

Legal Aspects of Medical Marijuana in Florida (2017)

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Overview

- **current status of the law in Florida relating to Medical Marijuana.**
 - Florida Statutes
 - Florida Administrative Code
 - Florida Right to Medical Marijuana Initiative, Amendment 2
- **Physician Obligations in Prescribing**
- **Dispensing Organizations**

Florida Statutes

- **Compassionate Medical Cannabis Act of 2014**
- **Applicable Florida Statutes:**
 - Florida Statutes, Sections: 381.986, 381.987, 385.211, 385.212 and 1004.441
- **Florida Administrative Code,**
 - Rules 64 – 4.001, 4.002, 4.004, 4.005, and 4.009
 - Several rule challenges are pending

Constitutional Amendment

- **Amendment 2 narrowly lost on election day**
 - Received 57% and needed 60%
- **United for Care**
 - Petitions are circulating to put medical marijuana on the November 8, 2016 ballot.
 - As of October 14, 2015, the effort needed approximately 680,000 more signatures
 - This was a set back as many of the petitions were kicked back for various reasons

Pending Legislation

- SB 460 and HB 407-Experimental Treatments for Terminal Conditions.
 - The bill revises the definition of “investigational drug, biological product, or device” allowing certain “...eligible patients to purchase and possess, sell, deliver, distribute, dispense & dispose of cannabis...”
- Medical marijuana cannot be in smokeable form.
- No new regulatory rules proposed
- Potentially allows euphoric strains of marijuana

Section 381.986

- authorizes low-THC cannabis, “Charlotte’s Web,” for patients with specified medical conditions
- Outlines implementation
- Nursery Requirements
 - Certificate to cultivate more than 400,000 plants
 - Operated by a licensed nurseryman
 - Operated continuously for 30 years
 - Various security and infrastructure requirements
 - Financial ability to operate and posting of a \$5 million dollar bond
 - Must employ a medical director

Section 381.963 cont.

- Creates the Compassionate Use Registry
- Also offers key definitions to terms like:
 - Dispensing organizations
 - Medical Use
 - Qualified Patient
 - Smoking

Section 381.986 –Physician Obligations

- Must be licensed under Chapter 458 or 459
 - Appears to eliminate nurse practitioners and physician assistants
 - Patients are permanent Florida residents
 - Determination that risk of ordering low-THC cannabis is reasonable in light of the benefits
 - Patients under 18 must receive a second confirmatory opinion
 - Physician registers in the Compassionate Use Registry as the provider for the specific patient
 - Maintenance of medical record covering dose, route of administration, planned duration, and documented monitoring of symptomology
 - Informed consent

Section 381.986 – Physicians cont.

- Physician Education:
 - Physicians will be required to complete an 8-hour training course and subsequent examination
 - Medical Directors for Dispensing Organizations will be required to take a 2 hour training course at initial licensure and renewal
 - Courses are to be offered by the Florida Medical Association and the Florida Osteopathic Medical Association

What is Low-THC Cannabis?

- A plant of the genus *Cannabis*, the dried flowers of which contain 0.8 percent or less of tetrahydrocannabinol and more than 10% of cannabidiol weight for weight; the seed 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.
- The definition was specifically written with the Charlotte's Web Strain in mind
 - The strain was known as Hippie's Disappointment

Compassionate Use Registry

Registry

- Physicians must register patients and maintain accuracy of this registration
- Physicians must also deactivate the patient

- Sound familiar?
 - Similar to the Prescription Drug Monitoring Program for controlled substances found in Section 893.055, Florida Statutes

Patient Privacy Rights

- Patients generally have a right to restrict access to their medical records both under federal and Florida law.
- Florida law is even more restrictive than HIPAA
- Under the Compassionate Use Act, physicians must release patient treatment plans to both UF and the Compassionate Use Registry.
- Physicians may want to consider updating their privacy notices/consent forms to include permission to release the required data as prescribed by the statute

Who can prescribe?

- It's not clear which specialties will have primary ordering responsibility
- The statute allows for prescribing by a registered physician that treated and examined the patient

Malpractice Issue

- Are physicians covered?
- Can malpractice insurance companies cover acts of malpractice that are essentially violations of federal drug laws?
- Who determines the standard of care?

