

Corrected Notice of Proposed Rule

DEPARTMENT OF HEALTH

RULE NO.: RULE TITLE:

64-4.001: Definitions

64-4.002: Application for Registration of Medical Marijuana Treatment Centers

PURPOSE AND EFFECT: These rules implement statutory changes to section 381.986, Florida Statutes, to update definitions and processes for the registration of medical marijuana treatment centers.

SUMMARY: Rule 64-4.001, F.A.C., provides the definitions necessary to implement the statutory changes creating medical marijuana treatment centers in Florida. Rule 64-4.002, F.A.C., provides the application requirements, forms, and process necessary to apply for registration as a medical marijuana treatment center.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:

The Agency has determined that this 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. A SERC has not been prepared by the Agency.

No SERC was prepared for rule 64-4.001, F.A.C.; however, a SERC was prepared for rule 64-4.002, F.A.C.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: Based on the SERC checklist for rule 64-4.001, F.A.C., the rulemaking will not have an adverse impact or regulatory costs in excess of \$1 million within five years as established in s.120.541(2)(a), F.S. Based on the SERC checklist for rule 64-4.002, F.A.C., the rulemaking will have an adverse impact or regulatory costs in excess of \$1 million within five years as established in s.120.541(2)(a), F.S.

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

RULEMAKING AUTHORITY: [381.986\(8\)\(b\) FS](#)

LAW IMPLEMENTED: [381.986\(8\)\(b\) FS](#)

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: Courtney Coppola at Courtney.Coppola@FLHealth.gov.

THE FULL TEXT OF THE PROPOSED RULE IS:

(Substantial rewording of Rule 64-4.001 follows. See Florida Administrative Code for present text.)

64-4.001 Definitions.

For the purposes of Department of Health (the “department”) medical marijuana treatment center rules and regulations, the following words and phrases shall have the meanings indicated:

(1) Applicant – An individual or entity that meets the requirements of section 381.986(8)(b), F.S., and applies for registration as a medical marijuana treatment center pursuant to section 381.986(8)(a), F.S., excluding subparagraph 1 and sub-subparagraph 2.a.

(2) Approval – Written notification from the department to an applicant that its application for registration as a medical marijuana treatment center has been found to be in compliance with the provisions of section 381.986, F.S., and department rules has been selected pursuant to the comparative review process set forth in Rule 64-4.002, F.A.C., and that the department is awaiting notification that the medical marijuana treatment center is prepared to be inspected and authorized to begin cultivation, processing, and dispensing.

(3) 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.

(4) Cultivation – The preparation of any soil or other medium for the planting of marijuana or the tending and care or harvesting of marijuana intended to be dispensed by a medical marijuana treatment center for medical use by a qualified patient.

(5) Cultivation Authorization – Written notification by the department to a medical marijuana treatment center that it may begin cultivating marijuana.

(6) Cultivation Facility – Any area designated in the application to be used for cultivation of marijuana.

(7) Derivative Product – Forms of marijuana suitable for routes of administration.

(8) Dispensing Authorization – Written notification by the department to a medical marijuana treatment center that it may begin dispensing derivative product.

(9) Dispensing Facility – Any area designated in the application that is accessible by the public and where derivative product and marijuana delivery devices are dispensed at retail.

(10) Employee – Any person whose duties involve any aspect of the cultivation, processing, transportation or dispensing of marijuana whether or not compensated for the performance of such duties.

(11) 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.

(12) Fulfillment and Storage Facility – Any area designated in the application, which is not open to the public, to be used for order fulfillment, shipping, transportation, or storage of low-THC cannabis, medical marijuana, derivative product or marijuana delivery devices.

(13) Interests – Any form of ownership in or control of an applicant or a medical marijuana treatment center, including, but not limited to, ownership of stock, membership interests, partnership interests, a sole proprietorship or otherwise which convey to the holder thereof an ownership right or an interest in or right to the profits, capital, or voting with respect to such applicant or medical marijuana treatment center.

