

RULE NO.:	RULE TITLE:
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64-4.001 Definitions.

For the purposes of this chapter, the following words and phrases shall have the meanings indicated:

(1) Applicant – A nursery that meets the requirements of Section 381.986(5)(b)1., F.S., applies for approval as a dispensing organization, and identifies a nurseryman as defined in s. 581.011 who will serve as the operator.

(2) Approval – Written notification from the department to an applicant that its application for dispensing organization approval has been found to be in compliance with the provisions of this chapter and that the department is awaiting notification that it is prepared to be inspected and authorized to begin cultivation and other operations.

(3) Authorization – Written notification by the department to a dispensing organization that it may begin specific phases of operation including cultivation, harvesting, processing, dispensing and other activities authorized by this chapter involving the possession of low-THC cannabis and the production of low-THC cannabis derivative products. Authorization may be requested and given in stages as the infrastructure and staffing requirements of the operation are completed.

(4) Batch - A specific lot of low-THC cannabis derivative product produced from one or more harvests of low-THC cannabis plants that are processed or blended into a uniform mixture before portioning such that all products bearing the same batch number would be expected to be representative of the entire batch for the purpose of laboratory testing.

(5) Batch number - A unique numeric or alphanumeric identifier assigned to a batch by a dispensing organization when the batch is portioned and packaged for dispensing.

(6) Certified financials – Financial statements that a Certified Public Accountant, licensed pursuant to chapter 473, F.S., attests to be true.

(7) Cultivation - The growth of source plant or tissue culture material.

(8) Derivative product – Forms of low-THC cannabis suitable for routes of administration, e.g., vapor, resins, salts, extracts, capsules, oral sprays, nasal sprays, and any compound, manufacture, mixture or preparation derived from low-THC cannabis that is dispensed by a dispensing organization.

(9) Dispensing Region – A geographical area where the cultivation and production of low-THC cannabis under the control of a dispensing organization occurs. The five dispensing regions shall be identified as follows:

(a) Northwest Florida Region consisting of Bay, Calhoun, Escambia, Franklin, Gadsden, Gulf, Holmes, Jackson, Jefferson, Leon, Liberty, Madison, Santa Rosa, Okaloosa, Taylor, Wakulla, Walton, and Washington counties.

(b) Northeast Florida Region consisting of Alachua, Baker, Bradford, Clay, Columbia, Dixie, Duval, Flagler, Gilchrist, Hamilton, Lafayette, Levy, Marion, Nassau, Putnam, St. Johns, Suwannee, and Union counties.

(c) Central Florida Region consisting of Brevard, Citrus, Hardee, Hernando, Indian River, Lake, Orange, Osceola, Pasco, Pinellas, Polk, Seminole, St. Lucie, Sumter, and Volusia counties.

(d) Southwest Florida Region consisting of Charlotte, Collier, DeSoto, Glades, Hendry, Highlands, Hillsborough, Lee, Manatee, Okeechobee, and Sarasota counties.

(e) Southeast Florida Region consisting of Broward, Dade, Martin, Monroe, and Palm Beach counties.

(10) Dispensing Organization – A nursery that meets the requirements of Section 381.986(5)(b)1., F.S., which has been approved by the department to cultivate, process and dispense low-THC cannabis.

(11) Dispensing Organization Facility – One or multiple structures on contiguous properties that are used by the dispensing organization for the preparation, cultivation, storage, production, or dispensing of low-THC cannabis.

(12) Financial Statements – A presentation of financial data, including accompanying notes, derived from accounting records that purports to show actual or anticipated financial position and intended to communicate an entity's economic resources or obligations at a point in time, and the results of operations and cash flows for a period of time, in accordance with generally accepted accounting principles or a comprehensive basis of accounting other

than generally accepted accounting principles. Financial presentations included in tax returns are not financial statements. The method of preparation (for example, manual or computer preparation) is not relevant to the definition of a financial statement.

(13) Harvest – A specific lot of low-THC cannabis plants grown from one or more seeds, cuttings or tissue cultures, that are planted, cloned or cultured and harvested at the same time such that any plant in the harvest is expected to be representative of the entire harvest for the purposes of laboratory testing.

(14) Harvest number - means a unique numeric or alphanumeric identifier assigned to a harvest by a dispensing organization when the harvest is planted.

(15) Inventory Agent – An employee of the dispensing organization who has been designated in writing to have oversight of the inventory control system.

