NOTICE OF PROPOSED RULE

DEPARTMENT OF HEALTH
Office of Compassionate Use

RULE NOS.:	RULE TITLES:
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 for 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

PURPOSE AND EFFECT: This rulemaking establishes a comprehensive regulatory framework for implementing the Compassionate Medical Cannabis Act of 2014. It establishes the requirements for persons who cultivate and produce the medical cannabis as well as the requirements for dispensing and use of the cannabis.

SUMMARY: The rulemaking establishes, licensure and biennial licensure renewal requirements for dispensing organizations, reasons for denial or revocation of dispensing organization approval, inspection procedures for dispensing organization facilities, medical direction for dispensing organizations, requirements for pre-dispensing identification, testing and labelling of low THC cannabis and derivative products, inventory control, recordkeeping and reporting requirements, procedural requirements including dispensing facility hours, policies and procedures for inventory control and patient records, facility security, staffing, facility cleanliness, and refuse removal, requirements for accessing and inputting information as well as maintenance of the compassionate use registry.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION: The agency has determined that seven of the nine rules associated with the regulatory framework will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. The agency has determined that two of the nine rules associated with the regulatory framework, Rules 64-4.002 and 64-4.003, F.A.C., will have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of $200,000 in the aggregate within one year after the implementation of the rule. A SERC has been prepared by the agency for Rules 64-4.002 and 64-4.003, F.A.C. The Agency has determined that proposed Rule 64-4.003, F.A.C., is expected to require legislative ratification based on the statement of estimated regulatory costs. Based on the SERC checklist, this rulemaking, except for proposed Rule 64-4.003, F.A.C., will not have an adverse impact or regulatory costs in excess of $1 million within five years as established in Section 120.541(2)(a), F.S. Proposed section 64-4.003 will have an adverse impact or regulatory costs in excess of $1 million within five years as established in Section 120.541(2)(a), F.S.

Any person who wishes to provide information regarding the statement of estimated regulatory costs, or to provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: 381.986(5)(d) FS.

LAW IMPLEMENTED: 381.986(5)(b) FS.

A HEARING WILL BE HELD AT THE DATE, TIME AND PLACE SHOWN BELOW:

DATE AND TIME: September 5, 2014, 9:00 a.m. – 5:00 p.m., Eastern Time or until the hearing is concluded

PLACE: Room 152, Betty Easley Conference Center, Esplanade Way, Tallahassee, Florida 32399

Any person wanting to request a hearing regarding the proposed rule must do so within 21 days of the date of publication of this notice by contacting the agency's designated contact, as described herein.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Linda N. McMullen, Director of Office of Compassionate Use, 4052 Bald Cypress Way, Bin A-02, Tallahassee, Florida 32399-1703, E-mail: linda.mcmullen@flhealth.gov

THE FULL TEXT OF THE PROPOSED RULE IS:

64-4.001 Definitions.

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

(1) Applicant – An entity with at least 25% ownership by a nursery that meets the requirements of Section 381.986(5)(b)1., F.S., that applies for approval as a dispensing organization.

(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 from the applicant 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 manufacturing 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 – means 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 – means a unique numeric or alphanumeric identifier assigned to a batch by a dispensing organization when the batch is portioned and packaged for dispensing.

(6) Cultivation – means the reproduction of source plant or tissue culture material.

(7) Derivative product – means forms of low-THC cannabis suitable for routes of medical administration, including but not limited to vapor, resins, salts, extracts, capsules, oral sprays and any compound, mixture or preparation derived from low-THC cannabis plants that is dispensed only from a dispensing organization.

(8) 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, Indian River, Lake, 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, Hillsborough, Lee, Manatee, Okeechobee, and Sarasota counties.

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

(9) Dispensing Organization – an entity which has been approved by the department to cultivate, process and dispense organically grown low-THC cannabis.

(10) Dispensing Organization Facility – One or multiple structures within the same contiguous property that are 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.

(11) Edible food product – Food products made with low-THC cannabis such as cakes, cookies, candies, brownies and other food items intended to be taken into the mouth, chewed and swallowed. Low-THC cannabis derivative products such as pills or ingestible substances used as delivery agents for low-THC cannabis such as olive oil are not considered edible food products.

(12) 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.

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

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

(15) 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 authority, including but not limited to 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 associated with each joint venture partner 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.

(16) Nursery block number – Subpart of a nursery certificate of registration that identifies where plants or grown or produced.

(17) Owner – Any person, including any individual or other legal entity, with a direct or indirect ownership interest of 5% of 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 and principal establishment 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 taken into the body, and includes oral, topical, transdermal, and nasal administration.

