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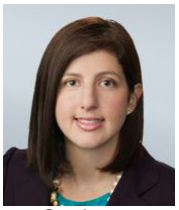
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2016 Update: What Health Care Providers Need to Know Regarding Medical Marijuana in Florida[1]

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Florida has enacted laws permitting Florida licensed physicians to order medical marijuana, in the limited forms of low-THC cannabis and medical cannabis (hereinafter collectively referred to as "medical marijuana"),[3] for their patients in compliance with state laws and regulations.[4] In November, Florida residents will vote on a revised proposed amendment to the Florida Constitution, called Amendment 2, potentially expanding the law regarding medical marijuana in the state. As patient demand for medical marijuana for various physical conditions increases, it is important for health care providers and their counsel to understand the current requirements for ordering and treating qualified patients with low-THC cannabis and medical cannabis. The purpose of this article is to provide an update on the current status of the medical marijuana laws in Florida and clarify what is required of Florida licensed physicians interested in treating qualified patients in compliance therewith. It is necessary to keep in mind that while distinguished technically from the "ordering" of medical marijuana under Florida law, the "prescribing" of medical marijuana remains illegal under federal law.

March 2016 Changes to Florida's Medical Marijuana Laws

Florida law regarding low-THC cannabis dates back only to June of 2014, when Governor Rick Scott signed Senate Bill 1030 into law, thereby enacting The Compassionate Medical Cannabis Act of 2014.[5] At that time, the act established a system to grow, cultivate, distribute, and prescribe certain low-THC strains of medical marijuana (referred to herein, including any amendments thereto, as the "Cannabis Act").[6]

As originally enacted, the statute only decriminalized the use of low-THC cannabis, exclusively in the form of oil or vapor, and specifically excluded administration of the low-THC cannabis by smoking.[7]

The following year, in May of 2015, Governor Rick Scott signed into law Florida's Right to Try Act, allowing eligible, terminally ill patients to access investigational drugs, biologic products or devices that have successfully completed phase 1 of a clinical trial but have yet to receive approval for general use by the Food and Drug Administration (referred to herein, including any amendments thereto, as the "RTTA").[8] At the time the RTTA was enacted, like the Cannabis Act, it did not apply to medical cannabis.

Prior to recent amendments, Florida law only permitted licensed physicians to order *low-THC cannabis*[9] for qualified patients. In March of 2016, Governor Rick Scott signed into law House Bill 307 and House Bill 1313 ("HB307/HB1313") making, for the first time, *medical cannabis*[10] available to terminally ill patients under certain conditions, and thereby also expanding the types of medical marijuana that can be grown and sold in Florida. The amendments also set forth additional regulatory standards about safety and security, labeling, physician ordering qualification criteria, use of independent treating laboratories, and Florida Department of Health ("FDOH") oversight, among other changes, to the preexisting law.

With the enactment of HB307/HB1313, in addition to low-THC cannabis, medical cannabis can be ordered by authorized Florida physicians under the Cannabis Act

for individuals who meet the definition of an "eligible patient" under the RTTA. The term "eligible patient" is defined "as a person who (1) has a terminal condition that is attested to by the patient's physician and confirmed by a second independent evaluation by a board-certified physician in an appropriate specialty for that condition; (2) has considered all other treatment options for the terminal condition currently approved by the United States Food and Drug Administration; (3) has given written informed consent for the use of an investigational drug, biological product, or device; and (4) has documentation from his or her treating physician that the patient meets the requirements of this paragraph."[11] The RTTA then defines "terminal condition" to mean "a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treatment 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." [12] Even as amended, the Cannabis Act and the RTTA prohibit administration of low-THC cannabis or medical cannabis by smoking.

The Cannabis Act and the RTTA set forth particular requirements that a physician in Florida must satisfy before he or she can order low-THC cannabis or medical cannabis for a qualified patient. Notably, physicians licensed under chapters 458 and 459, Florida Statutes, are required to take an 8-hour course and subsequent exam offered by the Florida Medical Association or the Florida Osteopathic Medical Association before ordering low-THC cannabis or medical cannabis for qualified patients.[13] These courses are currently offered by the Florida Medical and Osteopathic Associations and have been completed by 127 physicians as of September 17, 2016. [14] Failure to follow the guidelines established in the Cannabis Act is considered a first-degree misdemeanor, punishable by imprisonment for up to one year or $1,000.00 in fines.[15]

Requirements for Authorized Ordering

Under the Cannabis Act, a qualified physician is authorized to (1) order low-THC cannabis to (a) treat a qualified patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe or persistent muscle spasms; or (b) to alleviate symptoms of such disease, disorder, or condition, if no other satisfactory alternative treatment options exist for the qualified patient; (2) order medical cannabis to treat an eligible patient as defined in the RTTA; or (3) order a cannabis delivery device for the medical use of low-THC cannabis or medical cannabis, but only if the physician:

1. Holds an active, unrestricted Florida license as a physician under chapter 458 or an osteopathic physician under chapter 459 and meet the above described education requirements;

2. Has treated the patient for at least 3 months immediately preceding the patient's registration in the compassionate use registry;

3. Has determined that the risks of treating the patient with low-THC cannabis or medical cannabis are reasonable in light of the potential benefit to the patient. For patients younger than 18 years of age, has obtained concurrence of this determination from a second physician, and such determination is documented in the patient's medical record;

4. Registers as the orderer of low-THC cannabis or medical cannabis for the named patient on the compassionate use registry maintained by the FDOH and updates the registry to reflect the contents of the order, including the amount of low-THC cannabis or medical cannabis that will provide the patient with not more than a 45-day supply and a cannabis delivery device needed by the patient for the medical use of low-THC cannabis or medical cannabis. The physician must also update the registry within 7 days after any change is made to the original order to reflect the change. The physician must deactivate the registration of the patient and the patient's legal representative when treatment is discontinued;

5. 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 or medical cannabis;

6. For low-THC cannabis, submits the patient treatment plan quarterly to the University of Florida College of Pharmacy for research on the safety and efficacy of low-THC cannabis and medical cannabis to patients;

7. For low-THC cannabis, obtains the voluntary written informed consent of the patient or the patient's legal representative to treatment with low-THC cannabis after sufficiently explaining the current state of knowledge in the medical community of the effectiveness of treatment of the patient's condition with low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects;

8. For medical cannabis, obtains written informed consent as defined in and required under the RTTA, if the physician is ordering medical cannabis for an eligible patient pursuant to the RTTA; and

9. Is not a medical director employed by a dispensing organization.

The Office of Compassionate Use and the Compassionate Use Registry

Pursuant to the Cannabis Act, the FDOH was required to and did establish the Office of Compassionate Use ("OCU").[18] The FDOH was also required to create a "compassionate use registry" where ordering physicians are to register qualified patients. Notwithstanding a number of legal challenges, the FDOH and the OCU engaged in the task of rulemaking, with their efforts ultimately culminating in final rules, which became effective on June 17, 2015.[19]

On November 23, 2015, the FDOH approved five dispensing organizations that met the requirements of Florida Statutes, Section 381.986, and Chapter 64-4, of the Florida Administrative Code. In addition to the changes described above, HB307/HB1313 also allows for three additional dispensing organizations to qualify for approval once 250,000 patients register with the compassionate use registry. As of September 17, 2016, there are six approved dispensing organizations. Currently, two of those dispensing organizations, Trulieve in Gadsden County, and Surterra Therapeutics in Hillsborough County, are open for business and have commenced sale and delivery of low-THC cannabis products to registered patients across the state. At this time, medical cannabis is only available through Trulieve, though Surterra expects to begin providing medical cannabis to registered patients later this year.

Amendment 2

In November of 2014, shortly after the Cannabis Act was originally signed into law, Florida voters had the opportunity to vote on a proposed amendment to create a new section 29 to article X of the Florida Constitution, commonly referred to as "Amendment 2." The amendment, which would have expanded the type of medical marijuana available to Floridians, as well as the class of qualified patients, was ultimately defeated. Despite obtaining more than fifty-seven percent of votes in favor of the amendment, the votes fell just shy of the necessary 60 percent required to pass a constitutional amendment in Florida.

Notwithstanding, Florida voters will have another chance to vote on a proposed amendment to create a new section 29 to article X of the Florida Constitution regarding medical marijuana in November 2016. Also referred to as "Amendment 2," the updated proposed amendment similarly strives to broaden the circumstances under which medical marijuana could be ordered for a patient.[20] In contrast to the current laws, Amendment 2 does not specifically prohibit administration of medical marijuana by smoking. However the new proposed amendment is narrower than its 2014 predecessor in that it more narrowly defines a "debilitating medical condition" and requires parental consent for underage patients.

Medical Marijuana Remains Illegal Under Federal Law

Physicians should be aware, and their attorneys should point out,[21] that despite state law decriminalizing certain types and uses of medical marijuana in the state of Florida, marijuana remains illegal in the United States, even for medical use. Thus, under federal law, a physician cannot lawfully prescribe marijuana to a patient.[22] Notably, on August 11, 2016, the U.S. Department of Health and Human Services and the Drug Enforcement Administration denied two petitions seeking to reschedule marijuana under the Controlled Substances Act.[23] Simultaneously, however, the DEA took action to allow for additional medical marijuana research studies by increasing the number of authorized marijuana manufacturers allowed to supply researchers.[24] Changes to the legality of medical marijuana at the federal level are moving at a much slower pace than under state law. Even if physicians and patients in Florida operate in compliance with Florida law, they remain subject to enforcement under federal law.

