



STATE OF FLORIDA
DEPARTMENT OF HEALTH

Medical Marijuana Treatment Center Request for Application Variance

This Medical Marijuana Treatment Center Request for Application Variance (Variance Request) is designed to allow the Florida Department of Health (Department), Office of Medical Marijuana Use, to review a Medical Marijuana Treatment Center's (MMTC) proposed alternative from the representations made in the Department-approved initial application, to include any Department-approved variances.

Instructions

When submitting a Variance Request, it must be organized so that each submitted document is accurately and completely labeled. Variance Requests must be saved as optical character recognition portable document format (OCR PDF) files. A Variance Request is limited to one specific representation>

Requests must be submitted either electronically to OMMULicenseOperation@flhealth.gov or delivered to The Office of Medical Marijuana Use at 4052 Bald Cypress Way, Bin M-01, Tallahassee, Florida 32399. Requests physically delivered to the Department at the above address must be submitted on a USB Flash Drive.

Variance Requests submitted to the Department are public records. Any exemption to public records law must be identified at the time the Variance Request is submitted. In order to claim any public records exemption, the applicant must provide a redacted copy of the Variance Request and any attachments with a clearly identified statutory basis for each exemption sought.

UNLESS INFORMATION FALLS UNDER ANOTHER PUBLIC RECORDS EXEMPTION, FAILURE TO SPECIFY AND CLEARLY IDENTIFY INFORMATION CLAIMED AS EXEMPT AS A TRADE SECRET OR CONFIDENTIAL BUSINESS INFORMATION OR FAILURE TO PROVIDE A REDACTED COPY OF THIS VARIANCE REQUEST, INCLUDING ALL ATTACHMENTS, AT THE TIME OF SUBMISSION WILL RESULT IN THE RELEASE OF THE FULL VARIANCE REQUEST, INCLUDING ALL ATTACHMENTS, IN RESPONSE TO PUBLIC RECORDS REQUESTS.

In the event that the Variance Request requires an inspection(s) of a facility by the Department, the Department shall notify the applicant and schedule an inspection(s) within 30 days of the receipt of the Variance Request. The Variance Request shall not be deemed complete until the completion of the inspection(s) by the Department.

Part I

MMTC Entity Name:

(For the entity holding a MMTC license, provide the name as registered with the Florida Department of State)

MMTC Fictitious Name:

MMTC Mailing Address:

Street Address City ZIP Code

MMTC Contact Name: _____

Phone Number: _____ **Email Address:** _____

List all other MMTC contacts to be included in correspondence regarding this Variance Request below.

MMTC Contact Name	Phone Number	Email Address

Part II

Provide a detailed explanation of the Variance Request, including an explanation of how the requested variance fulfills the same or a similar purpose as the current specific representation(s) in the initial application, to include any previously approved variance(s) and how the proposed change will be implemented.

Provide the page number, specific section(s) and subsection(s) of the MMTC initial application, to include any previously approved variance, detailing the representation(s) at issue. If this submission was not contemplated in the original application, or a previously approved variance, please identify the appropriate section(s) or subsection(s) the Variance Request seeks to change.

Part III

For any Variance Request that involves a contract or agreement with a third-party entity, provide a copy of all proposed contracts or agreements.

Part IV

Please select all subjects addressed in the proposed variance. Part V includes the minimum required documentation and statutory requirements for each subject selected.

- 1. Property or Facility
- 2. Security
- 3. Derivative Product or Delivery Device
- 4. Equipment
- 5. Marijuana Strain
- 6. Standard Operating Procedure
- 7. Vehicle for Delivering or Transporting Marijuana
- 8. Sign for an Existing, previously approved Dispensing Facility
- 9. Marketing and/or Advertising
- 10. Trade Name, Fictitious Name, Logo, or Branding
- 11. Website or Webpage
- 12. Seed-to-Sale System
- 13. MMTC Management Agreement
- 14. Licensing Agreement
- 15. Bond, Irrevocable Letter of Credit, or Cash Held in Trust by the Department
- 16. Add or Remove a Medical Director
- 17. Marijuana Testing Laboratory
- 18. MMTC Business Structure
- 19. Other

