

DEPARTMENT OF HEALTH

64-4.001 Definitions

64-4.002 Initial Application Requirements for Dispensing Organizations

64-4.003 Biennial Renewal Requirements for Dispensing Organizations

64-4.004 Denial or Revocation of Dispensing Organization Approval

64-4.005 Inspection Procedures

64-4.006 Identification, Labeling and Testing Low-THC Cannabis Plants and Products

64-4.007 Recordkeeping and Reporting Requirements

64-4.008 Procedural Requirements

64-4.009 Compassionate Use Registry

THE FULL TEXT OF THE DRAFT RULE IS:

64-4.001 Definitions

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

(1) Approval – Written notification from the department to a dispensing organization 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 from the organization that it is prepared to be inspected and authorized to begin cultivation and other operations.

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

(3) Batch - means a specific lot of low-THC cannabis 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.

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

(5) Dispensing Region – A geographical area where the growing, production and dispensing of Low-THC cannabis under the control of a dispensing organization shall occur. 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, Hillsborough, Indian River, Lake, Manatee, Martin, Orange, Osceola, Pasco, Pinellas, Polk, Seminole, St. Lucie, Sumter, and Volusia counties.

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

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

(6) Dispensing Organization Facility – The physical location and structures used by the dispensing organization for the preparation, cultivation, storage, processing, dispensing, or any other action in the presence of or involving low-THC cannabis.

(7) Harvest - A specific lot of low-THC cannabis plants grown from one or more seeds or cuttings that are planted 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.

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

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

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History-New

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64-4.002 Initial Application Requirements for Dispensing Organizations

(1) An entity desiring to be authorized as a dispensing organization shall make application to the department using Form DHXXXX, 06/14, “Application for Low-THC Cannabis Dispensing Organization Approval” herein incorporated by reference and available at

<https://flrules.com/gateway/reference.asp?No=Ref-#####>.

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

(a) Written documentation demonstrating that the applicant meets the requirements of Section 381.986(5)(b)1., F.S.;

(b) Written documentation demonstrating that the applicant has the ability to obtain the premises, resources, and personnel necessary to operate as a dispensing organization. At a minimum, documentation shall include:

1. A map showing the location of the location of the applicant dispensing organization facilities;

2. A site plan drawn to scale of the cultivation, processing and dispensing location showing streets, property lines, buildings, parking areas, outdoor areas if applicable, fences, security features, fire hydrants if applicable, and access to water mains; and

3. A floor plan drawn to scale of the building or buildings where the cultivation, processing, and dispensing activities will occur showing the:

- a. Layout and dimensions of each room;
 - b. Name and function of each room;
 - c. Location of each hand-washing sink;
 - d. Location of each toilet room;
 - e. Means of egress;
 - f. Location of each video camera;
 - g. Location of each panic button; and
 - h. Location of natural and artificial lighting sources;
4. A list of current and proposed staffing including:
- a. Position, duties and responsibilities;
 - b. The age in years of each current staff member; and
 - c. Written documentation that each staff member has successfully completed Level-2 background screening within the last year;
- (c) Written documentation that the applicant has the ability to maintain accountability of all raw materials, finished products, and any byproducts by submission of an inventory control plan that meets the requirements of this chapter;
- (d) Written documentation that the applicant possesses an infrastructure reasonably located to dispense Low-THC cannabis to registered patients regionally. At minimum, such documentation shall include the physical address of the dispensing organization's dispensary and photographs showing the public access, driveway, parking and public access to the dispensary point;
- (e) Written documentation of compliance with the financial requirements of Section 381.986(5)(b)5., F.S. All documents shall be prepared by a Certified Public Accountant licensed pursuant to Chapter 473, F.S., who has performed an audit of the organization within one year of the application date;
- (f) Written documentation of the ability to post a \$5 million performance bond;

(h) Written documentation that all owners and managers in the organization have been fingerprinted and have successfully completed Level-2 background screening pursuant to Section 435.04, F.S., within the last year, to include:

1. A table of organization showing the supervisory structure of the organization; and
2. A list of all owners and managers indicating the date and status of each individual's most recent Level-2 background screening.

3. For the purposes of this chapter, the following individuals are considered owners and managers:

- a. All individual or individuals identified in the dispensing organization's by-laws as principal officers;

- b. If an individual is applying to become a dispensing organization, the individual;

- c. If a corporation is applying to become a dispensing organization, all individuals who are officers or directors of the corporation;

- d. If a partnership is applying to become a dispensing organization, all of the individuals who are partners;

- e. If a limited liability company is applying to become a dispensing organization, all managers or, if the limited liability company does not have a manager, any individual who is a member of the limited liability company;

- f. If an association or cooperative is applying to become a dispensing organization, all individuals who are members of the governing board of the association or cooperative;

- g. If a joint venture is applying to become a dispensing organization, all of the individuals who signed the joint venture agreement;

- h. If a business organization type other than those described in sub-subparagraphs 64-4.002(3)(h)3.b. through g. is applying to become a dispensing organization, all individuals who are members of the business organization;

- i. The dispensing organization's inventory agent;

j. The dispensing organization's medical director; and

k. Any individual with supervisory responsibility over any employee, contractor, volunteer, or other position in the organization.