For now, to ensure compliance with Florida law when ordering low-THC cannabis or medical cannabis for qualified patients, qualified Florida physicians should look to the Cannabis Act and the RTTA, along with Chapter 64-4, of the Florida Administrative Code and any additional regulations that may be enacted. Florida physicians should also keep an eye on the outcome of the impending vote on Amendment 2 in November, which has potential to change the framework of Florida's current medical marijuana law and lead to the creation of additional legislation.

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[3] Under Florida law, "medical 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 that is dispensed only from a dispensing organization for medical use by an eligible patient as defined in Florida Statutes. Florida law defines "low-THC" cannabis as a plant of the genus Cannabis, the dried flowers of which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent cannabidiol weight for weight; the seeds thereof; the resin extracted from any part of such plant; or any compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or resin that is dispensed only from a dispensing organization. Fla. Stat. § 381.986(1).

[4] Patient must be a Florida resident. *See* Fla. Stat. § 381.986.

[5] *See* Senate Bill 1030 creating Fla. Stat. §§ 381.986, 385.211, 385.212 and 1004.411 and amending Fla. Stat. § 893.02; *See* also companion Senate Bill 1700 creating Fla. Stat. 893.987 (exempting from public records requirements personal identifying information of patients and physicians held by the Department of Health in the compassionate use registry). This article does not address the legality of medical marijuana related businesses or enterprise**s**.

[6] *See* Senate Bill 1030 creating Fla. Stat. §§ 381.986, 385.211, 385.212 and 1004.411 and amending Fla. Stat. § 893.02; *See* also companion Senate Bill 1700 creating Fla. Stat. 893.987 (exempting from public records requirements personal identifying information of patients and physicians held by the Department of Health in the compassionate use registry). This article does not address the legality of medical marijuana related businesses or enterprises.

[7] The specific strain of low-THC cannabis is also known as "Charlotte's Web," after Charlotte Figi, a young girl suffering from Dravet Syndrome.

[8] *See* Senate Bill 1030 creating Fla. Stat. §§ 381.986, 385.211, 385.212 and 1004.411 and amending Fla. Stat. § 893.02; *See* also companion Senate Bill 1700 creating Fla. Stat. 893.987 (exempting from public records requirements personal identifying information of patients and physicians held by the Department of Health in the compassionate use registry). This article does not address the legality of medical marijuana related businesses or enterprises.

[9] *See* endnote 3 for complete definition of low-THC cannabis.

[10] *See* endnote 3 for complete definition of medical cannabis.

[11] Fla. Stat. 499.0295(b) (2016).

[12] Fla. Stat. 499.0295 (2016).

[13] Fla. Stat. § 381.986(4)(a).

[14] A list of the physicians who have completed the Low-THC and Medical cannabis Continuing Medical Education course is available at http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/resources/index.html (accessed on Sept. 17, 2016).

[15] Fla. Stat. § 381.986(3)(a)-(b)(2016).

[16] Cannabis delivery device means an object used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing low-THC cannabis or medical cannabis into the human body. *See* Fla. Stat. § 381.986 (2016).

[17] Pursuant to Florida Administrative Code Rule 64-4.009(1), ordering physicians that have satisfied the education requirements, may access the compassionate use registry using their existing FDOH Medical Quality Assurance Services credentials.

[18] Information about the Office of Compassionate Use is available at http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/.

[19] The Final Rule is found at Chapter 64-4, of the Florida Administrative Code.

[20] For the official petition form for the current proposed Amendment 2, see *Constitutional Amendment Petition Form*, FLA. DEP'T OF ST., available at http://dos.elections.myflorida.com/initiatives/initdetail.asp?account=50438&seqnum=3 (last approved).

[21] In 2014 the Florida Bar Board of Governors adopted a policy that the Bar will not prosecute Florida Bar members who advise a client regarding the validity, scope and meaning of the Florida laws regarding medical marijuana or for assisting a client in conduct the lawyer reasonably believes to be permitted by the laws of the State, so long as the lawyer also advises their client as to federal law and policies.

[22] *See* Bruce E. Reinhart, UP IN SMOKE OR DOWN IN FLAMES? 90 MAR Fla. B.J. 20, 23-24 (March 2016).

[23] *DEA Announces Actions Related to Marijuana and Industrial Hemp*; DEA Headquarters News (Aug. 11, 2016), https://www.dea.gov/divisions/hq/2016/hq081116.shtml (accessed Sept. 20, 2016).

[24] *Id.*