(14) Majority Ownership – Ownership of more than 50% of the interests of an applicant or registered medical marijuana treatment center, such ownership being determined by application of the requirements in paragraph (16) below.

(15) Manager – Any person with the authority, directly or indirectly, to exercise or contribute to the operational control, direction or management of an applicant or a medical marijuana treatment center or who has direct or indirect authority to supervise any employee of an applicant or a medical marijuana treatment center. The term shall be interpreted broadly and shall include, but not be limited to, all officers, managers, and members of board of directors as well as any other person engaged to undertake management or control of the applicant or a medical marijuana treatment center or any person or persons in control of an entity engaged to undertake management or control of the applicant or medical marijuana treatment center.

(16) Owner – Any person who, directly or indirectly, owns (actually or beneficially) or controls, a 5% or greater share of interests of the applicant or a medical marijuana treatment center. In the event that one person owns a beneficial right to interests and another person holds the voting rights with respect to such interests, then in such case, both shall be considered the owner of such interests. In determining the owners of the applicant or a medical marijuana treatment center, the attribution of ownership rules set forth in the Treasury Regulations cited as 26 CFR 1.414(c)-4(b) and (c) (4-1-17 edition), incorporated by reference and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>, shall apply, but with the following exceptions and additions:

(a) The use of the term “option” in 26 CFR 1.414(c)-4(b) shall be interpreted broadly to include, but not be limited to, any and all options, warrants, calls, rights of first refusal and any other right to acquire an interest (as defined herein), whether such right is vested or unvested and regardless of whether such right is then exercisable or becomes exercisable at a future date or upon the occurrence of a future event.

(b) The exception for attribution of a spouse's interest, as defined in paragraph (13) above and as set forth in 26 CFR 1.414(c)-4(b)(5)(ii), shall not apply.

(c) The age limitation contained in 26 CFR 1.414(c)-4(b)(6) shall apply only to children who have not attained the age of 18 years. The term “interest” as used in 26 CFR 1.414(c)-4(b)(6) shall have the meaning as set forth in paragraph (13) above.

(d) In the event that a person under the age of 18 owns or is deemed an owner of an interest, such person must be disclosed to the department. Persons under the age of 18 shall be required to submit to a background screening only in the event that the interest or ownership was not imputed to another family member or guardian as outlined in paragraph (16)(c) above.

(e) To the extent that the above alterations to the provisions of 26 CFR 1.414(c)-4 alter the outcome of any of the examples set forth therein, then, in such case, such example does not apply.

(f) As used in 26 CFR 1.414(c)-4(b)(3), the term “actuarial interest” shall be interpreted broadly and shall include, but not be limited to, the right of a beneficiary of a trust or an estate to receive either income or principal distributions with respect to an interest held by such trust or estate.

(g) With regard to publicly traded companies with ownership interests in the applicant, any person who holds 10% or more interest in the publicly traded company shall be considered an owner.

(17) Processing Authorization – Written notification by the department to a medical marijuana treatment center that it may begin processing marijuana to derivative product.

(18) Processing Facility – Any area designated in the application to be used for processing of derivative product.

(19) Registration as a Medical Marijuana Treatment Center – Approval and licensure as a medical marijuana treatment center pursuant to section 381.986(8), F.S.

(20) Resident – A person who meets the requirements of section 381.986(5)(b), F.S.

(21) Routes of Administration – The forms and delivery devices, as certified by a qualified physician, as the appropriate method for the derivative product to be taken into the body of the qualified patient, but does not include smoking.

Rulemaking Authority 381.986(8)(b) FS. Law Implemented 381.986 FS. History–New 6-17-15, Amended _____.

(Substantial rewording of Rule 64-4.002 follows. See Florida Administrative Code for present text.)

64-4.002 Application for Registration of Medical Marijuana Treatment Centers.

