

Florida's Medical Marijuana Law

Presented by:

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The FOMA Governmental Affairs

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Jason is a 1996 graduate of the University of Maryland and received his Juris Doctorate from Nova Southeastern University - Shepard Broad Law in Ft. Lauderdale, Florida. Mr. Winn was admitted to the Florida Bar in September 2001. From 2001 to 2004, Mr. Winn worked for the Assistant Public Defender in the Fifth Judicial Circuit where he conducted over 15 jury trials, numerous non-jury trials, and many hearings including, violations of probation, restitution, and early termination motions for defendants in Juvenile, Misdemeanor and Felony Court. Mr. Winn was also an adjunct professor at Lake Sumter Community College teaching Business Law during this time. In 2003, Mr. Winn was appointed by Governor Bush to serve a one year term on the Judicial Nominating Commission for Judicial Compensation Judges. From 2004-2006 Mr. Winn worked for the law office of Clyde M. Taylor, Jr. focusing on both state and federal criminal defense and parole violation hearings. In 2006, he opened his own practice, where he is the managing partner and continues to focus on criminal, administrative, governmental, civil, wills, and trusts. Mr. Winn currently serves as general counsel for the Florida Osteopathic Medical Association (FOMA), the Florida Podiatric Medical Association (FPMA), and the Florida Society of Hearing Healthcare Professionals (FSHHP). He is a member of the Florida Bar, Tallahassee Bar, Legal Services of Florida, a lifetime member of the state Florida Association of Criminal Defense Lawyers, and the local FACDL chapter. As a member of the Tallahassee Bar, Mr. Winn volunteers his legal services to the Wakulla County Senior Citizens Center through the Legal Services of North Florida.

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Passage of Amendment 2

Passage of Amendment 2

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• The Amendment 2 ballot initiative was amended to the Florida Constitution on November 8, 2016, with 71% of the vote – 11% higher than the required 60% supermajority threshold.

• The amendment officially became effective on January 3, 2017.

Passage of Amendment 2

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Expands Treatment

Cancer	Epilepsy	Glaucoma
Human Immune Deficiency virus (HIV)	Acquired Immune Deficiency syndrome (AIDS)	Post-Traumatic Stress Disorder (PTSD)
Amyotrophic Lateral Sclerosis (ALS)	Crohn's Disease	Parkinson's Disease
Multiple Sclerosis (MS)	Or other debilitating medical conditions of the same kind or class as or comparable to those enumerated, and for which a physician believes that the medical use of marijuana would likely outweigh the potential health risks for a patient.	

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2017a Legislative Session Highlights

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Definitions

- "Marijuana" to mean 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, including low-THC cannabis, which are dispensed from a MMTC for medical use by a qualified patient.
- "Caregiver" to mean a resident of the state who has agreed to assist with a qualified patient's medical use of marijuana, has a caregiver identification card, and meets the requirements for caregivers established in the section.
- "Chronic nonmalignant pain" to mean pain that is caused by a qualifying medical condition or that originates from a qualifying medical condition and persists beyond the usual course of that qualifying medical condition.
- "Close relative" to mean a spouse, parent, sibling, grandparent, child, or grandchild, whether related by whole or half blood, by marriage, or by adoption.
- "Edibles" to mean commercially produced food items made with marijuana oil, but no other form of marijuana, that are produced and dispensed by a MMTC.
- "Marijuana testing laboratory" to mean a facility that collects and analyzes marijuana samples from a MMTC and has been certified by the department pursuant to s. 381.988, F.S.

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Definitions

- "Medical use" to mean the acquisition, possession, use, delivery, transfer, or administration of marijuana authorized by a physician certification. The term does not include:
 - o Possession, use, or administration of marijuana that was not purchased or acquired from a MMTC.
 - O Possession, use, or administration of marijuana in a form for smoking, in the form of commercially produced food items other than edibles, or of marijuana seeds or flower, except for flower in a sealed, tamper-proof receptacle for vaping.
 - Use or administration of any form or amount of marijuana in a manner that is inconsistent with the qualified physician's directions or physician certification.
 - Transfer of marijuana to a person other than the qualified patient for whom it was authorized or the qualified patient's caregiver on behalf of the qualified patient.
 - Use or administration of marijuana in the following locations:
 - On any form of public transportation, except for low-THC cannabis.
 - ➤ In any public place, except for low-THC cannabis.
 - ➤ In a qualified patient's place of employment, except when permitted by his or her employer.
 - ➤ In a state correctional institution, as defined in s. 944.02, F.S., or a correctional
 - ➤ institution, as defined in s. 944.241, F.S.
 - On the grounds of a preschool, primary school, or secondary school, except as provided in s. 1006.062, F.S.
 - ➤ In a school bus, a vehicle, an aircraft, or a motorboat, except for low-THC cannabis.

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Definitions

- "Qualified physician" to mean a person who holds an active, unrestricted license as an allopathic physician under chapter 458 or as an osteopathic physician under chapter 459 and is in compliance with the physician education requirements.
- "Terminal condition" to mean a progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible without the administration of life-sustaining procedures, and will result in death within 1 year after diagnosis if the condition runs its normal course.

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Medical Marijuana Treatment Centers (MMTC)

- Grandfathers existing 7 dispensing organizations and re-classifies entities as licensed MMTCs.
- DOH is required to license 10 new MMTCs by October 3, 2017:
 - o By August 1, 2017 − 5 who placed second during the first round of licensure;
 - o By October 3, 2017 − 5 new MMTCs;
 - ▼ 1 must be a member of the *Pigford vs. Glickman* or *Black Farmer Litigation* and is a member of the Black Farmers and Agriculturalists Association-Florida Chapter
 - **▼** 4 open competitive, of which 2 citrus producers may be provided preferential scoring.
- Additionally, within 6 months of the registration of 100,000 qualified patients in the registry and at each additional 100,000 patients thereafter, the DOH must license 4 new MMTCs.

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MMTCs

- **Dispensary Caps** authorized to establish a maximum of 25 dispensaries statewide. The statewide maximum number of dispensaries is increased by 5 per MMTC each time the registry adds 100,000 additional qualified patients;
- Establishes new MMTC application process;
- Regulates MMTC changes of ownership;
- Establishes additional MMTC requirements;
- Establishes MMTC cultivation standards;
- Provides for MMTC processing and testing standards;
- Revises packaging and labeling requirements;
- Establishes dispensing requirements MMTCs may not dispense more than a 70-day supply to a qualified patient and may not dispense directly to a minor patient;
- Limits MMTC Advertising;
- Provides for additional background screening requirements;
- Preempts the regulation of cultivation, processing, and delivery of marijuana is preempted to the State.

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Other Regulations

- Revises policies for physicians certifying patient use of Medical Marijuana;
- Alters patient and caregiver requirements relating to Medical marijuana;
- Expands the qualifying medical conditions to include those enumerated within Amendment 2;
- Requires the electronic registry must be accessible on-line to law enforcement agencies, qualified physicians, and medical marijuana treatment centers (MMTC) to verify patient certifications;
- Requires the Department of Law Enforcement to develop training available to all law enforcement agencies that covers the legal parameters of marijuana-related activities by qualified patients, caregivers, MMTCs, and medical marijuana testing labs;
- Appropriates \$100,000 in recurring funds from the Highway Safety Operating Trust Fund to the DHSMV for the purpose of training additional law enforcement officers as drug recognition experts;
- Appropriates \$5,000,000 in nonrecurring funds from the Highway Safety Operating Trust Fund to the DHSMV to implement the impaired driving education campaign;
- Appropriates \$500,000 in nonrecurring funds from the General Revenue Fund to the DOH to implement the statewide marijuana education and use prevention campaign;
- Appropriates \$750,000 in nonrecurring General Revenue funds for the Coalition to conduct medical cannabis research.

