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The Regulatory Impact of Medical Marijuana on Health Care Providers

**PRESENTED DECEMBER 2015-MAY BE OUT OF
DATE**

WARNING:

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Presented by:

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George F. Indest III, J.D., M.P.A., LL.M.

**Board Certified by the Florida Bar in the Legal
Specialty of Health Law**

Website: www.TheHealthLawFirm.com



Main Office:

1101 Douglas Avenue
Altamonte Springs, Florida 32714

Phone: (407) 331-6620

Fax: (407) 331-3030

Website: www.TheHealthLawFirm.com

Program Goals

- **Provide an overview of the current status of the law in Florida as it relates to Medical Marijuana.**

Florida Statutes

Proposed Administrative Rules as revised- Pending Rule Challenge

Florida Right to Medical Marijuana Initiative, Amendment 2

Federal Law; Department of Justice Guidance; Drug Enforcement Agency; FDA- Are Florida Physicians and Patients in the Clear of Federal Law?

- **Understand Physician obligations under the current law.**

Regulatory Danger Zone?

Standard of Care?

- **Regulatory Requirements for Dispensing Organizations- Are these nurseries really ready??**
- **Unresolved issues without clear guidance.**

Florida Law-Current Status

- “Compassionate Medical Cannabis Act of 2014” was signed into law on June 16, 2014.
- **Applicable Florida Statutes:**
 - Senate Bill 1030 → Creating Florida Statutes, Sections: 381.986, 385.211, 385.212 and 1004.441; Amending Florida Statute, Section 893.02
 - Senate Bill 1700 → Creating Florida Statute 381.987
- **Florida Administrative Code, Rule 64 – 4.001, 4.002, 4.004, 4.005 and 4.009**
 - These rules became final on June 17, 2015 following the multiple rule challenges that were filed.
- **July 8, 2015 the applications were received by the DOH.**

Amendments-Generally

- Amendment 2 narrowly lost on election day. (57.62% in favor). The measure failed by 2.38%.
- Petitions are circulating to put medical marijuana on the November 8, 2016 ballot.

United for Care-“Florida Right to Medical Marijuana Initiative.”

Broadens usage to patients with a “debilitating medical condition, as determined by a licensed Florida Physician.”

To get on the ballot, the Supreme Court needs to approve ballot language and 609,436 validated signatures.

Current count as of 9/28/2015-511,340 petitions collected; 163,606 valid per FL DOE; 519,543 validated petitions to go.

“Right of Adults to Cannabis”

State would reserve the right to regulate the plant’s purchase and sale in the interest of health and safety.

“Regulate Florida” would legalize adult growing, consumption and possession of cannabis, but will also turn marijuana into a legal regulated product in Florida.

Proposed Legislation

- What recently failed-SB 528 and HB 683. Both were aimed at increasing access to Medical Marijuana, still medical use.
- Current-SB 460 and HB 407-Experimental Treatments for Terminal Conditions. The proposed legislation would revise the definition of “investigational drug, biological product, or device” to allow, “...eligible patients to purchase and possess, sell, deliver, distribute, dispense & dispose of cannabis...”
- The bill would not allow medical marijuana that can be smoked.
- However, the new bill would not be limited to non-euphoric medical marijuana.
- The bill would rely on the current regulatory rules in effect.

Section 381.986 “Compassionate use of low-THC cannabis”

- In general, this statute authorizes the use of low-THC cannabis, “Charlotte’s Web,” for medical patients suffering from specific medical conditions and sets forth the framework for implementation.
- Florida Administrative Code, Rule 64 – 4.001, 4.002, 4.004 and 4.009 applies to those Applicants seeking to become a Dispensing Organization.

Section 381.986 “:Compassionate use of low-THC cannabis” -Physicians

- Effective January 1, 2015, a licensed physician, “who has examined and is treating a patient suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms may order for the patient’s medical use [of] low-THC cannabis to treat such disease, disorder, or condition or to alleviate symptoms of such disease, disorder, or condition, if no other satisfactory alternative treatment options exist for that patient and all of the following conditions apply...”

