

PRELIMINARY TEXT

THE PRELIMINARY TEXT OF THE RULE IS:

64-4.206 Low-THC and Medical Marijuana Packaging and Labeling.

(1) All usable product shall be placed inside of a receptacle at the MMTC's department-approved processing facility. Receptacles shall be placed inside of a package with a patient package insert that complies with subsection (2) of this rule before the usable product is dispensed by an MMTC.

(2) The package for every usable product shall include a patient package insert intended for the patient or caregiver that provides the information required by s. 381.986(8)(e)12., F.S., and no additional information, except that the patient package insert may include the information identified in subsection (8).

(3) Before dispensing usable product in any receptacle and package, an MMTC must request and obtain department approval of the usable product, including the receptacle, label, and package, by submitting completed Form DH8029-OMMU-XX/2022 "Request for Usable Product and Packaging," incorporated by reference herein and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>, with applicable documentation, as specified in the request form, to the department.

(4) Receptacles for all usable products shall comply with the following:

(a) The receptacle shall be child-resistant. In the case of multiple-use usable products and multi-serving edibles, the receptacle shall be resealable such that it continues to be child-resistant after each use or serving.

(b) The receptacle, including the label, shall bear only the information required or permitted by s. 381.986(8)(e)11.f., F.S., and this rule. Required or permissible information shall be legibly printed directly on the receptacle or label. An MMTC may affix multiple labels to the receptacle as needed to convey required or permissible information. Labels may be accordion, expandable, extendable, or layered to permit labeling of small receptacles if all required information is unobstructed. All labels must be placed on the outside of the receptacle.

(c) All required information on the receptacle, including the label, shall be prominently and conspicuously placed on the outside of the receptacle.

(d) The universal symbol on every receptacle, or label, shall be red, at least ¼ inch wide and ¼ inch high, and placed on the outer layer of any receptacle labeling.

(e) The receptacle, or label, must include the MMTC's department-approved logo. The MMTC's department-approved logo may be displayed in the colors approved by the department or in grayscale.

29 (f) For the purposes of this rule, a Quick Response (QR) code, or similar barcode or smart code, and Product
30 Stock-Keeping Unit (SKU), barcode, or other similar product identifiers, shall not be considered graphics or images.

31 1. The receptacle or label must include a QR code, or similar barcode or smart code, that allows a patient to access
32 the usable product's certificate of analysis and information related to the usable product being dispensed, provided
33 that the information conveyed is information that is permitted to appear on the receptacle, package, or patient package
34 insert. Upon request of a patient or caregiver, an MMTC shall provide paper copies of the information available
35 pursuant to this subparagraph.

36 2. The receptacle, or label, may include a SKU, barcode, or other similar product identifiers.

37 (g) The receptacle, or label, may include instructions, health information, warnings and precautions, the MMTC's
38 contact information, and the MMTC's department-approved website. The receptacle must not include any depictions,
39 including words or images, of the usable product. An MMTC shall not include unsubstantiated health claims that the
40 usable product cures or treats any medical condition or disease.

41 (5) In addition to the requirements of subsection (4), receptacles for usable product, excluding edibles and
42 marijuana in a form for smoking, shall comply with the following:

43 (a) The receptacle shall be colorless or one single, solid color, which may be translucent, clear, or opaque. The
44 single, solid color shall not be neon. The lid of a receptacle shall be white, black, or the same single, solid color as the
45 receptacle.

46 (b) Any label shall be printed on a solid, white background.

47 (c) The text on the receptacle shall be black or white. The text on the label must be black. The label may also have
48 one additional text color (not including the MMTC's department-approved logo, any approved brand partner or
49 MMTC brand logo pursuant to paragraph (4)(e), the universal symbol, and text) that distinguishes the product strain
50 type (i.e., indica, sativa, hybrid). The additional text color shall not be neon.

51 (d) The receptacle may include a brand partner name and logo or MMTC brand name and logo if the name and
52 logo comply with requirements set forth in Emergency Rule 64ER22-2, "MMTC Trade Name and Logo."

53 (6) In addition to the requirements of subsection (4), receptacles and wrapping for edibles shall comply with the
54 following:

55 (a) The receptacle, including the label, shall be plain, opaque, and white.

56 (b) The receptacle shall include the following:

57 1. A list of all the edible's ingredients in order of prominence which uses the common or usual name of food
58 ingredients and identifies major allergens in accordance with the Food Allergen Labeling and Consumer Protection
59 Act of 2004, Public Law 108-282, Title II (effective 8/2/2004), which is incorporated by reference and available at
60 <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXXX>;

61 2. Storage instructions;

62 3. An expiration date;

63 4. A legible and prominent warning to keep away from children and pets; and

64 5. A warning stating that the edible has not been produced or inspected pursuant to federal food safety laws.