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Timeline of Medical Marijuana in Florida

Timeline of Medical Marijuana in Florida



June 16, 2014
Governor Scott
signs the
Compassionate
Medical
Cannabis Act of
2014

Sept. 9, 2014 Department published Final Rule Nov. 14, 2014 Final Order – Judge Watkins rules against DOH











June 18, 2014
First Round –
DOH begins
the Rule
Development
Process

Sept. 9-12, 2014 Rule Challenges filed

Timeline of Medical Marijuana in Florida



Dec. 30, 2014
Second Round
- Rule
Development

March 24, 2015 Rule challenged July 8, 2015
Accepted
applications for
Dispensing
Organizations

slots











Feb. 6, 2015 Department publishes new Rule May 27, 2015

DOH Rules
upheld by Judge
Watkins –
Challenge
dismissed

Timeline of Medical Marijuana in Florida



Nov. 23, 2015

Approved
Dispensing
Organizations
announced

March 25, 2016

Gov. Scott signs
HB 307 –
adopting major
revisions to the
Compassionate
Medical
Cannabis Act

November 8, 2016 Amendment 2 Passes













Dec. 11-14, 2015
Petitioners (13
petitions filed)
Challenge Nursery
Selection Process

Disposition of petitions to be determined

June 2017 Legislature Adopts and Governor signs Amendment 2 Implementing bill 18

Florida Medical Marijuana an Evolving and Fluid Process

Florida Medical Marijuana an Evolving and Fluid Process

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To date:

- Over 1,550 doctors have completed the course requirements to certify medical marijuana;
- Over 135,000total patients.
- Over 101,590 patients have been qualified on the Medical Marijuana Use Registry.

Florida Medical Marijuana an Evolving and Fluid Process



A Change in Federal Policy Toward Medical Cannabis

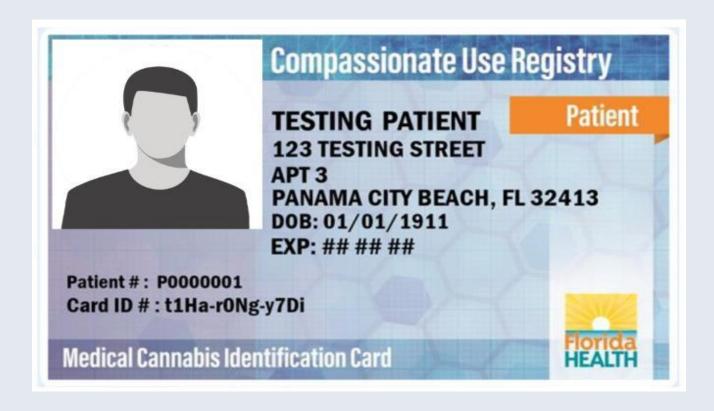
- S.683 Compassionate Access, Research Expansion, and Respect States (CARERS) Act of 2015 (Introduced 03-10-2015) Sponsor Sen. Corey Booker (D- NJ) 15 Senate Co-sponsors (Bipartisan Support); 3-10-2015: Referred to the Committee on Judiciary;
- H.R.1538 CARERS Act of 2015 (Introduced 03-23-2015) Sponsor Rep. Steve Cohen (D-TN) 16 House Co-sponsors (Bipartisan support); 4-21-2015: Referred to the Subcommittee on Crime, Terrorism, Homeland Security and Investigations;
- The aforementioned measures failed to garner Congressional approval. However, they do signal a potential policy shift at the federal level (bipartisan) in support of medical cannabis. The legislation would have remedied many state-federal conflicts over medical marijuana;
- <u>Congress has passed legislation to address physician, banking and medical cannabis industry concerns</u>. December 2015 Congress passed the Omnibus spending bill which restricts federal law enforcement activities in states that have legalized medical cannabis (restrictions apply to funds provided in the omnibus package);
- In August 2016 the DEA and FDA decided not to revise marijuana's Schedule I status (no accepted medical use and high potential for abuse). "The DEA and the FDA continue to believe that scientifically valid and well-controlled clinical trials conducted under investigational new drug (IND) applications are the most appropriate way to conduct research on the medicinal uses of marijuana," said a statement from the DEA" (CNN August 12, 2016). http://www.cnn.com/2016/08/11/health/dea-marijuana-schedule-l/

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Florida Medical Marijuana Law – Identification Card



Front of Card





Back of Card

This Compassionate Use Registry identification card is issued by the Florida Department of Health under authority of Section 381.986, F.S. and Rule 64-4.011, F.A.C. This card indicates that the pictured patient or legal representative is registered in the Compassionate Use Registry. All patients and legal representatives must have a Compassionate Use Registry identification card to possess, purchase, or use medical cannabis. Marijuana remains illegal under federal law.

An application for a replacement card must be submitted to the Department within 10 days of a name, address, or assigned legal representative change. Renewal applications must be submitted 45 days prior to expiration.

The Compassionate Use Registry can be accessed at: https://curegistry.flhealth.gov/

The Office of Compassionate Use can be reached by visiting: http://www.floridahealth.gov/OCU

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The DOH is required to begin issuing ID cards to qualified patients and caregivers by October 3, 2017. The ID cards must be resistant to tampering and counterfeiting and include, at a minimum:

- The name, address, and date of birth of the qualified patient or caregiver;
- A full-face, passport-type, color photograph of the qualified patient or caregiver taken within the 90 days immediately preceding registration or the Florida driver license or Florida identification card photograph of the qualified patient or caregiver obtained directly from the Department of Highway Safety and Motor Vehicles (DHSMV);
- Identification as a qualified patient or a caregiver;
- The unique numeric identifier used for the qualified patient in the medical marijuana use registry;
- For a caregiver, the name and unique numeric identifier of the caregiver and the qualified;
- patient or patients that the caregiver is assisting;
- The expiration date of the identification card.

Prior to issuing an ID card to a minor, the DOH must receive written consent from the minor's parent or guardian. Patients and caregivers must return their ID cards within five business days after their registration is revoked.



- A qualified patient or caregiver in possession of marijuana or a marijuana delivery device who fails or refuses to present his or her marijuana use registry identification card upon the request of a law enforcement officer commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083, unless it can be determined through the medical marijuana use registry that the person is authorized to be in possession of that marijuana or marijuana delivery device;
- A person charged with a violation of this paragraph may not be convicted if, before or at the time of his or her court or hearing appearance, the person produces in court or to the clerk of the court in which the charge is pending a medical marijuana use registry identification card issued to him or her which is valid at the time of his or her arrest. The clerk of the court is authorized to dismiss such case at any time before the defendant's appearance in court. The clerk of the court may assess a fee of \$5 for dismissing the case under this paragraph;
- Any person who possesses or manufactures a blank, forged, stolen, fictitious, fraudulent, counterfeit, or otherwise unlawfully issued medical marijuana use registry identification card commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

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Florida Medical Marijuana Law for Medical Marijuana Treatment Centers



- A person or entity that cultivates, processes, distributes, sells, or dispenses marijuana, as defined in s. 29(b)(4), Art. X of the State Constitution, and is not licensed as a medical marijuana treatment center violates s. 893.13 and is subject to the penalties provided therein.
- A person who manufactures, distributes, sells, gives, or possesses with the intent to manufacture, distribute, sell, or give marijuana or a marijuana delivery device that he or she holds out to have originated from a licensed medical marijuana treatment center but that is counterfeit commits a felony of the third degree:
 - o punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
 - o "counterfeit" means marijuana; a marijuana delivery device; or a marijuana or marijuana delivery device container, seal, or label which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a licensed medical marijuana treatment center and which thereby falsely purports or is represented to be the product of, or to have been distributed by, that licensed medical marijuana treatment facility.