Part V

1. **Property or Facility**. Please include the following as addendums, as applicable:
 - a. For any proposed facility, identify the type:
 - i. cultivation facility;
 - ii. processing facility;
 - iii. dispensing facility; or
 - iv. fulfillment center.
 - b. A proposed floor plan, site plan, and building layout. The included information must have sufficient detail to provide a description of each room and area's uses, dimensions, and must clearly show all ingress and egress points.
 - i. for a proposed dispensing facility, identify the indoor premises where dispensing occurs includes a waiting area with sufficient space and seating to accommodate qualified patients and caregivers and at least one private consultation area that is isolated from the waiting area and area where dispensing occurs
 - c. All executed leases, contracts, and other agreements related to the MMTC's use of the property, including the land where any facility or proposed facility is located.
 - d. Contract agreements related to waste management.
 - d. Provide a certificate of occupation, or equivalent, for any proposed property. If a certificate of occupation, or equivalent, is not available at the time of submission, provide a timeline for obtaining one and submitting it to Department.
 - e. Evidence of zoning approval where the proposed property is located.
 - f. A proposed site plan demonstrating all interior and exterior security measures, including the following:
 - i. Locking options and mechanisms for each means of ingress and egress;
 - ii. An alarm system that:
 1. Secures all entry points and perimeter windows; and
 2. Is equipped with motion detectors, pressure switches and duress, panic, and hold-up alarms.
 - iii. A video surveillance system that:
 1. Records continuously 24 hours a day;
 2. Has cameras in fixed places that allow for the clear identification of persons and activities in the controlled rooms and areas of the property. Controlled areas include grow rooms, processing rooms, storage rooms, disposal rooms or areas, and point-of-sale rooms;
 3. Has cameras fixed in all entrances and exits to the property which record both indoor and outdoor, and ingress and egress vantage points;
 4. Has the capability of recording clear images and displays the time and date of the recording; and
 5. Demonstrates retention of recordings for at least 45 days.
 - iv. Outdoor lighting from dusk until dawn;
 - v. The name and function of each room and area; and
 - vi. The layout and dimensions of each room and area.
 - g. Any variance requested under this heading must provide a descriptive narrative describing the 24 hour a day use of security personnel in any area or room of the proposed property where marijuana is cultivated, processed, or stored.
 - h. If a change in function of any existing approved room or area is contemplated due to

- any proposed change under this heading, clearly identify any such changes.
- k. Identify all equipment and fixtures to be used in the function of the property. For any equipment or fixture not identified on a floor plan or land survey, provide a list detailing the equipment or fixture's location on the property.
 - l. Provide a distance survey for the proposed property or facility.
 - m. For each MMTC-owned or controlled vehicle to be used, parked, or maintained on the proposed property, provide the following information:
 - i. Make;
 - ii. Model;
 - iii. Year;
 - iv. Vehicle Identification Number (VIN); and
 - v. License plate number.
 - n. For any dispensing facility sign provide:
 - i. Evidence of approval to post a business-related sign, if required by the local authority where the property the proposed sign is to be located.
 - ii. A site plan or building layout clearly showing the location of the proposed sign.
 - iii. Proof of registration of the proposed tradename or fictitious name used on the proposed sign with the Florida Department of State.
 - iv. Visual proofs of the proposed sign showing proposed dimensions.
2. **Security**. Please include the following as addendums:
- a. If the Variance Request proposes to add, remove, or change a security features, such as vaults, safes, secure rooms, or cameras, provide a floor plan and land survey indicating the location of any new or affected security features or camera positioning.
 - b. If the Variance Request proposes to alter a security standard operating procedure, provide a narrative description of all changes to be made.
 - c. If the Variance Request proposes to alter any aspect of service provided by a contracted security service, provide all contracts and other agreements related to the change of service, to include a narrative description of all changes to be made.
3. **Derivative Product or Delivery Device**. Please include the following as addendums:
- a. All proposed labeling, patient package insert, literature, and packaging with which the proposed product will be dispensed.
 - b. A clear description of how the proposed product's packaging fulfills the requirements of section 381.986(8)(e)10.e., F.S., and Department rule.
 - c. An explanation of the intended use of the proposed product, including the form and intended route of administration.
 - d. For any marijuana, provide a detailed list of all ingredients used in the manufacture of the product.
 - e. For any marijuana, provide a detailed manufacturing process for that product, to include any standard operating procedure.
 - f. For any item marijuana is packaged in or otherwise contained in, whatever the intended use, for dispensation provide the following information:
 - i. The manufacturer's instructions for use and storage;
 - ii. The materials used in the manufacture of the item; and
 - iii. Any licenses or agreements related to the MMTC's use and/or dispensation of the item.
 - g. For any delivery device, replaceable or interchangeable component of a delivery device, delivery device accessory, or item intended for use with a delivery device

