

PRELIMINARY TEXT

THE PRELIMINARY TEXT OF THE RULE IS:

64-4.001 Definitions

All the terms defined in section 381.986, F.S., shall have the meanings provided in that section, whenever used in this chapter. For the purposes of Department of Health (the “department”) medical marijuana treatment center rules and regulations, the following words and phrases shall have the following meanings indicated:

(1) AFRNP - The Applicant Fingerprint Retention and Notification Program authorized by section 943.05(2)(b), F.S., and established by the Florida Department of Law Enforcement, as provided in Rule 11C-6.010, F.A.C.

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

(3) Arrest Report – The detailed narrative written by the arresting law enforcement officer explaining the circumstances of the arrest.

(4) Certificate of analysis – The document created by a Certified Marijuana Testing Laboratory (CMTL) that meets the requirements of the CMTL Certificate of Analysis rule.

~~(5)(2)~~ 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.

(6) Child resistant – Satisfying the requirements of the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss.1471 et seq. (1-14-2019 edition), which is incorporated by reference and available at: <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>, and any regulations adopted thereunder.

(7) Commercially manufactured food product – Ready-to-eat food products available for immediate and final consumption.

~~(8)(3)~~ 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.

~~(9)(4)~~ Cultivation Authorization – Written notification by the department to a medical marijuana treatment center that it may begin cultivating marijuana.

~~(10)(5)~~ Cultivation Facility – Any area designated to be used for cultivation of marijuana.

29 (11)~~(6)~~ Derivative Product – Usable product created from, infused with, or that otherwise includes or contains
30 marijuana. Forms of marijuana suitable for medical use.

31 (12)~~(7)~~ Dispensing Authorization – Written notification by the department to a medical marijuana treatment center
32 that it may begin dispensing useable derivative product.

33 (13)~~(8)~~ Dispensing Facility – Any area designated to be accessible by the public and where useable derivative
34 product and marijuana delivery devices will be dispensed at retail.

35 (14) Edible – Derivative product that is a commercially produced food item made with, or infused with, marijuana
36 oil, but no other form of marijuana, that is produced and dispensed by an MMTC. The term edible includes any
37 derivative product made with, or infused with, marijuana oil, that otherwise meets the definition of “food” in section
38 500.03, F.S., and complies with the Standards for Production of Edibles rule. The term does not include pills, capsules,
39 tinctures, topicals, and similar usable products.

40 (15)~~(9)~~ Employee – Any person whose duties involve any aspect of the cultivation, processing, transportation or
41 dispensing of marijuana whether or not compensated for the performance of such duties.

42 (16) Expiration date – the month, day, and year, as determined by the MMTC on the basis of tests or other
43 information showing that the edible, when stored at room temperature in a sealed receptacle, is no longer fit for
44 consumption or optimally fresh.

45 (17) FDLE - The Florida Department of Law Enforcement.

46 (18)~~(10)~~ Financial Statements – A presentation of financial data, including accompanying notes, derived from
47 accounting records, that purports to show actual or anticipated financial position and intended to communicate an
48 entity's economic resources or obligations at a point in time, and the results of operations and cash flows for a period
49 of time, in accordance with generally accepted accounting principles or a comprehensive basis of accounting other
50 than generally accepted accounting principles. Financial presentations included in tax returns are not financial
51 statements. The method of preparation (for example, manual or computer preparation) is not relevant to the definition
52 of a financial statement.

53 (19) Firmly affixed – Attached such that the label is not easily removed or damaged upon opening of a usable
54 product receptacle.

55 (20)(11) Fulfillment and Storage Facility – Any area designated, which is not open to the public, to be used for
56 order fulfillment, shipping, transportation, or storage of low-THC cannabis, medical marijuana, usable derivative
57 product or marijuana delivery devices.

58 (21)(12) Interest(s) – Any form of ownership in or control of an applicant or a medical marijuana treatment center,
59 including, but not limited to, ownership of stock, membership interests, partnership interests, a sole proprietorship or
60 otherwise which convey to the holder thereof an ownership right or an interest in or right to the profits, capital, or
61 voting with respect to such applicant or medical marijuana treatment center.

62 (22) Label or labeling – The slip of paper or similar material inscribed with print or graphics and firmly affixed
63 to the derivative product receptacle in which usable product is dispensed or displayed.

64 (23) Livescan Service Provider - A vendor, entity, or agency authorized by s. 943.053(13), F.S., that scans
65 fingerprints electronically and submits them to FDLE.

66 (24)(13) Majority Ownership – Ownership of more than 50% of the interests of an applicant or medical marijuana
67 treatment center, such ownership being determined by application of the requirements in subsection (29)(15), below.

68 (25)(14) Manager – Any person with the authority, directly or indirectly, to exercise or contribute to the
69 operational control, direction or management of an applicant or a medical marijuana treatment center or who has direct
70 or indirect authority to supervise any employee of an applicant or a medical marijuana treatment center. The term shall
71 be interpreted broadly and shall include, but not be limited to, all officers, managers, and members of board of directors
72 as well as any other person engaged to undertake management or control of the applicant or a medical marijuana
73 treatment center or any person or persons in control of an entity engaged to undertake management or control of the
74 applicant or medical marijuana treatment center.

