WHAT YOU NEED TO KNOW ABOUT FLORIDA'S MEDICAL USE OF MARIJUANA ACT

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Introduction

On June 9, after months of hashing out the final details, the Florida Legislature rolled out its guidelines for Florida's budding medical marijuana industry. On June 23, Governor Rick Scott sparked it to life. Known as the Medical Use of Marijuana Act, it is the long-awaited outcome of last year's Medical Marijuana Legalization Initiative, also known as Amendment 2, which passed in November 2016 with nearly 71 percent of voters in favor of allowing certain individuals to have access to medical marijuana treatment. These guidelines allow for the use and availability of medical marijuana for those suffering from statutorily enumerated debilitating diseases or qualifying medical conditions as determined by a licensed state physician. ¹

The Medical Use of Marijuana Act regulates how patients become eligible to use medical marijuana, and what physicians and medical directors must do before prescribing marijuana to qualified patients. Additional highlights include: (1) a medical exemption from state sales tax of marijuana and marijuana delivery devices; (2) a cap on the number of retail dispensaries and treatment centers until April 2020; (3) required background checks of those individuals in ownership, management, or other high ranking positions in a marijuana treatment center; (4) periodic inspections of treatment centers; and (5) a ban on smoking medical marijuana that limits use to only the edible form and vaporizing.

Important Definitions

• Marijuana means all parts of the plant: seeds, extracted resins, and any other type of preparation of the plant, including low-THC cannabis. THC is the psychoactive compound known as tetrahydrocannabinol which causes the euphoric feeling and altered state of consciousness that users report experiencing when ingesting normal marijuana plant flowers. This allows many patients to escape the conscious feeling of pain and enhances the living experience in many ways for those who have used and encouraged it.²

¹ The Medical Use of Marijuana Act defines the following medical conditions as those which qualify a patient for medical marijuana: cancer, epilepsy, glaucoma, HIV, AIDS, post-traumatic stress disorder (PTSD), amyotrophic lateral sclerosis (ALS), Crohn's disease, Parkinson's disease, multiple sclerosis, chronic non-malignant pain, a terminal condition, 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.

² One author met Timothy Leary in 1979, and spent approximately 30 minutes with him in a car taking him from the airport to a college where he was speaking. He was a very pleasant

- Low-THC Cannabis is marijuana (as defined above) that contains 0.8 percent or less of THC and is required to be used for pregnant patients, and is the only form of medical marijuana allowed on public transportation, in a public place, in a school bus, vehicle, aircraft, or motorboat.
- *Marijuana Delivery Device* is an object from a medical marijuana treatment center that is used to prepare, store, ingest, inhale, or otherwise introduce marijuana into the body.
- *Edibles* are commercially produced food items made with marijuana oil. No other form of marijuana may be used in producing an edible.
- *Smoking* is the actual burning of marijuana and inhaling the smoke, which is not permitted. However, vaporizing, which uses a device to heat the active ingredients of plant material to the temperature at which the active compounds in marijuana become vaporized and available for inhalation, is permitted, and is said to provide optimum use of all parts of the plant, whereby smoking creates secondary smoke and higher temperatures which may cause loss of access to parts of the plant that would simply be burned out of existence at the higher temperature. Elderly patients who know how to smoke a cigarette may not be able to use a vaporizer without assistance.
- Qualifying Medical Conditions include: cancer, epilepsy, glaucoma, HIV, AIDS, post-traumatic stress disorder, amyotrophic lateral sclerosis, Crohn's disease, Parkinson's disease, multiple sclerosis, chronic non-malignant pain, a terminal condition, 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.
- Terminal Condition is defined as: (1) a progressive disease or a medical or surgical condition that causes significant functional impairment; (2) that is not considered by a treating physician to be reversible without the administration of life-sustaining procedures; and (3) will result in death within one year after diagnosis if the condition runs its normal course.
- Chronic Non-Malignant Pain is pain caused by a qualifying medical condition or originates from such condition and persists beyond the usual course of that condition.

