

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 Education

BILL: SB 1472

INTRODUCER: Senator Galvano

SUBJECT: Medicinal Cannabis Research and Education

DATE: March 24, 2017

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Androff	Graf	ED	Pre-meeting
2.			AHS	
3.			AP	

I. Summary:

SB 1472 creates the Medicinal Cannabis Research and Education Act. Specifically, the bill:

- Establishes the Coalition for Medicinal Cannabis Research and Education (Coalition), within the H. Lee Moffitt Cancer Center and Research Institute, Inc. (MCCRI) and specifies the Coalition’s purpose, duties and administration;
- Creates the Medicinal Cannabis Research and Education Board (Board) to direct the Coalition’s operations, annually adopt the Medicinal Cannabis Research and Education Plan (Plan), and annually report to the Governor and Legislature;
- Installs a Coalition director to fulfill certain Board-specified duties; and
- Requires the MCCRI to allocate staff, information and assistance to assist the Board.

The bill takes effect July 1, 2017.

II. Present Situation:

In 2014,¹ the Legislature enacted the Compassionate Medical Cannabis Act (CMCA), which authorizes dispensing organizations (DO) approved by the Florida Department of Health (DOH) to manufacture, possess, sell, and dispense low-THC cannabis for medical use by patients suffering from cancer or a condition that chronically produces symptoms of seizures or several and persistent muscle spasms.² In 2015,³ the Legislature enacted the Right to Try Act (RTTA), which authorizes an eligible patient with a terminal condition to receive an investigational drug, biological product, or device, but did not address cannabis.⁴ In 2016,⁵ the Legislature passed

¹ Chapter 2014-157, L.O.F.

² Section 381.986, F.S.

³ Chapter 2015-107, L.O.F.

⁴ Section 499.0295, F.S.

⁵ Chapter 2016-123, L.O.F.

legislation that allows a patient with a terminal condition to use “medical cannabis” under the RTTA.⁶

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

The CMCA required the DOH to establish the Office of Compassionate Use (Office) under the direction of the deputy state health officer to administer the CMCA.⁷ The Office is authorized to enhance access to investigational new drugs for Florida patients through approved clinical treatment plans or studies by:⁸

- 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;⁹
- Completing any necessary application to the United States Food and Drug Administration or 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.

The CMCA included several provisions related to research on low-THC cannabis and cannabidiol including:¹⁰

- Requiring physicians to submit quarterly patient treatment plans to the University of Florida College of Pharmacy (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 certain laws for such research purposes;
- Appropriating \$1 million to the James and Esther King Biomedical Research Program for research on cannabidiol and its effects on intractable childhood epilepsy.¹¹

The H. Lee Moffitt Cancer Center and Research Institute

The H. Lee Moffitt Cancer Center and Research Institute (MCCRI) at the University of South Florida (USF) is established as a statewide resource for basic and clinical research and multidisciplinary approaches to patient care.¹²

The sole mission of the MCCRI is to contribute to the prevention and cure of cancer.¹³ In 1999, the Moffitt Affiliate Network was established to further enhance the MCCRI’s ability to serve Florida communities by providing tertiary care, clinical trials, medical education, and community education and screening. This affiliate network consists of 14 hospitals located in Florida, one

⁶ Section 381.986, F.S.

⁷ Section 358.212, F.S.

⁸ *Id.*

⁹ *See s.* 381.925, F.S.

¹⁰ Section 381.986(b)(2)(e), F.S.

¹¹ Chapter 2014-157, L.O.F.

¹² Section 1004.43, F.S.

¹³ *See* Moffitt Cancer Center, <https://moffitt.org/> (last visited Mar 24, 2017); Moffitt Cancer Center, *Affiliate Hospitals*, <http://www.moffitt.org/Site.aspx?spid=5CE54FA5D8EE4D27A5BD6C496C99028D> (last visited Mar 24, 2017); Section 1004.43(5)(a), F.S.

hospital in Georgia, one hospital in Pennsylvania, and includes more than 400 community oncologists.¹⁴

The MCCRI is the only cancer research facility headquartered in Florida that is designated as a Comprehensive Cancer Center by the National Cancer Institute (NCI).¹⁵ The Mayo Clinic, which has a presence in Jacksonville, Florida, is also designated by the NCI as a comprehensive Cancer Center in Minnesota. According to the NCI, “the NCI-designated Cancer Centers are one of the anchors of the nation’s cancer research effort.”¹⁶

III. Effect of Proposed Changes:

SB 1472 creates the Medicinal Cannabis Research and Education Act. Specifically, the bill:

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

¹⁴ See Moffitt Cancer Center, *Affiliate Hospitals*, <http://www.moffitt.org/Site.aspx?spid=5CE54FA5D8EE4D27A5BD6C496C99028D> (last visited Mar 24, 2017)

¹⁵ See Moffitt Cancer Center, *Frequently Asked Questions*, <https://www.moffitt.org/about-moffitt/frequently-asked-questions/> (last visited Mar 24, 2017).

¹⁶ See National Cancer Institute, *Mayo Clinic Cancer Center*, <https://www.cancer.gov/research/nci-role/cancer-centers/find/mayoclinic> (last visited Mar 24, 2017).

The bill may increase the amount of data available to support the determination of safe and effective dosages of marijuana for patients seeking relief from pain and other medical symptoms or specific illnesses, including cancer patients, patients suffering from refractory pain, and pediatric patients with refractory epilepsy.

The bill takes effect July 1, 2017.

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.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 1004.4351 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.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