(16) Manager – Any person with the authority to exercise operational direction or management of the dispensing organization or the authority to supervise any employee of the dispensing organization such as, the following:

(a) All directors, officers, board members and managers identified in the most recent annual report filed with the Florida Division of Corporations;

(b) The inventory agent;

(c) The security director;

(d) The medical director; and

(e) If the dispensing organization is a joint venture, all persons who have a direct or indirect interest in each joint venture partner as well as all persons who have the authority to exercise operational direction or management of the dispensing organization or have the authority to supervise any employee of the dispensing organization.

(17) Owner – Any person, including any individual or other legal entity, with a direct or indirect ownership interest of 7% or more in the applicant, including the possession of stock, equity in capital, or any interest in the profits of the applicant.

(18) Permanent resident – A person has his or her true, fixed and permanent home in Florida to which, whenever absent, he or she has the intention of returning. Once a permanent residence is established in Florida it is presumed to continue until the resident shows that a change has occurred. Any person who has established a residence in this state may manifest and evidence the same by filing a sworn statement pursuant to Section 222.17, F.S.

(19) Routes of administration – means the path by which a low-THC cannabis derivative product is ordered by a physician to be taken into the body, and includes oral, topical, transdermal, and nasal administration.

(20) Sanitation Protocol - A set of identified policies and procedures of an applicant or dispensing organization that details required sanitation procedures within any dispensing organization facility including personnel and visitor dress protocols, equipment sanitation requirements, facility sanitation requirements, disposal procedures, and employee hygiene requirements.

(21) Tissue culture – Technique of cultivating low-THC cannabis plant tissue in a prepared medium and the low-THC cannabis plant tissue so cultivated.

~~(22) Transportation plan – Method of transporting up to a 90 day supply of low-THC cannabis derivative product for each qualified patient served on the trip from the dispensing organization to qualified patients in the state which documents, at a minimum, confirmation of the order from the registry, confirmation from the qualified patient that he or she requests delivery, place of delivery, date and time of trip, route of transportation, security of the low-THC cannabis product or products being transported, signature of the qualified patient or the qualified patient's legal representative receiving the order, and creation and maintenance of a log of all low-THC derivative products transported.~~

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History–New \_\_\_\_\_.

#### 64-4.002 Initial Application Requirements for Dispensing Organizations.

Each nursery that meets the requirements of Section 381.986(5)(b)1., F.S., desiring to be approved as a dispensing organization shall make application to the department using Form DH8006-OCU-12/2014, “Application for Low-THC Cannabis Dispensing Organization Approval” herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>. The completed application form must include the following:

(1) An initial application fee of \$x.xx;

(2) An explanation or written documentation, as applicable, showing how the Applicant meets the statutory criteria listed in section 381.986(5)(b), F.S. In any explanation, the Applicant must address each item listed for each

criterion below. The Applicant must disclose the name, position, and resume of the employee(s) who provides the knowledge or experience explained for each item.

(a) The technical and technological ability to cultivate, produce, and dispense low-THC cannabis. Please address the following items:

1. Experience cultivating cannabis;
2. Experience cultivating plants similar in genetic structure to cannabis;
3. Experience growing plants not native to Florida;
4. Experience introducing new varieties of plants;
5. Experience cultivating plants for human consumption such as food or medicine products;
6. Experience with tissue culturing or plant genetics;
7. Experience using clean growing rooms;
8. Knowledge of cannabis cultivation, including:
  - a. Proper cultivation conditions and techniques;
  - b. Additives that can be used when growing cannabis;
  - c. Pests and nutritional deficiencies common for cannabis;
  - d. Production of high quality product in a short time.
9. Experience with tracking each plant in a harvest;
10. Experience with U.S.D.A. Good Agricultural Practices;
11. Experience with U.S.D.A. Good Handling Practices;
12. Experience with good manufacturing practices;
13. Experience with analytical and organic chemistry;
14. Experience with analytical laboratory methods;
15. Experience with analytical laboratory quality control, including maintaining a chain of custody;
16. Knowledge of and experience with CBD/low-THC extraction techniques;
17. Knowledge of CBD/low-THC routes of administration;
18. Knowledge of and experience with producing CBD/low-THC products;
19. Knowledge of research about the entourage effect of all phytocannabinoids as well as terpenoids and

plant waxes:

20. Experience interacting with patients;
21. Experience with handling confidential information;
22. Experience gathering and managing data, i.e. data on patient reactions to products dispensed;
23. Training programs for employees addressing:
  - a. The Health Insurance Portability and Accountability Act (HIPAA);
  - b. Patient education;
  - c. Patient counseling; and
  - d. Data collection.
23. Any awards or recognition received for relevant expertise.

