Memorandum

MIAMI-DADE COUNTY

Date: August 2, 2016

Agenda Item No. 2B8
September 7, 2016

To: Honorable Chairman Jean Monestime
and Members, Board of County Commissioners

From: Carlos A. Gimenez
Mayor

Subject: Report on Potential Impacts of the Legalization of Medical Marijuana on the Agricultural Area – Directive 140662

The following report is pursuant to Resolution No. R-444-14, adopted by the Board of County Commissioners (Board) on May 6, 2014, which directed the County Mayor or County Mayor's designee to conduct a study to assess the potential impacts of the legalization of medical marijuana on agricultural areas.

Background

In 2014, the State of Florida (State) Legislature passed Senate Bill 1030 titled "The Compassionate Medical Cannabis Act of 2014," which was subsequently signed into law by Governor Rick Scott on June 16, 2014. This law allows for the highly regulated production, distribution, use and research of medical marijuana that contains less than 0.8 percent tetrahydrocannabinol (THC), which is the substance in marijuana that causes euphoric effects.

In essence, the marijuana must be processed into a derivative form that can be utilized for medical treatment. Such low-THC marijuana would be available to be prescribed by registered physicians for patients that suffer from:

- Cancer or a physical medical condition, which chronically produces symptoms of seizures or severe and persistent muscle spasms that can be treated with low-THC cannabis; or
- Symptoms of cancer or a physical medical condition, which chronically produces symptoms of seizures or severe and persistent muscle spasms that can be alleviated with low-THC cannabis.

On July 7, 2014, the State Department of Health released a draft of the rules governing the implementation of the new law, which garnered significant public comments that resulted in a number of public hearings, regulation changes and additional comment periods. Lawsuits were filed contesting various segments of the proposed rules and, in response, a final set of rules addressing the comments and legal challenges were released in February 2015 for comment. Those rules were also contested, but the final rules eventually became effective on June 17, 2015. Subsequently, applications for dispensing organizations were solicited with an application closing date of July 8, 2015. Dispensing organizations are those approved by the state to cultivate, process, transport, and dispense low-THC cannabis or medical cannabis, which are not to be confused with dispensing facilities that are buildings or structures where low-THC cannabis or medical cannabis, as well as cannabis delivery devices, are dispensed at retail.

The rules (Attachment A) that became effective dictate that the State is divided into five (5) regions, with one (1) producer per region. Miami-Dade County is in a region known as the "Southeast Region," which also includes Monroe, Broward, Martin and Palm Beach counties. Approved dispensing organizations must meet certain criteria, mainly that dispensing organizations must have been a State-certified plant nursery for the past 30 years and their current State Nursery Certificate

must be the largest certification (400,000 or more foliage plants per season). There are 99 nurseries in the State meeting that criteria, and, of those, 16 are in Miami-Dade County.

In March 2016, legislation was enacted by the State legislature that expands the type of cannabis available for medical uses and requires users to have a registration card. Under this most recent legislation, all forms of cannabis can be prescribed to patients with a terminal condition that without the administration of life-sustaining procedures will result in death within one (1) year after diagnosis if the condition runs its normal course The terminal condition must be attested to by the patients physician and confirmed by a second, independent evaluation by a board-certified physician with a specialty for that condition. This new legislation expands the market for dispensing organizations. Additional rule changes now allow the dispensing of derivative product by an approved producer in any region of the state regardless of their production region.

Economic Impact

Developing an economic impact study for an activity that will become legal is challenging given the lack of data for sale price, potential users, production and security costs, as well as prescription rate and frequency.

The State's approval of the medicinal usage of low-THC, non-euphoric marijuana for the treatment of very specific illnesses, and the limitation on medical cannabis to terminally ill individuals greatly limits the potential patient/customer base. Such limited allowance coupled with legislation not requiring coverage by medical insurance, creates an extremely restrictive marketplace. Also, as of November 6, 2015, only 55 medical doctors statewide have completed the Cannabis Continuing Medical Education pre-requisite needed to prescribe the marijuana derivatives produced and distributed by an approved dispensing organization. These facts could greatly affect the price and consumption of the product.