Dispensing Organizations

- Section 381.986(5), Florida Statutes, sets forth the duties of the Department of Health with respect to licensing dispensing organizations
- There were 28 applications submitted
- Only up to 5 licenses may be issued
- \$60,063 application fee
 - Authorize the establishment of 5 dispensing organizations to ensure reasonable statewide accessibility and availability to low-THC Cannabis; NW, NE, Central, SE and SW Florida.
- Applicants to become a Dispensing Organization must demonstrate:
 - The technical ability to cultivate, process and dispense low-THC Cannabis;

Dispensing Organizations (cont.)

- a valid certificate of registration issued by the Dept. of Agriculture and Consumer Services for the cultivation of more than 400,000 plants, be operated by a nurseryman, have been operating as a registered nursery in this state for at least 30 continuous years;
- Ability to secure the premises, resources and personnel necessary to operate a Dispensing Organization;
- Ability to maintain accountability of all raw materials to prevent diversion or unlawful access or possession;
- Reasonable location to provide access;
- Financial ability to operate for a two-year period;
- Level II background screening of all owners and managers;
- Employment of an M.D. or D.O. to supervise activities;
- Monitor physician registration and ordering of low-THC cannabis; and
- Verify that a patient has an active registration in the compassionate use registry prior to filling
- Record dispensing data

Dispensing Organizations (cont.)

- Rules 64-4.001, 4.002, 4.004, 4.005 and 4.009, Florida Administrative Code, define the requirements of applicants
 - Detailed definition of “technical and technological ability to cultivate, process, and dispense low-THC cannabis”
 - Defines “ability to secure premises, resources and personnel”
 - Defines Medical Director qualifications and duties

Federal Law Considerations

- Despite being legal in Florida prescribing cannabis is a violation of the Federal Controlled Substances Act.
 - See 21 CFR § 1306.04(a)
- Do physicians or patients face federal prosecution?
 - Attorney General Eric Holder announced formal prosecution guidelines
 - Ogden Memorandum
 - The memo makes clear that the focus of federal prosecutors should not be on individuals who are in compliance with state laws.
- It is important to note that this is not an exemption for physician orders for medical marijuana or for possession by patients
- With election year, there could be significant changes one way or the other

Federal Law Considerations

- The recently released Ogden Memorandum states:
- "...this memorandum does not alter in any way the Department's authority to enforce federal law... Nor does clear and unambiguous compliance with state law or the absence of one or all of the [factors] create a legal defense to a violation of the Controlled Substances Act. Rather this memorandum is intended solely as a guide to the exercise of investigative and prosecutorial discretion."

Federal Law Considerations

- The Supreme Court has declined to carve out an exception for prosecution under the CSA for medical marijuana under a theory of medical necessity.
- Many bills have been proposed in the House of Representatives and the U.S. Senate trying to amend the CSA, though none have passed

Federal Law Considerations

- Amendments to the recent federal budget include some new policies and renewed policies pertaining to the federal government and state medical marijuana laws. If Passed the budget would prohibit the use of federal dollars in the following ways:
 - DOJ and DEA may not spend money to interfere with the implementation of state medical marijuana laws
 - DOJ and DEA cannot spend money to interfere with state industrial hemp production research
 - The Veterans Administration may not spend money in a manner that would interfere with the ability of a veteran to participate in a state medical marijuana program

Marijuana Laws Across the U.S.

- Recreational Use:
 - Washington
 - Oregon
 - Colorado
- Medical Marijuana:
 - California, Nevada, Hawaii, Alaska, Arizona, New Mexico, Montana, Minnesota, Illinois, Michigan, New York, Maryland, Delaware, New Jersey, Connecticut, Rhode Island, Massachusetts, New Hampshire, Vermont, Maine, District of Columbia
 - Florida (*)
 - Some others have CBD-specific laws or permit only clinical trial participation

Lawyers and Medical Marijuana Advice

- Florida Bar Rule 4-1.2 states a lawyer shall not counsel the client to engage in or assist the client in conduct the lawyer knows or reasonably knows is criminal.
- The policy reads: "The Florida Bar will not prosecute a Florida Bar member solely for advising a client regarding the validity, scope and meaning of Florida Statutes regarding medical marijuana or for assisting a client in conduct the lawyer reasonably believes is permitted by Florida statutes, regulations, orders and other state or local provisions implementing them, as long as the lawyer also advises the client regarding related federal law and policy."



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