



Application for Low-THC Cannabis Dispensing Organization Approval

This Application for Low-THC Cannabis Dispensing Organization Approval (Application) is designed to allow the Florida Department of Health, Office of Compassionate Use (OCU) to fulfill its statutory duty to select the five Dispensing Organizations meeting the requirements of section 381.986(5)(b), F.S. (Statute), best able to further the statutory objective of ensuring accessibility and availability of Low-THC cannabis to patients. This has been further clarified to mean that OCU must choose the most dependable, most qualified dispensing organizations that can consistently deliver high-quality Derivative Products. It is important for each Applicant to remember that the Applicant is competing with other Applicants, not with any mandatory minimum criteria set by the OCU. The criteria used to determine which Applicants are selected are drawn directly from the Statute. The items requested in Rule 64-4.002, F.A.C., Initial Application Requirements for Dispensing Organizations (Rule) and this Application are designed to guide OCU in its determination of the most qualified Applicants that can ensure accessibility and availability of Derivative Products by dependably and consistently delivering high-quality Derivative Products.

This Application is divided into four parts:

- I. Part I requires the Applicant to provide basic information about the Applicant and Application.
- II. Part II requires the Applicant to document its compliance with requirements mandated by the Statute.
- III. Part III requires the Applicant to provide the OCU with all items listed in the Rule. Part III is organized differently than the Rule because it is organized based on the scoring system OCU will use to evaluate Applications. Each individual item listed in the Rule and the Application is not mandatory but is designed to elicit information from the Applicant that will assist the OCU in making its selection. Part III is organized as follows:

A. Cultivation (30%)

1. Technical Ability (4.002(2)(a)) [25%]
2. Infrastructure (4.002(2)(e)) [25%]
3. Premises Resources Personnel (4.002(2)(c)) [25%]
4. Accountability (4.002(2)(d)) [25%]

B. Processing (30%)

1. Technical Ability (4.002(2)(a)) [25%]
2. Infrastructure (4.002(2)(e)) [25%]
3. Premises Resources Personnel (4.002(2)(c)) [25%]
4. Accountability (4.002(2)(d)) [25%]

C. Dispensing (15%)

- 1. Technical Ability (4.002(2)(a)) [25%]
- 2. Infrastructure (4.002(2)(e)) [25%]
- 3. Premises Resources Personnel (4.002(2)(c)) [25%]
- 4. Accountability (4.002(2)(d)) [25%]

D. Medical Director (5%)

E. Financials (20%)

IV. Part IV explains how to submit an application, including the application fee.

For OCU review purposes, please be sure to organize the Application so that each document submitted with the Application is labeled accurately with the Part number and sub-Part number of the Application to which it corresponds. The better organized the Application is, the easier it will be to evaluate.

Part I

Application Type: Initial Application Renewal Application

Dispensing Region: Northwest Northeast Central Southwest Southeast

Nursery:

Name: _____
(Unless an individual, the organization name must be registered with the Department of State)

DACS Certificate Address: _____
Street Address City Zip Code

Mailing Address (if different): _____
P.O. Box or Street Address City Zip Code

Phone Number: _____ E-mail Address: _____

Nurseryman:

Operating Nurseryman: _____

Mailing Address: _____
P.O. Box or Street Address City Zip Code

Phone Number: _____ E-mail Address: _____

Medical Director:

Name: _____

Mailing Address: _____
P.O. Box or Street Address City Zip Code

Phone Number: _____ E-mail Address: _____

License Number: _____

Part II

The following information must be submitted and is required by the Statute. A failure to submit the information required by Part II will result in the application being denied prior to any scoring as contemplated in rule 64-4.002(5), F.A.C.

- A. Please submit documentation sufficient to establish the Applicant meets the requirements of Section 381.986(5)(b)1., F.S., specifically:
1. Certification by the Florida Department of Agriculture and Consumer Services for the cultivation of more than 400,000 plants; and
 2. Operation as a nursery in this state for at least 30 continuous years.
- B. Please submit documentation sufficient to establish that all owners and managers of the Applicant (and proposed Dispensing Organization) have been fingerprinted and have successfully passed a level 2 background screening pursuant to section 435.04, F.S.
1. As stated in rule 64-4.002(2)(g), F.A.C., this requirement can be satisfied by each owner or manager presenting to FDLE or one of its approved vendors for fingerprinting. At that time, give the entity ORI number FL924890Z (DOH – OFFICE OF COMPASSIONATE USE) to FDLE or its approved vendor. The report will be sent directly to the Office of Compassionate Use.
 2. Please submit a list of all owners and managers indicating the date of each individual's most recent level-2 background screening described above.