Pursuant to section 381.986, F.S., all applicants seeking registration as a medical marijuana treatment center shall comply with the process detailed below. The process set forth in this rule applies to individuals requesting registration as a medical marijuana treatment center pursuant to section 381.986(8)(a), F.S., but does not include registration pursuant to subparagraph 1 and sub-subparagraph 2.a.

(1) Each individual or entity that meets the requirements of section 381.986(8)(b), F.S., desiring to be registered as a medical marijuana treatment center pursuant to section 381.986, F.S., shall submit an application to the department using Form DH8013-OMMU-04/2018, “Application for Medical Marijuana Treatment Center Registration,” incorporated by reference herein and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>. The application must comply with the page limits, blind grading, format, and organization instructions detailed in the application. The applicant must include with the application at the time of submission the following:

(a) A non-refundable application fee of \$60,830.00.

(b) Written documentation from the Department of State or the Department of Revenue, as applicable under Florida law, demonstrating that the applicant has been registered to do business in Florida for the prior five (5) consecutive years. The name of the applicant as submitted to the department must match the name on any documents provided in accordance with this paragraph.

(c) Written documentation 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. The name of the applicant as submitted to the department must match the name on any documents provided in accordance with this paragraph.

(d) A list of all owners, officers, board members, and managers indicating the date of each individual’s most recent Level-2 background screening pursuant to section 381.986(9), F.S, within the calendar year prior to application. Each owner, officer, board member, and manager shall go to the Florida Department of Law Enforcement (FDLE) or one of its approved vendors for fingerprinting and, at such time, shall give to FDLE or the FDLE-approved vendor the entity ORI number FL924890Z (DOH – OFFICE OF MEDICAL MARIJUANA USE). The report will be sent directly to the Office of Medical Marijuana Use. The provision of this list is required as part of a complete application prior to review and scoring by the subject matter experts. The list does not indicate passage of any background screening and to be eligible for registration as a medical marijuana treatment center, all of the applicant’s owners, officers, board members, and managers must have successfully passed a Level-2 background screening.

(e) For applicants seeking registration as a medical marijuana treatment center pursuant to section 381.986(8)(a)2.b., F.S., the applicant must provide evidence that it is an individual or an entity majority-owned by individual(s) who is a recognized class member of *Pigford v. Glickman*, 185 F.R.D. 82 (D.D.C. 1999) (“*Pigford*”) or *In re Black Farmers Discrimination Litigation*, 856 F. Supp. 2d 1 (D.D.C. 2011) (“*BFDL*”).

1. Examples of acceptable evidence include:

a. Documentation from Poorman-Douglass Corporation (now Epiq Systems Inc.) that the applicant received a consent decree case number in *Pigford*;

b. Documentation that the applicant was granted class status by the *Pigford* adjudicator;

c. Court documents or United States Department of Agriculture (USDA) documents showing that the applicant received judgment discharging debt, providing a cash payment, or providing injunctive relief in *Pigford*;

d. Documentation that the applicant was determined to be a class member by Epiq Systems Inc. in *BFDL*;

e. Documentation that the applicant received a settlement award in *BFDL*; or

f. Other court documents or USDA documents demonstrating that the applicant was granted class member status in either *Pigford* or *BFDL*.

2. Applicants seeking registration as a medical marijuana treatment center pursuant to section 381.986(8)(a)2.b., F.S., are exempt from the evidentiary requirements of paragraph (1)(c) above and, therefore, are also exempt from the provisions of paragraph (4)(c) below. However, if an applicant wishes to be considered under sections 381.986(8)(a)2.b., 381.986(8)(a)2.c., and 381.986(8)(a)4., F.S., the applicant must provide the documentation required in paragraph (1)(c).

