OMMU Office of MEDICAL MARIJUANA Use

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Meeting Minutes
Department of Health
Office of Medical Marijuana Use
Rules Workshop
Online Meeting/Teleconference Call
January 20, 2021
9:00 a.m. ET

Florida HEALTH

DEPARTMENT OF HEALTH
OFFICE OF MEDICAL MARIJUANA USE
RULES WORKSHOP
January 20, 2021
9:00 a.m. ET
Call-In Number: (877) 309-2073
Conference Code: 663-694-157(#)
Link: GoToMeeting

Participants in this public workshop should be aware that these proceedings are being recorded and that an audio file of the workshop will be posted to the Office of Medical Marijuana Use (OMMU) website.

I. WELCOME AND MEETING OVERVIEW

The meeting was called to order by Director Christopher Ferguson at 9:00a.m. ET.

Mr. Ferguson welcomed all participants to the meeting and thanked them for their attendance. Those present during the meeting included the following:

Office of Medical Marijuana Use
Christopher Ferguson, Director
Lindsay Granger, Regulatory Compliance Manager
Breanne Ereckson, Rulemaking and Research Coordinator

Office of General Counsel
Alysson Bradley, Chief General Counsel

Mr. Ferguson provided a brief overview of the program and of today's proceedings. The OMMU is charged with writing and implementing the department's rules for medical marijuana, overseeing the statewide Medical Marijuana Use Registry, and licensing Florida businesses to cultivate, process, and dispense medical marijuana to qualified patients.

Each rule will be reviewed independently and, in the order dictated on the agenda. To ensure meeting efficiency, all lines have been muted and the chat feature has been disabled on the online forum for all participants. After the OMMU has presented the proposed rules, all participants will have an opportunity to provide public comment. Participation instructions will be provided to attendees at that time.

II. RULES DISCUSSION

The OMMU has published notices of rule development in the Florida Administrative Register (FAR) for all rules being discussed today.

A. 64-4.001 Definitions

This rule is being amended to provide additional definitions necessary for clarification and interpretation of the rules relating to medical marijuana treatment centers (MMTCs).

Mr. Ferguson opened the floor for public comment on the rule.

Dan Russell, representing Dean Meade, inquired about the possibility of the OMMU creating a specific, standardized patient package insert template and providing said template to the MMTCs to use as guidance.

In an effort to minimize background noise, Ms. Bradley reminded all callers to mute their lines if they are not speaking. She also acknowledged Mr. Russell and stated that patient package inserts are specific to each MMTC and its related products. The OMMU has not previously considered creating a standardized patient package insert template but will certainly take Mr. Russell's suggestion into consideration.

James Horvath, representing Kaycha Labs, addressed the OMMU and inquired about the term "lozenge." The OMMU defines "lozenge" as an edible, which would dictate that a lozenge would need to be homogenized during testing.

Ms. Bradley stated that the term "lozenge" was defined in Rule 64-4.205, F.A.C. Mr. Horvath's question will be addressed at that time.

Ron Watson, representing AltMed, addressed the OMMU and inquired about the differences between the proposed Rule 64-4.001, F.A.C., and its emergency rule counterpart 64ER20-31. Mr. Watson also asked if a brief summary of changes between the proposed rule texts and the emergency rules would be provided to attendees throughout the meeting.

Mr. Ferguson acknowledged Mr. Watson and confirmed that Ms. Bradley would summarize this information for attendees. Ms. Bradley further elaborated on the changes between Rule 64-4.001, F.A.C., and emergency rule 64ER20-31, F.A.R.

- For the term "plain," the definition specifies that the lettering must be on a solid white background.
    - Lines 109-110: "(32) Plain – Black, print lettering, in a sans-serif font, and ***on a solid white background*** (emphasis added) with no pictures or graphics other than one image of the MMTC's department-approved logo and the universal symbol."
- For the term "patient package insert," the definition clarifies that the patient package insert must be provided on a slip of paper.
    - Lines 107-108: "(31) Patient package insert – The ***slip of paper*** (emphasis added) provided to a qualified patient or caregiver inside of the package of every usable product that contains the information required by s. 381.986(8)(e)12., F.S."

Zachary Kobrin, representing Ackerman LLP, addressed the OMMU and inquired if any consideration has been given to authorizing an MMTC to use a QR code in lieu of a paper patient package insert. Mr. Ferguson explained that a slip of paper better meets the patient package insert requirements set forth in s. 381.986(8)(e)12., F.S.

Mr. Kobrin asked if it would be permissible for an MMTC to use both a QR code and slip of paper package insert. Mr. Ferguson confirmed that this would be allowable.

