

Alert | Florida Administrative & Regulatory Law



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Florida Department of Health/Office of Medical Marijuana Use Publishes Emergency Rules Allowing MMTCs to Produce Edibles

Three years after the Florida legislature revised section 381.986, Florida Statutes, and provided the Department of Health (Department) authority to “determine by rule any shapes, forms, and ingredients allowed and prohibited for edibles” (*see section 381.986(8)(e)8., Florida Statutes*), on Aug. 28, 2020, the Department’s Office of Medical Marijuana Use (OMMU) published emergency rules to provide standards for licensed medical marijuana treatment centers (MMTCs) to produce, package, label, and be authorized to dispense edible medical marijuana derivative products. The emergency rules are effective immediately upon publication, and are valid for 90 days, during which time OMMU may take steps to promulgate permanent rules, which may be substantially similar to, if not identical to, the emergency rules.

The emergency rules provide as follows:

- **64ER20-31** (amending 64-4.001) provides definitions (including the new definition of “Edible”);
- **64ER20-32** (Packaging and Labeling) provides detail as to the packaging and labeling of edibles (referencing a new “universal symbol” to be applied to all edible products; *see the new symbol*, which consists of a red diamond with an exclamation point atop the letters “THC”) and additionally revises packaging and labeling for other MMTC derivative products;

- **64ER20-33** (Standards for Production of Edibles), provides detail as to shapes, colors, dosage, directing that the edible products not “contain any color additives, whether natural or artificial,” restricting products that “are a primary or bright color,” and requiring production “in a manner to minimize color intensity and other color and visual characteristics attractive to children,” among other restrictions. Additionally, approved edibles cannot contain additives that could increase potency or toxicity, or any psychoactive substance such as nicotine, alcohol, or caffeine. Accordingly, THC-infused nicotine products or alcoholic beverages will not be permitted.

Licensed Florida MMTCs that plan to produce edibles must also comply with all requirements for food establishments in Chapter 500, Fla. Stat., and any rules adopted by the Florida Department of Agriculture and Consumer Services (FDACS) pursuant to that chapter. FDACS published rules for the production of MMTC edible products as early as March 16, 2020 (see FDACS Rules **5k-11.001**, **5k-11.002**, **5k11.003**, **5k11-004**, **5k-11005**), although by statute the FDACS’ rules were subject to and dependent upon the Department issuing its own rules for the MMTC production of edibles, which have now been published.

Section (3) of the new **Rule 64ER20-33**, Standards for Production of Edibles, requires MMTCs to first comply with the variance procedures in Rule 64-4.023, to obtain Department approval of the edible. This requirement applies to each edible product the MMTC intends to produce and dispense. The variance request must demonstrate that the proposed edible, including its packaging and labeling, complies with section 381.986, Florida Statutes, and Department rules (and prior compliance with the FDACS edibles rules discussed above).

As of Aug. 28, 2020, OMMU had issued 22 MMTC licenses and reported over 400,000 qualified patients.

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