Patient Requirements

While not precisely a requirement that is either easily satisfied or preferred, an individual must be suffering from one of the qualifying medical conditions in order to receive medical

gentleman, condoned the use of hallucinogenic drugs to college students and became very popular and unpopular as a result thereof.

marijuana.³ Interestingly, permanent Florida residency is not required. Seasonal residents of Florida ("snowbirds") who can provide the Department of Health with proof of residency may be eligible to receive medical marijuana for qualifying conditions.

Physician Requirements

The requirements for physicians to become qualified to order medical marijuana are more burdensome. To begin prescribing after the new rules take effect, which will be by October 2017, physicians must complete a two-hour course and examination offered by the Florida Medical Association or Osteopathic Medical Association, which will not cost more than \$500. Those who wish to be employed as a Medical Director of a marijuana treatment facility must also complete the two-hour course and examination.

Physicians that recommend medical marijuana to patients may not be employed by, or have any direct or indirect economic interest in a medical marijuana treatment center or marijuana testing laboratory.

Upon first meeting with a patient who will receive a prescription for medical marijuana, the physician must perform a physical examination while present in the room with the patient, in addition to a full assessment of the patient's medical history. Following the physical examination and review of medical history, the physician must have or be able to diagnose the patient with at least one qualifying medical condition.

It will be interesting to see how far some physicians are willing to push the ability to prescribe for "medical conditions of the same kind or class as, or comparable to, those enumerated." Whether the patient qualifies is based entirely on the opinion of the physician, provided that it fits within the overly broad category of being in the same class of or comparable to another qualifying condition. For example, symptoms of PTSD⁴ include flashbacks, nightmares, and severe anxiety. Is it enough to say that you suffer from comparable symptoms or must you experience some traumatic event?

Physicians must have a reasonable belief that the patient is suffering from a qualifying medical condition. Otherwise they risk committing a misdemeanor in the first degree punishable by one year in prison and a \$1,000 fine, in addition to losing their license to practice.

With the above information in mind, the physician must then independently determine that the medical use of marijuana would likely outweigh the potential health risks for the patient, which must be documented on the patient's medical record. Patients under the age of 18 must have a second physician concur with the above determination.

If the patient is female, the physician must ensure she is not pregnant, and if so, may only

³ See Footnote 1 for a list of qualifying medical conditions.

⁴ The Mayo Clinic defines PTSD as a mental health condition triggered by a terrifying event — either experiencing it or witnessing it. Symptoms may include flashbacks, nightmares and severe anxiety, as well as uncontrollable thoughts about the event.

issue a certification for low-THC cannabis.

The physician must also review the patient's controlled drug prescription history, and perform a search of the Medical Marijuana Use Registry to confirm that the patient does not already have an active physician certification for the medical use of marijuana.

Once a certification for the medical use of marijuana is issued, the physician must register the patient on the Medical Marijuana Use Registry. In doing so, they enter the patient's qualifying medical condition, the dosage recommended to the patient, the amount and forms of marijuana authorized, and the types of marijuana delivery devices needed by the patient. Any changes to the above must be documented and updated by the physician in the registry.

Finally, a patient must sign a written informed consent on the adverse side effects of marijuana and other treatment options that are available for the medical condition. This informed consent must be maintained in the patient's medical record and be given each time a physician issues a certification for the patient. Physicians must use a standardized informed consent form that is adopted by the Board of Medicine and the Board of Osteopathic Medicine. The requirements of what must be contained in this informed consent include the following:

- 1. Mention that the Federal Government continues to classify marijuana as a Schedule I controlled substance, which indicates that it has a high potential for abuse and no currently accepted medical use in treatment in the United States.⁵
- 2. A statement concerning the current approval and oversight status of marijuana by the Food and Drug Administration.
- 3. The current state of research on marijuana's ability to treat the patient's qualifying medical conditions. This likely acts as a notice to the patient that there is a possibility of new, unanticipated, different, or worse symptoms that might result from the use of marijuana.
- 4. A statement that mentions there is a potential for addiction.

