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 Criminal and Civil Justice

BILL:	SB 460
INTRODUCER:	Senators Bradley and Soto
SUBJECT:	Experimental Treatments for Terminal Conditions
DATE:	December 3, 2015 REVISED:

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

I. Summary:

SB 460 amends the Right to Try Act[1] to include cannabis that is sold and manufactured by an approved dispensing organization[2] in the definition of "investigational drug, biological product, or device."

The bill exempts eligible patients[3] and their legal representatives from criminal penalties under chapter 893, Florida Statutes,[4] as well as from any other section of law, but subject to the requirements in the bill, for the purchase and possession of cannabis for the patient's medical use with the requirement that the cannabis must be obtained from an approved dispensing organization. The bill also exempts approved dispensing organizations, as well as their owners, managers, and employees from the requirements of the Compassionate Medical Cannabis Act of 2014;[5] from criminal penalties under ch. 893, F.S.;[6] from licensure and regulation under ch. 465, F.S.;[7] and from any other section of law, but subject to the requirements in the bill, for manufacturing, possessing, selling, delivering, distributing, dispensing, and lawfully disposing of cannabis.

The bill states that its provisions do not impair the license of an approved dispensing organization under s. 381.986, F.S., relating to the compassionate use of low-THC Cannabis.

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[1] Section 499.0295, F.S.
[2] As defined in s. 381.986, F.S., relating to the compassionate use of low-THC cannabis.
[3] See the description of the Right to Try Act on pp. 7-8 for a definition of "eligible patient."
[4] Ch. 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.
[5] Ch. 2014-157, L.O.F., and more specifically the portion of the Act codified in s. 381.986, F.S.
[6] See supra n. 4.
[7] Ch. 465, F.S., is the Florida Pharmacy Act.

SB 460 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.

The bill has an effective date of July 1, 2016.

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,"[8] and places it, along with other sources of THC, on the list of Schedule I controlled substances.[9] 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. As a Schedule I controlled substance, possession and trafficking of cannabis carry criminal penalties that vary from a first degree misdemeanor[10] up to a first degree felony with a mandatory minimum sentence of 15 years in state prison and a $200,000 fine.[11] Paraphernalia[12] 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.[13]

[8] Section 893.02(3), F.S.
[9] Section 893.03(1)(c)7. and 37., F.S.
[10] 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.
[11] 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.
[12] This term is defined in s. 893.145, F.S.
[13] Section 893.147, F.S.

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

Patient Treatment with Low-THC Cannabis

The Compassionate Medical Cannabis Act of 2014[14] (act) legalized a low tetrahydrocannabinol (THC) and high cannabidiol (CBD) form of cannabis (low-THC cannabis)[15] for medical use[16] 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[17] 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 to meet the requirements of the act 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;[18]
- 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.

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[14] *See* ch. 2014-157, L.O.F., and s. 381.986, F.S.

[15] The act defines "low-THC cannabis," as the dried flowers of the plant *Cannabis* which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight, or the seeds, resin, or any compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. *See* s. 381.986(1)(b), F.S. Seventeen states allow limited access to marijuana products (low-THC and/or high CBD-cannabidiol): Alabama, Florida, Georgia, Louisiana, Iowa, Kentucky, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming. Twenty-three states, the District of Columbia, and Guam have laws that permit the use of marijuana for medicinal purposes. See infra note 24. *See* http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (Tables 1 and 2), (last visited on Nov. 30, 2015).

[16] Pursuant to s. 381.986(1)(c), F.S., "medical use" means 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.

[17] 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.

[18] 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.

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. DOs and their owners, managers, and employees are not subject to licensure and regulation under ch. 465, F.S., relating to pharmacies.[20]

Dispensing Organizations

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.[21] 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. Applicants are also 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 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.[22]

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.[23] An approved DO must also maintain all approval criteria at all times.

Beginning on July 7, 2014, the DOH held several rule workshops 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. 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

[19] *See* s. 381.986(1)(d), F.S., which 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 DO.
[20] *See* s. 381.986(7)(c), F.S.
[21] *See* s. 381.986(5)(b), F.S.
[22] Id.
[23] Id.

by an administrative law judge on November 14, 2014. 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. The new proposed rule was also challenged on, among other things, the DOH's statement of estimated regulatory costs (SERC) 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. 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.

