes Affected:

This bill substantially amends section 499.0295 of the Florida Statutes.

IX. Additional Information:

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

None.

B. Amendments:

None.