

Florida Rules on Medical Cannabis

- Review of the Florida Medical Marijuana Law
 - Certification of physicians and patients
- Compliance with HIPAA (Health Insurance Portability and Accountability Act)
 - Privacy and security
- Rules and procedures to be followed by Dispensary Staff



The Florida Dept of Health **Office of Medical Marijuana Use** is charged with:

- writing and implementing the department's rules for medical marijuana
- overseeing the statewide Medical Marijuana Use Registry licensing Florida businesses to cultivate, process, and dispense medical marijuana to qualified patients.



“Conditions” of the State Law

- The patient must be a permanent resident of this state
- The treating (certified) physician determines that the health risks of ordering cannabis are reasonable in light of the potential benefit for that patient
 - If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must concur with this determination, and such determination must be documented in the patient’s medical record



Certification of Physicians

Before being approved as a physician qualified to recommend medical cannabis, and before each medical license renewal, a physician must successfully complete a 2-hour course and subsequent examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association



Certification of Patients

- A qualified physician must conduct a physical examination while physically present in the same room as the patient and a full assessment of the medical history of the patient.
- Patient must be diagnosed with at least one qualifying medical condition.
- Physician must determine that the medical use of marijuana would likely outweigh the potential health risks for the patient, and such determination must be documented in the patient's medical record.
 - If a patient is younger than 18 years of age, a second physician must concur with this determination, and such concurrence must be documented in the patient's medical record.



Certification of Patients

- Physician must determine whether the patient is pregnant and document this in the patient's medical record. A physician may not issue a physician certification, except for low-THC cannabis, to a patient who is pregnant.
- Physician must review the patient's controlled drug prescription history in the prescription drug monitoring program database.
- Physician must review the medical marijuana use registry and confirm that the patient does not have an active physician certification from another qualified physician.



Qualifying Medical Conditions

- (a) Cancer
- (b) Epilepsy
- (c) Glaucoma
- (d) Positive status for HIV
- (e) Acquired immune deficiency syndrome
- (f) Post-traumatic stress disorder
- (g) Amyotrophic lateral sclerosis
- (h) Crohn's disease
- (i) Parkinson's disease
- (j) Multiple sclerosis



Qualifying Medical Conditions (continued)

- (k) Medical conditions of the same kind or class as or comparable to those enumerated in items(a)-(j).
- (l) A terminal condition diagnosed by a physician other than the qualified physician issuing the physician certification.
- (m) Chronic nonmalignant pain (i.e., 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).



Protection of Personal Health Information (PHI)



Health Insurance Portability and Accountability Act (HIPAA)

- HIPAA is United States legislation that provides data privacy and security provisions for safeguarding personal medical information
- The law has emerged into greater prominence in recent years with the proliferation of health data breaches caused by cyberattacks and ransomware attacks on health insurers and providers



Who is covered by and must follow HIPAA?

- The law applies to organizations that are considered HIPAA-covered entities, including health plans, healthcare clearinghouses, healthcare providers, including doctors, clinics, hospitals, nursing homes, pharmacies and Medical Marijuana Treatment Centers and Dispensaries)



HIPAA

- Two of the rules most important for Medical Marijuana Dispensaries (MMD) are:
- HIPAA Privacy Rule. Officially known as the Standards for Privacy of Individually Identifiable Health Information, this rule establishes national standards to protect patient health information.
- HIPAA Security Rule. The Security Standards for the Protection of Electronic Protected Health Information sets standards for patient data



HIPAA Privacy Rule

- The rule limits the use and disclosure of sensitive personal or protected health information (PHI)
- It seeks to protect the privacy of patients by requiring doctors to provide patients with an account of each entity to which the doctor discloses PHI for billing and administrative purposes, while still allowing relevant health information to flow through the proper channels.
- Guarantees patients the right to receive their own PHI, upon request, from healthcare providers covered by HIPAA.



What is considered protected health information under HIPAA?

- PHI includes:
 - a patient's name, address, birth date and Social Security number;
 - an individual's physical or mental health condition;
 - any care provided to an individual; or
 - information concerning the payment for the care provided to the individual that identifies the patient, or information for which there is a reasonable basis to believe could be used to identify the patient.



Compliance of Dispensary Staff with HIPAA

- The General Manager of 3BF dispensaries in consultation with the Medical Director, will be in charge of ensuring staff compliance with HIPAA (see link below)
- The Dispensary will keep Protected Health Information (PHI) secure and private.
- Each dispensary manager will ensure implementation procedures and training for dispensary staff in their specific dispensary.
- Patients must be informed of their rights and support those rights.
- Patient information access will be limited to businesses outside the dispensaries

<http://thepracticesolution.net/2005/05/05/five-steps-hipaa-privacy-rule-compliance/>

Compliance with Rules Set by Office of Medical Marijuana Use

- The patient must be a permanent resident of Florida
- The physician determines that the risk of ordering cannabis medications are reasonable in light of the potential benefit for that patient
 - If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must concur with this determination, and such determination must be documented in the patient's medical record



Rules (Office of Medical Marijuana Use)

- The physician must be registered as the orderer of cannabis meds for the named patient on the compassionate use registry maintained by the department and updates the registry to reflect the contents of the order.
- Patients will be provided an ID card certifying their registration in the Medical Marijuana Use database
- The physician shall deactivate the patient's registration when treatment is discontinued
- The physician maintains a patient treatment plan including dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of tolerance or reaction to the cannabis.