(b) Written documentation demonstrating that the applicant must possess a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131 that is issued for the cultivation of more than 400,000 plants, is operated by a nurseryman as defined in s. 581.011, and has been operated as a registered nursery in this state for at least 30 continuous years.

(c) The ability to secure the premises, resources, and personnel necessary to operate as a dispensing organization. Please address the following items, and include maps and/or photos for each:

1. Location of all properties Applicant proposes to utilize to cultivate, produce, and dispense low-THC cannabis, including ownership information for the properties and any lease terms if applicable;
  - a. For any property that is leased by the Applicant, include documentation that the property owner consents to the use for the property for the purposes of cultivation, production, or dispensing of low-THC cannabis.
  - b. For any property owned by the Applicant but subject to a mortgage or lien, include documentation that the mortgagor or lienholder consents to the use for the property for the purposes of cultivation, production, or dispensing of low-THC cannabis.
2. Compliance with local regulations regarding zoning, sanitation, and waste disposal;
3. Site plan for each property proposed;
4. Description of the areas proposed for the cultivation of low-THC cannabis, including the following:
  - a. Capacity, in square feet of growing area;
  - b. Cultivation environment, e.g., greenhouse, clean room, aseptic, et cetera;
  - c. Irrigation system(s);

- d. Lighting control system(s);
  - e. Temperature control system(s); and
  - f. Any equipment or processes designed to reduce the environmental impact of the chosen cultivation technique(s);
5. Back-up systems for all cultivation and processing systems;
  6. Access to one or more strains of low-THC cannabis;
  7. Access to water resources, e.g., possession of a Consumptive Use Permit that allows for sufficient irrigation;
  8. Description of any onsite laboratory facilities, including the following:
    - a. Extraction equipment and location;
    - b. Concentration equipment and location;
    - c. Analytical equipment, including separators and detectors, and location;
    - d. Safety equipment and facilities and location;
    - e. Computer systems and software;
    - f. Any equipment or processes designed to reduce the environmental impact of the any laboratory processes, e.g., solvent recapture;
  9. Description of the areas proposed for the production of low-THC cannabis derivative products, including the following:
    - a. Production equipment; and
    - b. Any equipment designed to reduce the environmental impact of the chosen production technique(s).
  10. Description of the areas proposed for the distribution of low-THC cannabis derivative products, including the following:
    - a. 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; and
    - b. Proximity of dispensing facilities to patient populations.
  11. A list of current and proposed staffing including position, duties and responsibilities;
  12. An organizational chart illustrating the supervisory structure of the proposed dispensing organization;
  13. Plans and procedures for loss of key personnel; and
  14. Relationship(s) with an independent laboratory(ies) with cannabis testing protocols and methods.
- (d) The ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances. Please address the following items for each property or location:
1. Floor plan of each facility or proposed floor plans for proposed facilities, including the following:
    - a. Locking options for each means of ingress and egress;
    - b. Alarm systems;
    - c. Video surveillance;
    - d. Name and function of each room;
    - e. Layout and dimensions of each room;
  2. Diversion and trafficking prevention procedures;
  3. A facility emergency management plan;
  4. System for tracking cuttings, seedlings, or seeds throughout the cultivation, processing, and distribution processes;
  5. Vehicle tracking systems;
  6. Vehicle security systems;
  7. Methods of screening and monitoring employees;
  8. Personnel qualifications and experience with chain of custody or other tracking mechanisms;
  9. Personnel reserved solely for inventory control purposes;
  10. Personnel reserved solely for security purposes;
  11. Waste disposal plan;
  12. 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.
  12. Access to specialized resources or expertise regarding data collection, security, and tracking.
- (e) An infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department. Please address the following items:
1. A map showing the location of the applicant's proposed dispensing facilities;

2. A site plan of the actual or proposed dispensing location 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; and

3. A floor plan of the actual or proposed building or buildings where dispensing activities will occur showing:

- a. Areas designed to protect patient privacy;
- b. Areas designed for patient consultation;
4. A centralized computer system or network utilized by all facilities;
5. Vehicles that will be used to transport product among cultivating, producing, and dispensing facilities;
6. Communication systems;
7. Vehicle tracking and security systems; and
8. Hours of operation of each dispensing facility.