75 (26) Marijuana Oil – Oil derived from marijuana or low-THC cannabis.

76 (27) MMTC - A medical marijuana treatment center licensed by the department pursuant to s. 381.986(8)(a), F.S.

77 (28) Opaque – Not transparent or translucent.

78 (29)(15) Owner – Any person who, directly or indirectly, owns (actually or beneficially) or controls, a 5% or
79 greater share of interests of the applicant or a medical marijuana treatment center. In the event that one person owns
80 a beneficial right to interests and another person holds the voting rights with respect to such interests, then in such
81 case, both shall be considered the owner of such interests. In determining the owners of the applicant or a medical
82 marijuana treatment center, the attribution of ownership rules set forth in the Treasury Regulations cited as 26 CFR

83 1.414(c)-4(b) and (c) (4-1-17 edition), incorporated by reference and available at
84 <https://www.flrules.org/Gateway/reference.asp?No=Ref-09656>, shall apply, but with the following exceptions and
85 additions:

86 (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
87 to, any and all options, warrants, calls, rights of first refusal and any other right to acquire an interest (as defined
88 herein), whether such right is vested or unvested and regardless of whether such right is then exercisable or becomes
89 exercisable at a future date or upon the occurrence of a future event.

90 (b) The exception for attribution of a spouse’s interest, as defined in subsection ~~(21)(42)~~, above, and as set forth
91 in 26 CFR 1.414(c)-4(b)(5)(ii), shall not apply.

92 (c) The age limitation contained in 26 CFR 1.414(c)-4(b)(6) shall apply only to children who have not attained
93 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
94 subsection ~~(21)(42)~~, above.

95 (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
96 disclosed to the department. Persons under the age of 18 shall be required to submit to a background screening unless
97 the interest or ownership is imputed to another family member or guardian as outlined in paragraph ~~(29)(c)(15)(e)~~,
98 above.

99 (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
100 examples set forth therein, then, in such case, such example does not apply.

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

104 (g) With regard to publicly traded companies with ownership interests in the applicant, any person who holds
105 10% or more interest in the publicly traded company shall be considered an owner.

106 (30) Package – The box, bag, or other vessel that contains the receptacle.

107 (31) Patient package insert – The slip of paper provided to a qualified patient or caregiver inside of the package
108 of every usable product that contains the information required by s. 381.986(8)(e)12., F.S.

109 (32) Plain – Black, print lettering, in a sans-serif font, and on a solid white background with no pictures or graphics
110 other than one image of the MMTC’s department-approved logo and the universal symbol.

111 ~~(33)~~(16) Processing Authorization – Written notification by the department to a medical marijuana treatment
112 center that it may begin processing marijuana to usable derivative product.

113 ~~(34)~~(17) Processing Facility – Any area designated to be used for processing of usable derivative product.

114 ~~(35)~~ Product name – The brand name and any other name assigned to the usable product.

115 ~~(36)~~ Receptacle – The container, canister, or material that comes into direct contact with the usable product. In
116 the case of some derivative products, “receptacle” means the container, canister, or material that comes into direct
117 contact with the usable derivative product’s immediate covering (e.g., a vape cartridge that contains derivative
118 product). In the case of edibles, “receptacle” means the container, canister, or material that comes into direct contact
119 with the individually wrapped edible. Where the usable product is dispensed inside of a marijuana delivery device
120 (e.g., a vape pen that contains derivative product), the receptacle means the container, canister, or material that comes
121 into direct contact with the delivery device.

122 ~~(18) Registration as a Medical Marijuana Treatment Center – Licensure as a medical marijuana treatment center~~
123 ~~pursuant to section 381.986(8), F.S.~~

124 ~~(37)~~(19) Resident – A person who meets the requirements of section 381.986(5)(b), F.S.

125 ~~(38)~~(20) Routes of Administration – The appropriate method for the usable derivative product to be taken into
126 the body of the qualified patient, as certified by a qualified physician, ~~but does not include smoking.~~

127 ~~(39)~~ Universal symbol – The image available at [https://www.flrules.org/Gateway/reference.asp?No=Ref-](https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX)
128 XXXXX which is incorporated by reference.

129 ~~(40)~~ Usable Product - All forms of marijuana suitable for medical use by a qualified patient.

130 ~~(41)~~ Usable whole flower marijuana – The flowers of the female cannabis plant, including low-THC cannabis,
131 that is suitable to be dispensed from an MMTC for use by a qualified patient. Usable whole flower marijuana does not
132 include seeds, stems, roots, leaves, resin extracted from any part of the plant, or any compound, manufacture, salt,
133 derivative, mixture, or preparation of the plant or its seeds or resin. Usable whole flower marijuana is not considered
134 a derivative product.

135 ~~(42)~~ Written Notice – Notice sent via email to the MMTC’s email address of record if the notice is intended for
136 the MMTC, or notice sent via email to OMMU at OMMULicenseOperation@flhealth.gov if the notice is intended for
137 the department, unless another means of written notice is specified by rule or statute.

138 *Rulemaking Authority 381.986(8)(b) FS. Law Implemented 381.986 FS. History—New 6-17-15, Amended 9-19-18, XX-*
139 *XX-21.*

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