Low-THC Cannabis

- Means a plant of the genus cannabis, the dried flowers of which contain .8 percent or less of THC (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.
- A/k/a Charlotte's Web Strain – The strain was developed in 2011 by crossbreeding a strain of marijuana with industrial hemp. Was known as the Hippie's Disappointment.

Section 381.986 “Compassionate use of low-THC cannabis” - Physicians

- Conditions for Physician Order:
 - Patient is a permanent resident of Florida;
 - Physician determination that the benefit of low-THC cannabis to the patient is outweighed by the risk;
 - A patient under 18 years of age requires a 2 physician determination.
 - Physician must register as the “orderer” of low-THC cannabis for the named patient on the compassionate use registry;
 - Ongoing updates to the relevant order for a specific patient.
 - Affirmative Duty for Physician to deactivate a patient’s registration if and when treatment is discontinued.

Section 381.986 “Compassionate use of low-THC cannabis” - Physicians

- Physician must maintain a patient treatment plan that includes: dose, route of administration, planned duration, ongoing monitoring of the patient’s symptoms and other indicators of tolerance or reaction to the low-THC cannabis.
- Physician submits the patient treatment plan to The University of Florida of Pharmacy for ongoing safety and efficacy monitoring.
- Physician obtains a voluntary informed consent from the patient or the patient’s legal guardian.

Sufficient explanation to the patient about safety and efficacy of low-THC, knowledge in the medical community and alternative therapies.

Section 381.986 "Compassionate use of low-THC cannabis" - Physicians

- Physician Education:
 - BEFORE ORDERING, Physicians will be required to complete an 8-hour training course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medicine. Training and course and test now and at the time of renewal.
 - Medical Directors for Dispensing Organizations will be required to take a 2 hour training course now and at the time of license renewal.
 - Training courses are not available through the Florida Medical Association and Florida Osteopathic Medical Association.
48 Physicians in Florida as of a publication on October 6, 2015.

Potential Issues for Physicians??

Adequate Documentation of the patient's treatment plan.

Adequate documentation is required under 64B8-9.003 F.A.C.

Here: Dose, route of administration, duration of treatment...

Unclear how much documentation will be enough, especially given that many physicians have been investigated and disciplined by the Department of Health for misprescribing and inadequate documentation of controlled substance prescribing.

Affirmative duty to submit patient treatment plans to UF on a quarterly basis.

Prescription Drug Monitoring Program requires: H&P, History of drug abuse or dependence, diagnosis, therapeutic results, laboratory results (UA), treatment objectives, medications, instructions and controlled substance agreements, results of any drug testing, photocopy of patient's government issued ID, duplicate of the prescription if written. Fla. Stat. 893.055

Informed Consent?

- What constitutes adequate informed consent in this situation?
 - Nature of the low-THC cannabis;
 - Risks of low-THC cannabis vs. anticipated benefits;
 - Alternatives to low-THC cannabis.
- Written or oral informed consent? See Fla. Stat. 381.026(3).
- Do patients need to be consented on the fact that their treatment plan will be submitted to UF for ongoing efficacy and safety studies? Is this considered experimental under a patient bill of rights? See Fla. Stat. 381.026.
- Should ordering physicians adopt something like the Informed Consent for Psychotherapeutic Medication issued by Medicaid for minors to standardize their consent language?

Compassionate Use Registry

Registry – Potential Problems?

Physicians will need to register patients and maintain accuracy of this registration.

Deactivating the patient when time to discontinue use.

What will qualify as timely deactivation?

Similar Registry to the Prescription Drug Monitoring Program for controlled substances. Fla. Stat. 893.055.
Requires report within 7 days of dispensing.

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, not providing for an exception for the unauthorized release of protected health information for health care operations, like insurance billing.
- Under HIPAA, insured patients can restrict an insurer's access to their medical records when they pay cash for a medical service as well.
- Under this law, physicians are required to release patient treatment plans to both UF and the Compassionate Use Registry.
- Although a statutory obligation, Physicians who order low-THC cannabis should update their privacy practices and should consider obtaining consent for the release of a patient's treatment plan as required by law, as there has been no modification to Section 456.057, Fla. Stat.