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. 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. The DOH has indicated that the registry is built and ready to move to the operational phase.[24]

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

The act requires the DOH to establish the Office of Compassionate Use under the direction of the deputy state health officer to administer the act. 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.[25]
- Making any necessary application to the United States Food and Drug Administration 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.[26]

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;
- 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; and

[24] Conversation with Jennifer Tschetter, Chief of Staff (DOH) (March 20, 2015).
[25] *See* s. 381.925, F.S.
[26] *See* s. 385.212, F.S.

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

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*[27] 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.

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[28] have some form of law that permits the use of marijuana for medicinal purposes. These laws vary widely in detail but most are similar in that they touch on several recurring themes. Most state laws include the following in some form:

- A list of medical conditions for which a practitioner can recommend the use of medical marijuana to a patient.
    - Nearly every state that permits the use of marijuana for medicinal purposes has a list of applicable medical conditions, though 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.[29] Most states require that the patient receive certification from at least one, but often two, physicians designating that the patient has a qualifying condition before the patient may be issued an identification card needed for the acquisition of medical marijuana.

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

[28] 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. The New York legislation became effective July 5, 2014. Seventeen states allow limited access to marijuana products (low-THC and/or high CBD-cannabidiol). Alabama, Florida, Georgia, Louisiana, Iowa, Kentucky, Mississippi, Missouri, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Utah, Virginia, Wisconsin, and Wyoming. *See* http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx (last visited on Nov. 30, 2015).

[29] An example is California's law that includes "any other chronic or persistent medical symptom that either: Substantially limits the ability of the person to conduct one or more major life activities as defined in the Americans with Disabilities Act of 1990, or if not alleviated, may cause serious harm to the patient's safety or physical or mental health."

- Provisions for the patient to designate one or more caregivers who can possess the medical marijuana and assist the patient in preparing and using the medical marijuana.
  - The number of caregivers allowed and the qualifications to become a caregiver vary from state to state. Most states allow one or two caregivers and require that they be at least 21 years of age and, typically, cannot be the patient's physician. Caregivers are generally allowed to purchase or grow marijuana for the patient, be in possession of the allowed quantity of marijuana, and aid the patient in using the marijuana, but are strictly prohibited from using the marijuana themselves.
- A required identification card for the patient, caregiver, or both that is typically issued by a state agency.
- A registry of people who have been issued an identification card.
- A method for registered patients and caregivers to obtain medical marijuana.
  - There are two general methods by which patients can obtain medical marijuana. They must either self-cultivate the marijuana in their homes or the state allows specified marijuana points-of-sale or dispensaries. The regulations governing such dispensaries vary widely.
- General restrictions on where medical marijuana may be used.
  - Typically, medical marijuana 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.

Most states with low-THC cannabis laws similar to s. 381.986, F.S., specify that the use of such low-THC cannabis is reserved for patients with epileptic or seizure disorders. Of the 11 states with such laws, only Florida allows the treatment of cancer with low-THC cannabis. Additionally, the definition of low-THC cannabis differs from state to state. Iowa has the highest THC level allowed in such states at 3 percent and most other states have the level of THC restricted to below 1 percent. CBD levels are generally required to be high with most states requiring at least 10 percent CBD.[30]

State Medical Marijuana Laws and Their Interaction with the Federal Government

The Federal Controlled Substances Act lists Marijuana as a Schedule 1 drug with no accepted medical uses. Possession, manufacture, and distribution of marijuana is a crime under federal law.[31] Although a state's medical marijuana laws protect patients from prosecution for the legitimate use of marijuana under the guidelines established in that state, such laws do not protect individuals from prosecution under federal law if the federal government decides to enforce those laws.

In August 2013, the United States Justice Department (USDOJ) issued a publication entitled "Smart on Crime: Reforming the Criminal Justice System for the 21st Century."[32] This document details the federal government's current stance on low-level drug crimes and contains the following passage:

[30] Supra note 28, table 2.
[31] The punishments vary depending on the amount of marijuana and the intent with which the marijuana is possessed. *See* http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm#cntlsbd (last visited on Nov. 30, 2015).
[32] *See* http://www.justice.gov/ag/smart-on-crime.pdf (last visited on Nov. 30, 2015).

> … the Attorney General is 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.