⁵ United for Care listed the following arguments and quotations about "marijuana's medical value." (1) Studies show that many patients suffering from HIV/AIDS, glaucoma, cancer and chemotherapy, multiple sclerosis, epilepsy, and other debilitating illnesses find that marijuana provides relief from their symptoms. (2) Nausea, appetite loss, pain and anxiety are all afflictions that can be mitigated by marijuana. (3) Available prescription drugs often come with far more serious side effects than marijuana, and many patients who find relief from marijuana simply do not respond to prescription medications. Smoking or vaporizing marijuana are much more effective delivery methods than pills for many patients: The drug works almost instantly and will wear off after approximately 20 minutes if smoked or vaporized, and the dosage may be controlled by the patient, and there is no problem "keeping it down" since it cannot be regurgitated. The drug will begin to work slower, and may typically last for 4 hours or longer when digested.

- 5. A notice to the patient that marijuana has the potential to affect his or her 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.
- 6. A statement of the potential side effects of using marijuana.
- 7. A list of the risks, benefits, and drug interactions of marijuana.
- 8. An agreement that the patient's de-identified health information contained in the physician certification and medical marijuana use registry may be used for research purposes.

Medical Use of Marijuana Discussion

As of July 2017, Florida had 23,350 patients registered to use medical marijuana and 944 physicians permitted to prescribe it.

Assuming the above requirements have all been met and the physician believes that marijuana is suitable for the patient, what then does it mean for a patient to "medically use" marijuana?

Subsection (j) of the Definitions in the Medical Use of Marijuana Act defines *medical use* as the "acquisition, possession, use, delivery, transfer, or administration of marijuana authorized by a physician certification." The term, however, does not include the following:

- 1. Possession or use of marijuana that was not purchased or acquired from a medical marijuana treatment center. Essentially, you cannot purchase from an unauthorized dealer or grow your own marijuana for consumption.
- 2. Possession or use of marijuana in a form for *smoking* (as defined above), or prepared food items other than edibles made from only marijuana oil and non-marijuana materials. Vaporizing marijuana extracts and flowers may only be done from sealed, tamper-proof receptacles.
- 3. Using marijuana in any form or amount that is inconsistent with the directions given by the qualified physician.
- 4. Any transfer of marijuana to a person other than the patient, or his or her caregiver on behalf of the patient.

There are also restrictions on the locations in which a patient may use medical marijuana, including:

• On any form of public transportation, except when using low-THC cannabis.

- In any public place, except for low-THC cannabis.
- In the patient's place of employment, except when permitted by his or her employer. There will doubtlessly be Americans with Disabilities Act analysis and possible litigation where employers will not grant consent for employees who would benefit from the use of medical marijuana.
- On the grounds of a preschool, primary school, or secondary school except as provided in Florida Statute § 1006.062, which allows each district school board to adopt policies and procedures for administering medications and other medical services to students.
- In a school bus, vehicle, aircraft, or motorboat, except for low-THC cannabis.
- In a state correctional institution in which prisoners are housed, worked, or maintained. This include those facilities that are under the authority of the Department of Corrections, Department of Juvenile Justice, a county or municipal detention facility, or a detention facility operated by a private entity.

Sales Tax Exemption

Florida Statute § 212.08 will be amended to read, "The sale at retail, the rental, the use, the consumption, the distribution, and the storage to be used or consumed in this state" of marijuana and marijuana delivery devices are exempt from any sales, rental, use, consumption, distribution, or storage tax.