Department of Health Approved Medical Marijuana Treatment Centers

Name	Dispensing Locations	
Trulieve	Tallahassee, Tampa, Clearwater, Pensacola, Miami, Edgewater, Lady Lake, Jacksonville, Orlando, St. Petersburg, Bradenton, Fort Myers, Gainesville, Vero Beach, New Port Richey, delivery	
Surterra Therapeutics	Pensacola, Tallahassee, Tampa, North Port, Deltona, Orlando, Largo, Miami Beach, delivery	
Curaleaf	Miami, Kendall, Lake Worth, St Petersburg, Ft. Myers, Palm Bay, Palm Harbor, delivery	
Knox Medical	Tallahassee, Gainesville, Orlando, Jacksonville, Lake Worth, St. Petersburg, Fort Walton Beach, delivery	
Liberty Health Science (formerly Aphria)	Summerfield, St. Petersburg, Tampa, Port St. Lucie, delivery	
The Green Solution	Dispensing via delivery	
GrowHealthy	Dispensing via delivery	
3 Boys Farm	Cultivation Authorization only	
Vidacann (formerly Loop's Nursery & Greenhouses, Inc.)	Holly Hill, delivery	
Altmed Florida	Apollo Beach, delivery	
Sunbulb Company, Inc	Cultivation Authorization only	
Treadwell Nursery	Cultivation Authorization only	
Columbia Care Florida	Dispensing via delivery	

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• An MMTC is approved by the Department of Health to cultivate, process, transport, and dispense low-THC cannabis and medical marijuana.

Safety and Security Measures

- MMTCs must implement and maintain certain safety and security measures which include:
 - Maintain a fully operational surveillance and alarm system;
 - Store medical marijuana in secured, locked rooms or a vault;
 - Have at least 2 employees of the dispensing organization or of a contracted security agency be on the dispensing organization premises at all times;



Safety and Security Measures

- Safety and security measures continued...
 - All employees must wear a photo identification badge while on the premises;
 - All visitors must wear a visitor's pass at all times while on the premises;
 - Must implement an alcohol and drug free workplace policy;
 - Report to local law enforcement within 24 hours the theft, diversion, or loss of low-THC cannabis or medical cannabis;

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Safety and Security Measures

- Safety and security measures continued...
 - Ensure the outdoor premises has sufficient lighting from dusk until dawn;
 - Dispensing is authorized between the hours of 7 a.m. and 9 p.m. However, the dispensing organizations are able to perform all other operations and deliveries of its product 24 hours a day.

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Transportation

- Transportation requirements for MMTCs:
 - Maintain a marijuana transportation manifest in any vehicle transporting marijuana. The manifest must be generated from a MMTC's seed-to-sale tracking system and include:
 - Date and approximate time of departure and arrival;
 - Name, location address, and license number of the originating MMTC;
 - Name and address of recipient of the delivery;
 - Quantity and form of any marijuana or delivery device being transported;
 - Delivery vehicle make and model and license plate number;
 - Name and signature of the MMTC employees delivering the product.

Transportation

- Transportation requirements for MMTCs:
 - A copy of the manifest must be provided to each individual, MMTC, or marijuana laboratory that receives a delivery;
 - The individual, or a representative of the center or laboratory, must sign a copy of the manifest acknowledging receipt;
 - An individual transporting marijuana or a marijuana delivery device must present a copy of the relevant manifest and his or her employee ID card to a law enforcement office upon request;
 - MMTCs and marijuana testing laboratories must retain copies of all marijuana transportation manifests for at least 3 years;

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Transportation

- Transportation requirements for MMTCs:
 - Ensure only vehicles in good-working order are used to transport medical marijuana or medical marijuana delivery devices;
 - Requires medical marijuana and marijuana delivery devices to be locked in a separate compartment or container within the vehicle;
 - Employees must be in possession of their employee identification card at all times when transporting marijuana or marijuana delivery devices;
 - Have at least two persons in a vehicle transporting medical marijuana or medical marijuana delivery devices. At least one person must remain in the vehicle throughout the delivery process;
 - Provide specific safety and security training to those employees transporting medical marijuana or medical marijuana delivery devices.

Transportation

A person transporting marijuana or marijuana delivery devices on behalf of a medical marijuana treatment center or marijuana testing laboratory who fails or refuses to present a transportation manifest upon the request of a law enforcement officer commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083.



Growing

- When growing medical marijuana, MMTCs:
 - May use pesticides determined by the DOH and Department of Agriculture and Consumer Services;
 - Must be in an enclosed structure and in a room separate from any other plant;
 - Must inspect seeds and growing plants for plant pests that endanger or threaten the state;
 - Must perform fumigation or treatment of plants, or remove and destroy infested or infected plants, in accordance with chapter 581 and any rules adopted thereunder.

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Processing

- When processing medical marijuana, MMTCs must:
 - Process the medical marijuana in an enclosure separate from other plants or products;
 - Comply with department rules when processing marijuana with hydrocarbon solvents or other solvents or gases exhibiting potential toxicity to humans;
 - Package the low-THC cannabis or medical marijuana in compliance with the U.S. Poison Prevention Packaging Act (15 U.S.C. §§1471-1477);
 - Test the processed marijuana using a medical marijuana testing laboratory before it is dispensed.

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Processing

- Package the medical marijuana in a receptacle that has a firmly affixed and legible label stating the following information:
 - The marijuana or low-THC cannabis meets the requirements;
 - The name of the medical marijuana treatment center from which the marijuana originates;
 - The batch number and harvest number from which the marijuana originates and the date dispensed;
 - The name of the physician who issued the physician certification;
 - The name of the patient;
 - The product name, if applicable, and dosage form, including concentration of tetrahydrocannabinol and cannabidiol. The product name may not contain wording commonly associated with products marketed by or to children;
 - The recommended dose;
 - A warning that it is illegal to transfer medical marijuana to another person;
 - A marijuana universal symbol developed by the department.

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Processing

- The medical marijuana treatment center shall include in each package a patient package insert with information on the specific product;
- Each edible shall be individually sealed in plain, opaque wrapping marked only with the marijuana universal symbol. Where practical, each edible shall be marked with the marijuana universal symbol. In addition to the packaging and labeling requirements;
- Edible receptacles must be plain, opaque, and white without depictions of the product or images other than the medical marijuana treatment center's department-approved logo and the marijuana universal symbol. The receptacle must also include a list all of the edible's ingredients, storage instructions, an expiration date, a legible and prominent warning to keep away from children and pets, and a warning that the edible has not been produced or inspected pursuant to federal food safety laws.

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Dispensing

- When dispensing low-THC cannabis or medical cannabis, dispensing organizations must:
 - Not dispense more than 70 day supply to a patient or the patient's legal representative;
 - The employee dispensing the low-THC cannabis or medical cannabis must enter into the medical marijuana use registry his or her name or unique employee identifier;
 - Must verify that the qualified patient and the caregiver, if applicable, each have an active registration in the medical marijuana use registry and an active and valid medical marijuana use registry identification card, the amount and type of marijuana dispensed matches the physician certification in the medical marijuana use registry for that qualified patient, and the physician certification has not already been filled;
 - May not dispense marijuana to a qualified patient who is younger than 18 years of age. If the qualified patient is younger than 18 years of age, marijuana may only be dispensed to the qualified patient's caregiver.