Patient Privacy Rights (cont.)

- Section 381.987, Fla. Stat. does exempt out personal patient information and a physician's identifying information registered in the compassionate use registry under Section 119.07 and 24(a) Article 1 of the State Constitution.
- The DOH must still provide access to law enforcement, Dispensing Organizations and physicians who have written orders for low-THC cannabis.
- Not a completely well settled situation for private physicians.

Insurance Considerations

- It is extremely unlikely that low-THC cannabis will be covered by third-party insurers or governmental payors.
- Will physicians need to provide an Advanced Beneficiary Notice of Non-coverage ("ABN") for the mere evaluation of a patient? The Physician isn't dispensing.
- Will the physician order for the low-THC cannabis make an office evaluation that would otherwise be a covered service non-covered? OR will this be like when a prescription is ordered for a non-covered prescription? An ABN is not generally required in that instance.

What Specialty?

- Unclear as to what specialty will have primary ordering responsibility: oncology, neurology, pain medicine?
- Statute states any physician who has treated and examined the patient. We know the Department has been aggressive in its pursuit against physicians who prescribe pain medications. **Should we anticipate that this will be different for our physician clients under this scenario?**

Frequency of Patient Visits?

- One would assume as often as needed to evaluate therapeutic benefit of low-THC cannabis therapy.
- Reports are required to UF on a quarterly basis, so at least q. 3 months?
- Section 456.44, Fla. Stat., requires no more than 3 months for the prescribing of controlled substances.

Status of Required Training?

- Section 381.986(4), Fla. Stat., requires physician training by October 1st?
 - Training courses are now available through the Florida Medical Association and Florida Osteopathic Medical Association.
 - There are separate courses for ordering physicians and Medical Directors of Dispensing Organizations.
 - 48 Physicians in Florida as of a publication on October 6, 2015.

Malpractice Issue

- Physicians may want to contact their professional liability insurer to determine if the carrier has taken an official position for coverage when ordering low-THC cannabis to qualifying patients.
- What is the standard of care in the medical community? The opinion of many is that additional training is necessary on the use of medical marijuana.

Self-Referral – Caution

- Reminder that under Florida law, regardless of payor, a health care provider may not refer a patient for the provision of any other health care item or service to an entity in which the health care provider is an investor.
- “Referral” means any referral of a patient by a health care provider for health care services, including, without limitation: The forwarding of a patient by a health care provider to another health care provider or to an entity which provides or supplies designated health services or any other health care item or service...
- If low-THC cannabis is deemed a health care item, then a physician’s relationship with a Dispensing Organization or Marijuana Treatment Center will need to be evaluated to avoid any prohibited referrals.

Patient Brokering – Caution

It is unlawful for any person, including any health care provider or health care facility, to:

- (a) Offer or pay any commission, bonus, rebate, kickback, or bribe, directly or indirectly, in cash or in kind, or engage in any split-fee arrangement, in any form whatsoever, to induce the referral of patients or patronage to or from a health care provider or health care facility; or
- (b) Solicit or receive any commission, bonus, rebate, kickback, or bribe, directly or indirectly, in cash or in kind, or engage in any split-fee arrangement, in any form whatsoever, in return for referring patients or patronage to or from a health care provider or health care facility.

Patient Brokering – Caution (cont.)

- “Health care provider or health care facility” means any person or entity licensed, certified, or registered; required to be licensed, certified, or registered; or lawfully exempt from being required to be licensed, certified, or registered with the Agency for Health Care Administration or the Department of Health.
- In this instance either a Dispensing Organization or Marijuana Treatment Center will be required to be licensed/registered with the DOH and may fall under the definition above. A licensed physician is subject to the definition.
- Physicians should be reminded of this prohibition.