provide the following information:

- i. The manufacturer's instructions for use and storage;
 - ii. The materials used in the manufacture of the product and any component thereof; and
 - iii. Any licenses or agreements related to the MMTC's use and/or dispensation of the product.
- h. For any item contemplated by Part I.D.3.f.-g., provide:
- i. All proposed labeling, literature, and packaging with which the proposed product will be dispensed; and
 - ii. A sample of the item or product without marijuana.
 - i. Any patent, or application filing related thereto, regarding the proposed item or product.

4. **Equipment**, Please include the following as addendums:

- a. A detailed list identifying the proposed new process or equipment and the property in which it will be utilized.
- b. For each proposed process or equipment provide:
 - i. A detailed description of the intended use in the cultivation, processing, storage, transport, or dispensation of marijuana;
 - ii. The manufacturer or developer's instructions for use or application;
 - iii. A standard operating procedure to be used by the MMTC;
 - iv. Any licenses or agreements related to the MMTC's use of the proposed new process or equipment; and
 - v. Any patent, or application filing related thereto, by the MMTC regarding the proposed new process or equipment.

5. Marijuana Strain,

- c. For each proposed marijuana strain provide a plant profile that includes:
 - i. The strain's name;
 - ii. Whether the strain is an indica, sativa, ruderalis, or hybrid;
 - iii. The range, median, and average milligram amount of THC per plant;
 - iv. The range, median, and average milligram amount of CBD per plant;
 - v. Any licenses or agreements related to the MMTC's use of the strain; and
 - vi. Any patent, or application filing related thereto, by the MMTC regarding the proposed new strain.
- d. For any proposed marijuana strain, provide a detailed cultivation process for that plant, to include a standard operating procedure.

6. **Standard Operating Procedure**. Please include the following as addendums:

- a. A narrative description explaining the purpose and use of the standard operating procedure in the MMTC's cultivation, processing, storage, transport, or dispensation of marijuana.
- b. A copy of the proposed standard operating procedure, to include copies of any manufacturer's instructions for any equipment contemplated for use in the standard operating procedure.
- c. Any independent, third-party accreditation or certification related to MMTC's implementation of the standard operating procedure.
- d. Any licenses or agreements related to the MMTC's use of a standard operating procedure.

- e. Any licenses or agreements related to third-party use of the MMTC's standard operating procedure.