Cynthia Brewer, representing Kaycha Labs on behalf of James Horvath, inquired about the determination of expiration dates for usable products by an MMTC. Ms. Bradley stated that, as written, the MMTC would need to determine this information based on tests and information.

Ms. Brewer asked if there was guidance on the types of tests performed by a certified marijuana testing laboratory (CMTL) to determine this information. Mr. Ferguson stated that there is not a specific test that the CMTLs would need perform. The expiration date is determined solely by the MMTCs.

Mr. Watson inquired about recycling paper package inserts, meaning that a paper package insert may be returned to an MMTC for use by multiple patients. Mr. Ferguson acknowledged Mr. Watson and stated that the OMMU would consider this information.

Ms. Bradley clarified that the intent of a patient package insert is for the patient to always have access the information contained therein.

Grant Schuster addressed the OMMU and commented on the plain packaging requirement. Mr. Schuster indicated that it may be difficult for a patient to confirm that he or she is taking the correct dosage and product if there is no differentiation in packaging color. Mr. Ferguson thanked Mr. Schuster for his comment.

Mr. Kobrin requested clarification on whether a patient package insert must be located directly inside the package. Mr. Kobrin further inquired if it would be permissible for the patient package insert to be provided separately to patient rather than located directly inside the package.

Ms. Bradley confirmed that s. 381.986(8)(e)12., F.S., requires the patient package insert be included in each package. Ms. Bradley clarified that patient package inserts included in the box or bag the receptacle comes in would also be permissible.

Mr. Ferguson presented the universal symbol and reiterated that any modifications made to the universal symbol by MMTCs are not permissible.

There being no further discussion on the proposed rule text for Rule 64-4.001, F.A.C., Mr. Ferguson continued the meeting and introduced the proposed rule text for Rule 64-4.013, F.A.C.

B. 64-4.013 Pesticide Use on Medical Marijuana

This rule is being amended to add to existing requirements for certain pesticides registered with the U.S. EPA. The new requirements include that the pesticide product label must expressly have directions for use on unspecified crops or unspecified plants, must expressly have directions for use on crops or plants intended for human consumption, and the active ingredient(s) in such pesticide are allowed for use on tobacco by the U.S. EPA.

Mr. Ferguson opened the floor for public comment on the rule.

Devon Nunneley, representing the Lockwood Law Firm, addressed the OMMU and inquired if the OMMU was planning on establishing a list of approved pesticides. Mr. Ferguson acknowledged Ms. Nunneley's comment and indicated that the OMMU has not discussed establishing a list this at this time.

Ms. Bradley also communicated that it may be difficult to incorporate this information into rule because the list of approved pesticides may need to be updated quite frequently based on new research/information. However, Ms. Bradley indicated that the OMMU will certainly consider Ms. Nunneley's recommendation.

Mr. Russell expressed support of Ms. Nunneley's comment.

Gabriel Harris addressed the OMMU and requested a summary of the changes to the rule. Ms. Bradley provided a summary of the proposed changes.

There being no further discussion on the proposed rule text for Rule 64-4.013, F.A.C., Mr. Ferguson continued the meeting and introduced the proposed rule text for Rule 64-4.201, F.A.C.

C. 64-4.201 Renewal Application Requirements for MMTCs

This rule establishes the requirements for renewal of medical marijuana treatment center licenses. The rule adopts the renewal form and instructions.

Mr. Ferguson opened the floor for public comment on the rule.

Ms. Nunneley addressed the OMMU and offered the suggestion of measuring an MMTC's renewal date from the license issue date rather than establishing a blanket expiration date.

Ms. Nunneley also commented on the proposed renewal application form, particularly the section on certified financials. Ms. Nunneley expressed that many MMTCs are now publicly traded in Canada; therefore, Ms. Nunneley suggested expanding the permitted certifying bodies allowing an MMTC to also submit consolidated financial statements.

Mr. Ferguson thanked Ms. Nunneley for her suggestions.

Mr. Kobrin addressed the OMMU and inquired about the rationale behind not permitting an MMTC to submit a variance request as part of the renewal process. Mr. Ferguson expressed that the variance process and renewal process are separate; therefore, each has a different procedure.

Mr. Watson addressed the OMMU and inquired about the differences between the proposed Rule 64-4.201, F.A.C., and its emergency rule counterpart 64ER19-8.

Ms. Bradley confirmed that subsection (4) of the emergency rule was updated in the proposed text to reflect the current year and that the title of the application form was amended; there are no other substantive changes between the two rules.