(f) For applicants seeking preference for registration as a medical marijuana treatment center pursuant to section 381.986(8)(a)3., F.S., the applicant must provide evidence that:

1. The property at issue currently is or was previously used for the canning, concentrating, or otherwise processing of citrus fruit or citrus molasses. In order to demonstrate the property meets this criteria, the applicant may provide documentation that the applicant currently holds or has held a registration certificate pursuant to section 601.40, F.S. A letter from the Department of Citrus certifying that the property currently is or was previously used for the canning, concentrating, or otherwise processing of citrus fruit or citrus molasses will be accepted as sufficient evidence;

2. The applicant as an individual holds, in his or her name, or the applicant as an entity holds, in the legal name of the entity, the deed to property meeting the criteria set forth in subparagraph 1. above; and

3. A brief explanation of how the property will be used for purposes of growing, processing, or dispensing medical marijuana if the applicant is selected for registration.

(2) 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 concurrent with the submission of the application for approval under subsection (5) below. Failure to provide a redacted copy of the application at the time of submission or failure to identify and redact information claimed as trade secret will result in the release of all application information in response to a public records request, unless the information falls under another public records exemption. All identified trade secrets are subject to the department review in accordance with section 381.83, F.S.

(3) The department will review each application and notify the applicant of any omissions related to the items in paragraphs (1)(a)-(1)(f) above within 15 days. An applicant will have five (5) business days to respond to complete its application. Applications considered complete will be provided to subject matter experts for review and scoring. An applicant may not add, remove, or change information in its application once it is complete and has been provided to the subject matter experts for review.

(4) Failure to provide the following, after the notice and cure period set forth in subsection (3) above, shall result in the application being denied prior to any scoring as contemplated in subsection (6) of this rule:

(a) The \$60,830.00 application fee;

(b) Documentation required under paragraph (1)(b);

(c) Documentation required under paragraph (1)(c); or

(d) The list of owners, officers, board members, and managers required under paragraph (1)(d).

(5) Applications and all required exhibits and supporting documents shall be hand delivered to the Department of Health, ATTN: Office of Medical Marijuana Use, at 4052 Bald Cypress Way, Tallahassee, Florida, during normal business hours, but no earlier than 10:00 a.m. (Eastern Time), 21 days after the effective date of this rule and no later than 5:00 p.m. (Eastern Time) 42 days after the effective date of this rule. Applications submitted after 5:00 p.m. Eastern Time on the final day of the application period will be denied.

(6) Subject matter experts will substantively and comparatively review, evaluate, and score applications using Form DH8014-OMMU-04/2018, "Scorecard for Medical Marijuana Treatment Center Selection," incorporated by reference herein and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>.

(a) The subject matter experts shall have the following qualifications:

1. Subject matter experts reviewing Sections 1-3 of the application, the cultivation components, shall have at least two (2) years of professional experience or advanced degree in one of the following areas: agriculture, horticulture, or agronomy, or comparable field.

2. Subject matter experts reviewing Sections 4-5 of the application, the processing components, shall have at least two (2) years of professional experience or advanced degree in chemistry, biology, or biochemistry.

3. Subject matter experts reviewing Sections 6-8 of the application, the dispensing components, shall have at least two (2) years of professional experience or advanced degree in industrial engineering, supply chain management, or strategic management.

4. Subject matter experts reviewing Sections 9, 10, 12, and 16 of the application, the compliance components, shall have at least two (2) years of professional experience or advanced degree related to operating a business in a highly regulated environment.

5. Subject matter experts reviewing Section 13 of the application shall have at least two (2) years of management experience within a business operating in a regulated industry or at least two (2) years of experience working in human resources.

6. Subject matter experts reviewing Section 11 of the application shall have at least two (2) years of management experience within a business operating in the health care industry or an active, unrestricted license as a medical doctor or doctor of osteopathic medicine.

7. Subject matter experts reviewing Sections 14-15 of the application, the legal and financial components, shall have an active CPA license or an active license to practice law and experience in business structuring.