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Dispensing

- May not dispense or sell any other type of cannabis, alcohol, or illicit drugrelated product, including pipes, bongs, or wrapping papers, other than a marijuana delivery device required for the medical use of marijuana and which is specified in a physician certification.
- Must, upon dispensing the marijuana or marijuana delivery device, record in the registry the date, time, quantity, and form of marijuana dispensed; the type of marijuana delivery device dispensed; and the name and medical marijuana use registry identification number of the qualified patient or caregiver to whom the marijuana delivery device was dispensed.
- Must ensure that patient records are not visible to anyone other than the qualified patient, his or her caregiver, and authorized medical marijuana treatment center employees.

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Florida Medical Marijuana Law for Physicians and Patients

Physician Certifications in the Registry



- In the July 20, 2018 OMMU Update, 1,573 Physicians were reported to have access to the Registry.
- Number of Complete Patient certifications from July 1, 2017 through July 1, 2018 based upon the physician's self-reported place of location:
- 909 physicians created patient certifications and 892 physicians created Complete certifications. Complete certifications include identification of a qualifying condition and at least one order for Medical Marijuana (either or both Low-THC Cannabis of Full Potency Cannabis).
- Number of Complete Patient Certifications in the Medical Marijuana Use Registry = 112,224.
- Incomplete Patient certifications accounted for 2,963 entries in the Medical Marijuana Use Registry.
- These numbers include duplicate head counts; some patients have more than one certification in this period.

Physician Certifications for Medical Marijuana



- A total of **97,522 Florida patients** were certified by **909 physicians** for **115,187** orders for medical marijuana from July 1, 2017 through July 1, 2018.
- Approximately 3% of the orders certifying patients for medical marijuana were incomplete (did not include type or form or dose) resulting in a total of **96,080 patients receiving 112,224 orders from 892 physicians** (1,343 patients had both complete and incomplete certifications in the MMUR). Many patients had orders for both types of Medical Marijuana.

Physician Certifications for Medical Marijuana



Number of Physicians who have Certified Patient	Number of Patients (with Dispensations)	Percent of Patients
21	1	0.001%
16	1	0.001%
12-14	4	0.005%
10-11	8	0.01%
8-9	19	0.02%
6-7	68	0.08%
4-5	292	0.35%
3	1,234	1.49%
2	9,277	11.16%
1	72,188	86.88%
Total Number of Patients	83,092	

Table 3. Patients with Medical Marijuana dispensations by the number of physicians who have certified (ordered) those dispensations from July 1, 2017 through July 1, 2018.

High Potency Cannabis Dispensations



- 4,591 different dispensation amounts
- 414,182 dispensations (includes all certifications/orders whether partially or fully dispensed)
- 872 Physicians (130 w/ NO Low-THC dispensations)
- 80,952 Patients; 52,716 with only High Potency Cannabis dispensation
- Range in Amount Dispensed: 1 mg to 68,250 mg
- Mode in Amount Dispensed: 600 mg [w/ 83,207 dispensations]

High Potency Cannabis Dispensations

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Percent of Total	Number of Individual Dispensations ¹	Amount Dispensed
13%	83,507	600 mg
8%	96,144	850 mg; 1200 mg
7%	40,493	250 mg
4%	71,877	300 mg; 500 mg; 800 mg
3%	34,661	1700 mg; 1800 mg
2%	66,882	200 mg; 400 mg; 750 mg; 900 mg; 1600 mg; 2400 mg
1%	58,006	1000 mg; 1050 mg; 1100 mg; 1250 mg; 1400 mg; 1450 mg; 1500 mg; 2000 mg; 2550 mg; 3,000 mg
<1%	170,160	1 mg to 68,250 mg [4,566 different amounts]
Total	621,730	[4,591 different amounts dispensed]

Table 4. Frequency of Dispensation Amounts (mg) for Full Potency Cannabis from July 1, 2017 through July 1, 2018.

¹ Patients may choose to ask for a dispensation of their entire order (a maximum 70-day supply) or a subset of the order.

Low-THC Cannabis Dispensations



- 598 different dispensation amounts
- 72,504 dispensations (includes all certifications/orders whether partially or fully dispensed)
- 766 Physicians (24 with NO High Potency Dispensations)
- 30,376 Patients; 2,140 with only Low-THC Cannabis dispensations
- Range in Amount Dispensed: 1 mg to 38,400 mg
- Mode in Amount Dispensed: 500 mg [w/ 13,534 dispensations]

Low-THC Cannabis Dispensations

((_	1a))

Percent of Total	Number of Individual Dispensations ¹	Amount Dispensed
19%	13,534	500 mg
14%	10,445	600 mg
11%	7,924	200 mg
7%	5,337	300 mg
6%	4,263	250 mg
4%	11,430	213 mg; 200 mg; 1000 mg; 1200 mg
3%	4,384	556 mg; 750 mg
2%	2,531	216 mg; 1250 mg
1%	6,561	150 mg; 278 mg; 426 mg; 432 mg; 700 mg; 800 mg; 900 mg; 1500 mg; 1800 mg; 2000 mg
<1%	6,095	1 mg to 38400 mg [575 different amounts]
Total	72,504	[598 different amounts dispensed]

Table 5. Frequency of Dispensation Amounts (mg) for Low-THC Cannabis from July 1, 2017 through June 30, 2018.

¹ Patients may choose to ask for a dispensation of their entire order (a maximum 70-day supply) or a subset of the order.

Both Types of Medical Marijuana Dispensations



- 598 different dispensation amounts
- 229,314 dispensations (both Low THC and High Potency Cannabis)
- 742 Physicians
- 28,236 Patients
- Range in Amount Dispensed: Low: 4 mg –
 38,400; High: 14 mg to 68,250,400 mg

Penalties



- A qualified physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, if the qualified physician issues a physician certification for the medical use of marijuana for a patient without a reasonable belief that the patient is suffering from a qualifying medical condition.
- A person who fraudulently represents that he or she has a qualifying medical condition to a qualified physician for the purpose of being issued a physician certification commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.
- A qualified physician who issues a physician certification for marijuana or a marijuana delivery device and receives compensation from a medical marijuana treatment center related to the issuance of a physician certification for marijuana or a marijuana delivery device is subject to disciplinary action under the applicable practice act and s. 456.072(1)(n).
- The Board of Osteopathic Medicine and Board of Medicine have grounds for disciplinary action if the issuing physician certification, as defined in s. 381.986, is performed in a manner not in compliance with the requirements set forth in statute and rule.

Qualifying Medical Conditions

Other debilitating medical conditions of the same kind or class as or comparable to those enumerated, and for which a physician believes that the medical use of marijuana would likely outweigh the potential health risks for a patient.

Cancer	Epilepsy	Glaucoma
Human Immune Deficiency virus (HIV)	Acquired Immune Deficiency syndrome (AIDS)	Post-Traumatic Stress Disorder (PTSD)
Amyotrophic Lateral Sclerosis (ALS)	Crohn's Disease	Parkinson's Disease
Multiple Sclerosis (MS)	Terminal Condition	Chronic Nonmalignant Pain

Medical Conditions of the same kind or class as or comparable to those above

The medical use of medical marijuana does NOT include the following:

- The possession, use or administration of medical marijuana by smoking.
- The transfer of medical marijuana to a person other than the qualified patient for whom it was ordered or their legal representative.
- The use or administration of medical marijuana on any form of public transportation, in any public place, in a qualified patient's place of employment, if restricted by his or her employer, in a state correctional institution, on the grounds of a preschool, primary school, or secondary school or any school bus or vehicle.