There being no further discussion on the proposed rule text for Rule 64-4.201, F.A.C., Mr. Ferguson continued the meeting and introduced the proposed rule text for Rule 64-4.205, F.A.C.

D. 64-4.205 Standards for Production of Edibles

This rule implements section 381.986(8)(e)8., F.S., by establishing the standards for production of edibles by medical marijuana treatment centers, including any shapes, forms, and ingredients allowed and prohibited for edibles. This rule ensures that the consumption of edibles by children is discouraged.

Mr. Ferguson opened the floor for public comment on the rule.

TJ Morton, representing the Lockwood Law Firm, addressed the OMMU and suggested that the OMMU consider adding a catchall phrase, e.g. “other similar geometric shapes,” to the rule regarding the permissible shapes of edibles. Many MMTCs are interested in creating edibles that are dome-shaped, which is not listed as permissible edible shape in the current rule language.

Mr. Morton also commented on the prohibition on edibles being primary colors and expressed support for the removal of this prohibition.

Mr. Ferguson thanked Mr. Morton for his comments.

Ms. Nunneley addressed the OMMU and suggested that the imprint requirement for gelatin edibles be removed or designated as impractical. Ms. Nunneley also commented on unflavored drink powders. Ms. Nunneley suggested categorizing unflavored drink powders as a sublingual route of administration rather than as an edible. Ms. Nunneley further suggested the inclusion of a fruit or nut ingredient in chocolate edibles so long as the addition of the ingredient does not change the shape or appearance of the product. Ms. Nunneley also inquired about including ready-to-drink beverages in the edibles rule.

Mr. Ferguson thanked Ms. Nunneley for her comments.

William Spicola, representing Surterra, addressed the OMMU and sought additional clarification on liquid routes of administration, whether it be sublingual drops or ready-to-drink beverages.

Mr. Ferguson acknowledged Ms. Nunneley and Mr. Spicola’s comments on ready-to-drink beverages and provided clarification. Mr. Ferguson reiterated that the OMMU is a conservative medical program and its goal is to minimize the attractiveness of products to children.

Tim Gunther, representing I Love Compliance, addressed the OMMU. Mr. Gunther inquired about the nationally certifying bodies referenced in lines 18-20 of the proposed rule text, reiterated Ms. Nunneley’s

comment on placing the universal symbol on gelatins, and requested clarification on edibles containing or bearing a reasonable resemblance to commercially available candy.

Mr. Ferguson acknowledged Mr. Gunther's comments and provided clarification. Ms. Bradley further supplied additional clarification on Mr. Gunther's comment regarding edibles containing or bearing a reasonable resemblance to commercially available candy.

Mr. Horvath addressed the OMMU and inquired if homogeneity is required for the testing of lozenges. Mr. Ferguson confirmed that lozenges must be homogenized prior to testing. Mr. Horvath also sought to confirm that is not the responsibility of the CMTLs to determine a product's expiration date. Mr. Ferguson reiterated that a product's expiration date is to be determined by an MMTC.

Mr. Kobrin addressed the OMMU and inquired about the differences between the proposed Rule 64-4.205, F.A.C., and its emergency rule counterpart 64ER20-35. Ms. Bradley confirmed that the proposed rule text is fairly similar to the emergency rule.

Mr. Watson addressed the OMMU and inquired if specific colors of edibles are prohibited in statute. Ms. Bradley indicated that while this is not specifically required in statute, it is important to minimize the attractiveness of these products to children. Mr. Watson expressed support for Mr. Morton's suggestion regarding the removal of the prohibition on edibles being primary colors.

There being no further discussion on the proposed rule text for Rule 64-4.205, F.A.C., Mr. Ferguson continued the meeting and introduced the proposed rule text for Rule 64-4.206, F.A.C.

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

This rule establishes the packaging and labeling requirements for low-THC cannabis and medical marijuana products dispensed by medical marijuana treatment centers to ensure the protection of the public by preventing unlawful use.

Ms. Bradley summarized the proposed changes between the proposed rule text and its emergency rule counterpart 64ER20-32. The proposed changes are as follows:

- Adds a provision to allow QR codes on the receptacles for all products;
- Adds a provision to allow a SKU or similar product identifier on receptacles for all products;
- Permits an MMTC's contact and website information to be included on receptacles of all products;
- Permits an accent color on the receptacles for derivative products;
- Clarifies labeling requirements for receptables for derivative products. The label must be firmly affixed and white. The text on receptacles for derivative products must be a single, solid color.
- Permits an MMTC's brand partner name on packages and receptacles for derivative products; and
- Clarifies that receptacles for usable whole flower and edible products must be plain, opaque and white, to include the label.