Subject matter experts will certify that they do not have a conflict of interest and will evaluate and score each assigned section of the application according to the rubric set forth in DH8014-OMMU-04/2018.

(b) Scores for each section of the application will be combined to create an applicant's total score. The department shall generate a final ranking of the applicants in order of highest to lowest scores. Any application which demonstrates a failure to pass background screening as required by section 381.986(8)(b)8., F.S., and to comply with the minimum statutory requirements for cultivation, processing, dispensing, security, or general operations, as identified in DH8014-OMMU-04/2018, shall be denied and will not be considered in the final ranking of applications.

(c) In accordance with section 381.986(8)(a)3., F.S., the two highest scoring applicants that own one or more facilities that are, or were, used for the canning, concentrating, or otherwise processing of citrus fruit or citrus molasses and will use or convert the facility or facilities for the processing or marijuana will receive an additional 35 points to their respective total score.

(7) Licenses will be awarded, subject to availability as set forth in sections 381.986(8)(a)2. and 381.986(8)(a)4., F.S., based on the highest total score in the following manner:

(a) The highest scoring applicant that is a recognized member of *Pigford* or *BFDL* will receive a license.

(b) The remaining highest scoring applicants, after the addition of the preference points for applicants pursuant to paragraph (6)(c) above, will receive licenses up to the statutory cap set forth in section 381.986(8)(a)2., F.S.

(c) The remaining highest scoring applications, after removing any preference points received under paragraph (6)(c), will receive licenses up to the statutory cap set forth in section 381.986(8)(a)4., F.S. Eligibility for additional licenses pursuant to section 381.986, F.S. shall be determined pursuant to the number of active qualified patients in the medical marijuana use registry as of the date the department issues approvals for registration.

(d) In the event of a tie that will determine the awarding of a license, the following tiebreakers will be applied:

1. The first tiebreaker shall be the score for Section 14 – Financials: Certified Financial Documents. The applicant with the highest score in Section 14 shall be awarded a license. In the event that this does not resolve the tie, then

2. The second tiebreaker shall be the score for Section 15 – Financials: Business Structure. The applicant with the highest score in Section 15 shall be awarded a license. In the event that this does not resolve the tie, then

3. The third tiebreaker shall be the score for Section 13 – Diversity Plan. The applicant with the highest score in Section 13 shall be awarded a license. In the event that this does not resolve the tie, then

4. The final tiebreaker shall be the score for Section 10 – Accountability: Operations.

(8) Upon notification that it has been approved as a medical marijuana treatment center, the applicant shall have 10 business days to:

(a) Post a performance bond, provide an irrevocable letter of credit payable to the department or provide cash to the department in the amount of \$5 million (collectively “financial assurance”) pursuant to section 381.986(8)(b)7., F.S. If a bond is provided, the bond shall:

1. Be payable to the department in the event the medical marijuana treatment center's registration is revoked;

2. Be written by an authorized surety company rated in one of the three (3) highest rating categories by a nationally recognized rating service; and

3. Be written so that the individual or entity name on the bond corresponds exactly with the applicant name.

4. 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 may use Form DH8015-OMMU-04/2018, "Florida Medical Marijuana Performance Bond," incorporated by reference herein and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>.

(b) Provide documentation supporting representations related to property ownership and/or leases made in the application.

(9) If a financial assurance is canceled or revoked in any manner and the medical marijuana treatment center fails to provide new financial assurance to the department in the required amount on or before the effective date of cancellation or revocation, the medical marijuana treatment center's registration shall be revoked.

(10) If a selected applicant fails to post the financial assurance or supporting property ownership and/or use documents within the required timeframe, the applicant with the next highest score shall be notified of department approval.

Rulemaking Authority 381.986(8)(b) FS. Law Implemented 381.986(8) FS. History--New 6-17-15,
Amended _____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Courtney Coppola

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Celeste Philip, MD, MPH, Surgeon
General and Secretary

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: April 30, 2018

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: December 29, 2017