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

(21) Transportation plan – Method of transporting up to a 90-day supply of low-THC cannabis derivative product for each qualified registered patient served on the trip from the dispensing organization to qualified registered patients in the state which documents, at a minimum, confirmation of the order from the registry, confirmation from the qualified registered 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 registered patient or the qualified registered patient's legal guardian receiving the order, and creation and maintenance of a log of all low-THC derivative products transported on an annual basis.

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.

(1) An entity desiring to be authorized as a dispensing organization shall make application to the department using Form DH8006-OCU-06/2014, "Application for Low-THC Cannabis Dispensing Organization Approval" herein incorporated by reference and available at https://flrules.com/gateway/reference.asp?No=Ref-#####. Each nursery that meets the requirements of Section 381.986(5)(b)1., F.S., may have an ownership interest in only one application per qualifying nursery registration. The qualifying nursery certificate of registration or nursery block thereof must be located within the dispensing region applied for.

(2) In addition to the completed application form, 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 of the applicant's plan for cultivating low-THC cannabis, and processing and dispensing low-THC cannabis derivative products, including a business plan showing applicant's expected production.

(c) Written documentation of a detailed security and safety plan to include, but not be limited to:

1. Locking options, alarm systems, and video surveillance;

2. Diversion and trafficking prevention procedures;

3. A facility emergency management plan;

4. Proof of compliance or the ability to comply with the current local and state building codes, fire codes and electric codes.

(d) Written documentation of the applicant's quality assurance plan to ensure the quality and consistency of low-THC cannabis grown, processed and dispensed.

(e) Written documentation demonstrating the applicant's ability to obtain and maintain the premises, facilities, resources, and personnel necessary to operate as a dispensing organization. At a minimum, documentation shall include:

1. A map showing the location of the applicant's dispensing organization facility;

2. A site plan drawn to scale of the actual or proposed 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 actual or proposed 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 ingress and egress; and

f. 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 employee; and

c. Written documentation that each employee has successfully completed Level-2 background screening within the last year;

(f) 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;

(g) Written documentation that the applicant possesses an infrastructure reasonably located to dispense low-THC cannabis derivative products to registered patients in the state. At a minimum, such documentation shall include the physical address of the dispensing organization's dispensing facility and photographs showing the public access, driveway, parking and public access to the dispensary location and a transportation plan, if applicable, for delivery to qualified registered patients;

(h) Written documentation that the applicant has the experience, equipment, training, ability and personnel necessary to safely manufacture or produce low-THC cannabis derivative products that will be ingested by qualified registered patients.

(i) Written documentation of the applicant's financial strength as required by Section 381.986(5)(b)5., F.S., including a financial statement prepared in accordance with generally accepted auditing standards by a Certified Public Accountant licensed pursuant to Chapter 473, F.S.

(j) Written documentation of the ability to post a $5 million performance bond for the biennial approval period. The condition of the bond shall be that in the event the dispensing organization fails to renew its approval or its approval is revoked, it shall destroy all low-THC cannabis remaining under its control. The bond, or a portion thereof, shall be paid to the Office of Compassionate Use in an amount necessary to cover the costs of securing and destroying all low-THC cannabis not so destroyed and remaining under the control of the dispensing organization.

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

1. An organizational chart illustrating the supervisory structure of the dispensing 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 or managers:

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

b. The dispensing organization's inventory agent;

c. The dispensing organization's security director; and

d. The dispensing organization's medical director.

(l) Written documentation that the organization employs a medical director who is a physician licensed pursuant to Chapter 458 or 459, F.S., who does not register qualified patients or place orders for low-THC cannabis derivative products in the Compassionate Use Registry. For the purposes of this chapter, employment means a relationship evidenced by an independent contract or where compensation can be documented by the regular deduction of FICA and federal withholding tax as required by law.

(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) Any completed "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, 15 calendar days after the effective date of this rule. A courtesy copy of the completed application shall also be delivered to the Sheriff of the county in which the dispensing organization facility is located.

(a) The Department will substantively review and evaluate all timely received applications to determine if the applicant is qualified by meeting the requirements of Section 381.986(5)(b), F.S., and this Chapter. If more than one applicant for a dispensing region is qualified and its application is timely received, the department will provide a computer program method for a double random lottery-type selection by public drawing to designate the approved applicant and the rank order of other applications within each dispensing region.

(b) Upon notification that it has been selected as a region's dispensing organization, the applicant shall have ten calendar days to pay a non-refundable $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 applicant next in rank order and located in the applicable dispensing region shall be selected and the selected applicant 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 60 calendar days prior to the expiration of an existing dispensing organization's 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-06/2014, "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, 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 financial 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 calendar days to pay a nonrefundable $300,000 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 products after midnight local time on the date that its authorization expires and shall destroy all low-THC cannabis in its possession within 24 hours of the last dispensing day. Any undestroyed low-THC cannabis remaining under the control of the dispensing organization more than 24 hours after the last dispensing day shall be seized and destroyed by the Department.