In addition, the USDOJ published, on August 29, 2013, a memorandum with the subject "Guidance Regarding Marijuana Enforcement." This memorandum makes clear that the United States Department of Justice (USDOJ) considers small-scale marijuana use to be a state matter which states may choose to punish or not, and, while larger operations would fall into the purview of the USDOJ, those operations that adhere to state laws legalizing marijuana in conjunction with robust regulatory systems would be far less likely to come under federal scrutiny.[33] These announcements generally indicate the USDOJ's current unwillingness to prosecute such cases and its inclination to leave such prosecutions largely up to state authorities. In addition, a rider in recent appropriations acts and continuing resolutions has prohibited USDOJ from using appropriated funds to prevent specified states (including Florida) from implementing their own medical marijuana laws.[34]

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[35] 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[36] attested to by that patient's physician and confirmed by a second independent specialist physician;
- Has considered all other treatment options for that condition approved by the United States Food and Drug Administration (FDA);

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[33] *See* USDOJ memo on "Guidance Regarding Marijuana Enforcement," (August 29, 2013) *available at* http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf (last visited on Nov. 30, 2015).

[34] A recent order by a judge of the United States District Court for the Northern District of California rejected USDOJ's position that the Rohrabacher-Farr amendment to the Consolidated and Further Continuing Appropriations Act of 2015 (Section 538, Pub. L. 113-235, 128 Stat. 2130 (2014)) does not prohibit USDOJ from enforcing violations of federal marijuana laws by individuals or private businesses who are complying with state medical marijuana laws in the specified states. (Order unreported but available at http://www.scribd.com/doc/286089509/US-vs-Marin-Alliance-for-Medical-Marijuana#scribd (last visited on November 30, 2015)). The amendment is included in the current federal appropriations act that is effective until December 11, 2015.

[35] "Investigational drug, biological product, or device" is defined 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 United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.

[36] "Terminal Condition" 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 1 year after diagnosis if the condition runs its normal course.

- Has given written informed consent for the use of an investigational drug, biological product, or device 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 investigational drug, biological product, or device the patient is seeking to use;
  - A realistic description of the most likely outcomes of using the investigational drug, biological product or device;
  - 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 investigational drug, biological product, or device 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 investigational drug, biological product, or device and that the liability extends to the patient's estate unless otherwise stated in the contract;
- Has documentation from his or her treating physician that the patient meets the above requirements.

The Right to Try Act also details how the eligible patient's use of the investigational drug, biological product, or device may impact certain third parties including stating that:

- A health plan, third party administrator, or governmental agency may, but is not required to, provide coverage for the costs of such treatment;
- 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;
- 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;
- 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;
- The Right to Try Act does not create a private cause of action:
  - Against the manufacturer of the investigational drug, biological product, or device;
  - Against a person or entity involved in the care of an eligible patient who is using the investigational drug, biological product, or device; or
  - For any harm to the patient that is the result of the use of the investigational drug, biological product, or device if the manufacturer or other person or entity complies in good faith with the terms of Right to Try Act and exercises reasonable care.

III. Effect of Proposed Changes:

SB 460 amends the Right to Try Act[37] to include cannabis that is sold and manufactured by an approved dispensing organization[38] in the definition of "investigational drug, biological product, or device."

The bill exempts eligible patients[39] and their legal representatives from criminal penalties under ch. 893, F.S.,[40] as well as from any other section of law, but subject to the requirements in the bill, for the purchase and possession of cannabis for the patient's medical use with the requirement that the cannabis must be obtained from an approved dispensing organization. The bill also exempts approved dispensing organizations, as well as their owners, managers, and employees from the requirements of the Compassionate Medical Cannabis Act of 2014;[41] from criminal penalties under ch. 893, F.S.;[42] from licensure and regulation under ch. 465, F.S.;[43] and from any other section of law, but subject to the requirements in the bill, for manufacturing, possessing, selling, delivering, distributing, dispensing, and lawfully disposing of cannabis.

The bill states that its provisions do not impair the license of an approved dispensing organization under s. 381.986, F.S.

The provisions of the bill take 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.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

[37] Section 499.0295, F.S.
[38] As defined in s. 381.986, F.S.
[39] See the description of the Right to Try Act on pp. 7-8 for a definition of "eligible patient."
[40] See supra n. 4.
[41] Ch. 2014-157, L.O.F., and more specifically s. 381.986, F.S.
[42] See supra n. 4.
[43] Ch. 465, F.S., is the Florida Pharmacy 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:

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.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill is silent on the regulatory authority of the DOH to develop rules for oversight to regulate activities of dispensing organizations for activities that are authorized under this act. 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 that cannabis that is authorized to be manufactured by this act.

Additionally, the act 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 act 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.