Qualifying Physicians



- Hold an active, unrestricted license as a physician under chapter 458, F.S. or an osteopathic physician under chapter 459, F.S.;
- Not be a medical director employed by a Medical Marijuana Treatment Center;
- Successfully complete the 2-hour medical marijuana course;
- Register as a qualifying physician with the Department of Health.

Physician Education Requirements



Physician Course Requirements

- In order to issue physician certifications or to be a medical director of an MMTC, the statute requires that a physician complete a **2-hour training course prior to being approved to issue physician certifications** and at each licensure renewal.
- The course must encompass the requirements of the section and any rules adopted to implement the section.
- Further, it requires the Florida Medical Association (FMA) or the Florida Osteopathic Medical Association (FOMA) to develop and offer the course annually.
- The FMA or FOMA may not charge more than \$500 to take the course and may offer the course in a distance learning format, including online.



Restrictions on Issuing Physician Certifications

- A physician may not issue a physician certification:
 - If he or she is employed by an MMTC or marijuana testing laboratory;
 - If he or she has any direct or indirect economic interest in an MMTC or marijuana testing laboratory.



Procedures for Issuing a Physician Certification

A physician must:

- Conduct an in-person physical examination of the patient and a full assessment of the patient's medical history;
- Diagnose the patient with at least one qualifying medical condition;
- Determine that the patient's use of marijuana would outweigh the risks if the patient is under the age of 18, two physicians must make this determination;
- Determine whether the patient is pregnant physicians may only certify pregnant patients for low-THC cannabis;
- Review the patient's controlled substance prescription history in the prescription drug monitoring program database;
 - Ouestion "TO PRINT OR NOT TO PRINT?"



Procedures for Issuing a Physician Certification

A physician must:

- Review the medical marijuana use registry (registry) to determine that the patient does not have an active physician certification from another qualified physician;
- Register as the issuer of the physician certification on the registry. The physician must also:
 - Enter the contents of the physician certification into the registry including the patient's qualifying condition, the dosage not to exceed the daily dose amount determined by the DOH, the amount and forms of marijuana authorized for the patient, and any types of marijuana delivery devices needed by the patient;
 - Update the registry if any change is made to the physician certification;
 - Deactivate the patient's registration when the physician no longer recommends the patient medically use marijuana.



Procedures for Issuing a Physician Certification

Informed Consent

- A physician must also obtain the patient's voluntary and written informed consent each time he or she issues the patient a physician certification.
- The physician must use a standardized form created by the Board of Medicine (BOM) or the Board of Osteopathic Medicine (BOOM) and, if the patient is a minor, the physician must also obtain the consent of the patient's parent or legal guardian.



Procedures for Issuing a Physician Certification

The standardized informed consent form must include:

- The Federal Government's classification of marijuana as a Schedule I controlled substance;
- The approval and oversight status of marijuana by the Food and Drug Administration;
- The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in this section;
- The potential for addiction;
- The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly;
- The potential side effects of marijuana use;
- The risks, benefits, and drug interactions of marijuana;
- That the patient's de-identified health information contained in the physician certification and registry may be used for research purposes.



Medical Marijuana Consent Form

A qualified physician may not delegate the responsibility of obtaining written informed consent to another person. The qualified patient or the patient's parent or legal guardian if the patient is a minor must initial each section of this consent form to indicate that the physician explained the information and, along with the qualified physician, must sign and date the informed consent form.

- a. The Federal Government's classification of marijuana as a Schedule I controlled substance.
- The federal government has classified marijuana as a Schedule I controlled substance. Schedule I substances are defined, in part, as having (1) a high potential for abuse; (2) no currently accepted medical use in treatment in the United States; and (3) a lack of accepted safety for use under medical supervision. Federal law prohibits the manufacture, distribution and possession of marijuana even in states, such as Florida, which have modified their state laws to treat marijuana as a medicine.
- ____When in the possession or under the influence of medical marijuana, the patient or the patient's caregiver must have his or her medical marijuana use registry identification card in his or her possession at all times.
- b. The approval and oversight status of marijuana by the Food and Drug
- Marijuana has not been approved by the Food and Drug Administration for marketing as a drug. Therefore, the "manufacture" of marijuana for medical use is not subject to any federal standards, quality control, or other oversight. Marijuana may contain unknown quantities of active ingredients, which may vary in potency, impurities, contaminants, and substances in addition to THC, which is the primary psychoactive chemical component of marijuana.
- c. The potential for addiction.
- Some studies suggest that the use of marijuana by individuals may lead to a tolerance to, dependence on, or addiction to marijuana. I understand that if I require increasingly higher doses to achieve the same benefit or if I think that I may be developing a dependency on marijuana, I should contact Dr. ______ (name of qualified physician).
- d. The potential effect that marijuana may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require a person to be alert or respond quickly.

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	The use of marijuana can affect coordination, motor skills and cognition, i.e., the ability to think, judge and reason. Driving under the influence of cannabis can double the risk of
	crashing, which escalates if alcohol is also influencing the driver. While using medical
	marijuana, I should not drive, operate heavy machinery or engage in any activities that
	require me to be alert and/or respond quickly and I should not participate in activities that
	may be dangerous to myself or others. I understand that if I drive while under the
	influence of marijuana, I can be arrested for "driving under the influence."
e.	The potential side effects of medical marijuana use.
	Potential side effects from the use of marijuana include, but are not limited to, the
	following: dizziness, anxiety, confusion, sedation, low blood pressure, impairment of
	short term memory, euphoria, difficulty in completing complex tasks, suppression of the
	body's immune system, may affect the production of sex hormones that lead to adverse
	effects, inability to concentrate, impaired motor skills, paranoia, psychotic symptoms, general apathy, depression and/or restlessness. Marijuana may exacerbate
	schizophrenia in persons predisposed to that disorder. In addition, the use of medical
	marijuana may cause me to talk or eat in excess, alter my perception of time and space
	and impair my judgment. Many medical authorities claim that use of medical marijuana,
	especially by persons younger than 25, can result in long-term problems with attention,
	memory, learning, drug abuse, and schizophrenia.
	I understand that using marijuana while consuming alcohol is not recommended.
	Additional side effects may become present when using both alcohol and marijuana.
	I agree to contact Dr. if I experience any of the side effects listed
	above, or if I become depressed or psychotic, have suicidal thoughts, or experience
	crying spells. I will also contact Dr if I experience respiratory
	problems, changes in my normal sleeping patterns, extreme fatigue, increased irritability
	or begin to withdraw from my family and/or friends.
g.	The risks, benefits, and drug interactions of marijuana.
	Signs of withdrawal can include; feelings of depression, sadness, irritability, insomnia,
	restlessness, agitation, loss of appetite, trouble concentrating, sleep disturbances and
	unusual tiredness.
	Symptoms of marijuana overdose include, but are not limited to, nausea, vomiting,
	hacking cough, disturbances in heart rhythms, numbness in the hands, feet, arms or
	legs, anxiety attacks and incapacitation. If I experience these symptoms, I agree to
	contact Dr immediately or go to the nearest emergency room.
	Numerous drugs are known to interact with marijuana and not all drug interactions are
	known. Some mixtures of medications can lead to serious and even fatal consequences
	I agree to follow the directions of Dr regarding the use of prescription
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and non-prescription medication. I will advise any other of my treating physician(s) of my use of medical marijuana. Marijuana may increase the risk of bleeding, low blood pressure, elevated blood sugar, liver enzymes, and other bodily systems when taken with herbs and supplements. I immediately or go to the nearest emergency agree to contact Dr. room if these symptoms occur. I understand that medical marijuana may have serious risks and may cause low birthweight or other abnormalities in babies. I will advise Dr. become pregnant, try to get pregnant, or will be breastfeeding. h. The current state of research on the efficacy of marijuana to treat the qualifying Cancer . There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for cancers, including glioma. There is evidence to suggest that cannabinoids (and the endocannabinoid system more generally) may play a role in the cancer regulation processes. Due to a lack of recent, high quality reviews, a research gap exists concerning the effectiveness of cannabis or cannabinoids in treating cancer in general. . There is conclusive evidence that oral cannabinoids are effective antiemetics in the treatment of chemotherapy-induced nausea and vomiting. There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for cancer-associated anorexia-cachexia syndrome and anorexia nervosa. . There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for epilepsy. Recent systematic reviews were unable to identify any randomized controlled trials evaluating the efficacy of cannabinoids for the treatment of epilepsy. Currently available clinical data therefore consist solely of uncontrolled case series, which do not provide high-quality evidence of efficacy. Randomized trials of the efficacy of cannabidiol for different forms of epilepsy have been completed and await publication. . There is limited evidence that cannabinoids are an ineffective treatment for improving intraocular pressure associated with glaucoma.