7. **Vehicle for Delivering or Transporting Marijuana.** Please include the following as addendums:
- a. The make, model, year, Vehicle Identification Number (VIN), and license plate number of the vehicle.
 - b. A detailed narrative describing any proposed modification or fabrication to be undertaken on the vehicle and its function. Include any schematics, contracts, or work orders related to the proposed modifications or fabrications.
 - c. A detailed narrative describing the vehicle's security systems, including a plan to incorporate separate locking compartments to store any marijuana or delivery devices.
 - d. A detailed narrative regarding the manner which any vehicle to be replaced is repurposed, phased out of use, transferred, or otherwise disposed of.
8. **Sign for an Existing Dispensing Facility.** Please include the following as addendums:
- a. All executed leases, contracts, and other agreements related to the MMTC's use of the property, including the land where the facility is located.
 - b. Evidence of approval to post a business-related sign, if required by the local authority where the property the proposed sign is to be located.
 - c. A site plan or building layout clearly showing the location of the proposed sign.
 - d. Proof of registration of the proposed tradename or fictitious name used on the proposed sign with the Florida Department of State.
 - e. Visual proofs of the proposed sign showing proposed dimensions.
9. **Marketing and/or Advertising.** Please include the following as addendums:
- a. A narrative description of the marketing campaign, to include a detailed description of all advertisements to be used.
 - b. A detailed description of the location or locations of use or dissemination, to include any method of dissemination, of each advertisement.
 - c. Proofs of visuals, the advertisement's script, and a video or audio recording of the advertisement.
 - d. If any advertising material is not in English, provide an English translation of all verbiage or scripts from a certified translation service.
 - e. Provide audience composition data, marketing markups, creative content, purchase placement, and any other documentation necessary to demonstrate that the marketing or advertising does not target children.
 - f. Provide a narrative description of how any proposed opt-in marketing includes an easy and permanent opt-out feature.
 - g. Provide any and all contracts or other agreements related to the creation and dissemination of the MMTC's proposed new marketing or advertising.
10. **Trade Name, Fictitious Name, Logo, or Branding.** Please include the following as addendums:
- a. Proofs of visuals for the proposed logo and branding.
 - b. Certified copies of any filings for trademark and copyright protection for the proposed trade name, fictitious name, logo, or branding.
 - d. Proof of registration of the proposed tradename or fictitious name with the Florida Department of State.

- e. If any trade name, fictitious name, logo, or branding is not in English, provide an English translation from a certified translation service.
 - f. Provide any and all contracts or other agreements related to the use of any MMTC trade name, fictitious name, logo, or branding by a third-party.
11. **Website or Webpage**. Please include the following as addendums:
- a. A narrative description of the proposed website or webpage, to include a detailed description of all content, functionality, and menus.
 - b. Page layouts, proofs of visuals, any script for video or audio, and any video or audio recordings to be posted on the website or webpage.
 - c. Clearly identify any item on the webpage or website that links to an outside website or webpage.
 - d. If any text is not in English, provide an English translation of all verbiage or scripts from a certified translation service.
 - e. Provide the Department access to an unpublished proposed final build of the website or webpage or equivalent.
 - f. Provide any and all contracts or other agreements related to the creation, dissemination, and the optimization of web traffic of the MMTC's proposed modified website or webpage.
12. **Seed-to-Sale System**. Please include the following as addendums:
- a. Clearly identify the provider of the seed-to-sale system, to include all registered names and fictitious names, and to provide certified documentation of any registration to do business in Florida.
 - b. Provide a narrative description of the seed-to-sale agreement which clearly describes its operation and the consideration paid by the MMTC for its use. This narrative is to include a detailed comparison of the proposed modification or change and the Department-approved seed-to-sale system.
 - c. Provide an updated inventory control plan and plan for the tracking and securing of marijuana throughout the supply chain.
13. **MMTC Management Agreement**. Please include the following as addendums:
- a. Clearly identify the proposed management services provider, to include all registered names and fictitious names, and to provide certified documentation of any registration to do business in Florida.
 - b. Provide a narrative description of the agreement which clearly describes the operation of management agreement, to include the services provided by the proposed management services provider and the consideration to paid for the services by the MMTC.
 - c. Provide certified copies of any proposed contract or other agreements relating to the services to be provided, and the consideration to be paid in exchange for the services to be provided.
 - d. Provide a narrative description of any changes to the MMTC's organizational structure accompanied by an organization chart illustrating the described changes.
14. **Licensing Agreement**. Please include the following as addendums:
- a. Clearly identify the proposed licensor, to include all registered names and fictitious names, and to provide certified documentation of any registration to do business in Florida.