PROPOSED EFFECTIVE DATE: Upon Legislative ratification.

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

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 1000 feet, as measured from the primary dispensing organization structure to the nearest property line of an elementary, middle or secondary school, day care facility as defined in Section 402.302, F.S., county or municipal park, or place of worship 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 any entity or organization in any state that has had its authority to cultivate, harvest, process or dispense low-THC cannabis or low-THC cannabis derivative product revoked;

3. Is under 21 years of age;

4. Is a physician currently ordering low-THC cannabis derivative products for use by qualified registered patients;

5. Is a law enforcement official; or

6. Is an employee or contractor of the department;

(c) The application of 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 in accordance with its corrective action plan; or

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

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

(a) The dispensing organization:

1. Cultivates low-THC cannabis before obtaining department authorization; or

2. Knowingly dispenses, delivers, or otherwise transfers low-THC cannabis derivative product to an individual or entity other than a qualified registered patient or a qualified registered patient’s legal guardian; or

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

(3) 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 75 calendar days of application approval; or

(d) Begin dispensing within 150 calendar 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 and agents 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 at any reasonable time. 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 and the sheriff of the county in which the dispensing organization facility is located 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, tissue culture, 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 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_____.

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

(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 manufacture;

(d) A list of all additives, including 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 registered patient.

(2) Prior to dispensing any low-THC derivative product, a dispensing organization shall sample and have tested by a department approved testing laboratory each batch of each product to be distributed. 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, but is not limited to:

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

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

(c) Bacteria and molds, including aerobic bacteria, e coli, enterobacteria, powdery mildew, penicillium, yeast, aspergillus, cladosporin, fusarium, botrytis, aureobasidium and acremonium.

(d) Heavy metals;

(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 a chemical additive over the Health Advisory Level (HAL) as provided in the department's Environmental Chemistry Analyte List, 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 dispensing. If

the batch cannot be made to conform in a reasonable period of time, any 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 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) Compliance with the testing requirements constitutes the legal authority to possess and transmit low-THC cannabis and low-THC cannabis derivative products under Florida law.

(9) All low-THC derivative products shall be maintained in a climate-controlled and appropriate 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 culture, cuttings, harvests, processed low-THC cannabis derivative products, sales, disbursements, and disposal of 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 chemical additives, including organic pesticides, herbicides, and fertilizers used in the cultivation;

7. The number of low-THC 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 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 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 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 low-THC cannabis derivative products 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. Amount of each low-THC cannabis derivative product dispensed; and

5. 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 5 working 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.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History–New_____.

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 registered patient on a regular schedule which shall be prominently displayed in the dispensary, posted online and available upon request to qualified registered patients, their legal guardians and ordering physicians;

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

1. Training and adherence to confidentiality requirements;

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 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;

(e) Limit access to the dispensing organization to owners, agents, managers, designated employees and qualified registered patients, their legal guardians, authorized inspectors and authorized visitors. Authorized visitors must wear an identifying badge and be escorted and monitored at all times by an owner, manager, agent 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 the log. All authorized visitors must comply with the sanitary 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 contracted or employed medical director.

(2) The dispensing organization shall cultivate, process, store, dispense, and perform any other activity involving low-THC cannabis in an enclosed and locked facility that protects the growing and processing operations from view.

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

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

(5) 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 in a clean and sanitary condition.

(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 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.

(6) The medical director must be onsite or available by telephone, pager or other electronic communication 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, sanitary practices, 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 of Health 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.

(7) Dispensing organizations shall ensure that all owners, managers and employees are at least 21 years of age and have successfully completed Level-2 background screening within the last year before commencing employment. Any owner, manager or employee arrested for a disqualifying felony shall be immediately suspended. Any owner, manager or employee shall be immediately terminated upon conviction of a disqualifying felony.

(8) With approval from the Department, dispensing organizations may alter, expand or consolidate their infrastructure, operations or staffing structure in order to better serve patients, provided the changes comply with the requirements of Section 381.986(5)(b), F.S., and this chapter. Dispensing organizations shall request approval using Form DH8007-OCU-06/2014, "Request to Alter, Expand or Consolidate Dispensing Organization" herein incorporated by reference and available at https://flrules.com/gateway/reference.asp?No=Ref-####.

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) Designated persons may request access to the Compassionate Use Registry by completing form DH8008-OCU-06/2014, "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 designate up to five employees for access to the Compassionate Use Registry;

(b) Law enforcement official;

(c) Authorized employee of the University of Florida, College of Pharmacy Program – The University of Florida College of Pharmacy 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 Section 381.987(3)(f), F.S.

(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 filled.

(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) FS. History–New_____.

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NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: John H. Armstrong, MD, FACS, Surgeon General and Secretary

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