Dispensary and Treatment Center Limitations

Treatment centers will be the only licensed entities permitted to grow, process, transport, sell and dispense medical marijuana and medical marijuana delivery devices in Florida. The initial number of these treatment centers is limited to ten, which appears low given that according to a 2017 State Revenue Impact Study it was suggested that once the market reaches a mature state, Florida will have 106,000 medical marijuana patients with sales totaling \$140 million.⁶

Operating under the license, direction, and control of treatment centers will be dispensary facilities. The Medical Use of Marijuana Act states that these entities may deliver medical marijuana products to patients through a courier service, but does not provide any other information concerning their purpose. In all likelihood, dispensary facilities will be additional

⁶ These figures assume that the current list of qualifying medical conditions will not be expanded to include conditions such as chronic pain. However, higher estimates suggest Florida could have as many as 350,000 users of medical marijuana and see more than \$410 million in sales. See Florida Impact Revenue Estimating Conference on marijuana at: http://edr.state.fl.us/Content/conferences/generalrevenue/Marijuana_A2_SB1030_HB307_Special-Impact_2017Pre-Session_final.pdf

storefronts owned by the larger "treatment center" that will offer medical marijuana to patients.

The maximum number of dispensary facilities each treatment center can have statewide is set at 25, until the total active qualified patients in the medical marijuana use registry rises above 100,000. Once reaching that threshold, and upon every subsequent increase of 100,000 in the registry, each center may add an additional five dispensaries. Additional treatment centers will be authorized by the Department of Health at the rate of four for every 100,000 patients registered.

Nonetheless, the limitation on the quantity of treatment centers has sparked contention within the legislature. In a press release accompanying a previous version of the Medical Use of Marijuana Act, Senator Jeff Brandes, R-St. Petersburg, stated that this cap on the number of retail dispensaries and treatment centers will effectively "promote a state-sanctioned cartel system that limits competition, inhibits access, and results in higher prices for patients. Florida should focus on what is best for patients."

Brandes submitted a bill to the Senate that would have limited the number of treatment centers to not exceed one per 25,000 residents in a county. This would have shifted the limits from statewide to an individual county basis.

In addition to his belief that Florida businesses and investors should be able to become part of a budding industry and experience similar profitability as those do in states such as Colorado, Washington, and California, Brandes asserts that companies should be able select the areas of the medical marijuana business they want to take part in.

Currently, businesses have to engage in Florida's vertical integration system, or seed-to-sale, for medical marijuana. Each medical marijuana treatment center must grow its own product to sell, and track it at every stage. Brandes' amendment, which did not pass, removed the requirement that those who grow and sell share ownership. This stipulation on the sale of medical marijuana drew the ire of both lawmakers and voters in Florida, who say it limits access, makes the industry less competitive, and raises prices.

Treatment Center Background Checks and Inspections

Those who wish to own or manage a treatment center are required to pass a level 2 background check. In addition, they also have to submit their fingerprints to either the Department of Health or to a vendor, entity, or agency authorized to collect fingerprints by the State of Florida. Those fingerprints will be forwarded to the Department of Law Enforcement for state processing and who will disseminate it to the Federal Bureau of Investigation for national processing. The Department of Health will, of course, be notified of any arrest records.

The Medical Use of Marijuana Act also states that treatment centers are subject to inspections, both announced and unannounced. The Department of Health must conduct inspections on "at least a biennial" basis, in order to "evaluate the medical marijuana treatment center's records, personnel, equipment, processes, security measures, sanitation practices, and quality assurance practices." The department is also tasked with inspecting any treatment center flagged by a complaint or notice of mold, bacteria or other contaminants having adverse effects

to human health or the environment.

Pursuant to the Medical Use of Marijuana Act, the Department of Health must publish a list of the approved medical marijuana treatment centers, medical directors, and physicians on its website. It will also be granted the power to levy fines on any treatment centers for enumerated violations, with a maximum amount not to exceed \$10,000 for acts such as, violating the statute or a department rule, or endangering the health, safety, or security of a qualified patient.

Ban on Smoking

Currently, the popular belief is that vaporizing cannabis is healthier and less irritating to the lungs than smoking it, but also that the vaporization method provides more potent forms of marijuana than the traditional method of smoking.

The use of vaporizers for both marijuana and nicotine is relatively new and any research concerning the long-term effects of vaporizing is limited. In effect, this rule forces treatment centers to only provide marijuana products that are prepackaged, preapproved, and tamper proof. Individuals cannot purchase the seeds or actual flowers ("buds") of marijuana plants to use in the traditional manner.

