

MEDICAL MARIJUANA TREATMENT CENTER

# Application Instructions Manual for License Renewal

## **OMMU** Office of **MEDICAL MARIJUANA** Use









### MEDICAL MARIJUANA TREATMENT CENTER Application Instructions Manual for License Renewal

#### **SECTION 1 – INTRODUCTION**

This Medical Marijuana Treatment Center Application Instructions Manual for License Renewal (renewal application) is designed to collect the information necessary to process and complete your license renewal in a timely manner. Your assistance in providing all required information will help the Florida Department of Health's Office of Medical Marijuana Use (OMMU) to process your renewal application as soon as possible.

Please read these instructions carefully and completely before submitting your renewal application. Questions regarding your renewal application may be emailed to the OMMU at <u>OMMULicenseOperation@flhealth.gov</u>. Emails are generally responded to within 48 hours during normal business hours.

#### SECTION 2 – THE RENEWAL PROCESS

For your renewal application to be considered for approval by OMMU, you must submit a complete license renewal application and the renewal fee. Upon receipt of your renewal application and renewal fee, OMMU will review the renewal application to ensure that all required written materials are included. When your renewal application arrives, your renewal fee will be deposited.

If your renewal application contains any apparent errors or omissions, the OMMU will notify you in writing and request any additional information, responses, or materials required ("Errors and Omissions Letter"). The OMMU must receive the additional information, responses, or materials requested in the Department's Errors and Omissions Letter within fourteen (14) calendar days of your receipt of the Letter. The Department's Errors and Omissions Letter will be sent to renewal applicants via email at the designated email address supplied on Form 1 and included behind Tab A of the application. If the correct information and materials requested are timely received, your renewal application will be deemed complete and ready for evaluation.

#### SECTION 3 – PREPARING AND SUBMITTING A RENEWAL APPLICATION

Renewal applications should provide a straightforward, concise description of the information or materials requested. Within the renewal application, renewal applicants shall not include or apply any conditions or exceptions to any statutory or rule requirements. A renewal application or response to an Errors and Omissions Letter shall not cross-reference materials previously submitted to the Department in an initial application, application amendment, or variance request.

It is solely the renewal applicant's responsibility to ensure that the renewal application and any additional information is supplied timely and completely to the Department. Renewal applications must be received by the Department on or before the date and time set forth in Rule 64-4.201, Florida Administrative Code. Renewal applications delivered by hand must be delivered to the physical address listed below. Renewal applications that are shipped or mailed, must be sent to the mailing address listed below.

#### Physical Address:

Florida Department of Health Office of the General Counsel ATTN: Agency Clerk 2585 Merchants Row Blvd., Suite 110 Tallahassee, Florida 32399 Mailing Address:

Florida Department of Health Office of the General Counsel ATTN: Agency Clerk 4052 Bald Cypress Way, Bin A-02 Tallahassee, FL 32399

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#### Format of Renewal Application

Renewal applications must be submitted in a properly marked box or envelope containing the following:

- a. One electronic renewal application in PDF format and <u>bookmarked</u> on a portable drive. The renewal application must be bookmarked by "Tab" as provided below. Acceptable portable drives include a portable hard drive, thumb drive, and similar devices. The portable drive must have a USB connection and must be compatible with Microsoft operating systems. The PDF file containing the unredacted renewal application must be named in the following format: "Renewal Applicant Name" (e.g., "John Smith, Inc.");
- b. One electronic, redacted renewal application in PDF format and <u>bookmarked</u> on a portable drive, as described Tab B, if an exemption is claimed. The PDF file containing the redacted renewal application must be named in the following Format: "Renewal Applicant Name Redacted" (e.g., "John Smith, Inc. Redacted");
- c. A hardcopy of completed Form 1 for the Agency Clerk to stamp; and
- d. An envelope that contains a cashier's check made payable to "Florida Department of Health" for the renewal application fee.

The face of each box or envelope submitted must be addressed to the attention of the Agency Clerk and indicate the Agency Clerk's address, as provided in Section 3, above. In addition, the face of each box or envelope must state "Renewal Application for MMTC Licensure." Any documents, information, or materials claimed to be exempt from Florida's Public Records Law must comply with the provisions of Tab B at the time of the application submission.

Renewal applicants desiring to retain a hardcopy of the time-stamped Form 1 should provide an extra hardcopy of Form 1 for the Agency Clerk to stamp.