Part III

Please attach the documentation that provides the information listed in Rule 64-4.002 including (when appropriate) the name, position, and resume' of the employee(s) who provides the knowledge or experience explained for each item shown below:

A. Cultivation (30%)

1. Technical Ability (4.002(2)(a)) [25%]
 - a. Experience cultivating cannabis;
 - b. Experience cultivating in Florida plants not native to Florida;
 - c. Experience introducing new varieties of plants;
 - d. Regional cultivation knowledge and experience;
 - e. Experience cultivating plants for human consumption such as food or medicine products;
 - f. Experience with in-house propagation;
 - g. Experience with genetic modification or breeding;

- h. Experience using clean growing rooms;
 - i. Knowledge of cannabis cultivation, including:
 - i. Proper cultivation conditions and techniques;
 - ii. Additives that can be used when growing cannabis;
 - iii. Pests, disease and deficiencies common for cannabis;
 - iv. Production of high quality product in a short time;
 - j. Experience with tracking each plant in a harvest;
 - k. Experience with good agricultural practices;
 - l. Experience with good handling practices;
 - m. Experience with recalls; and
 - n. Any awards, recognition or certifications received for relevant expertise.
2. Infrastructure (4.002(2)(e)) [25%]
- a. Vehicles that will be used to transport product among cultivating, processing, and dispensing facilities;
 - b. Communication systems; and
 - c. Methods of mitigating odors if applicable.
3. Premises, Resources, Personnel (4.002(2)(c)) [25%]
- a. Location of all properties Applicant proposes to utilize to cultivate low-THC cannabis, including ownership information for the properties and any lease terms if applicable:
 - i. For any property that is leased by the Applicant, include documentation that the property owner consents to the use of the property for the purposes of cultivation of low-THC cannabis and documentation that the mortgagor or lienholder has been given notice of the use of the property for the purpose of cultivation of low-THC cannabis; and
 - ii. For any property owned by the Applicant but subject to a mortgage or lien, include documentation that the mortgagor or lienholder has been notified of the use of the property for the purpose of cultivation of low-THC cannabis.
 - b. Compliance with local regulations regarding sanitation and waste disposal;
 - c. The ability to obtain zoning approval;
 - d. Sketch or other illustration approximating the property boundaries, land topography, vegetation, proposed and/or existing structures, easements, wells, and roadways for each cultivation property proposed;
 - e. Description of the areas proposed for the cultivation of low-THC cannabis, including the following:
 - i. Capacity, in square feet of growing area;
 - ii. Cultivation environment, e.g., greenhouse, clean room, aseptic, et cetera;
 - iii. Irrigation system(s);
 - iv. Cultivation environment, e.g., greenhouse, clean room, aseptic, et cetera; and
 - v. Environmental control system(s).
 - f. A description of the ability or plan to expand any of the areas proposed for cultivating low-THC cannabis;
 - g. Back-up systems for all cultivation systems;

- h. A description of one or more strains of low-THC cannabis the applicant intends to cultivate;
 - i. Access to water resources that allow for sufficient irrigation;
 - j. A list of current and proposed staffing for cultivation, including:
 - i. Position, duties and responsibilities;
 - ii. Resume; and
 - iii. Professional licensure disciplinary action in all jurisdictions.
 - k. An organizational chart illustrating the supervisory structure of the cultivation function of the proposed Dispensing Organization;
 - l. Plans and procedures for loss of key personnel;
 - m. Plans and procedures for complying with OSHA regulations for workplace safety.
4. Accountability (4.002(2)(d)) [25%]
- a. Floor plan of each cultivation facility or proposed floor plans for proposed cultivation facilities, including the following:
 - i. Locking options for each means of ingress and egress;
 - ii. Alarm systems;
 - iii. Video surveillance;
 - iv. Name and function of each room; and
 - v. Layout and dimensions of each room.
 - b. Storage, including the following:
 - i. Safes;
 - ii. Vaults; and
 - iii. Climate control.
 - c. Diversion and trafficking prevention procedures;
 - d. A facility emergency management plan;
 - e. System for tracking low-THC source plant material throughout cultivation;
 - f. Inventory control system for low-THC cannabis;
 - g. Policies and procedures for recordkeeping;
 - h. Methods of screening and monitoring employees;
 - i. Personnel qualifications and experience with chain of custody or other tracking mechanisms;
 - j. Personnel reserved solely for inventory control purposes;
 - k. Personnel reserved solely for security purposes;
 - l. Waste disposal plan; and
 - m. Access to specialized resources or expertise regarding data collection, security, and tracking.