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Lower intraocular pressure is a key target for glaucoma treatments. Nonrandomized studies in healthy volunteers and glaucoma patients have shown
short-term reductions in intraocular pressure with oral, topical eye drops, and
intravenous cannabinoids, suggesting the potential for therapeutic benefit. A
good-quality systemic review identified a single small trial that found no effect of
two cannabinoids, given as an oromucosal spray, on intraocular pressure. The
quality of evidence for the finding of no effect is limited. However, to be effective,
treatments targeting lower intraocular pressure must provide continual rather
than transient reductions in intraocular pressure. To date, those studies showing
positive effects have shown only short-term benefit on intraocular pressure
(hours), suggesting a limited potential for cannabinoids in the treatment of
olaucoma

Positive status for human immunodeficiency virus

 There is limited evidence that cannabis and oral cannabinoids are effective in increasing appetite and decreasing weight loss associated with HIV/AIDS.

There does not appear to be good-quality primary literature that reported on cannabis or cannabinoids as effective treatments for AIDS wasting syndrome.

Acquired immune deficiency syndrome

 There is limited evidence that cannabis and oral cannabinoids are effective in increasing appetite and decreasing weight loss associated with HIV/AIDS.

There does not appear to be good-quality primary literature that reported on cannabis or cannabinoids as effective treatments for AIDS wasting syndrome.

Post-traumatic stress disorder

 There is limited evidence (a single, small fair-quality trial) that nabilone is effective for improving symptoms of posttraumatic stress disorder.

A single, small crossover trial suggests potential benefit from the pharmaceutical cannabinoid nabilione. This limited evidence is most applicable to male veterans and contrasts with non-randomized studies showing limited evidence of a statistical association between cannabis use (plant derived forms) and increased severity of posttraumatic stress disorder. Simple symptoms among individuals with posttraumatic stress disorder. There are other trials that are in the process of being conducted and if successfully completed, they will add substantially to the knowledge base.

__ Amyotrophic lateral sclerosis

 There is insufficient evidence that cannabinoids are an effective treatment for symptoms associated with amyotrophic lateral sclerosis.

Two small studies investigated the effect of dronabinol on symptoms associated with ALS. Although there were no differences from placebo in either trial, the

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sample sizes were small, the duration of the studies was short, and the dose of dronabinol may have been too small to ascertain any activity. The effect of cannabis was not investigated.

Crohn's disease

 There is insufficient evidence to support or refute the conclusion that dronabinol is an effective treatment for the symptoms of irritable bowel syndrome.

Some studies suggest that marijuana in the form of cannabidiol may be beneficial in the treatment of inflammatory bowel diseases, including Crohn's disease.

Parkinson's disease

 There is insufficient evidence that cannabinoids are an effective treatment for the motor system symptoms associated with Parkinson's disease or the levodopainduced dyskinesia.

Evidence suggests that the endocannabinoid system plays a meaningful role in certain neurodegenerative processes; thus, it may be useful to determine the efficacy of cannabinoids in treating the symptoms of neurodegenerative diseases. Small trials of oral cannabinoid preparations have demonstrated no benefit compared to a placebo in ameliorating the side effects of Parkinson's disease. A seven-patient trial of nabilone suggested that it improved the dyskinesia associated with levodopa therapy, but the sample size limits the interpretation of the data. An observational study demonstrated improved outcomes, but the lack of a control group and the small sample size are limitations.

Multiple sclerosis

 There is substantial evidence that oral cannabinoids are an effective treatment for improving patient-reported multiple sclerosis spasticity symptoms, but limited evidence for an effect on clinician-measured spasticity.

Based on evidence from randomized controlled trials included in systematic reviews, an oral cannabis extract, nabiximols, and orally administered THC are probably effective for reducing patient-reported spasticity scores in patients with MS. The effect appears to be modest. These agents have not consistently demonstrated a benefit on clinician-measured spasticity indices.

____ Medical conditions of same kind or class as or comparable to the above qualifying medical conditions

- The qualifying physician has provided the patient or the patient's caregiver a summary of the current research on the efficacy of marijuana to treat the patient's medical condition.
- The summary is attached to this informed consent as Addendum

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_____Terminal conditions diagnosed by a physician other than the qualified physician issuing the physician certification

- The qualifying physician has provided the patient or the patient's caregiver a summary of the current research on the efficacy of marijuana to treat the patient's terminal condition.
- The summary is attached to this informed consent as Addendum .

Chronic nonmalignant pain

 There is substantial evidence that cannabis is an effective treatment for chronic pain in adults.

The majority of studies on pain evaluated nabiximols outside the United States. Only a handful of studies have evaluated the use of cannabis in the United States, and all of them evaluated cannabis in flower form provided by the National Institute on Drug Abuse. In contrast, many of the cannabis products that are sold in state-regulated markets bear little resemblance to the products that are available for research at the federal level in the United States. Pain patients also use topical forms.

While the use of cannabis for the treatment of pain is supported by wellcontrolled clinical trials, very little is known about the efficacy, dose, routes of administration, or side effects of commonly used and commercially available cannabis products in the United States.

 That the patient's de-identified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

The Department of Health submits a data set to The Medical Marijuana Research and Education Coalition for each patient registered in the medical marijuana use registry that includes the patient's qualifying medical condition and the daily dose amount and forms of marijuana certified for the patient.

_____I have had the opportunity to discuss these matters with the physician and to ask questions regarding anything I may not understand or that I believe needed to be clarified. I acknowledge that Dr. _____ has informed me of the nature of a recommended treatment, including but not limited to, any recommendation regarding medical marijuana.

Dr. also informed me of the risks, complications, and expected benefits of any recommended treatment, including its likelihood of success and failure. I acknowledge that Dr. informed me of any alternatives to the recommended treatment, including the alternative of no treatment, and the risks and benefits.