The medical marijuana industry estimates the State's market for low-THC, non-euphoric medical marijuana is $785 million per year, with approximately 260,000 patients statewide. The population estimates for the terminally ill patients allowed to utilize medical cannabis are much lower, currently at 47,000 persons statewide. If these estimates are accurate, the population that qualifies for all forms of medical marijuana under the approved Compassionate Care Act is 307,000 statewide and 96,059 in the Southeast Region. Based on population modeling, Miami-Dade County would have approximately 41,515 patients.

The best case scenario for sales are estimated to be $124.545 million per year in Miami-Dade County and $288.177 million per year in the Southeast Region if all eligible persons receive prescriptions and purchase the medicinal product at a base cost of $3,000.00 per prescription. However, as explained earlier, due to the limited market, lack of insurance coverage, and competition with covered medications, sales are expected to be lower.

Based on the information provided by those entities that applied to become dispensing organizations and cannabis industry organizations, employment projections for construction related jobs is 102 with a payroll of $2.24 million over the project construction period. The anticipated number of jobs created in Miami-Dade County for these operations will be 125 direct and 75 indirect/induced. The annual payroll for the jobs created by operations is anticipated to be $11.15 million. Given the sales and employment figures, it is expected that an approved medical marijuana facility and dispensing operations will create an annual economic impact to Miami-Dade County of $61.9 million, growing to $62.8 million by 2025.

Current Status of Implementation

The State received 28 applications for dispensing organizations, five (5) of which applied for the Southeast Region. The five (5) applicants were:

- Bill's Nursery, Inc. d/b/a Almond Tree Nursery;
- Costa Nursery Farms, LLC;
- Nature's Way Nursery of Miami;
- Alpha Foliage, Inc.; and
- Redland Nursery, Inc.

On November 23, 2015, the State Department of Health announced the organizations that were selected to become production and dispensing organizations and Costa Nursery Farms operating under the name of Modern Health Concepts was approved as the dispensing organization for the Southeast Region. Costa Nursery Farms is headquartered in Miami-Dade County, and their operations for production of this product will be located within Miami-Dade County.

In addition, following the selection of dispensing organizations by the State Department of Health, there were 18 petitions filed for administrative hearings contesting the awards. As a result, some regions will have more than one (1) dispensing organization approved for cultivation and dispensing. It is our understanding that the Southeast region will not one of the regions approved for additional production organizations as the petitioner in the area dismissed their case.

The production of cannabis by the approved dispensing organizations is anticipated to begin by September 2016, with dispensing to begin in October 2016.

Pursuant to Ordinance 14-65, this item will be placed on the next available Board of County Commissioners meeting agenda.

Should you have any questions or concerns, please contact Charles LaPradd, Agricultural Manager in the Department of Regulatory and Economic Resources, at 305-951-5091 or lapradd@miamidade.gov.

Attachment

c: Abigail Price-Williams, County Attorney
Office of the Mayor Senior Staff
Lourdes Gomez, Deputy Director, Department of Regulatory and Economic Resources
Leland Salomon, Deputy Director, Department of Regulatory and Economic Resources
Charles LaPradd, Agricultural Manager, Department of Regulatory and Economic Resources
Eugene Love, Agenda Coordinator
Neil Singh, Interim Commission Auditor

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 Section 581.011, F.S., 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, processing, and dispensing.

(3) Cultivation Authorization – Written notification by the department to a Dispensing Organization that it may begin cultivating low-THC cannabis.

(4) Processing Authorization – Written notification by the department to a Dispensing Organization that it may begin processing low-THC cannabis to Derivative Product.

(5) Dispensing Authorization – Written notification by the department to a Dispensing Organization that it may begin dispensing Derivative Product.

(6) Certified Financials – Financial statements that have been audited in accordance with Generally Accepted Auditing Standards (GAAS) by a Certified Public Accountant, licensed pursuant to Chapter 473, F.S.