B. Processing (30%)

- 1. Technical Ability (4.002(2)(a)) [25%]
 - a. Experience with good manufacturing practices;
 - b. Experience with analytical, organic chemistry, and micro-biology;
 - c. Experience with analytical laboratory methods;
 - d. Experience with analytical laboratory quality control, including maintaining a chain of custody;
 - e. Knowledge of and experience with cannabis extraction techniques;
 - f. Knowledge of cannabis routes of administration;

- g. Experience with recalls;
 - h. Knowledge of and experience with producing cannabis products; and
 - i. Any awards, recognition or certifications received for relevant expertise.
2. Infrastructure (4.002(2)(e)) [25%]
- a. Vehicles that will be used to transport product among cultivating, processing, and dispensing facilities;
 - b. Communication systems; and
 - c. Methods of mitigating odors if applicable.
3. Premises, Resources, Personnel (4.002(2)(c)) [25%]
- a. Location of all properties Applicant proposes to utilize to process low-THC cannabis and Derivative Products, including ownership information for the properties and any lease terms if applicable:
 - i. For any property that is leased by the Applicant, include documentation that the property owner consents to the use of the property for the purposes of processing of low-THC cannabis and Derivative Products and documentation that the mortgagor or lienholder has been given notice of the use of the property for the purposes of processing of low-THC cannabis and Derivative Products; and
 - ii. For any property owned by the Applicant but subject to a mortgage or lien, include documentation that the mortgagor or lienholder has been notified of the use of the property for the purposes of processing of low-THC cannabis and Derivative Products.
 - b. Compliance with local regulations regarding sanitation and waste disposal;
 - c. The ability to obtain zoning approval;
 - d. Sketch or other illustration approximating the property boundaries, land topography, vegetation, proposed and/or existing structures, easements, wells, and roadways for each processing property proposed;
 - e. A description of the ability or plan to expand any of the areas proposed for processing low-THC cannabis;
 - f. Back-up systems for all processing systems;
 - g. Description of the areas proposed for the processing of Derivative Products, including the following:
 - i. Extraction equipment and location;
 - ii. Concentration equipment and location;
 - iii. Access to sufficient potable water and hot water;
 - iv. Analytical equipment, including separators and detectors, and location;
 - v. Safety equipment and facilities and location;
 - vi. Computer systems and software; and
 - vii. Ventilation and exhaust system.
 - h. A list of current and proposed staffing, including:
 - i. Position, duties and responsibilities;
 - ii. Resume; and
 - iii. Professional licensure disciplinary action in all jurisdictions.
 - i. An organizational chart illustrating the supervisory structure of the processing function of the proposed Dispensing Organization;

- j. Plans and procedures for loss of key personnel;
 - k. Plans and procedures for complying with OSHA regulations for workplace safety; and
 - l. Relationship(s) with an independent laboratory(ies) with cannabis testing protocols and methods.
4. Accountability (4.002(2)(d)) [25%]
- a. Floor plan of each facility or proposed floor plans for proposed processing facilities, including the following:
 - i. Locking options for each means of ingress and egress;
 - ii. Alarm systems;
 - iii. Video surveillance;
 - iv. Name and function of each room
 - v. Layout and dimensions of each room.
 - b. Storage, including the following:
 - i. Safes;
 - ii. Vaults; and
 - iii. Climate control.
 - c. Diversion and trafficking prevention procedures for the processing facilities;
 - d. A facility emergency management plan for the processing facilities;
 - e. System for tracking low-THC source plant material throughout processing;
 - f. Inventory control system for low-THC cannabis and Derivative Products;
 - g. Policies and procedures for recordkeeping;
 - h. Vehicle tracking systems;
 - i. Vehicle security systems;
 - j. Methods of screening and monitoring employees;
 - k. Personnel qualifications and experience with chain of custody or other tracking mechanisms;
 - l. Personnel reserved solely for inventory control purposes;
 - m. Personnel reserved solely for security purposes;
 - n. Waste disposal plan; and
 - o. Access to specialized resources or expertise regarding data collection, security, and tracking.