Renewal applicants must submit applications in the following format and order per the instructions provided in each corresponding Tab of this Application Instructions Manual for Renewal. The application must be bookmarked by "Tab," as follows:

- □ Tab A Form 1: General Information
- □ Tab B Declaration of Exempt Information
- □ Tab C Entity Ownership
- □ Tab D Florida Business Registration and DACS Certification
- □ Tab E Personnel
- □ Tab F Operations
- □ Tab G Financial Ability
- □ Tab H Diversity Plan
- □ Tab I Medical Director
- □ Tab J Performance Bond
- Tab K Form 2: Attestation of Accuracy and Familiarity with Medical Marijuana Law

#### Tab A – General Information and Renewal Application Fee

Complete each section in Form 1 and include the completed form behind Tab A of your submission.



#### Tab B – Declaration of Exempt Information

All renewal application materials and electronic and written communications pertaining to a renewal application, whether sent from or received by the Department, are subject to the Florida Public Records Law. Approval or denial of a renewal application does not affect the public record status of the materials. Unless exempted by law, all public records are subject to public inspection and copying under Florida's Public Records Law, Chapter 119, Florida Statutes.

#### How to Claim Protection for Exempt Materials

If a renewal applicant considers any portion of the documents, data or records submitted in its license renewal application to be a trade secret and/or otherwise exempt from public inspection or disclosure pursuant to Florida's Public Records Law, the renewal applicant must prominently and conspicuously mark all such information in the renewal application as "Confidential – Exempt from Public Disclosure." The renewal applicant must submit a brief, written description of the grounds for claiming exemption from the Public Records Law, including the specific statutory citation for such exemption.

A renewal applicant must also simultaneously provide the Department with a separate, electronic, redacted copy of its renewal application, redacting all data or information claimed to be exempt from public disclosure. The first page of the electronic, redacted copy and each page on which information is redacted must prominently display the phrase "Redacted Copy." Except for the redactions, the redacted copy must be an exact duplicate of the original, unredacted renewal application. The redacted copy must be submitted simultaneously with the original, unredacted renewal application.

If a renewal applicant fails to mark any materials submitted to the Department as exempt from public disclosure, the applicant waives the exemption under Chapter 119, Florida Statutes. Any claim of trade secret exemption for any information contained in the renewal application will be waived upon submission of the renewal application to the Department, unless the claimed trade secret information is submitted in accordance with these instructions. Renewal applicants exclusively bear the burden of complying with these instructions to ensure their exempt information is appropriately marked.

#### Tab C – Entity Ownership

Renewal applicants must include the following ownership information behind Tab C:

- 1. An organizational chart illustrating the supervisory structure of the renewal applicant. The organizational chart must include the identities of all employees, owners and managers of the renewal applicant, as those terms are defined in Rule 64-4.001, F.A.C.
- 2. A fully diluted capitalization table listing all share types and the aggregate sum of shares associated to any natural persons, whether considered owners or investors. In addition, identify the natural person owners and natural person beneficiaries of all entities listed on the capitalization table. See Rule 64-4.001, F.A.C. and 26 C.F.R. 1.414(c)-4(b) and (c) for the applicable attribution of ownership rules.
  - a. If the renewal applicant is a publicly traded corporation, the capitalization table must:
    - i. List all share types and aggregate sum of shares associated to any officers and directors;
    - ii. List the share types and aggregate sum of shares associated to any investor who acquired shares during the issuance of a private placement offering or any other type of offering in which shares were acquired by pre-selected investors and institutions ("private equity investors"), as opposed to shares acquired on the open market by public investors; and
    - iii. List the share types and aggregate sum of shares associated to the entirety of public investors ("shares held in public float"), as opposed to company officers, directors, private equity investors, or any other shareholder considered an owner as defined in Rule 64-4.001, F.A.C.
- 3. All agreements concerning control of the renewal applicant, or any change of control, including changes to management, owners, partners, or investors, regardless of whether the change is contingent or vested; and

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- 4. Identify all entities related to the renewal applicant, including parent companies, subsidiary companies, sister companies, and any other affiliated companies.
- 5. A statement identifying whether the renewal applicant, or any individual or entity that owns, controls, or holds power to vote five (5) percent or more of the voting shares of the renewal applicant, holds direct or indirect ownership or control of voting shares or has any other form of ownership in another licensed MMTC.

#### Tab D – Florida Business Registration and DACS Certification

Behind Tab D, provide documentation, as described below, demonstrating that the renewal applicant has been registered to do business in Florida for the previous five consecutive years.

1. If the renewal applicant is an *entity*, the renewal applicant must provide certified documentation from the Florida Department of State ("DOS") demonstrating that the renewal applicant has been registered to do business in the state of Florida for the previous five consecutive years. Such documentation must include a letter or other certification directly originating from the DOS certifying the renewal applicant's registration to do business in Florida for the previous five consecutive years.