- b. Provide a narrative description of the licensing agreement which clearly describes its operation, to include the rights provided to the MMTC by the licensor, and the consideration paid by the MMTC for these rights.
- c. Provide certified copies of any proposed contract or other agreement relating to the rights or services to be provided, and the consideration to be paid in exchange for the rights and services to be provided.
- d. In the event that the MMTC is the proposed licensor:
 - i. Clearly identify the proposed licensee, to include all registered names and fictitious names, and to provide certified documentation of any registration to do business in Florida.
 - ii. Provide a narrative description of the licensing agreement which clearly describes its operation, to include the rights provided to the licensee by the MMTC and the consideration paid by the licensee for these rights.
 - iii. Provide certified copies of any proposed contract or other agreement relating to the rights or services to be provided, and the consideration to be paid in exchange for the rights and services to be provided.

15. Bond, Irrevocable Letter of Credit, or Cash Held in Trust by the Department.

Please include the following as addendums:

- a. An MMTC seeking to use a new performance bond shall provide a certified copy of the proposed new performance bond.
- b. An MMTC seeking to downgrade its \$5 million performance bond to a \$2 million performance bond due to serving at least 1,000 qualified patients must:
 - i. Provide a certified copy of the \$2 million performance bond; and
 - ii. Provide proof from the Medical Marijuana Use Registry that it is currently providing marijuana to at least 1,000 qualified patients.
- c. An MMTC seeking to cancel a performance bond in favor of providing an irrevocable letter of credit payable to the Department or cash must provide certified financials that such line of credit or deposit will not adversely affect the MMTC's financial ability to maintain operations for the duration of the 2-year approval cycle.
- d. An MMTC seeking to downgrade its \$5 million irrevocable letter of credit payable to the Department or cash to \$2 million due to serving at least 1,000 qualified patients must provide proof from the Medical Marijuana Use Registry that it is currently providing marijuana to at least 1,000 qualified patients.

- 16. Add or Remove a Medical Director.** Please include a narrative description of the request; documentation, including a resume, demonstrating that the individual meets the requirements of sections 381.986(1)(i) and 381.986(3)(c), F.S.; and documentation indicating the date of the individual's most recent level 2 background screening pursuant to section 381.986(9), F.S. If the requested application variance will result in any change to how the activities of the MMTC are supervised, provide a narrative description of any change and an updated organizational chart illustrating the applicant's proposed supervisory structure. Include the narrative description and resume as an addendum.

- 17. Marijuana Testing Laboratory.** Please include the following as addendums:

- a. Clearly identify the proposed marijuana testing laboratory.
- b. A narrative description of the contract or agreement between the marijuana testing laboratory and the MMTC which clearly describes the services to be provided by the marijuana testing laboratory.

- c. Copies of any proposed contract or other agreements relating to the services to be provided.
- d. Provide all standard operating procedures to be used by the marijuana testing center regarding the testing of the MMTC's marijuana and the performing of audits on the MMTC's standard operating procedures, testing records, and samples.

18. **MMTC Business Structure**. Please include the following as addendums:

- a. Provide a detailed narrative description of any proposed change to the MMTC's business structure, to include the management structure.
- b. Provide certified documentation, contracts, notices, or filings related to any proposed mergers, acquisitions, initial public offerings, and exchange listings. Such documentation shall include any item provided to any securities regulator.
- c. If the requested application variance will result in any change to how the activities of the MMTC are supervised, provide a narrative description of any change and an updated organizational chart illustrating the applicant's proposed supervisory structure.

19. **Other**. The Variance Request is to modify MMTC operations in a manner that is not contemplated by any of the other enumerated headings. For any such request, provide a narrative description of the request and all supporting documentation, such as proposed contracts or other agreements. If the requested application variance will result in any change to how the activities of the medical marijuana treatment center are supervised, provide a narrative description of any change and an updated organizational chart illustrating the applicant's proposed supervisory structure. Include the narrative description and support documentation as an addendum.

Part VI

Attestation of accuracy of representations to the Department:

I do hereby attest that all information submitted and attached to this Variance Request is true and correct to the best of my knowledge.

Signature of MMTC Representative

Date

Name of MMTC Representative (print or type)

Position

DRAFT