(7) Cultivation – Growth of low-THC plant source material.

(8) Derivative Product – Forms of low-THC cannabis suitable for routes of administration.

(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, Miami-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., including its contractual agents, which has been authorized by the department to cultivate, process and dispense low-THC cannabis.

(11) Dispensing Organization Facility – Any of the following facilities:

(a) Cultivation Facility: Any area designated in the application to be used for cultivation of low-THC cannabis.

(b) Processing Facility: Any area designated in the application to be used for processing of Derivative Product.

(c) Dispensing Facility: Any area designated in the application where Derivative Product is dispensed at retail.

(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) 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.

(14) Permanent resident – A person who 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.

(15) Routes of administration – means the path by which a Derivative Product is ordered by a physician to be taken into the body of the qualified patient, but does not include smoking.

(16) Visitation Protocol – A set of identified policies and procedures of an applicant or Dispensing Organization that details requirements for visitor access to any proposed or existing Dispensing Organization facility.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History–New 6-17-15.

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, either electronically or in hard copy, to the department using Form DH8006-OCU-2/2015, "Application for Low-THC Cannabis Dispensing Organization Approval" herein incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-05457. The completed application form must include the following:

(1) An initial application fee of $60,063.00.

(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, process, and dispense low-THC cannabis. Please address the following items:

1. Experience cultivating cannabis;
2. Experience cultivating in Florida plants not native to Florida;
3. Experience introducing new varieties of plants;
4. Regional cultivation knowledge and experience;
5. Experience cultivating plants for human consumption such as food or medicine products;
6. Experience with in-house propagation;
7. Experience with genetic modification or breeding;
8. Experience using clean growing rooms;
9. Knowledge of cannabis cultivation, including:
a. Proper cultivation conditions and techniques;
b. Additives that can be used when growing cannabis;
c. Pests, disease and deficiencies common for cannabis;
d. Production of high quality product in a short time;
10. Experience with tracking each plant in a harvest;
11. Experience with good agricultural practices;
12. Experience with good handling practices;
13. Experience with good manufacturing practices;
14. Experience with analytical organic chemistry and micro-biology;
15. Experience with analytical laboratory methods;
16. Experience with analytical laboratory quality control, including maintaining a chain of custody;
17. Knowledge of, and experience with, cannabis extraction techniques;
18. Knowledge of cannabis routes of administration;
19. Knowledge of, and experience with, producing cannabis products;
20. Experience interacting with patients;
21. Experience with handling confidential information;
22. A marketing plan;
23. Experience gathering and managing data, i.e. data on patient reactions to products dispensed;
24. Experience with recalls;
25. Training programs for employees addressing:
a. The Health Insurance Portability and Accountability Act (HIPAA);
b. Patient education;
c. Compliance;
d. Patient counseling; and,
e. Data collection.
26. Any awards, recognition or certifications received for relevant expertise.

(b) Written documentation demonstrating that the applicant possesses a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to Section 581.131, F.S., that is issued for the cultivation of more than 400,000

plants, is operated by a nurseryman as defined in Section 581.011, F.S., 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 a sketch or other illustration:

1. Location of all properties Applicant proposes to utilize to cultivate, process, and dispense low-THC cannabis and Derivative Product, 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 of the property for the purposes of cultivation, processing, or dispensing of low-THC cannabis and Derivative Products and documentation that the mortgagor or lienholder has been given notice of the use of the property for the purposes of cultivation, processing, or dispensing of low-THC cannabis and Derivative Products.

b. For any property owned by the Applicant but subject to a mortgage or lien, include documentation that the mortgagor or lienholder has been notified of the use of the property for the purposes of cultivation, processing, or dispensing of low-THC cannabis and Derivative Products.

