

PRELIMINARY TEXT

THE PRELIMINARY TEXT OF THE PROPOSED 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 (10) of this rule before the usable product is dispensed by an MMTC.

(2) Before dispensing usable product in any receptacle and package, an MMTC shall comply with the procedure in Rule 64-4.023, F.A.C., to obtain department approval of the use of the receptacle, label, and package.

(3) 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 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 on the 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 as long as all required information is unobstructed.

(c) All required information on the receptacle shall be prominently and conspicuously placed thereon.

(d) The universal symbol on every receptacle 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 may include a Quick Response (QR) code, or similar bar code or smart code that allows a patient to access the usable product's certificate of analysis and information related to the usable product being dispensed, provided that the information conveyed is information that is permitted to appear on the receptacle, package, or patient package insert. Upon request of a patient or caregiver, an MMTC shall provide paper copies of the information available pursuant to this paragraph.

(f) The receptacle may include a Product Stock-Keeping Unit (SKU), barcode, or other similar product identifier.

(h) The receptacle may include instructions, health information, warnings and precautions, the MMTC's contact information, and the MMTC's website. An MMTC shall not include unsubstantiated claims that the usable product cures any medical condition.

29 (4) In addition to the requirements of subsection (3), receptacles for derivative products that are not edibles shall
30 comply with the following:

31 (a) The receptacle shall be one single solid color or clear and may have one additional accent color (not including
32 the MMTC's department-approved logo, any approved brand partner or MMTC brand logo pursuant to paragraph
33 (4)(c), the universal symbol, and text). The single solid color and the additional accent color shall not be neon. Where
34 applicable, the lid of a receptacle shall be the same single solid color as the receptacle or white.

35 (b) Any label shall be printed on a solid white background. The text on the receptacle and label shall be a single
36 solid color which shall not be neon.

37 (c) The receptacle may include a brand partner name and logo or MMTC brand name and logo if the name and
38 logo:

39 1. Do not contain wording or images commonly associated with marketing targeted towards children or which
40 promote or imply the recreational use of marijuana; and

41 2. Are approved by the department pursuant to the variance request procedure required by subsection (2).

42 (5) In addition to the requirements of subsection (3), receptacles and wrapping for edibles shall comply with the
43 following:

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

45 (b) The receptacle shall include the following:

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

50 2. Storage instructions;

51 3. An expiration date;

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

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

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

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

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

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

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

64 (6) In addition to the requirements of subsection (3), receptacles for usable products in a form for smoking shall
65 comply with the following:

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

67 (b) The receptacle shall include the following:

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

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

70 (7) Packages for derivative products that are not edibles shall comply with the following:

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

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

75 (c) The package may include a brand partner name and logo or MMTC brand name and logo subject to the
76 requirements of subparagraphs (4)(c)1. and 2.

77 (d) The universal symbol shall be red, printed on or firmly affixed on the package, and no less than 10 percent of
78 the overall surface area of the package.

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

81 (8) Packaging for edibles and marijuana in a form for smoking shall comply with the following:

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

83 (b)The universal symbol shall be red, printed or firmly affixed on the package, and no less than 10 percent of the
84 overall surface area of the package.

85 (9) Packaging for all usable products may include the following permissive information:

86 (a) The MMTC’s department-approved logo;

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

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

93 (d) Product Stock-Keeping Unit (SKU), barcode, or other similar product identifier;

94 (f) Instructions, health information, warnings and precautions, the MMTC’s contact information, and the
95 MMTC’s website. An MMTC shall not include unsubstantiated claims that the usable product cures any medical
96 condition.

97 (10) The package for every usable product shall include a patient package insert intended for the patient or
98 caregiver that provides the information required by s. 381.986(8)(e)12., F.S., and no additional information, except
99 that the patient package insert may include the information identified in subsection (9).

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

102 (12) Prior to December 31, 2026, the department shall review this rule and amend, modify or repeal the rule if it
103 is determined to create barriers to entry for private business competition, is duplicative, outdated, obsolete, overly
104 burdensome, or imposes excessive costs. In the event the department fails to complete this rule review, the department
105 shall begin the rule repeal process in accordance with chapter 120, F.S.

106 *Rulemaking Authority 381.986(8)(k), 381.986(10)(h), 381.0011(1), 381.0011(2), 381.0011(7), FS. Law Implemented*
107 *381.986(8)(e), 381.0011(1), 381.0011(2), 381.0011(7) FS. History-New.*