Mr. Ferguson opened the floor for public comment on the rule.

Mr. Morton addressed the OMMU and inquired if a QR code could be used in lieu of a patient package insert or if a QR code could be used in addition to the patient package insert. Mr. Ferguson clarified that the QR code could be supplied in addition to the patient package insert.

Mr. Morton suggested that a QR code sans paper patient package insert could be permissible based on the current statutory language. Mr. Morton recommended allowing a QR code card to be placed inside the package.

Mr. Ferguson thanked Mr. Morton for his comments and suggestions.

Ms. Nunneley addressed the OMMU and echoed Mr. Morton's suggestion to allow a QR code card be placed inside a package in lieu of a patient package insert.

Ms. Nunneley further expressed concern over the universal symbol size requirement on the receptacle. Ms. Nunneley requested guidance on the wording or images associated with marketing towards children and expressed that basic food description words should be permissible.

Mr. Ferguson thanked Ms. Nunneley for her comments.

Mr. Spicola addressed the OMMU and provided a suggestion regarding allowing educational or informational iconography on packaging.

Mr. Watson addressed the OMMU and requested an explanation of changes made to the firmly affixed label requirement for receptacles. Ms. Bradley stated that the required information could be printed directly on the receptacle or on the label.

Mr. Watson sought additional clarification on packaging colors and statutory requirements. Ms. Bradley provided clarification and stated that the decision to require a package be plain, opaque, and white was made to protect the health and safety of qualified patients and is consistent with legislature's intent.

Christine Senne, representing Fluent, addressed the OMMU. Ms. Senne stated that she understands the OMMU's rationale for the package color requirements; however, she expressed concern over all product packaging being the same color.

Mr. Ferguson thanked Ms. Senne for her comments.

There being no further discussion on the proposed rule text for Rule 64-4.206, F.A.C., Mr. Ferguson continued the meeting and introduced the proposed rule text for Rule 64-4.207, F.A.C.

F. 64-4.207 Marijuana Waste Management and Disposal

This rule implements section 381.986(8)(e)11.c., F.S., by establishing procedures for the storage, handling, transportation, management, and disposal of solid and liquid waste generated during marijuana production and processing by medical marijuana treatment centers.

Ms. Bradley summarized the proposed changes between the proposed rule text and its emergency rule counterpart 64ER20-16. Ms. Bradley indicated that the proposed rule text clarifies an MMTC's ability to transport marijuana waste between its approved facilities.

Mr. Ferguson opened the floor for public comment on the rule.

Ms. Nunneley addressed the OMMU and suggested permitting the use of composting facilities located in other states. Ms. Nunneley also inquired if an MMTC could be permitted to sanitize or reuse receptacles returned by patients.

Mr. Ferguson acknowledged Ms. Nunneley's comments and suggestion.

Mr. Morton addressed the OMMU and suggested that the "root ball" should be removed from the definition of plant material waste, indicating that root balls may be better suited with another method of disposal. Mr. Mr. Morton also sought clarification on the use of waste disposal vendors by an MMTC.

Mr. Ferguson acknowledged Mr. Morton's comments and suggestions.

There being no further discussion on the proposed rule text for Rule 64-4.207, F.A.C., Mr. Ferguson continued the meeting and introduced the proposed rule text for Rule 64-4.209, F.A.C.

G. 64-4.209 Low-THC and Medical Marijuana Solvent Based Extraction and Related Products

This rule implements section 381.986(8)(e)11.b., F.S., by establishing requirements for the processing of marijuana with hydrocarbon solvents or other solvents or gases exhibiting potential toxicity to humans by medical marijuana treatment centers. This rule will ensure the protection of the public's health.

Mr. Ferguson opened the floor for public comment on the rule.

Mr. Watson addressed the OMMU and inquired if there was an emergency rule promulgated on this topic. Ms. Bradley indicated that there is not currently an emergency rule published on this topic.

Bruce Vanaman, representing IRC Botanicals, addressed the OMMU and expressed concern over the use of hydrocarbon solvents.

Mr. Ferguson thanked Mr. Vanaman for this comment.

Mr. Ferguson informed attendees of the proposed Request for Inspection form and indicated that the submittal of this form is separate from the variance request process set forth in Rule 64-4.023, F.A.C.

There being no further discussion on the proposed rule text for Rule 64-4.209, F.A.C., Mr. Ferguson continued the meeting and introduced the proposed rule text for Rule 64-4.211, F.A.C.