2. Compliance with local regulations regarding sanitation and waste disposal;

3. The ability to obtain zoning approval;

4. Sketch or other illustration approximating the property boundaries, land topography, vegetation, proposed and/or existing structures, easements, wells, and roadways for each property proposed;

5. 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); and,

d. Environmental control system(s);

6. A description of the ability or plan to expand any of the areas proposed for low-THC cannabis;

7. Back-up systems for all cultivation and processing systems;

8. A description of one or more strains of low-THC cannabis the applicant intends to cultivate;

9. Access to water resources that allow for sufficient irrigation;

10. Description of the areas proposed for the processing of Derivative Products, including the following:

a. Extraction equipment and location;

b. Concentration equipment and location;

c. Access to sufficient potable water and hot water;

d. Analytical equipment, including separators and detectors, and location;

e. Safety equipment and facilities and location;

f. Computer systems and software; and,

g. Ventilation and exhaust system.

11. Description of the methods proposed for the dispensing of 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;

b. Proximity of dispensing facilities to patient populations; and,

c. Alternative dispensing, e.g. delivery.

12. A list of current and proposed staffing, including;

a. Position, duties and responsibilities;

b. Resume; and,

c. Professional licensure disciplinary action in all jurisdictions.

13. An organizational chart illustrating the supervisory structure of the proposed Dispensing Organization;

14. Plans and procedures for loss of key personnel;

15. Plans and procedures for complying with OSHA regulations for workplace safety; and,

16. 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. Storage, including the following;

a. Safes;

b. Vaults;

c. Climate control;

3. Diversion and trafficking prevention procedures;

4. A facility emergency management plan;

5. System for tracking low-THC source plant material throughout cultivation, processing, and dispensing;

6. Inventory control system for low-THC cannabis and Derivative Products;

7. Policies and procedures for recordkeeping;

8. Vehicle tracking systems;

9. Vehicle security systems;

10. Methods of screening and monitoring employees;

11. Personnel qualifications and experience with chain of custody or other tracking mechanisms;

12. Personnel reserved solely for inventory control purposes;

13. Personnel reserved solely for security purposes;

14. Waste disposal plan;

15. Plans for the recall of any Derivative Products that have a reasonable probability of causing adverse health consequences based on a testing result, bad patient reaction, or other reason; and,

16. 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 sketch or other illustration 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 retail sales;

4. A HIPAA compliant computer network utilized by all facilities;

5. Vehicles that will be used to transport product among cultivating, processing, and dispensing facilities;

6. Communication systems;

7. Hours of operation of each dispensing facility; and,

8. Methods of mitigating odors if applicable.

(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. Please provide the following items:

1. Certified Financials issued within the immediately preceding 12 months;

2. Applicant's corporate structure;

3. All owners of the Applicant;

4. All individuals and entities that can exercise control of the Applicant;

5. All individuals and entities that share in the profits and losses of the Applicant;

6. All subsidiaries of the Applicant;

7. Any other individuals or entities for which the Applicant is financially responsible;

8. Assets of the Applicant and Applicant's subsidiaries;

9. Liabilities of the Applicant and Applicant's subsidiaries;

10. Any pending lawsuits to which the Applicant is a party;

11. Any lawsuits within the past 7 years to which the Applicant was a party;

12. All financial obligations of Applicant that are not listed as a "liability" in the Certified Financials;

13. A projected two year budget; and,

14. Specific reference to sufficient assets available to support the Dispensing Organization activities.

(g) That all owners and managers have been fingerprinted and have successfully passed a level 2 background screening pursuant to Section 435.04, F.S., within the calendar year prior to application. Each owner and manager should present to FDLE or one of its approved vendors for fingerprinting. At that time, give the entity ORI number FL924890Z (DOH – OFFICE OF COMPASSIONATE USE). The report will be sent directly to the Office of Compassionate Use. Please submit 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 Chapters 458 or 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;

13. Knowledge of, and experience with, producing CBD/low-THC products;

14. Experience with or knowledge of botanical medicines;

15. Experience with dispensing medications;

16. Description of how the medical director will supervise the activities of the Dispensing Organization; and,

17. Description of how the Dispensing Organization will ensure it has a medical director at all times.

(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 statutory basis for the exemption. The Applicant shall submit a redacted copy of the application redacting those items identified as exempt.