(f) The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department. In addition to submitting certified financials, please address the following items (or reference to where that item appears in the certified financials):

1. Applicant's corporate structure;
2. All owners of the Applicant;
3. All subsidiaries of the Applicant;
4. Any other individuals or entities for which the Applicant is financially responsible;
5. Assets of the Applicant and Applicant's subsidiaries;
6. Liabilities of the Applicant and Applicant's subsidiaries;
7. Any pending lawsuits to which the Applicant is a party;
8. Any lawsuits within the past 10 years to which the Applicant was a party;
9. All financial obligations of Applicant that are not listed as a "liability" in the certified financials; and
10. A two-year business plan with a budget and specific reference to the assets available to support the

plan.

(g) That all owners and managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to s. 435.04, F.S. within the calendar year prior to application. Please submit the screening report for each owner and manager, including a list of all owners and managers indicating the date of each individual's most recent Level-2 background screening.;

(h) The employment of a medical director who is a physician licensed pursuant to chapter 458 or chapter 459, F.S., to supervise the activities of the proposed dispensing organization. Please address the following items for the physician chosen as medical director:

1. Specialty area, if any;
2. Experience with epileptic patients;
3. Experience with cancer patients;
4. Experience with patients with severe seizures or muscle spasms;
5. 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;
6. Knowledge of good manufacturing practices;
7. Knowledge of analytical and organic chemistry;
8. Knowledge of analytical laboratory methods;
9. Knowledge of analytical laboratory quality control, including maintaining a chain of custody;
10. Knowledge of and experience with CBD/low-THC extraction techniques;
11. Knowledge of CBD/low-THC routes of administration;
12. Experience in or knowledge of clinical trials or observational studies;
18. Knowledge of and experience with producing CBD/low-THC products;

(i) The ability to post a \$5 million performance bond for the biennial approval cycle.

(3) If the applicant intends to claim any exemption from public records disclosure under Section 119.07, F.S., or any other exemption from public records disclosure provided by law for any part of its application, it shall indicate on the application the specific sections for which it claims an exemption and the basis for the exemption.

(4) Failure to submit the \$x.xx application fee or documentation sufficient to establish the applicant meets the requirements of section 381.986(5)(b), F.S., shall result in the application being denied prior to any scoring as contemplated in section (5) of this rule.

(5) Any "Application for Low-THC Cannabis Dispensing Organization Approval" and all required exhibits and supporting documents shall be delivered to the Agency Clerk of the Department of Health physically located at

2585 Merchants Row Boulevard in Tallahassee, Florida, no earlier than 10:00 AM, Eastern Time, on the effective date of this rule and no later than 5:00 PM, Eastern Time, xx calendar days after the effective date of this rule.

(a) The department will substantively review, evaluate, and score applications using Form DH8007-OCU-12/2014, "Scorecard for Low-THC Cannabis Dispensing Organization Selection" herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>. The scorecard includes each of the items listed above with each item weighted [TBD]. Each item will be scored on a scale of [TBD] then multiplied by the weighting factor [TBD]. The department's substantive review will be completed by:

1. Director of the Office of Compassionate Use;
2. A member of the Drug Policy Advisory Council appointed by the State Surgeon General; and
3. A Certified Public Accountant appointed by the State Surgeon General.

Scorecards from each of the three substantive review panel members will be combined to generate an aggregate score for each application. The applicant with the highest aggregate score in each dispensing region shall be selected as the region's dispensing organization.

(b) Upon notification that it has been selected as a region's dispensing organization, the applicant shall have 10 calendar days to post a \$5 million performance bond. The bond shall:

1. Be payable to the department in the event the dispensing organization fails to comply as follows: complete construction or acquisition, through purchase or lease, of all facilities set forth in the application; refrain from cultivation until obtaining department authorization; begin cultivation within 105 days after the application has been approved; begin dispensing within 150 calendar days of being authorized to cultivate; continue to operate the dispensing organization in a manner that provides an uninterrupted supply of low-THC cannabis to qualified patients during the biennial approval cycle, sufficient enough to supply qualified patients with an adequate supply of low-THC cannabis; and refrain from knowingly dispensing, low-THC cannabis derivative product to an individual other than a qualified patient or a qualified patient's legal representative.