4. Except where otherwise specified by rule or statute, when a dispensing organization is required by this chapter to provide information, sign documents, or ensure actions are taken, an individual in sub-subparagraph 64-4.002(3)(h)3.a. through h., F.A.C., shall comply with the requirement on behalf of the organization.

(i) Written documentation that the organization employs a medical director who is a physician licensed pursuant to Chapter 458 or 459, F.S. For the purposes of this chapter, employment means a relationship where compensation can be documented by the regular deduction of FICA and federal withholding tax as required by law. Principal officers of a corporation or partners of a partnership shall be recognized as employees of the corporation or partnership.

(3) Completed "Applications 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, ten days after the effective date of this rule.

(a) If more than one application for a dispensing region is timely received, a public lottery will be held to determine the order in which applications are considered. The first complete application for a dispensing region that describes an organization meeting the requirements of Section 381.986(5)(b), F.S., and this chapter shall be selected as the dispensing organization for that region.

(b) Upon notification that it has been selected as a region's dispensing organization, the applicant shall have 30 days to pay a \$150,000 application fee to the department and post a \$5 million performance bond.

(c) If the selected applicant fails to pay the application fee and post the bond within the required timeframes, the application up next for consideration and located in the applicable dispensing region shall be selected for review and the selected applicant notified.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History-New

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64-4.003 Biennial Renewal Requirements for Dispensing Organizations

(1) No less than 60 days prior to the expiration of an existing dispensing organization's authorization to dispense low-THC cannabis, the dispensing organization shall make application for renewal of the dispensing organization approval using Form DHXXX, "Application for Low-THC Cannabis Dispensing Organization Approval", indicating that the application is a renewal application.

(2) In addition to the completed application form, dispensing organization 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 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, Department of Agriculture and Consumer Services or law enforcement officials have been corrected; and

(c) Provide written documentation of compliance with the financial requirements of Section 381.986(5)(b)5., F.S., including a report of an audit by a Florida Certified Public Accountant of the financial statement for the previous two years.

(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 days to pay a \$150,000 renewal fee to the department and to provide proof that its \$5 million performance bond remains in effect.

(5) If the applicant fails to renew within the required timeframes, the department shall seek new applications for a dispensing organization in the applicable dispensing region.

(6) A dispensing organization that fails to renew its approval shall not dispense low-THC cannabis after midnight local time on the date that their authorization expires. Within 24 hours following the last dispensing day, the dispensing organization shall destroy all low-THC cannabis remaining under its control.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History-New

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64-4.004 Denial or Revocation of Dispensing Organization Approval

(1) The department shall deny an application for a dispensing organization approval or renewal if:

(a) Any dispensing organization facility is within 500 feet of a private school or a public school that existed before the date the dispensing organization submitted its initial application for approval;

(b). Any owner or manager:

1. Has been convicted of a felony offense;
2. Has served as an owner or manager for a dispensing organization that has had the dispensing organization approval revoked;
3. Is under 21 years of age;
4. Is a physician currently ordering low-THC cannabis for use by qualified patients;
5. Is a law enforcement official; or
6. Is an employee or contractor of the department;

(c) The application or the dispensing organization does not comply with the requirements Section 381.986, F.S., or this chapter;

(d) The dispensing organization has failed to correct any violation noted during an inspection; or

(e) The applicant provides false or misleading information to the department.

(3) The department shall revoke its approval of the dispensing organization if:

(a) The dispensing organization:

1. Operates before obtaining department authorization; or

2. Dispenses, delivers, or otherwise transfers low-THC cannabis to an entity other than a qualified patient or a patient's legal guardian; or

(b) An owner or manager has been convicted of a felony offense.

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

(a) Comply with the requirements in Section 381.986, F.S., or this chapter;

(b) Implement the policies and procedures or comply with the statements provided to the department with the dispensing organization's application;

(c) Seek authorization to begin cultivation within 60 days of application approval; or

(d) Begin dispensing within 120 days of the authorization granted 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 Procedures

(1) Submission of an application for dispensing organization approval constitutes permission for entry by the department, the Department of Agriculture and Consumer Services or law enforcement officials 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 for laboratory examination.

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

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

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History-New

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64-4.006 Identification, Labeling and Testing Low-THC Cannabis Plants and Products

(1) A dispensing organization shall ensure that the low-THC cannabis provided to a qualified patient is labeled with:

(a) The dispensing organization name and location;

(b) The amount, harvest number, and batch number of the low-THC cannabis product being dispensed;

(c) The date of product processing or manufacture;

(d) A list of all chemical additives, including nonorganic pesticides, herbicides, and fertilizers, used in the cultivation and production of the low-THC Cannabis;

(e) The percent by weight of tetrahydrocannabinol and cannabidiol; and

(f) The registry identification number of the qualified patient.

(2) Prior to distribution of any product, a dispensing organization shall sample and have tested by an accredited testing laboratory each batch of each product to be distributed.