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Dr	
form about the medical use of marijua	
Patient (print name)	
Patient signature or signature of the p	parent or legal guardian if the patient is a minor:
	Date
I have explained the information in thi	is consent form about the medical use of marijuana (Print patient name).
Qualified physician signature:	
	Date
Witness:	
	Date

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DOCUMENTATION REQUIRED UNDER SECTION 381.986 (4)(b), FLORIDA STATUTES

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Section 381.986(4)(b), Florida Statutes, requires a qualified physician who issues a physician certification for a qualified patient diagnosed with a medical condition of the same kind or class as or comparable to those conditions listed in Section 381.986(2)(a)-(j), Florida Statutes, to submit the documentation below to the Boards of Medicine or Osteopathic Medicine within 14 days after issuing the physician certification. In addition, information on subsequent certifications for these diagnoses must also be submitted. Do not provide any patient identifying information other than what is requested in this form.

Send the completed form to: BOARD OF OSTEOPATHIC MEDICINE

4052 Bald Cypress Way Bin C-06, Tallahassee, FL 32399-1708

or

BOARD OF MEDICINE

4052 Bald Cypress Way Bin C-03, Tallahassee, FL 32399-1708

The Department of Health is required by law to provide documentation to the Coalition for Medical Marijuana Research and Education. Patient identifying information will not be provided to the Coalition.

DOCUMENTATION REQUIRED UNDER SECTION 381.986 (4)(b), FLORIDA STATUTES

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- 1. Qualified Patient ID:
- 2. Qualified MD/DO License Number:
- 3. Date physician certification issued:
- 4. Qualifying patient's year of birth:
- 5. Florida resident: Yes No If No, what is qualifying patient's state of permanent residence:
- 6. Qualifying patient's county of residence:
- 7. Gender: Male Female
- 8. Specify qualifying patient's medical condition of the same kind or class as or comparable to those enumerated in

Section 381.986(2), (a)-(j), Florida Statutes:

9. Documentation supporting qualified physician's opinion that the medical condition is of the same kind or class as the

Conditions in paragraphs (2)(a)-(j):

- 10. Documentation (clinical, medical, or scientific data) that establishes the efficacy of marijuana as treatment for the condition:
- 11. Documentation supporting the qualified physician's opinion that the benefits of medical use of marijuana would likely outweigh the potential health risks for the patient.

Signature of qualified physician Date



Issuing a Physician Certification for a Condition of the "Same Kind or Class"

If a physician issues a certification for a condition of the same kind or class as a listed condition, the physician must provide his or her applicable board (BOM or BOOM) with additional information within 14 days after issuing the physician certification. The additional information includes:

- Documentation supporting the qualified physician's opinion that the medical condition is
 of the same kind or class as the conditions enumerated;
- Documentation that establishes the efficacy of marijuana as treatment for the condition;
- Documentation supporting the qualified physician's opinion that the benefits of medical use of marijuana would likely outweigh the potential health risks for the patient;
- Any other documentation as required by board rule.

The DOH must also submit this additional documentation to the Coalition for Medical Marijuana Research and Education (Coalition) for research purposes.



Supply Limits

A qualified physician may not issue more than three 70-day supplies of marijuana. The DOH must quantify by rule a daily dose amount for each allowable form of marijuana. A physician may request an exception to the daily dose limit by electronically submitting a form adopted by the DOH in rule to the department. At a minimum, the form must include:

- The qualified patient's qualifying medical condition;
- The dosage and route of administration that was insufficient to provide relief to the qualified patient;
- A description of how the patient will benefit from an increased amount;
- The minimum daily dose amount of marijuana that would be sufficient for the treatment of the qualified patient's qualifying medical condition.

A qualified physician must provide the qualified patient's records upon the request of the department. The department must approve or disapprove the request within 14 days after receipt of the complete documentation required by this paragraph or the request is deemed approved.



Patient Recertification

A physician must recertify a patient at least once every 30 weeks. In order to recertify a patient a physician must:

- Determine if the patient still meets the requirements to be issued a physician certification;
- Identify and document in the qualified patient's medical records whether the qualified patient experienced either of the following related to the medical use of marijuana:
 - An adverse drug interaction with any prescription or nonprescription medication; or
 - o A reduction in the use of, or dependence on, other types of controlled substances as defined in s. 893.02, F.S.

Other Regulations of Interest



Residency Requirements

Before registering a patient with the registry, the DOH must determine whether the patient is a resident of Florida, which may include a "seasonal resident." A "seasonal resident" includes any person who:

- Temporarily resides in this state for a period of at least 31 consecutive days in each calendar year;
- Maintains a temporary residence in this state;
- Returns to the state or jurisdiction of his or her residence at least one time during each calendar year; and
- Is registered to vote or pays income tax in another state or jurisdiction.

To prove residency a Florida resident must provide the DOH with copy of his or her valid Florida driver license or identification card. A minor must have a parent or legal guardian who meets this requirements and must also provide the DOH with a certified copy of his or her birth certificate or his or her school registration from a Florida K-12 school.

Other Regulations of Interest

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Residency Requirements

A seasonal resident who cannot provide a copy of a Florida driver license or identification card may provide the DOH with two of the following to demonstrate a residential address in this state:

- A deed, mortgage, monthly mortgage statement, mortgage payment booklet or residential
- rental or lease agreement.;
- One proof of residential address from the seasonal resident's parent, step-parent, legal;
- guardian or other person with whom the seasonal resident resides and a statement from the person with whom the seasonal resident resides stating that the seasonal resident does reside with him or her;
- A utility hookup or work order dated within 60 days before registration in the medical use registry;
- A utility bill, not more than 2 months old;
- Mail from a financial institution, including checking, savings, or investment account
- statements, not more than 2 months old;
- Mail from a federal, state, county, or municipal government agency, not more than 2 months old;
- Any other documentation that provides proof of residential address as determined by
- department rule.

Other Regulations of Interest



Physician Monitoring

- The DOH is required to monitor physician registration in the registry and the issuance of physician certifications for practices that could facilitate the unlawful diversion or misuse of marijuana and take disciplinary actions as appropriate.
- Additionally, the BOM and the BOOM must jointly create a physician certification review panel to review all physician certifications submitted to the registry. The review panel is required to collect specified certification data and report such data individually by physician and in the aggregate by county and statewide. Starting January 1, 2018, and annually thereafter, the panel must submit a report to the Governor and the Legislature with findings and recommendations.



The Medical Marijuana Use Registry

- The previously named Compassionate Use Registry is renamed the Medical Marijuana Use Registry.
- The DOH is required to maintain the registry for physicians, patients, and caregivers.
- The electronic registry must be accessible online to law enforcement agencies, qualified physicians, and medical marijuana treatment centers (MMTC) to verify patient certifications.
- The registry must also be accessible to practitioners licensed to prescribe prescription drugs to ensure proper care for patients before prescribing medications that may interact with the medical use of marijuana.



Patient and Caregiver Disqualification

The DOH may suspend or revoke the registration of any qualified patient or caregiver if he or she:

- Provides misleading, incorrect, false, or fraudulent information to the department;
- Obtains a supply of marijuana in an amount greater than the amount authorized by the physician certification;
- Falsifies, alters, or otherwise modifies an identification card;
- Fails to timely notify the department of any changes to his or her qualified patient status;
- Violates the requirements of this section or any rule adopted under this section.

The DOH must suspend the registration of a qualified patient who is charged with a violation of ch. 893, F.S., until the final disposition of the offense. The DOH may revoke the registration of a qualified patient or caregiver who cultivates, acquires, possesses, or delivers marijuana that was not obtained from an MMTC. Additionally, the DOH must revoke the registration of any qualified patient and his or her caregiver if such patient no longer meets the criteria of a qualified patient.