2. Be written by a surety company licensed by the Florida Office of Insurance Regulation.

3. Be written so that the nursery name on the bond corresponds exactly with the nursery name in the department's records.

4. If a bond is canceled and the dispensing organization fails to file a new bond with the department in the required amount on or before the effective date of cancellation, the dispensing organization's approval shall be revoked. The total and aggregate liability of the surety on the bond is limited to the amount specified on the bond.

5. Provide that a dispensing organization will not be held in default should the failure to comply be the direct result of an event or effect that cannot be reasonably anticipated or controlled, such as an act of God or nature and not the result of a lack of good faith effort.

(c) If the selected applicant fails to post the bond within the required timeframe, the applicant with the next highest score in the dispensing region shall be selected and notified.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History—New\_\_\_\_\_.

#### 64-4.003 Biennial Renewal Requirements for Dispensing Organizations.

(1) No less than six months prior to the expiration of an existing dispensing organization's two year authorization to dispense low-THC cannabis derivative products, the dispensing organization shall make application for renewal of the dispensing organization approval using Form DH8006-OCU-096/2014, "Application for Low-THC Cannabis Dispensing Organization Approval" herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>, indicating that the application is a renewal application.

(2) In addition to the completed application form, dispensing organization renewal applicants shall:

- (a) Demonstrate that they continue to meet the requirements of Section 381.986(5)(b)1.-7., F.S., by updating the documentation submitted with the original application or providing a notarized statement that there have been no changes;

- (b) Provide written documentation that any violations noted during any inspections or investigations by the department have been corrected;

- (c) Provide written documentation of compliance with the financial requirements of Section 381.986(5)(b)5., F.S., for the previous two years;

- (d) Report how much cannabis oil was produced in the previous two years of operation; and

- (e) Report how many patients were served in the previous two years of operation.

(3) If the dispensing organization meets the requirements of Section 381.986(5)(b), F.S., and this chapter, the department shall notify the dispensing organization that it intends to renew the approval.

(4) Upon notification that its renewal will be approved, the dispensing organization shall have 30 calendar days to pay a nonrefundable \$xx renewal fee to the department and to provide proof that its \$5 million performance bond remains in effect.

(5) If the dispensing organization fails to renew within the required timeframes, the department shall seek new applications for a dispensing organization in the applicable dispensing region by posting notice in the Florida Administrative Register and thereafter following the procedures in rule 64-4.002, F.A.C.

(6) A dispensing organization that fails to renew its approval shall not dispense low-THC cannabis products after midnight local time on the date that its authorization expires and shall destroy through incineration all low-THC cannabis in its possession within 48 hours of the last dispensing day. Any undestroyed low-THC cannabis remaining under the control of the dispensing organization more than 48 hours after the last dispensing day shall be seized and destroyed by the department.

#### 64-4.004 Revocation of Dispensing Organization Approval.

(1) The department shall revoke its approval of the dispensing organization if the dispensing organization does any of the following:

- (a) Cultivates low-THC cannabis before obtaining department authorization; ~~or~~
- (b) Knowingly dispenses, ~~delivers, or otherwise transfers~~ low-THC cannabis derivative product to an individual other than a qualified patient or a qualified patient's legal representative; ~~or~~

~~(2) The department may revoke a dispensing organization's approval or authorization if the dispensing organization does not:~~

- ~~(c) Fails to comply with the requirements in Section 381.986, F.S., or this rule chapter;~~
- ~~(d) Fails to implement the policies and procedures or comply with the statements provided to the department with the original or renewal application;~~
- ~~(e) Fails to seek authorization to begin cultivation within 75 calendar days of application approval; or~~
- ~~(f) Fails to begin dispensing within 150 calendar days of the being granted the authorization to cultivate pursuant to subsection 64-4.005(2), F.A.C.~~

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History—New\_\_\_\_\_.

#### 64-4.005 Inspection and Authorization Procedures.

(1) Submission of an application for dispensing organization approval constitutes permission for entry by the department at any reasonable time into any dispensing organization facility to inspect any portion of the facility; review the records required pursuant to Section 381.986, F.S., or this chapter; and collect samples of any low-THC cannabis or low-THC cannabis derivative product for laboratory analysis. All inspectors shall follow the dispensing organization's sanitation protocol when conducting any inspection.