Physician Considerations- Federal Law

- Despite being legal in Florida effective January 1, 2015, the prescribing of even low-THC cannabis is a violation of the Federal Controlled Substances Act. See 21 CFR § 1306.04(a).
- Do physicians face federal prosecution?
 - October 19, 2009 – Attorney General Eric Holder announced formal prosecution guidelines, as set forth in the memorandum by Deputy Attorney General David Ogden.
 - The memo makes clear that the focus of federal prosecutors should not be on individuals who are in compliance with state laws.
 - More recent Cole memo makes clear that states where medical marijuana has been approved require strong regulatory and enforcement systems.
- This guidance was issued to federal prosecutors.
- This is not a carve-out or exemption for physician orders for low-THC cannabis or medical marijuana in general.

Physician Considerations- Federal Law (cont.)

- It is important to note that Mr. Ogden's memo clearly provides, "...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."
- The DEA's Position Paper on Marijuana issued in April 2013, cites the guidance provided by Mr. Holder and Mr. Ogden.

Physician Considerations- Federal Law (cont.)

- The Supreme Court has declined to carve out an exception for prosecution under the CSA for medical marijuana under a theory of medical necessity.
- It should also be noted that many attempts (HR 3093 in 2007; HR 5842 and HR 5843 in 2008; HR 2835 in 2009; HR1983 and 2306 in 2011; and HR 5326 in 2012) have been made to pass federal law to prevent the arrest of providers and patients under the CSA in states where medical marijuana is legal.
- None have been passed.

Dispensing Organizations

- Section 381.986(5), Fla. Stat., sets forth the duties of the Department and provides that by January 1, 2015 the Department shall, in addition to other action items:
- That time-line has come and gone.
- There were 28 applications submitted.
 - 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 and technological ability to cultivate, process and dispense low-THC Cannabis;

Dispensing Organizations (cont.)

- Applicant must possess 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 a Medical Director 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, at which time any dispensed amount is recorded.

Dispensing Organizations (cont.)

- Florida Administrative Code, Rule 64-4.001, 4.002, 4.004, 4.005 and 4.009

The Rules further explain requirements for applicants:

- Organization that meets the statutory requirements of Section 381.986(5)(b)1 and identifies the nurseryman as defined in Section 581.011.
- Substantial requirements and plans for the submission of the Application, such as:
 - Plan for cultivation, processing and dispensing;
 - Detailed security and safety plan;
 - Site plan for all aspects of the operation;
 - Written documentation that demonstrates an ability to produce low-THC cannabis; and
 - Certified Financials.

Dispensing Organizations (cont.)

- Employment of a Medical Director—
A physician licensed under Ch. 458 or 459.
- The application seeks information related to that physician's experience treating epileptic patients, cancer patients and those patients with severe seizures or muscle spasms.

Florida Bar-Medical Marijuana Advice Policy

- Issued June 16, 2014
- Bar Rule 4-1.2 provides that a lawyer shall not counsel the client to engage 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.”

What we did not address:

Federal preemption;

Other constitutional issues;

Banking issues and required Suspicious Activity Reports as of February 14, 2014;

- Marijuana limited SAR – Fully compliant

- Marijuana priority SAR – Some prohibited activities

- Marijuana termination – When a banking relationship must be terminated in order to maintain an effective anti-money laundering program

Employment considerations – both state and federal law provide for firing an employee for marijuana use; government employees; and

Taxation issues – Business operators cannot deduct operating expenses.



Main Office:

1101 Douglas Avenue
Altamonte Springs, FL 32714

Phone: (407) 331-6620

Fax: (407) 331-3030

Website: www.TheHealthLawFirm.com



Orlando Office (By Appointment):

37 North Orange Avenue, Suite 500
Orlando, Florida 32801

Phone: (407) 331-6620

Fax: (407) 331-3030

Website: www.TheHealthLawFirm.com



Pensacola Office (By Appointment):

201 East Government Street
Pensacola, Florida 32502

Phone: (850) 439-1001

Fax: (407) 331-3030

Website: www.TheHealthLawFirm.com



Denver, Colorado Office (By Appointment):

155 East Boardwalk Drive, Suite 424
Fort Collins, Colorado 80525

Phone: (970) 416-7454

Fax: (866) 203-1464

Website: www.TheHealthLawFirm.com



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