C. Dispensing (15%)

- 1. Technical Ability (4.002(2)(a)) [25%]
 - a. Experience interacting with patients;
 - b. Experience with handling confidential information;
 - c. A marketing plan;
 - d. Experience gathering and managing data, i.e. data on patient reactions to products dispensed;
 - e. Experience with recalls;
 - f. Knowledge of cannabis routes of administration;
 - g. Training programs for employees addressing:
 - i. The Health Insurance Portability and Accountability Act (HIPAA);
 - ii. Patient education;
 - iii. Compliance;
 - iv. Patient counseling; and

- v. Data collection.
 - h. Any awards, recognition or certifications received for relevant expertise.
- 2. Infrastructure (4.002(2)(e)) [25%]
 - a. A map showing the location of the applicant's proposed dispensing facilities;
 - b. A sketch or other illustration of the actual or proposed dispensing locations showing streets; property lines; buildings; parking areas; outdoor areas, if applicable; fences; security features; fire hydrants, if applicable; and access to water and sanitation systems;
 - c. A floor plan of the actual or proposed building or buildings where dispensing activities will occur showing:
 - i. Areas designed to protect patient privacy; and
 - ii. Areas designed for retail sales.
 - d. A HIPAA compliant computer network utilized by all facilities;
 - e. Vehicles that will be used to transport product among cultivating, processing, and dispensing facilities;
 - f. Communication systems;
 - g. Hours of operation of each dispensing facility; and
 - h. Methods of mitigating odors if applicable.
- 3. Premises, Resources, Personnel (4.002(2)(c)) [25%]
 - a. Location of all properties Applicant proposes to utilize to dispense Derivative Products, including ownership information for the properties and any lease terms if applicable:
 - i. For any property that is leased by the Applicant, include documentation that the property owner consents to the use of the property for the purposes of dispensing of Derivative Products and documentation that the mortgagor or lienholder has been given notice of the use of the property for the purposes of dispensing of Derivative Products; and
 - ii. For any property owned by the Applicant but subject to a mortgage or lien, include documentation that the mortgagor or lienholder has been notified of the use of the property for the purposes of dispensing of Derivative Products.
 - b. Compliance with local regulations regarding sanitation and waste disposal;
 - c. The ability to obtain zoning approval;
 - d. Sketch or other illustration approximating the dispensing property boundaries, land topography, vegetation, proposed and/or existing structures, easements, wells, and roadways for each property proposed;
 - e. A description of the ability or plan to expand any of the areas proposed for dispensing Derivative Products;
 - f. Description of the methods proposed for the dispensing of Derivative Products, including the following:
 - i. Accessibility of dispensing facilities, e.g., centrally located to several populated areas, located on a main roadway, not in a high crime area, et cetera;
 - ii. Proximity of dispensing facilities to patient populations; and
 - iii. Alternative dispensing, e.g. delivery.
 - g. A list of current and proposed dispensing staffing, including:

- i. Position, duties and responsibilities;
 - ii. Resume; and
 - iii. Professional licensure disciplinary action in all jurisdictions.
 - h. An organizational chart illustrating the supervisory structure of the dispensing function of the proposed Dispensing Organization;
 - i. Plans and procedures for loss of key personnel; and
 - j. Plans and procedures for complying with OSHA regulations for workplace safety.
- 4. Accountability (4.002(2)(d)) [25%]
 - a. Floor plan of each facility or proposed floor plans for proposed dispensing facilities, including the following:
 - i. Locking options for each means of ingress and egress;
 - ii. Alarm systems;
 - iii. Video surveillance;
 - iv. Name and function of each room; and
 - v. Layout and dimensions of each room.
 - b. Storage, including the following:
 - i. Safes;
 - ii. Vaults; and
 - iii. Climate control.
 - c. Diversion and trafficking prevention procedures for the dispensing facilities;
 - d. A facility emergency management plan for the dispensing facilities;
 - e. System for tracking Derivative Products throughout dispensing;
 - f. Inventory control system for Derivative Products;
 - g. Policies and procedures for recordkeeping;
 - h. Methods of screening and monitoring employees;
 - i. Personnel qualifications and experience with chain of custody or other tracking mechanisms;
 - j. Personnel reserved solely for inventory control purposes;
 - k. Personnel reserved solely for security purposes;
 - l. Plans for the recall of any Derivative Products that have a reasonable probability of causing adverse health consequences based on a testing result, bad patient reaction, or other reason; and
 - m. Access to specialized resources or expertise regarding data collection, security, and tracking.