The name of the renewal applicant, as listed in Form 1 and included in Tab A, must match the name appearing in the documentation from DOS. However, if you have not been operating under the same name for the duration of the five-year period, you must submit documents from DOS establishing and documenting any name-changes that have occurred and demonstrating that the entity submitting the renewal application for licensure has been registered to do business in Florida for the previous five consecutive years. "Entity" for purposes of this Application Instructions Manual for Renewal means any renewal applicant other than a natural person and includes all business forms, except individuals acting as sole proprietors and general partnerships.

2. If the renewal applicant is an *individual/sole proprietor or a general partnership*, the renewal applicant must provide at least one of the following: 1) a letter or other certification directly originating from the DOS certifying the renewal applicant's registration to do business in Florida for the previous five consecutive years; 2) a letter or other certification directly originating from the Florida Department of Revenue ("DOR") certifying the renewal applicant's registration to do business in Florida for the previous five consecutive years; 3) certified copies of valid certificates of registration issued by the Department of Agriculture and Consumer Services ("DACS") pursuant to section 581.131, Florida Statutes, evidencing the renewal applicant's registration with DACS for the previous five consecutive years; or 4) a letter or other certification from any other Florida state agency or local government entity in Florida establishing that the renewal applicant, as listed in Form 1 and included in Tab A, must match the name appearing in the documentation from DOS, DOR, DACS, or other Florida state agency or local government entity, as applicable. "Individual" for purposes of these Renewal Application Instruction Manual means a natural person.

The renewal applicant must provide documentation demonstrating that it continues to possess a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to section 581.131, Florida Statutes. The name of the renewal applicant as provided on Form I of the renewal application, must match the name that appears on a current certificate of registration from the Department of Agriculture and Consumer Services.



#### Tab E – Personnel

Behind Tab E, the renewal applicant must include information that will allow the Department to confirm that the renewal applicant's current employees, owners and managers, as those terms are defined in Rule 64-4.001, F.A.C., have passed a background screening as provided by section 381.986(9), Florida Statutes. Such information shall include the following:

An alphabetical listing of all current employees, owners and managers of the renewal applicant, as those terms are defined in Rule 64-4.001, F.A.C., together with all of the following information for each individual:

- a. Last name, first name
- b. Date of birth
- c. Social Security number
- d. Hire date
- e. Job title

The information supplied by the renewal applicant will be compared to the data in the Applicant Fingerprint Retention and Notification Program authorized by section 943.05(2)(b), Florida Statutes, and established by the Florida Department of Law Enforcement, as provided in Rule 11C-6.010, F.A.C.

#### Tab F – Operations

Behind Tab F, the renewal applicant must include information concerning the MMTC's compliance with, and ability to continue operations pursuant to, the requirements in section 381.986, Florida Statutes. Specifically, the renewal applicant shall provide the following information:

#### 1. Cultivation.

- a. Provide a list of the additives, pesticides, fungicides and herbicides you use for the cultivation of marijuana in compliance with Rule 64-4.013, F.A.C.
- b. Provide your standard operating procedures regarding the inspection processes for pests that endanger or threaten the horticulture or agriculture of the state in accordance with Chapter 581, Florida Statutes, and any rules adopted thereunder.
- c. Provide your standard operating procedures for the fumigation or treatment of plants in accordance with Chapter 581, Florida Statutes, and any rules adopted thereunder.
- d. Identify and describe all marijuana and low-THC cannabis product(s) that you produce and make available for purchase.

#### 2. Processing.

- a. Provide your standard operating procedures for testing marijuana for contaminants and potency of active ingredients before it is dispensed, including your record maintenance practices for all testing and samples of each homogenous batch of marijuana.
- b. Provide documentation that the each of your processing facilities has passed a Food Safety Good Manufacturing Practices inspection by a nationally accredited certifying body.
- c. Provide your standard operating procedures concerning the storage, handling, management and disposal of solid and liquid waste generated during marijuana production and processing.
- d. Explain how you package the marijuana products identified in response to request 1.d. above.
- e. State whether pre-rolled marijuana cigarettes are included in your product offerings, and if so, identify the wrapping paper you use for the cigarettes.



#### 3. Dispensing.

- a. Provide your dispensing policies and procedures that relate to the following:
- b. Confidentiality of patients' medical conditions, health status and purchases of medical marijuana.
- c. Ensuring all qualified patients and caregivers have an active profile in the Medical Marijuana Use Registry and present Medical Marijuana Use identification cards prior to purchasing medical marijuana.
- d. Ensuring that no more than the maximum supply of marijuana is dispensed to a qualified patient or caregiver within the specified statutory time frames.
- e. Ensuring employees record in the registry all information required pursuant to sections 381.986(8)(e)16.c. and (8)(e)16.g., Florida Statutes.
- f. Ensuring employees and volunteers receive training on the legal requirements to dispense marijuana to qualified patients.