Orlando attorney, John Morgan, one of the principal supporters and funders of Amendment 2, is preparing a lawsuit against the state for its prohibition on smoking marijuana as a method of treatment, as it is the most common method of consumption.

Conclusion

There is well-merited concern that medically prescribed marijuana will cause public harm when people under the influence drive, use it recreationally and in an inappropriate manner, or allow it to be used by children and young adults who may suffer from addiction, apathy, and other adverse side effects. However, the documented medical benefits it provides to many who suffer from certain medical conditions in undeniable. As compassionate humans we should no longer hide behind antiquated, misinformed and fearful ideas that a plant will be the downfall of our society when it can provide relief to those who need it.

INFORMED CONSENT FORM (update with new form from the Board of Medicine when it is released)

Consider including the following forms:

Patient Information and Qualifying Condition Checkbox Form

Medical Records Release

VA Records Release *if necessary

Cancellation/No Show Policy

Health Questionnaire

HIPAA Privacy Policy

SAMPLE CONSENT FORM

Informed Consent for Treatment with Medical Cannabis (marijuana) and/or low-THC Cannabis (marijuana)

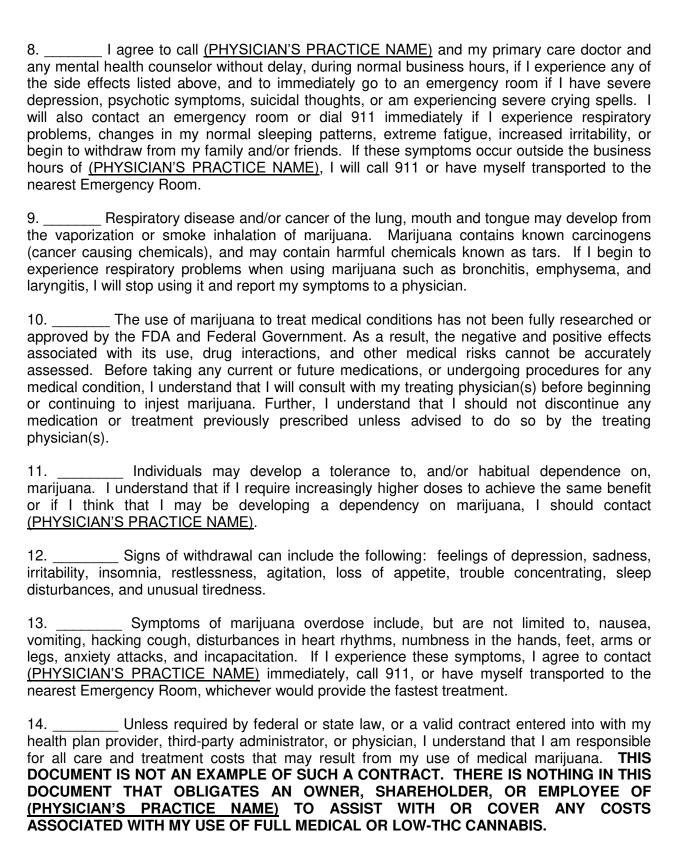
Upon execution of this Informed Consent, I agree that I have been duly informed by my physician of the risks and effects associated with the therapeutic utilization of medicinal marijuana in the State of Florida. I have provided my physician with a detailed report of my medical history, such that they may be better suited to make this assessment of my medical condition and the recommendation that medicinal marijuana may be useful in relieving my symptoms. Further, I have not misrepresented my medical condition in order to obtain this recommendation and it is my intent to use marijuana only as need for the treatment of my medical condition, and not for recreational or non-medical purposes. I understand that it is my responsibility to be informed of, and adhere to all current and future state and federal laws regarding the possession, use, sale/purchase, and/or distribution of marijuana. I have been informed that the federal government has classified marijuana as a Schedule I controlled substance, which 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 standards for use under medical supervision.