(4) Failure to submit the $60,063.00 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 subsection (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 a.m. (Eastern Time), on the effective date of this rule and no later than 5:00 p.m. (Eastern Time), 21 calendar days after the effective date of this rule.

(a) The department will substantively review, evaluate, and score applications using Form DH8007-OCU-2/2015, "Scorecard for Low-THC Cannabis Dispensing Organization Selection" herein incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-05461. 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.

(b) Each reviewer will independently review each application and score using Form DH8007-OCU-2/2015, "Scorecard for Low-THC Cannabis Dispensing Organization Selection." Scorecards from each reviewer 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.

(c) In the event of a tie in a region, each reviewer will re-review the tied applications and select a winning application. The department will approve the application selected by the majority of the reviewers.

(d) In the event one nursery receives the high score in multiple regions, one of which is the region represented by the address on the nursery's certificate of registration, the Applicant will be approved for that region, and the second highest scored Applicant will be approved for the other region(s). In the event one nursery receives the high score in multiple regions, none of which is the region represented by the address on the nursery's certificate of registration, the Applicant will be approved for the region for which it had the highest aggregate infrastructure score, and the second highest scored Applicant will be approved for the other region(s).

(e) Upon notification that it has been approved as a region's Dispensing Organization, the Applicant shall have 10 business days to post a $5 million performance bond. The bond shall:

1. Be payable to the department in the event the Dispensing Organization's approval is revoked;
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 Applicant name.
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.

(f) 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.

(g) The surety company can use any form it prefers for the performance bond as long as it complies with this rule. For convenience, the surety company can also use Form DH8008-OCU-2/2015, "Florida Low-THC Cannabis Performance Bond" herein incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-05460.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History–New 6-17-15.

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;

(b) Knowingly dispenses Derivative Product to an individual other than a qualified patient or a qualified patient's legal representative without noticing the department and taking appropriate corrective action;

(2) The department may revoke its approval of the Dispensing Organization if any of the following failures impact the accessibility, availability, or safety of the Derivative Product and are not corrected within 30 calendar days after notification to the Dispensing Organization of the failure;

(a) Failure to comply with the requirements in Section 381.986, F.S., or this rule chapter;

(b) Failure to implement the policies and procedures or comply with the statements provided to the department with the original or renewal application;

(3) The department may revoke its approval of the Dispensing Organization for failure to meet the following deadlines if failure is not corrected within 10 calendar days:

(a) Failure to seek Cultivation Authorization within 75 calendar days of application approval; or

(b) Failure to begin dispensing within 210 calendar days of the being granted the Cultivation Authorization requested in subsection 64-4.005(2), F.A.C.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History–New 6-17-15.

64-4.005 Inspection and Authorization Procedures.

(1) Submission of an application for Dispensing Organization approval or renewal constitutes permission for entry by the department at any reasonable time during the approval or renewal process, 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 identify samples of any low-THC cannabis or Derivative Product for laboratory analysis, the results of which shall be forwarded to the department. All inspectors shall follow the Dispensing Organization's Visitation Protocol when conducting any inspection.

(2) A Dispensing Organization must request Cultivation Authorization within 75 days of being notified that it has been approved as a region's Dispensing Organization. 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 Cultivation Authorization. No low-THC cannabis plant source material may be present in any Dispensing Organization facility prior to Cultivation Authorization.

(3) No less than 10 calendar days prior to the initial processing of low-THC cannabis, the Dispensing Organization shall notify the department that the Dispensing Organization is ready to begin processing, the Dispensing Organization is in compliance with Section 381.986, F.S., and this chapter, and is seeking Processing Authorization.

(4) A Dispensing Organization must begin dispensing Derivative Product within 210 days of being granted Cultivation Authorization. No less than 10 calendar days prior to the initial dispensing of Derivative Product, the Dispensing Organization shall notify the department that the Dispensing Organization is ready to begin dispensing, the Dispensing Organization is in compliance with Section 381.986, F.S., and this chapter, and is seeking Dispensing Authorization.

(5) 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 calendar 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 6-17-15.