Caregivers

In order to qualify as a caregiver an individual must:

- Not be a qualified physician and not be employed by or have an economic interest in an MMTC or a marijuana testing laboratory;
- Be 21 years of age or older and a resident of this state;
- Agree in writing to assist with the qualified patient's medical use of marijuana;
- Be registered in the medical marijuana use registry as a caregiver for no more than one qualified patient, with certain exceptions discussed below;
- Successfully complete a caregiver certification course developed and administered by the department or its designee, which must be renewed biennially. The price of the course may not exceed \$100;
- Pass a background screening, unless the patient is a close relative of the caregiver.



Caregivers

A qualified patient may only have one caregiver unless:

- The qualified patient is a minor and the designated caregivers are parents or legal guardians of the qualified patient;
- The qualified patient is an adult who has an intellectual or developmental disability that prevents the patient from being able to protect or care for himself or herself without assistance or supervision and the designated caregivers are the parents or legal guardians of the qualified patient; or
- The qualified patient is admitted to a hospice program.



Caregivers

A caregiver may only assist one qualified patient unless:

- The caregiver is a parent or legal guardian of more than one minor who is a qualified patient;
- The caregiver is a parent or legal guardian of more than one adult who is a qualified patient and who has an intellectual or developmental disability that prevents the patient from being able to protect or care for himself or herself without assistance or supervision; or
- All qualified patients the caregiver has agreed to assist are admitted to a hospice program and have requested the assistance of that caregiver with the medical use of marijuana; the caregiver is an employee of the hospice; and the caregiver provides personal care or other services directly to clients of the hospice in the scope of that employment.



Caregivers

- A caregiver may not receive compensation for providing caregiver services other than actual expenses.
- A caregiver must be in immediate possession of his or her medical marijuana use registry identification card at all times when in possession of marijuana or a marijuana delivery device and must present his or her card if requested by a law enforcement officer.
- If a qualified patient is younger than 18 years of age, only a caregiver may purchase or administer marijuana for the patient's medical use.

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Federal Guidelines and Medical Marijuana



- According to Federal Law, marijuana is classified as a Schedule 1 Drug.
- A Schedule 1 Drug is defined as:
 - Drugs with no currently accepted medical use and a high potential for abuse.
- Medical Marijuana is **not FDA approved** for the treatment of any medical condition.
- Both medical and recreational marijuana use still remains illegal under federal law.



• Currently, 29 other states have legislation in place allowing the use of marijuana for medicinal purposes (either full THC or low-THC/CBD).

• 8 states: Alaska, California, Colorado, Maine, Massachusetts, Nevada, Washington, Oregon, and Washington D.C. have legalized marijuana for both medicinal and recreational purposes.



- Previous U.S. Attorney Generals, have suggested focusing prosecutions on significant traffickers, not individual users.
- Therefore, in the past, U.S. attorneys have been asked not to prosecute patients "with cancer or other serious illnesses" who are using cannabis as part of a "recommended treatment regimen consistent with state law" or physicians who provide cannabis to such patients (Barber 2014).



- Since Federal Guidelines label marijuana as a Schedule I Drug, many research-based organizations, who receive federal funding, have voiced concerns regarding the study of medical cannabis;
- This concern was expressed by the University of Florida when SB 1030 originally passed in 2014. However, in 2015, the University changed its position on the basis of the FDA's move to allow investigational new drug studies on "purified cannabidiols" for use as anti-seizure medications.

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Banking

• The absence of banks providing financial services has resulted in marijuana becoming a prominently cash-only business. In order to address public safety concerns surrounding stockpiles of cash - the federal government issued guidelines intended to make financial services available to marijuana businesses providing legal services under a particular state's marijuana laws. Please see the following link for the Treasury Department's The Financial Crimes Enforcement Network ("FinCEN") guidelines:

http://www.fincen.gov/statutes_regs/guidance/pdf/FIN-2014-Goo1.pdf

- Under the Treasury Department's plan "guidelines," banks would file a suspicious activity report (SAR) for any financial transactions by any marijuana-related business. In turn, the financial institution is required to certify that it did not believe the business engaged in any illegal activity beyond dealing within the structure of the State's marijuana laws;
- According to Forbes Magazine: The <u>guidelines have not persuaded many banks</u> to offer services because federal laws still prohibit such acts. For a copy of the <u>article please see the following link:</u>

http://www.forbes.com/sites/jacobsullum/2014/09/18/local-banks-terrified-by-friendly-neighborhood-marijuana-merchants/



Banking

- In Florida, there is one bank that is working with six currently licensed medical marijuana dispensing companies in Florida;
- First Green Bank, a community bank based in Orlando, has six branches, mostly in Central Florida and one in South Florida;
- With \$662 million in assets, First Green Bank actively promotes environmental and social responsibility and is known for offering discounts and low-interest loans on "green" initiatives, like electric cars, LEED-certified construction and solar systems;
- Ken LaRoe, the bank's founder has added cannabis to the list, because his wife used to use marijuana as treatment for seizures;
- Since medical marijuana is mostly a cash business, First Green bank hires armored cars to pick up the cash from the dispensaries. From there, the cash is sent to the Federal Reserve and then the money is electronically transferred to the bank.;
- Under guidance from the Federal Deposit Insurance Corporation and Florida Office of Financial Regulation, First Green must file regular reports of all marijuana transactions as "suspicious activities" under the "FinCen" guidelines (see previous slide).
- http://www.sun-sentinel.com/business/fl-bz-first-green-banks-med-marijuana-20170810-story.html

Proposed Change to Federal Guidelines



- In early April 2016, the DEA released a lengthy memo to lawmakers saying it hopes to decide whether to change the schedule designation of marijuana in the first half of 2016.
- In August 2016 the DEA and FDA decided not to revise marijuana's Schedule I status (no accepted medical use and high potential for abuse).
- "The DEA and the FDA continue to believe that scientifically valid and well-controlled clinical trials conducted under investigational new drug (IND) applications are the most appropriate way to conduct research on the medicinal uses of marijuana," said a statement from the DEA" (CNN August 12, 2016). http://www.cnn.com/2016/08/11/health/dea-marijuana-schedule-l/



The FDA & Medical Marijuana – Working Toward Valid Research

- The FDA has not approved any product containing or derived from botanical marijuana for any indication;
- The FDA has not found any such product to be safe or effective for the treatment of any disease or condition;
- Study of marijuana in clinical trial settings is needed to assess the safety and effectiveness of marijuana for medical use;
- According to the FDA, they will continue to facilitate the work of companies interested in appropriately bringing safe, effective, and quality products to market, including scientifically-based research concerning the medicinal uses of marijuana;
- The FDA believes that scientifically valid research conducted under an investigational new drug (IND) application is the best way to determine what patients could benefit from the use of drugs derived from marijuana.



The FDA & Medical Marijuana – Working Toward Valid Research

- Presently, clinical research using marijuana involves interactions with several federal agencies:
 - As a Schedule I controlled substance under the Controlled Substances Act, DEA provides researchers with a special registration and has certain requirements at the site marijuana will be studied;
 - o The National Institute on Drug Abuse (NIDA) provides research-grade marijuana for scientific study. The agency is responsible for overseeing the cultivation of marijuana for medical research and has contracted with the University of Mississippi to grow marijuana for research at a secure facility. Marijuana of varying strengths and potencies is available;
 - Researchers work with the FDA and submit an IND application.

Legal Disclaimer



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