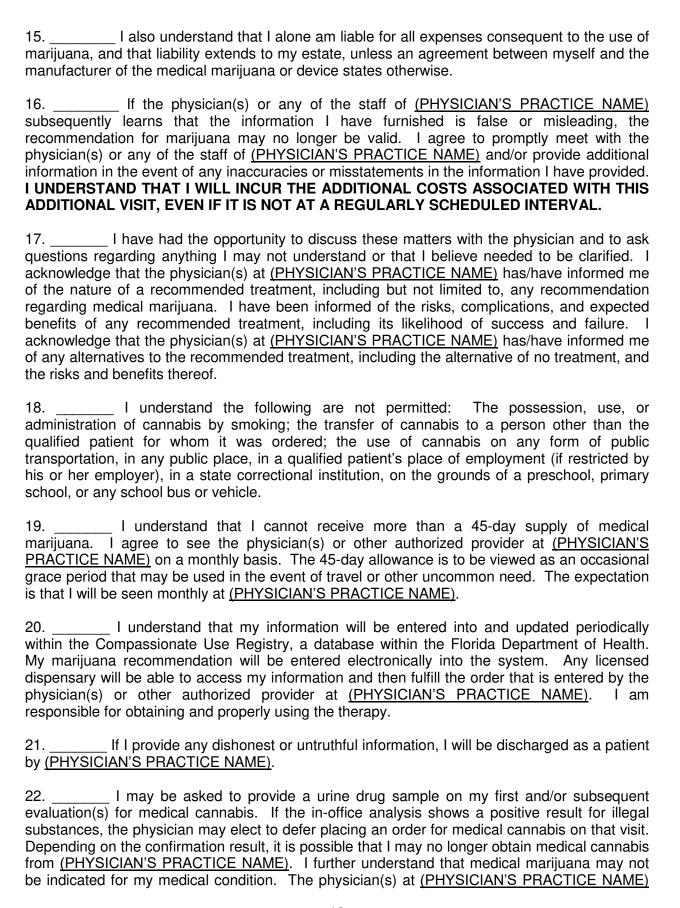
I have been informed of and understand the following: [please initial each item]

1a . (FOR MEDICAL CANNABIS ONLY)currently be treated with FDA approved product	I understand that my terminal condition may
As explained by my	and reiterated by the physician(s) at , my options include the following:
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specialty physician and discussing the various concur with my physician's suggestion that all omedications are unlikely to prolong my estimate	Upon meeting with my primary and/or soptions available to me at this point in time, I currently approved FDA products, treatments and ed lifespan, and that the use of medical cannabis ic approach to treating my symptoms than other
1b . (FOR LOW-THC CANNABIS ONLY) may currently be treated with medically accepta	I understand that my seizures and/or spasms able alternatives.
	and reiterated by the, my options include the following:
2b. (FOR LOW-THC CANNABIS ONLY) _ specialty physician and discussing the various	Upon meeting with my primary and/ors options available to me at this point in time, I

concur with my physician's suggestion that all currently approved FDA products, treatments,