D. Medical Director (5%)

- a. Specialty area, if any;
- b. Experience with epileptic patients;
- c. Experience with cancer patients;
- d. Experience with patients with severe seizures or muscle spasms;
- e. Knowledge of the use of low-THC cannabis for treatment of cancer or physical medical conditions that chronically produce symptoms of seizures or severe and persistent muscle spasms;
- f. Knowledge of good manufacturing practices;
- g. Knowledge of analytical and organic chemistry;
- h. Knowledge of analytical laboratory methods;

- i. Knowledge of analytical laboratory quality control, including maintaining a chain of custody;
- j. Knowledge of and experience with CBD/low-THC extraction techniques;
- k. Knowledge of CBD/low-THC routes of administration;
- l. Experience in or knowledge of clinical trials or observational studies;
- m. Knowledge of and experience with producing CBD/low-THC products;
- n. Experience with or knowledge of botanical medicines;
- o. Experience with dispensing medications;
- p. Description of how the medical director will supervise the activities of the Dispensing Organization; and
- q. Description of how the Dispensing Organization will ensure it has a medical director at all times.

E. Financials (20%)

- a. Certified Financials issued within the immediately preceding 12 months;
- b. Applicant's corporate structure;
- c. All owners of the Applicant;
- d. All individuals and entities that can exercise control of the Applicant;
- e. All individuals and entities that share in the profits and losses of the Applicant;
- f. All subsidiaries of the Applicant;
- g. Any other individuals or entities for which the Applicant is financially responsible;
- h. Assets of the Applicant and Applicant's subsidiaries;
- i. Liabilities of the Applicant and Applicant's subsidiaries;
- j. Any pending lawsuits to which the Applicant is a party;
- k. Any lawsuits within the past 7 years to which the Applicant was a party;
- l. All financial obligations of Applicant that are not listed as a "liability" in the Certified Financials;
- m. A projected two year budget for the Dispensing Organization; and
- n. Specific reference to sufficient assets available to support the Dispensing Organization activities.

Part IV

The completed Application must be delivered to the Agency Clerk of the Department of Health physically located at 2585 Merchants Row Boulevard in Tallahassee, Florida, 32399, no earlier than 10:00 AM, Eastern Daylight Time, on the (effective date) and no later than 5:00 PM, Eastern Daylight Time, 21 calendar days after (effective date). The Application MUST include:

- 1. A non-refundable \$60,036 application fee in the form of a money order or cashier's check made payable to the Florida Department of Health;**
- 2. All supporting explanations and documents;**
- 3. Any supporting maps, photographs, or illustrations;**
- 4. A list of ALL supporting materials for which the Applicant claims ANY public records exemption, including a specific legal citation to the exemption; and**
- 5. A full proposed redacted version of the Application, if applicable.**

The completed Application with and supporting explanations, documents, maps, photographs, or illustrations can be submitted in the following formats:

1. Hard Copy;
2. USB Drive; and
3. CD/DVD.

The undersigned Applicant /Representative hereby agrees to operate the Dispensing Organization described in this application in accordance with the requirements of Section 381.986, Florida Statutes, and Chapter 64-4, F.A.C. The information contained in this application and the attached exhibits required by Chapter 64-4, F.A.C., which serves as a basis for licensure, is true and correct. I

understand that any misrepresentation of the facts in this application, or failure to comply with requirements of the rules and statutes, is grounds for denial or revocation of the Low-THC Cannabis Dispensing Organization Approval. I understand that knowingly making a false statement in writing with the intent to mislead a public servant in the performance of his or her official duty shall be guilty of a misdemeanor of the second degree punishable as provided in sections 775.082 or 775.083, Florida Statutes.

Signature of Applicant _____ Date _____

Name of Applicant (print or type) _____

Agency Clerk Use Only

Date and Time Received: _____

Delivered by: _____

Agency Clerk: _____