Rules (Office of Medical Marijuana Use)

- The physician submits the patient treatment plan quarterly to the University of Florida College of Pharmacy for research on the safety and efficacy of cannabis on patients
- The physician obtains the voluntary informed consent of the patient or the patient's legal guardian to treatment with cannabis after sufficiently explaining the current state of knowledge in the medical community of the effectiveness of treatment of the patient's condition with cannabis, the medically acceptable alternatives, and the potential risks and side effects



Penalties if conditions are not met

- A physician commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, if the physician orders cannabis for a patient without a reasonable belief that the patient is suffering from the conditions listed earlier



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Labeling of the Packaged Medical Cannabis

The medical cannabis will be packaged in a receptacle that has a firmly affixed and legible label stating the following information:

1. The marijuana or low-THC cannabis has been certified to have been tested by a medical marijuana testing laboratory before it is dispensed. Results must be verified and signed by two medical marijuana treatment center employees
2. The name of the medical marijuana treatment center from which the marijuana originates.
3. The batch number and harvest number from which the marijuana originates and the date dispensed.
4. The name of the physician who issued the physician certification.
5. The name of the patient.
6. 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.
7. The recommended dose.
8. A warning that it is illegal to transfer medical marijuana to another person.



Rules for Dispensing Marijuana or a Marijuana Delivery Device

- Do 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.
- Do not dispense or sell any other type of cannabis, alcohol, or illicit drug-related 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.
- You 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.



New Rules for Proper Dispensation and Medical Marijuana Use Registry (MMUR) (As of Oct 24, 2017)

Failure to comply with these rules will be penalized by fines and
other measures including withdrawal of license from MMTC



Rules

- The MMTC employee's name or unique employee identifier must be entered into the MMUR for each dispensation of low-THC cannabis, medical cannabis, or cannabis delivery device
- MMTC staff must verify in the MMUR, prior to dispensing to the patient or their caregiver, that a physician has entered a valid order for low-THC cannabis, medical cannabis, or a cannabis delivery device for that patient
- MMTC staff must verify in the MMUR, prior to dispensing to the patient or their caregiver, that: (1) the patient has an active registration in the MMUR, (2) the patient or the patient's caregiver holds a valid and active identification card, and (3) that there is a sufficient number of milligrams of recommended product remaining to fill an order.



Rules

- The MMTC must not dispense more than a 70-day supply of low-THC cannabis or medical cannabis to a patient or caregiver.
- MMTC staff must record in the MMUR the: (1) date, (2) time, (3) quantity of medical marijuana dispensed, (4) form of medical marijuana dispensed, (5) type of marijuana delivery device dispensed if applicable, and (6) the name and MMUR identification number of the patient or caregiver for each dispensation.
- MMTC must NOT dispense low-THC cannabis, medical cannabis, or cannabis delivery device by a MMTC to a qualified patient who is younger than 18 years of age.



DAILY DOSAGE AMOUNT LIMITS FOR 5 IDENTIFIABLE “FORMS” OF MEDICAL CANNABIS

	THC (mg)	CBD (mg)
Daily Dose Amount Limits	1000	1500
Inhalation	750	1500
Oral	1000	1500
Rectal	600	1000
Sublingual	1000	1500
Topical	600	1000

“Forms” reflects different routes of administration or delivery rather than flower, oil or topical cream formulations.

Rules

- MMTC cannot dispense or sell any other type of cannabis, alcohol, or illicit drug-related product, including pipes, bongs, or wrapping papers, other than a marijuana delivery device required for the medical use of marijuana as specified in a physician certification, by an MMTC at a dispensing facility
- MMTC staff must not dispense low-THC cannabis, medical cannabis, or a cannabis delivery device from the premises of a MMTC between the hours of 9 p.m. and 7 a.m.
- MMTC staff must not create a patient or caregiver in the MMUR using misleading, incorrect, false, or fraudulent information.



Rules

- MMTC staff must not misuse or have improper access to the MMUR. Misuse or improper access includes:
 - Failure of a MMTC or other approved user to establish or enforce policies and procedures restricting access to the MMUR only to those individuals authorized by section 381.986, Florida Statutes, and whose access has been approved by the department;
 - Failure of a MMTC or other approved user to establish or enforce policies and procedures preventing personnel from sharing login and password information or accessing the MMUR on another individual's account; and
 - Use of data from the MMUR for cold-calling or otherwise soliciting patients or caregivers.



Rules

- MMTC staff must not Improperly disclose the personal information of a qualified patient or caregiver. Personal information includes the patient and caregiver names, birth dates, telephone numbers, addresses, electronic mail addresses, social security numbers and biometric identifiers.(See HIPAA rules)
- Dispensary staff must wear a photo identification badge at all times while on the premises.
- Dispensaries are required to be alcohol and drug-free workplace; no alcohol or illicit drugs allowed on premises



Rules

Staff must follow procedures for **safe transport** of low-THC cannabis or medical marijuana to MMTC facilities, independent testing laboratories, or patients or caregiver. The minimum requirements are:

- Maintenance of a transportation manifest for each delivery, which must be retained for at least 1 year;
- Ensuring that only vehicles in good working order are used to transport low-THC and medical cannabis;
- Ensuring that low-THC cannabis and medical cannabis is locked in a separate compartment or container within the vehicle;
- Ensuring that at least two persons are in a vehicle transporting low-THC cannabis or medical cannabis, and that at least one person remains in the vehicle while low-THC cannabis or medical cannabis is being delivered; and
- Ensuring that all employees transporting or delivering low-THC cannabis or medical cannabis receive specific safety and security training.

