

Alert | Florida Administrative & Regulatory Law



November 2020

Florida Department of Health Issues 5 Notices of Emergency Rules Related to Medical Marijuana Treatment Centers

In November 2020 the Florida Department of Health released 5 significant emergency rules related to Medical Marijuana Treatment Centers (MMTCs). This GT Alert summarizes the emergency rules.

Emergency Rule 64ER20-35 sets Standards for the Production of Edibles. The emergency rule repeals and replaces 64ER20-33, F.A.C., and describes the standards for production of edibles by MMTCs, including the shapes and forms of permissible edibles, prohibited ingredients, and sanitation requirements. The rule clarifies the applicability of Chapter 500, F.S. from the Department of Agriculture and Consumer Services to the production of edibles and that a MMTC's processing facility, including the area where edibles will be produced, must be accredited by a national certifying body that has passed a Food Safety Good Manufacturing Practices inspection. The rule further requires MMTCs to submit a picture or detailed depiction of the proposed edible bearing the **universal symbol**, and the measurements of the edible. The rule restricts the shape and form of edibles, as well as caps the THC levels for edibles at a potency variance of up to 15% from the 200-milligram and 10-milligram THC thresholds.

Emergency Rule 64ER20-36 creates Regulatory Compliance Testing Standards for MMTCs. The emergency rule requires MMTCs to contact a Certified Marijuana Testing Laboratory (CMTL) and arrange for the CMTL to select and collect a random and representative sample of Final Product from every Retail Batch for regulatory compliance testing from an MMTC's department-approved processing facility or

department-approved fulfillment and storage facility. The rule provides procedures that MMTCs must follow if they receive a failed Certificate of Analysis from a CMTL due to Contaminants Unsafe for Human Consumption. The rule allows an MMTC to arrange for a previously failed Retail Batch to be resampled and retested by a CMTL.

Emergency Rule 64ER20-37 establishes procedures for an MMTC to remediate a Retail Batch that initially fails regulatory compliance testing. The rule establishes that Usable Whole Flower Marijuana that fails regulatory compliance testing may be remediated through processing to create Derivative Product. Usable Whole Flower Marijuana that fails regulatory compliance testing due to Water Activity or Moisture Content may also be remediated by subjecting the Retail Batch to additional drying or curing. Derivative Products, excluding Edibles, that fail regulatory compliance testing for Heavy Metals or Agricultural Agents must be disposed of in accordance with the MMTC Marijuana Waste Management and Disposal rule. Derivative Products, excluding Edibles, that fail regulatory compliance testing for Residual Solvents, Microbes, or Mycotoxins may be remediated through further processing. Edibles that fail regulatory compliance testing for any reason may not be remediated and must be disposed of in accordance with the MMTC Marijuana Waste Management and Disposal rule. The rule requires all remediated products to undergo and pass regulatory compliance testing in accordance with the MMTC Regulatory Compliance Testing rule as a new Retail Batch.

Emergency Rule 64ER20-38 establishes procedures for CMTLs to follow when sampling, tracking, transporting, and storing samples from MMTCs. The rule requires a CMTL to collect a random and representative sample of Final Product from every Retail Batch for regulatory compliance testing and follow a field sampling protocol approved under the scope of ISO 17025 accreditation. A CMTL must develop and implement a chain of custody protocol to ensure accurate documentation is recorded for the transport, handling, storage, and destruction of samples. The CMTL must homogenize all Final Products into one Testing Sample for each Retail Batch sampled, except in the case of homogeneity testing of edibles. A minimum of three (3) Final Products must be sampled from each Retail Batch. While transporting samples collected from an MMTC, a CMTL must ensure the samples are not visible to the public. Samples must be locked in a fully enclosed box, container, or cage that is secured to the inside of the vehicle used for transport.

Emergency Rule 64ER20-39 repeals and replaces 64ER20-9, F.A.C., and provides the acceptable limits and testing requirements to be applied by CMTLs when conducting regulatory compliance testing of Final Products from MMTCs. The rule requires CMTLs to test Final Products for tetrahydrocannabinol potency, concentration of cannabidiol, and Contaminants Unsafe for Human Consumption. Contaminants Unsafe for Human Consumption include Microbes, Mycotoxins, Residual Solvents, Heavy Metals, Agricultural Agents, and Filth and Foreign Material. The rule provides acceptable limits for certain contaminants that may be found in testing. The rule also requires CMTLs to maintain at least one sterile untested portion of each Testing Sample, whether having passed or failed any testing. These Testing Samples must be securely stored for a minimum of 45 days before being destroyed. Every Testing Sample that is destroyed must be logged by the CMTL. Testing Samples that have been stored a minimum of 45 days may be used by the CMTL for in-house method development and validation prior to being destroyed.

Authors

This GT Alert was prepared by:

- [David C. Ashburn](#) | +1 850.425.8550 | ashburnd@gtlaw.com

- Fred E. Karlinsky | +1 954.768.8278 | karlinskyf@gtlaw.com
- Timothy F. Stanfield | +1 850.222.6891 | stanfieldt@gtlaw.com

Albany. Amsterdam. Atlanta. Austin. Boston. Chicago. Dallas. Delaware. Denver. Fort Lauderdale. Germany. ~ Houston. Las Vegas. London.* Los Angeles. Mexico City.+ Miami. Milan.* Minneapolis. New Jersey. New York. Northern Virginia. Orange County. Orlando. Philadelphia. Phoenix. Sacramento. Salt Lake City. San Francisco. Seoul.∞ Shanghai. Silicon Valley. Tallahassee. Tampa. Tel Aviv.^ Tokyo.* Warsaw.~ Washington, D.C.. West Palm Beach. Westchester County.

*This Greenberg Traurig Alert is issued for informational purposes only and is not intended to be construed or used as general legal advice nor as a solicitation of any type. Please contact the author(s) or your Greenberg Traurig contact if you have questions regarding the currency of this information. The hiring of a lawyer is an important decision. Before you decide, ask for written information about the lawyer's legal qualifications and experience. Greenberg Traurig is a service mark and trade name of Greenberg Traurig, LLP and Greenberg Traurig, P.A. ~Greenberg Traurig's Berlin office is operated by Greenberg Traurig Germany, an affiliate of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. *Operates as a separate UK registered legal entity. +Greenberg Traurig's Mexico City office is operated by Greenberg Traurig, S.C., an affiliate of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. »Greenberg Traurig's Milan office is operated by Greenberg Traurig Santa Maria, an affiliate of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. ∞Operates as Greenberg Traurig LLP Foreign Legal Consultant Office. ^Greenberg Traurig's Tel Aviv office is a branch of Greenberg Traurig, P.A., Florida, USA. ¢Greenberg Traurig's Tokyo Office is operated by GT Tokyo Horitsu Jimusho and Greenberg Traurig Gaikokuhojimubengoshi Jimusho, affiliates of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. ~Greenberg Traurig's Warsaw office is operated by Greenberg Traurig Grzesiak sp.k., an affiliate of Greenberg Traurig, P.A. and Greenberg Traurig, LLP. Certain partners in Greenberg Traurig Grzesiak sp.k. are also shareholders in Greenberg Traurig, P.A. Images in this advertisement do not depict Greenberg Traurig attorneys, clients, staff or facilities. No aspect of this advertisement has been approved by the Supreme Court of New Jersey. ©2020 Greenberg Traurig, LLP. All rights reserved.*