H. 64-4.211 Supplemental Licensure Fee for MMTCs

This rule establishes the supplemental licensure fee required by s. 381.986(8)(b), F.S., and the process required for submittal of the fee.

Mr. Ferguson opened the floor for public comment on the rule.

Many participants indicated that they would be submitting written public comments to the OMMU on this rule.

There being no further discussion on the proposed rule text for Rule 64-4.211, F.A.C., Mr. Ferguson continued the meeting and introduced the proposed rule text for Rule 64-4.212, F.A.C.

I. 64-4.212 MMTC Regulatory Compliance Testing

This rulemaking initiates nonemergency rulemaking to replace the emergency rule 64ER20-36 adopted by the Department to implement section 381.986, Florida Statutes. Rule 64-4.212, F.A.C., establishes procedures for regulatory compliance testing of Final Products, including requirements for resampling and retesting of Retail Batches that fail regulatory compliance testing.

Ms. Bradley indicated there are not any substantive changes between the proposed rule text and its emergency rule counterpart.

Mr. Ferguson opened the floor for public comment on the rule

Ms. Nunneley addressed the OMMU and suggested that an MMTC should be able to request voluntary retesting even if a product does not necessarily fail testing.

Mr. Horvath addressed the OMMU and inquired about an MMTC's responsibility as it pertains to approved storage and processing facilities. Mr. Horvath also sought clarification on line 48 of the proposed rule regarding a retail batch failing testing due to potency label claims.

Mr. Ferguson acknowledged Ms. Nunneley and Mr. Horvath's comments and suggestions.

There being no further discussion on the proposed rule text for Rule 64-4.212, F.A.C., Mr. Ferguson continued the meeting and introduced the proposed rule text for Rule 64-4.213, F.A.C.

J. 64-4.213 MMTC Remediation

This rulemaking initiates nonemergency rulemaking to replace the emergency rule 64ER20-37adopted by the Department to implement section 381.986, Florida Statutes. Rule 64-4.213, F.A.C., establishes procedures for an MMTC to remediate a Retail Batch that initially fails regulatory compliance testing.

Ms. Bradley indicated there are not any substantive changes between the proposed rule text and its emergency rule counterpart.

Mr. Ferguson opened the floor for public comment on the rule

Mr. Horvath addressed the OMMU and inquired about the process for remediating a product that fails testing for water activity or moisture. The OMMU provided clarification on Mr. Horvath's question.

Mr. Vanaman addressed the OMMU and sought clarification on the remediation of CBD products. Ms. Bradley indicated that the OMMU regulates low-THC cannabis and medical marijuana and the proposed rule applies to these products; the Department of Agriculture and Consumer Services regulates hemp and hemp-related products.

Ms. Bradley addressed questions regarding the destruction of edibles that fail potency requirements and clarified that an edible that fails potency testing must be relabeled to accurately reflect potency. Ms. Bradley indicated that this process is not considered remediation and that remediation only applies to products that fail for contaminants unsafe for human consumption and water activity or moisture.

Ms. Senne addressed the OMMU and suggested adding the ability for MMTCs to remediate whole flower products that fail testing for microbials.

Mr. Horvath addressed the OMMU and suggested requiring MMTCs to provide label information to the CMTLs for all products.

Ms. Bradley indicated that while a potency label is not necessarily required, it must be accurate if it is provided for the product. Ms. Bradley further stated that potency testing is required regardless of if a label has been provided to the CMTL.

Mr. Ferguson expressed that the certificate of analysis and label for each product must match.

There being no further discussion on the proposed rule text for Rule 64-4.213, F.A.C., Mr. Ferguson continued the meeting to provide closing remarks.

III. CLOSING REMARKS AND ADJOURMENT

The OMMU will continue to accept public comments for the rules discussed today until 5:00 p.m. ET on Thursday, January 28, 2021. Individuals may submit these comments to OMMUInformationRequests@flhealth.gov. Please note, under Florida law, public comments are public record.

Upon conclusion of this meeting and public record submission deadline, all public comment will be considered, and a notice of proposed rule shall be filed for each rule discussed in today's proceedings.

New developments regarding OMMU's rulemaking can be found on the Florida Administrative Code and Register, by searching for Chapter 64-4, which can be found at https://www.flrules.org/, or on the OMMU website at https://knowthefactsmmj.com/rules-and-regulations/. Interested parties may also subscribe for any updates on https://www.flrules.org/.

Mr. Ferguson thanked all participants for their attendance and participation in today's proceedings. He also informed all attendees that an audio recording of today's proceedings will be available on the OMMU website.

There being no further discussion, the meeting was adjourned at 11:22 a.m. ET.