#### 4. Security.

- a. Provide a copy of your personnel policy(ies) reflecting your compliance with sections 381.986(8)(f)6., (8)(f)7., and (8)(f)8, Florida Statutes.
- b. Provide your alcohol and drug-free workplace policy.

#### 5. Transportation.

- a. Provide a list of the make, model and VIN number of each vehicle you use for the transportation of marijuana and marijuana delivery devices.
- b. Provide a copy of your transportation policy(ies) that addresses your compliance with the requirements of section 381.986(8)(g), Florida Statutes.

#### 6. Facilities.

a. List the physical address of all properties you utilize in any way for the operation of your MMTC business, including, but not limited to, cultivation facilities, processing facilities, call centers, fulfillment centers, storage centers, management offices and record retention centers.

#### Tab G – Financial Ability

Behind Tab G, the renewal applicant must provide audited, certified financial statements of the renewal applicant that were issued within the immediately preceding 12 months of submission of the renewal application and that have been prepared in accordance with Generally Accepted Auditing Principles (GAAP) and Generally Accepted Auditing Standards (GAAS) by a Certified Public Accountant, licensed pursuant to Chapter 473, Florida Statutes, or equivalent law of another state.

The certified financials included in this section must belong to the identified renewal applicant. Certified financials for parent companies, subsidiaries or other entities or persons that are not the identified renewal applicant will not be accepted.

#### Tab H – Diversity Plan

Behind Tab H, the renewal applicant must submit a statement showing the effectiveness of the diversity plan required under section 381.986(8)(b)10., Florida Statutes, including the following information:

The representation of minority persons and veterans in the Medical Marijuana Treatment Center's workforce.

Efforts to recruit minority persons and veterans for employment.

A record of contracts for services with minority business enterprises and veteran business enterprises.



#### Tab I – Medical Director

Behind Tab I, renewal applicants must provide a response to each of the following questions and requests for information.

Identity of Medical Director. Identify your medical director (together with his/her Florida MD or DO license number) and provide documentation evidencing the medical director's most recent completion of the 2-hour Florida Medical Marijuana

Course for MMTC Medical Directors and subsequent examination offered by the Florida Medical Association or Florida Osteopathic Medical Association.

Scope of Oversight. Describe the scope of the medical director's supervision and oversight over the activities of the licensed MMTC.

Managing Conflicts of Interests. Describe your plan for ensuring that your medical director (and other owners, managers and employees) do not engage in behavior that creates, or may create, a conflict of interest with ordering physicians, including, but not limited to, kickbacks.

#### Tab J – Performance Bond

Behind Tab J, renewal applicants must demonstrate their ability to maintain their existing performance bond for the duration of the 2-year renewal period, as required under section 381.986(8)(b)7.a., Florida Statutes, by providing a commitment letter from the surety issuing the performance bond. Alternatively, renewal applicants may provide an irrevocable letter of credit payable to the Department of Health, as authorized under section 381.986(8)(b)7.b., Florida Statutes.

#### Tab K – Attestation of Accuracy

Complete each section in Form 2 and include the completed form behind Tab K of your submission.





#### FORM 1: RENEWAL APPLICANT GENERAL INFORMATION

Renewal Applicant Information						
Renewal Applicant Name (Name must match name registered with DOS/DOR/DACS)						
Fictitious Name (if any)						
	• /					
Department of Agriculture and Consumer Services Certificate Address						
City	Apt/Ste #	State	Zip Code	Country		
Mailing Address (if different)						
City	Apt/Ste #	State	Zip Code	Country		

Contact Information					
First Name	Last Name	Middle Initial			
Telephone Number (Input without dashes)	Designated Email for Department/Renewal Applicant				
	Communications				



#### FORM 2: ATTESTATION OF ACCURACY, COMPLIANCE, AND FAMILIARITY WITH THE LAW

I do hereby attest that, at the time of this renewal application, the renewal applicant is in compliance with all representations made to the Florida Department of Health, Office of Medical Marijuana Use, for licensure as a Medical Marijuana Treatment Center, including representations in the renewal application and the initial application, except as modified by application amendments or variances approved by the Department.

In addition, I do hereby attest that I have read and am familiar with section 381.986, Florida Statutes, and Department rules adopted thereunder.

Signature of Renewal Applicant/Representative

Date

Name of Renewal Applicant/Representative (Print or Type)