65 (c) Each edible shall be individually sealed in plain, opaque, and white wrapping. For the purposes of this
66 paragraph, plain shall mean an opaque, white wrapper marked only with the universal symbol, which shall be red.

67 1. Any edible dispensed as a single-serving portion shall be individually wrapped and placed inside of the
68 receptacle.

69 2. Multi-serving lozenges, gelatins, and chocolates may be wrapped as single-serving portions or together as a
70 multi-serving edible and placed inside of the receptacle.

71 3. Each single-serving portion of a multi-serving baked good shall be individually wrapped and placed inside of
72 the receptacle.

73 4. Each single-serving portion of a multi-serving drink powder shall be individually wrapped and placed inside
74 of the receptacle.

75 (7) In addition to the requirements of subsection (4), receptacles for usable products in a form for smoking shall
76 comply with the following:

77 (a) The receptacle, including the label, shall be plain, opaque, and white.

78 (b) The receptacle shall include the following:

79 1. A legible and prominent warning to keep the product away from children; and

80 2. A warning stating that marijuana smoke contains carcinogens and may negatively affect health.

81 (c) The potency of usable product in a form for smoking must be reported on the receptacle label as the CMTL-
82 tested moisture content.

83 (8) Packages for all usable products may include the following permissive information:

84 (a) The MMTC's department-approved logo;

85 (b) Any information required by s. 381.986(8)(e)11.f. and 12., F.S.;

86 (c) A QR code, or similar barcode or smart code, that allows a patient to access the usable product's certificate of
87 analysis and information related to the usable product being dispensed, provided that the information conveyed is
88 information that is permitted to appear on the receptacle label, package, or patient package insert. Upon request of a
89 patient or caregiver, an MMTC shall provide paper copies of the information available pursuant to this paragraph.

90 (d) SKU, barcode, or other similar product identifiers; and

91 (e) Instructions, health information, warnings and precautions, the MMTC's contact information, and the
92 MMTC's department-approved website. An MMTC shall not include unsubstantiated health claims that the usable
93 product cures or treats any medical condition or disease.

94 (9) Packages for usable products, excluding edibles and marijuana in a form for smoking, shall comply with the
95 following:

96 (a) A package shall be one single, solid color and may have one additional accent color (not including the
97 MMTC's department-approved logo, any approved brand partner or MMTC brand logo pursuant to paragraph (4)(e),
98 the universal symbol, and text). The single, solid color and the additional accent color shall not be neon.

99 (b) The text on a package shall be a single, solid color which shall not be neon.

100 (c) The package may include a brand partner name and logo or MMTC brand name and logo if the name and logo
101 comply with requirements set forth in Emergency Rule 64ER22-2, "MMTC Trade Name and Logo."

102 (d) The universal symbol shall be red, printed on or firmly affixed on the package, and no less than ¼ inch by ¼
103 inch.

104 (e) The package shall identify every ingredient, in order of prominence, unless the ingredients are identified on
105 the receptacle or patient package insert.

106 (10) Packages for edibles and marijuana in a form for smoking shall comply with the following:

107 (a) The package shall be plain, opaque, and white.

108 (b)The universal symbol shall be red, printed or firmly affixed on the package, and no less than ¼ inch by ¼ inch.

109 (11) Notwithstanding the foregoing, this rule shall not preclude an MMTC from including information on a
110 receptacle label, or package that is otherwise required by law or rule.

111 (12) All new packaging and labeling must immediately comply with the requirements of this rule and be approved
112 pursuant to subsection (3). An MMTC shall have six months from the effective date of this rule to comply with the

113 requirements herein for previously approved packaging and labeling. At the end of the six-month period, an MMTC
114 shall be prohibited from using any packaging and labeling that does not comply with this rule.

115 (13) This rule shall be reviewed, and if necessary, repealed, modified, or renewed through the rulemaking process
116 five years from the effective date.

117 Rulemaking Authority Art. X, § 29, Fla. Const., 381.986(8)(k), 381.986(10)(h), 381.0011(1), 381.0011(2),
118 381.0011(7), FS. Law Implemented Art. X, § 29, Fla. Const., 381.986(8)(e), 381.0011(1), 381.0011(2), 381.0011(7)

119 FS. History-New.

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