Distribution shall not occur until the test results have been received by the dispensing organization. Testing shall include:

(a) Tetrahydrocannabinol concentration reported as a percentage by weight;

(b) Cannabidiol concentration reported as percentage by weight; and

(c) All chemical additives, including nonorganic pesticides, herbicides, and fertilizers, used in the cultivation and production of the low-THC Cannabis reported as parts per billion.

(3) The dispensing organization shall provide copies of test results to the department upon request.

(4) If any batch sample test result shows the presence of a chemical additive over the Health Advisory Level (HAL), the entire batch from which the sample was derived shall be identified and segregated to prevent further processing or distribution. The entire batch and harvest shall be destroyed.

(5) Any batch sample or any other sample that exceeds 0.8% tetrahydrocannabinol by weight or 10% or less of cannabidiol by weight shall be reported immediately to law enforcement officials. The entire batch or other material from which the sample was derived shall be identified and segregated to prevent further processing or distribution. The further handling and destruction of the material shall be conducted with the consent of law enforcement officials.

(6) Upon request from the department, a dispensing organization shall submit a sample of any specific plant or product from the low-THC cannabis inventory to an accredited testing laboratory selected by the department for analysis and reporting to the department.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History-New

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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 that documents:

(a) Each day's beginning inventory, seeds and cuttings, harvests, processed products, sales, disbursements, disposal of unusable plants or products, and ending inventory;

(b) For each harvest of low-THC cannabis cultivated:

1. The harvest number;
2. Whether the harvest originated from seeds or cuttings;
3. The origin and strain of the seeds or cuttings planted;
4. The number of seeds or cuttings planted;
5. The date the seeds or cuttings were planted;
6. A list of all chemical additives, including nonorganic pesticides, herbicides, and fertilizers used in the cultivation;
7. The number of plants grown to maturity;
8. Date of harvest;
9. Final harvest yield weight;
10. Name of the inventory agent responsible for the harvest, and
11. The disposal of 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 inventory agent responsible for the disposal;

(c) For each batch of low-THC cannabis produced:

1. The batch number;
2. The harvest number(s) of the plants incorporated into the batch;
3. The name (if applicable) of the product produced;
4. Form and quantity of product produced;
5. Date sampled for laboratory analysis;
6. Laboratory sample results; and
7. Date laboratory results were received;

(d) For products dispensed:

1. Name (if applicable) of the product;
2. Form of the product;
3. Batch number; and
4. Amount of each product dispensed;

(e) For products disposed:

1. Name (if applicable), 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, the dispensing organization shall determine where the discrepancy has occurred and take and document corrective action. The dispensing organization shall notify the department of any identified discrepancy and the corrective action taken within 5 days of the identification of the discrepancy. If criminal activity is suspected, the dispensing organization shall report the suspicion to law enforcement officials.

(4) The dispensing organization shall maintain the required documentation for 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 its dispensary is operating and available to dispense low-THC cannabis to qualified patients at least 30 hours weekly between the hours of 7:00 a.m. and 10:00 p.m. local time;

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

1. Training and adherence to confidentiality requirements;
2. Inventory control;
3. Patient records; and
4. Patient education and support;

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

and

(d) Post the following information in a place that can be viewed by people entering the dispensary:

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

(2) The dispensing organization shall cultivate, process, store, dispense, and perform any other activity involving low-THC cannabis in an enclosed and locked facility.

(3) Dispensing organizations shall not produce or provide low-THC cannabis that is part of, mixed with, or added to an edible food product.

(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 are maintained in a clean and sanitary condition.

(a) Low-THC cannabis in the process of preparation, production, packing, storage, sale or distribution shall be protected from flies, 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 shall be destroyed on-site at least once every 24 hours.

(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.

(5) 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, 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.

(6) Dispensing organizations shall ensure that all owners, managers and staff are at least 21 years of age and have successfully completed Level-2 background screening within the last year before commencing employment. Upon arrest for a disqualifying felony, employees shall be suspended. Upon conviction for a disqualifying felony, employees shall be terminated.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History-New

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) Dispensing organization medical directors may access the Compassionate Use Registry using their MQA Service Credentials provided they are listed as the medical director on the dispensing organization's application for approval.

(3) Other persons requesting access to the Compassionate Use Registry shall complete form DH YYYY (06/14) "Request for access to the Compassionate Use Registry", herein incorporated by reference and available at <https://flrules.com/gateway/reference.asp?No=Ref-#####>. Applicants must meet one the following criteria:

(a) Authorized employee of a dispensing organization - Each dispensing organization may designate up to five employees for access to the Compassionate Use Registry;

(b) Law enforcement official;

(c) Authorized employee of the University of Florida, Pharmacy Program - The University of Florida may designate up to five employees for access to the Compassionate Use Registry;

(d) Authorized employee of the department; or

(e) A person authorized by the department to conduct research pursuant to s. 381.987(3)(f), F.S.

(4) Persons seeking to access to the registry shall have successfully completed a department-approved course in their responsibilities related to patient confidentiality.

(5) A physician's registry access expiration date shall not be set to a date that occurs after the expiration date of his or her license to practice.

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

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(a) FS. History-New

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