(2) No less than 30 calendar days prior to the initial cultivation of low-THC cannabis, the dispensing organization shall notify the department that the dispensing organization is ready to begin cultivation, the dispensing organization is in compliance with Section 381.986, F.S., and this rule chapter and is seeking authorization to begin cultivation. No low-THC cannabis, including seeds, tissue culture, and cuttings, may be present in any dispensing organization facility prior to authorization by the department.

(3) No less than 10 calendar days prior to the initial production or dispensing of low-THC cannabis, the dispensing organization shall notify the department that the dispensing organization is ready to begin production or dispensing, the dispensing organization is in compliance with Section 381.986, F.S., and this chapter and is seeking authorization to begin production or dispensing.

(4) If the department identifies a violation of Section 381.986, F.S., or this chapter during an inspection of a dispensing organization facility, the dispensing organization shall notify the department in writing, within 20 business days after the date of receipt of the written notice of violation, identifying the corrective action taken and the date of the correction.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History—New\_\_\_\_\_.

#### 64-4.006 Identification, Labeling and Testing Low-THC Cannabis Seeds, Dried Flowers and Derivative Products.

*[Use 21 C.F.R. Part 111, Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements?]*

(1) A dispensing organization shall ensure that the low-THC cannabis derivative product provided to a qualified patient is in medical grade, childproof containers labeled with:

- (a) The dispensing organization name and location;

- (b) The amount, harvest number, and batch number of the low-THC cannabis derivative product being dispensed;
  - (c) The date of product processing or production;
  - (d) A list of all additives, including pesticides, herbicides, fertilizers, and solvents, used in the cultivation and production of the low-THC cannabis derivative product;
  - (e) A list of all matrix ingredients used to make the low-THC cannabis derivative product, e.g., olive oil, canola oil, et cetera;
  - (f) The percent by weight of tetrahydrocannabinol (THC) and cannabidiol (CBD);
  - (g) Identification and percentages of all specific cannabinoids in the low-THC cannabis derivative product, if known;
  - (h) Identification and percentages of all specific terpenes in the low-THC cannabis derivative product, if known;
  - (i) The name of the ordering physician; and
  - (j) The registry identification number of the qualified patient.
- (2) Prior to dispensing any low-THC derivative product, a dispensing organization shall sample and have tested by a [TBD] each batch of each product to be dispensed. The testing laboratory shall file with the department an electronic copy of each laboratory test result for any batch that does not pass the microbial, mycotoxin, heavy metal, pesticide, chemical residue or residual solvents levels test or meet the composition requirements required by s. 381.986(1)(b), F.S. Dispensing shall not occur until the test results have been received by the dispensing organization. Testing shall include at a minimum [use *U.S. Pharmacopeia Herbal Medicines Compendium?*]:
- (a) Tetrahydrocannabinol concentration reported as a percentage by weight;
  - (b) Cannabidiol concentration reported as percentage by weight;
  - (c) Bacteria and molds, including aerobic bacteria, E. coli, enterobacteria, powdery mildew, penicillium, yeast, aspergillus, cladosporin, fusarium, botrytis, aureobasidium and acremonium;
  - (d) Heavy metals; and
  - (e) All chemical additives, including nonorganic pesticides, herbicides, and fertilizers, and solvents used in the cultivation and production of the low-THC cannabis reported as parts per billion.
- (3) The dispensing organization shall provide copies of any test results to the department upon request.
- (4) If any batch sample test result shows the presence of any bacteria, mold, heavy metal, or chemical additive over the Health Advisory Level (HAL) as provided in the department's Environmental Chemistry Analyte List [use *U.S. Pharmacopeia Herbal Medicines Compendium?*], dated July 31, 2014, herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>, the entire batch from which the sample was derived shall be identified and segregated to prevent further processing or distribution. The entire batch shall be [TBD].
- (5) Any batch sample or any other sample that exceeds 0.8% tetrahydrocannabinol by weight or has 10% or less of cannabidiol by weight shall be segregated to prevent further processing or dispensing. If the batch cannot be made to conform to the requirements of section 381.986(1)(b), F.S., within 10 days, the batch shall be destroyed.
- (6) Upon request from the department, a dispensing organization shall submit a sample of any specific seed, dried flower or derivative product from the low-THC cannabis inventory to a laboratory selected by the department for analysis and reporting to the department.
- (7) Laboratories shall immediately destroy any untested low-THC cannabis or low-THC cannabis derivative product upon the completion of the testing. Laboratories shall retain the tested sample for 30 calendar days to allow for retesting before destroying the sample. If the low-THC cannabis or low-THC cannabis derivative product is destroyed, the time and method of destruction or disposal shall be documented.
- (8) All low-THC derivative products shall be maintained in an appropriately climate-controlled environment.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History—New\_\_\_\_\_.

#### 64-4.007 Recordkeeping and Reporting Requirements.

- (1) A dispensing organization shall designate in writing an inventory agent who has oversight of the inventory control system.
- (2) A dispensing organization shall establish and implement an inventory control system for the low-THC cannabis plants and derivative products that documents:
  - (a) Each day's beginning and ending inventory of seeds, tissue cultures, cuttings, plants harvests, processed low-THC cannabis derivative products, sales, disbursements, and disposed, unusable plants or low-THC cannabis derivative products;

- (b) For each harvest of low-THC cannabis cultivated:
1. The harvest number;
  2. Whether the harvest originated from seeds, tissue culture, or cuttings;
  3. The strain of the seeds, tissue culture, or cuttings planted;
  4. The number of seeds, tissue culture, or cuttings planted;
  5. The date the seeds, tissue culture, or cuttings were planted;
  6. A list of all additives, including pesticides, herbicides, and fertilizers used in the cultivation;
  7. The number of low-THC plants grown to maturity and harvested;
  8. Method and date of disposal of plants not grown to maturity;
  9. Date of harvest;
  10. Final harvest yield weight - gross;
  11. Weight of low-THC plants or plant parts not used for the production of dispensable products;
  12. Final harvest yield weight - net;
  13. Name of the inventory agent responsible for the harvest, and
  14. The disposal through incineration or composting of low-THC plants or plant parts not used for the production of dispensable products including the:
    - a. Description of and reason for disposal including, if applicable, the number of failed or other unusable plants;
    - b. Date of disposal;
    - c. Method of disposal; and
    - d. Name of the employee responsible for the disposal.
- (c) For each batch of low-THC cannabis derivative product produced:
1. The batch number;
  2. The harvest number(s) of the low-THC plants incorporated into the batch;
  3. The name (if applicable) of the low-THC cannabis derivative product produced;
  4. Form and quantity of low-THC cannabis derivative product produced;
  5. Date sampled for laboratory analysis;
  6. Laboratory sample results; and
  7. Date laboratory results were received.
- (d) For each low-THC cannabis derivative product dispensed:
1. Name (if applicable) of the low-THC cannabis derivative product;
  2. Form of the low-THC cannabis derivative product;
  3. Batch number;
  4. A list of all matrix ingredients used to make the low-THC cannabis derivative product, e.g., olive oil, canola oil, et cetera;
  5. The percent by weight of tetrahydrocannabinol (THC) and cannabidiol (CBD);
  6. Identification and percentages of all specific cannabinoids in the low-THC cannabis derivative product, if known;
  7. Amount of each low-THC cannabis derivative product dispensed;
  8. The name of the ordering physician;
  9. The registry identification number of the qualified patient; and
  10. The price of the low-THC cannabis derivative product dispensed.
- (e) For low-THC cannabis derivative products disposed:
1. Name (if applicable) of the low-THC cannabis derivative product, form, batch number and amount;
  2. Reason for disposal; and
  3. Method of disposal.
- (3) The inventory agent shall conduct and document an audit of the dispensing organization's inventory at least once every 30 days. If the audit identifies a discrepancy in the amount of low-THC cannabis or low-THC cannabis derivative product, the dispensing organization shall determine where the discrepancy has occurred and take and document immediate corrective action. The dispensing organization shall notify the department of any identified discrepancy and the corrective action taken within five business days of the identification of the discrepancy. If criminal activity is suspected, the dispensing organization shall immediately report the suspicion to law enforcement officials.
- (4) The dispensing organization shall maintain the required documentation for a minimum of five years from the date of the document and provide the documentation to the department upon request.

64-4.008 Procedural Requirements.

(1) A dispensing organization shall:

(a) Ensure that dispensing hours of operation, at a minimum, adhere to the dispensing availability proposed in the approved application, and that its dispensary is operating and available to dispense low-THC cannabis derivative product to any qualified patient on a regular schedule. The dispensing hours of operation shall be prominently displayed in the dispensary, posted on the dispensing organization's website, and available upon request to qualified patients, their legal representatives, the department, and ordering physicians;

(b) Develop, document, and implement policies and procedures regarding:

1. Training and adherence to requirements for protecting patient privacy;
2. Inventory control; and
3. Patient records;

(c) Maintain policies and procedures and provide copies to the department upon request;

(d) Post the following information in a place that can be viewed by individuals entering the dispensing facility:

1. Name of the dispensing organization;
2. Name of the medical director and the medical director's license number; and
3. Hours of operation;

(e) Limit access to all dispensing organization facilities to owners, managers, dispensing organization employees, qualified patients, legal representatives of qualified patients, authorized inspectors, and authorized visitors. Authorized visitors must wear an identifying badge and be escorted and monitored at all times by an owner, manager, or employee. The dispensing organization shall create and maintain a visitor log and the name of any visitor and the date and duration of the visit shall be entered in the log. All authorized visitors must comply with the sanitation protocol of the dispensing organization; and

(f) Advise the department within seven calendar days of any change in medical director. A dispensing organization cannot operate in the absence of a medical director.

(2) The dispensing organization shall cultivate, process, store, dispense, and perform any other activity involving low-THC cannabis in [TBD].

(3) The dispensing organization shall make reasonable efforts to mitigate odors.

(4) The dispensing organization shall ensure that all buildings and equipment used for the cultivation, harvest, preparation, packaging, storage, or sale of low-THC cannabis and low-THC cannabis derivative products are maintained [TBD].

(a) Low-THC cannabis in the process of preparation, production, packing, storage, sale or dispensing shall be protected from insects, dust, dirt and other contamination in fully enclosed rooms.

(b) Refuse or waste products incident to the manufacture, preparation, packing, selling, or distribution of low-THC cannabis and low-THC cannabis derivative products shall be [TBD].

(c) All trucks, trays, buckets, other receptacles, platforms, racks, tables, shelves, knives, saws, cleavers, other utensils, or the machinery used in moving, handling, cutting, chopping, mixing, canning, packaging, or other processes shall be cleaned at least once every 24 hours.

(6) The medical director must be [TBD- and must designate a back-up medical director when not so available. The medical director shall provide for standards and protocols that ensure proper testing of low-THC medical cannabis derivative products for potency and contamination. The medical director shall assist with the development and implementation of policies and procedures regarding, at a minimum, emergency responses, sanitation protocols, compliance with state and federal regulations regarding confidentiality of personally identifiable health information, quality assurance, and disease prevention. The medical director shall also respond to the department and local municipalities regarding compliance with rules and regulations and community health and public safety concerns. If the medical director determines that any employee of the dispensing organization has a health condition that may adversely affect the safety or quality of the low-THC cannabis or derivative products, the employee shall be prohibited from direct contact with any product or equipment or materials for processing low-THC cannabis until the medical director determines that the employee's health condition will not adversely affect the safety and quality of the low-THC cannabis.]

64-4.009 Compassionate Use Registry.

(1) Ordering physicians licensed under Chapter 458 or 459, F.S., meeting the educational requirements of Section 381.986(4), F.S., may access the Compassionate Use Registry using their existing MQA Services credentials.

(2) Designated persons may request access to the Compassionate Use Registry by completing form DH8008-OCU-12/2014, "Request for Access to the Compassionate Use Registry," herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>. Those requesting access must meet one of the following criteria:

(a) Authorized employee of a dispensing organization - each dispensing organization may have up to five employees with access to the Compassionate Use Registry;

(b) Law enforcement official; or

(c) Authorized employee of the department.

(3) Persons seeking to access to the registry shall have successfully completed a department-approved course in their responsibilities related to patient confidentiality and shall make documentation of completion available to the department upon request.

(4) Before dispensing any low-THC cannabis derivative product to a qualified registered patient or the patient's legal guardian, the dispensing organization must verify that the patient has an active registration, the order presented matches the order contents as recorded by the physician in the registry, and the order has not already been dispensed.

(5) The dispensing organization shall enter a dispensing action into the registry immediately upon dispensing the low-THC cannabis to the qualified registered patient or the patient's legal guardian.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(a); 837.06 FS. History--New \_\_\_\_\_.

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