7 I understand that combining marijuana and alcohol is not recommended, and that additional side effects from using both may become present from such use. Cannabis should be treated as an open container of alcohol and should not be within reach in a vehicle.
If filled in, the following describes further possible outcomes and side effects that might apply in my situation due to my current terminal condition:
6 Potential side effects from the use of marijuana include, but are not limited to, the following: happiness, relaxation, euphoria, dizziness, shallow breathing, dilated pupils, anxiety, confusion, low blood pressure, loss of short term memory, difficulty completing complex tasks, decreased immune system, inability to concentrate, a distorted sense of time, impaired motor skills, slowed reaction times, paranoia, psychotic symptoms, general apathy, depression, restlessness, and/or increased appetite. There is the possibility that new, unanticipated, different, or worsened symptoms might result and death could be hastened by the proposed use of medical marijuana. Marijuana may also exacerbate schizophrenia in persons who were already predisposed to the disorder. Many medical authorities claim that use of cannabis, especially by persons younger than 25, can result in long-term problems with attention, memory, learning, a tendency to drug abuse, and schizophrenia. The physician(s) at (PHYSICIAN'S PRACTICE NAME) recommend cannabis use only for the relief of serious symptoms when all the above risks and sides effects are considered, and not for habitual use.
5 I have been advised that marijuana is known to affect coordination, reaction times, motor skills, and cognition, i.e. the ability to think, judge and reason. While using marijuana, I will not drive, operate heavy machinery, or engage in any activities that require me to be alert and/or respond quickly. I understand that if I drive while under the influence of marijuana, I can be arrested for "driving under the influence."
4 Marijuana may contain unknown quantities of other active ingredients, impurities, or substances, in addition to THC, which is the primary psychoactive chemical component of marijuana. Further, due to the hybridization of different plant strains, genetic diversity between marijuana plants of the same species (i.e., indica vs. sativa) or variety can lead to significantly different effects on strength, effect, and duration of the psychoactive effects of marijuana. I accept these risks associated with consuming this product and hereby release (PHYSICIAN'S PRACTICE NAME) and its owners, shareholders, and employees from any liability due to the recommendation of and my use of this product.
3 I understand that the specific investigational drug, biological product, or device I am seeking to use is cannabis, often referred to as marijuana. Currently, the Food and Drug Administration has not approved the "manufacture" of marijuana for medical use. Thus, any marijuana lawfully produced in a state will not be subject to the same sets of standards, quality control assurances, or other oversight mechanisms that conventionally accepted treatments and medications must adhere to. Until such time, each state will have a different set of standards in place to ensure some level of compliance with how marijuana is manufactured.
and/or spasms, and that the use of medical cannabis will provide me with a more natural and holistic approach to treating my symptoms than other currently available options.





will only order medical cannabis if it is an indicated therapy. Therefore, I understand that me payment is for the physician evaluation and NOT in exchange for medical cannabis (marijuana Thus, I agree that a refund for services rendered will not be provided if, for any reason, the physicians(s) elect not to recommend medical cannabis.
23 I understand that physicians who recommend medical marijuana must submit the details of that recommendation to the UF College of Pharmacy. I accept the following statement: University of Florida has no role in treatment of any patient or determination for efficacy or safety of medical marijuana being prescribed by any physician. The UF College of Pharmacy is merely receiving data (including physicians' treatment plans for patients) for an potential future research on medical marijuana efficacy and safety generally (not for individual patients), if dedicated funds were to be provided by the state for this purpose in the future Each patient's consent to treatment with marijuana prescribed by a physician, including the statutorily required submission by the physician of treatment plans to the College, includes the patient's acknowledgment of and consent to the absence of any treatment or safety related role of the University of Florida.
24 I understand that my eligibility for hospice care may be withdrawn if I begintreatment with medical marijuana, however hospice care may be reinstated if I end the treatment with marijuana and continue to meet all hospice care eligibility requirements.
UPON SIGNING BELOW, I AGREE THAT I HAVE BEEN ADVISED BY M PHYSICIAN AND FULLY INFORMED OF ALL OTHER APPROVED PRODUCTS O TREATMENTS AVAILABLE FOR MY CONDITION. I FURTHER AGREE THAT M PHYSICIAN HAS DISCUSSED THE RELATIVE RISKS AND SIDE EFFECTS ASSOCIATE WITH THE USE OF MEDICAL CANNABIS, AND THE POTENTIAL HARM IT COULD HAV ON MY OVERALL HEALTH. FINALLY, DUE TO MY PHYSICIAN'S RECOMMENDATION O ORDERING OF LOW-THC OR MEDICAL CANNABIS, I AGREE THAT I HAVE DISCLOSE TO MY PHYSICIAN ALL OTHER PRODUCTS, TREATMENTS, AND/OR MEDICATIONS I AI CURRENTLY PRESCRIBED OR OTHERWISE TAKING TO TREAT MY CONDITION, A THEY MAY ALSO HAVE AN ADVERSE EFFECT ON MY HEALTH.
Patient Name (printed):
Patient Signature: Date: