Dykema Gossett PLLC
Capitol View
201 Townsend Street, Suite 900
Lansing, MI 48933
WWW.DYKEMA.COM
Tel: (517) 374-9100
Fax: (517) 374-9191

R. Lance Boldrey
Direct Dial: (517) 374-9162
Direct Fax: (855) 259-3563
Email: LBoldrey@dykema.com

February 17, 2020

Marijuana Regulatory Agency
Legal Section
P.O. Box 30205
Lansing, MI 48909

Re: Comments to Proposed Combined Topic-Based Rule Sets

To Whom it May Concern:

As the chair of the Cannabis Law Practice at Dykema, I am writing to offer comments on the Michigan Marijuana Regulatory Agency's (the "MRA") proposed combined topic-based rule sets: Marijuana Licenses; Marijuana Licensees; Marijuana Operations; Marijuana Sampling and Testing; Marijuana Infused Products and Edible Marijuana Products; Marijuana Sale or Transfer; Marijuana Employees; Marijuana Hearings; Marijuana Disciplinary Proceedings; Industrial Hemp for Marijuana Businesses; and Medical Marijuana Facilities (Rescinded) (collectively referred to as the "Proposed Rules") being promulgated pursuant to the Medical Marihuana Facilities Licensing Act ("MMFLA") and the Michigan Regulation and Taxation of Marihuana Act ("MRTMA").

As you know, our attorneys and government policy advisors represent clients in all facets of the medical and adult use cannabis industry. Our comments are based on our collective experience and the experience and views of many of our clients. Pursuant to the rulemaking process and the request for public comments, please find below Dykema's comments and recommendations on the proposed rules.

1. General Global Comments

Although most of our comments are targeted to isolated provisions within the Proposed Rules, and are set forth below on a rule by rule basis, two of our comments implicate issues that are reflected by multiple proposed rules.

First, as a general matter, all provisions related to Labor Peace Agreements should be eliminated. A mandate to enter into Labor Peace Agreements as a condition of licensure violates the National Labor Relations Act ("NLRA") and exceeds the statutory authority given to the

Department. Additionally, Labor Peace Agreements effectively place the terms and conditions of employment in the hands of an arbitrator. In an industry that is just beginning to find its way, and where income and expenses already fluctuate wildly, requiring critical economic decisions to be made by a third party does nothing to protect the interests of the industry, patients, consumers, and the state. Therefore, all provisions related to Labor Peace Agreements should be removed in entirety from all rule sets.

Second, we believe that there should be significant rewrites of the testing provisions. We have already seen instances where MRA has imposed new standards and ordered hundreds of thousands of dollars of product to be destroyed, only to then realize that the standards were flawed or should be implemented differently, and reverse course. Producers who were ordered to destroy product that MRA later determined was not harmful have suffered significant economic harm with no recompense. We believe these concerns are best addressed by allowing greater flexibility when it comes to remediation and by broadening the concept of administrative holds beyond simply cases of rules violations, to also encompass product that has initially failed testing. This would provide producers the ability to contest the appropriateness or sufficiency of testing standards without having to destroy viable product.

Third, we believe that the MRA should exercise its authority to establish new license types to establish a license for receiver businesses. As we have learned from other states, we should expect significant business failures in this industry. Yet, cannabis businesses cannot avail themselves of federal bankruptcy protection. Additionally, MRA's rules provide for the suspension and revocation of licenses. In an industry where licensees may have product midstream in growth or production, or significant inventories, suspending operations can lead to significant loss, and jeopardize the interests of creditors. This can also incentivize product diversion. Having licensed receivers able to step in to operate or liquidate facilities serves numerous public interests.

2. Marijuana Licenses 2019-67 LR

<u>R 420.1(1)(c)—Definition of "Applicant"</u>

The term "indirect ownership interest," used in 420.1(1)(c)(i), comes directly from the MMFLA but was not defined by the Legislature, leading to confusion and inconsistent practice and advice from attorneys in the industry. The Proposed Rules should either define the term or state that MRA will provide guidance as to the MRA's interpretation. We often see what may be considered indirect interests arise through the provision of equity in only one license of an entity that possesses multiple licenses, or with respect to one product line. Today, it is not clear if an indirect interest of 10% should be calculated based on total equity, total revenues, or some other metric. MRA guidance would be useful.

Also, we appreciate the express permission for both financing arrangements and licensing agreements. Under 420.1(1)(c)(ii)(A) and (D), however, we recommend defining the terms "reasonable interest rate" and "reasonable payment," respectively. At a minimum, the rules should state that MRA will provide guidance to the industry with respect to these terms.

R 420.1(1)(l)—Definition of "Employee"

Under 420.1(1)(l), the definition of "Employee" excludes "individuals providing trade services who are not normally engaged in the operation of a marihuana business." Dykema suggests that the language read "Employee" does not include "individuals providing trade ***or professional*** services who are not normally engaged in the operation of a marihuana business.

R 420.3—Application procedure; requirements

Under 420.3(2), Dykema suggests allowing prequalification status for grow facilities currently under construction to extend beyond 1 year to avoid having to re-qualify grow facilities whose municipal approval process and construction schedule often extends far beyond that timeframe. This is especially problematic when a municipality requires prequalification status as a condition to local approval, and prequalification status could be temporarily lost. Dykema suggests providing that the MRA may request updated information from an applicant within 90 days prior to the expiration of prequalification status, and allow applicants with their facility under construction to maintain uninterrupted prequalification status so long as circumstances have not changed in a manner that affects suitability.

R 420.4—Application requirements; financial and criminal background

Under 420.4(2)(a)(i)(C), Dykema suggests amending the language "all loans" to read "all loan types specified by the Department," thus providing explicit authority for the MRA to exclude auto loans, credit cards, student loans or other loans that the MRA may find to be unnecessary to examine.

Under 420.4(13), while we understand the need to have adult-use licensees pass a facility inspection on a timely basis, we also believe that this requirement provides municipalities the ability to sidestep important MRTMA protections, at least insofar as MRA requires local certificates of occupancy as a condition for passing inspection. As you know, MRTMA provides municipalities the ability to opt out of allowing adult use businesses in their communities, but MRTMA also explicitly states that ineligibility of an applicant to receive a license on this basis must be tested as of the time the applicant files its application. MRTMA also expressly provides that a municipal ordinance may not prevent an applicant from operating certain types of adult-use establishments where the applicant already has an operating MMFLA facility. Despite the fact that MMFLA and MRTMA operations and impacts are identical in nature (indeed, for many

license types the only observable difference is the color of the Metrc tag), we have seen municipalities refusing to issue certificates of occupancy for adult-use purposes to existing medical facilities. A licensee should have the ability to demonstrate to MRA that a municipality is improperly withholding documentation, without being forced to suffer a license denial and then sue either the MRA or the municipality.

R 420.5—Application requirements; complete application

Under 420.5(4)-(5), Dykema suggests allowing more than 5 days for applicants to supply missing information or proof of corrected deficiencies to the agency, at least in the case of MMFLA applicants for whom there is no 90-day deadline for MRA decision making.

R 420.10—Proof of financial responsibility; insurance

Dykema suggests adding language to sections (1) and (4) that would require licensees to maintain $100,000 in liability insurance ***per location*** as opposed to per license.

R 420.11—Capitalization requirements; medical marihuana facilities licensing act

Dykema suggests amending section (1) to read "On its initial application for licensure under the medical marihuana facilities licensing act, an applicant shall disclose the sources and total amount of capitalization to operate and maintain a proposed marihuana facility." In other words, the capitalization requirements should not be applicable to the expansion of existing facilities.

R 420.12—Denial of a marihuana license; additional reasons

Dykema suggests that 420.12(2)(e) and (n) apply to adult-use applicants only, as they again stem from the MRA's need to more quickly process adult-use applications.

R 420.13—Renewal of state license

Under section (1)(a) and (2) the MRA is requiring spouses on renewal applications to be fingerprinted, and apparently treating a disqualified spouse as a basis to disqualify an entity on renewal. This applies new "applicant" language from 2018 statutory amendments to both initial applicants ***and*** renewals. We believe this is entirely contrary to legislative intent and to the language of the MMFLA.

The original set of amendments proposed by LARA/BMMR in 2018 made the definitional change equally applicable to those in the application process and those who had yet to file. This caused a particular concern by essentially retroactively changing the standard for

those who had already filed applications. More specifically, this caused specific concerns for applicants who worked with Rep. Kesto to ensure the changes would not be retroactively applied; this was the genesis of the language limiting the effectiveness of the change to only applications submitted "on or after January 1, 2019." To now include and enforce these standards on renewal to entities that applied before January 1, 2019, would completely subvert and undermine the Legislature's intent in adding the January 1, 2019, language.

Additionally, to add these requirements on renewal is inconsistent with the statutory language itself. The MMFLA, as amended, makes an express distinction between "Applicant" and "Licensee" under the MMFLA, as amended, along with a possible argument about MRA not properly exercising its deference when carrying out the MMFLA depending on its ultimate position. The MMFLA has specifically defined both "Applicant" and "Licensee" and references the various definitions based on whether the license is being applied for or whether it is being renewed. Thus, an "Applicant" is not a "Licensee" and a "Licensee" is not an "Applicant." Michigan courts have continuously held that "[w]hen interpreting a statute, our primary obligation is to ascertain and effectuate the intent of the Legislature. To do so, we begin with the language of the statute, ascertaining the intent that may be reasonably inferred from its language." *Lash v Traverse City*, 479 Mich 180, 187 (2007). "When the language of a statute is unambiguous, the Legislature's intent is clear and judicial construction is neither necessary nor permitted." *Id*. The Michigan Supreme Court has further held that "ambiguity is a finding of last resort." *Stone v Williamson*, 482 Mich 144, FN 21 (2008).

The MMFLA defines "applicant" as "a person who applies for a state operating license." MCL 333. 27102(c). The statute further clarifies that applicant includes, "with respect to disclosures in an application, for purposes of ineligibility for a license under section 402, or for purposes of prior board approval of a transfer of interest under section 406, and only for applications submitted on or after January 1, 2019, a managerial employee of the applicant, a person holding a direct or indirect ownership interest of more than 10% in the applicant." *Id.* The MMFLA defines "Licensee" as "a person holding a state operating license." MCL 333.27102(j).

MCL 333.27402 provides that "[t]he board shall issue a license to an applicant who submits a complete application and pays both the nonrefundable application fee required under section 401(5) and the regulatory assessment established by the board for the first year of operation, if the board determines that the applicant is qualified to receive a license under this act." MCL 333.27402(1). Section 27402 further provides that "[a] license shall be issued for a 1-year period and is renewable annually. Except as otherwise provided in this act, the board shall renew a license if all of the following requirements are met: (a) The licensee applies to the board on a renewal form provided by the board that requires information prescribed in the rules; (b) The application is received by the board on or before the expiration date of the current license; (c) The licensee pays the regulatory assessment under section 603; and (d) The licensee meets the

requirements of this act and any other renewal requirements set forth in the rules." MCL 333.27402(9).

From the statutory language it is apparent that the Legislature intended to distinguish applicants (persons applying for a state license) and licensees (persons holding a state license). Section 27402 outlines the requirements for applicants to obtain a license, throughout the entire section pre licensure requirements are referred to by "applicant." However, provisions outlining the requirements for licensure renewal specifically reference the "licensee." Thus, the Legislature intended that the definition of applicant apply to only those seeking licensure, while the definition of licensee refer to holders of licenses.

Dykema suggests adding qualifying language to section (1)(a) and (2) carving out an exception for spouses of applicants and licensees whose original application was filed prior to January 1, 2019.

R 420.21—Designated consumption establishment license

Dykema suggests adding "***program or manual***" to section (2)(k) to read: "A documented employee training ***program or manual*** that addresses all components of the responsible operations plan."

R 420.27—Marihuana delivery business

Dykema recommends removing rule 420.27 in its entirety. Licensees who make significant investments in facility construction, inventory, and operating costs have a meaningful financial incentive to fully comply with statutory and regulatory obligations. A licensee who makes no such investment and has a role simply limited to delivering retail product does not have such incentives. This new license type simply presents too much risk.

3. Marijuana Licensees 2019-68 LR

R 420.108—Grower license

Under section (6), Dykema suggests defining "investor."

R 420.109—Processor license; exception for industrial hemp

Under section (1), Dykema suggests re-wording the section to read "A processor license authorizes purchase of marihuana only from a grower or another processor." Currently, the section allows the sale of marihuana from another processor but not the purchase. If the sale is authorized to another processor, it is inherent that the purchase would also be allowed. (We note

also that the title of this rule includes "exception for industrial hemp," yet the rule does not mention hemp.)

4. Marijuana Operations 2019-69 LR

R 420.201—Definitions

Under 420.201(1)(c), Dykema suggests extending the definition of Administrative Hold to include the failure to meet testing standards, and allow facilities having product that fails testing standards to hold the product during an investigation into alleged violations or sufficiency of testing standards.

Under 420.201(1)(e)(ii)(D), the MRA should define what is a "reasonable payment" under a licensing agreement.

R 420.203—Marihuana licenses; licensees; operations; general

420.203(2)(a) provides that "a marihuana business shall be partitioned from any other marihuana business or activity, any other business, or any other dwelling." While section (2)(a) provides an exception for operation of separate licenses at the same location and for operation of equivalent licenses at the same location, we believe that the current language does not fully contemplate the processing of industrial hemp. Section 7(1) of the Industrial Hemp Research and Development Act (the "Hemp Act") states that a processor licensed under the MMFLA may process industrial hemp. Therefore, we believe that language should be added at the end of section (2)(a) of proposed rule 420.203 to read "a marihuana business shall be partitioned from any other marihuana business or activity, any other business, or any other dwelling, ***other than activities in which marihuana businesses are entitled to participate, and provided further that growers and processors operated at the same location under R 420.204 shall not be required to partition.***" (This latter provision would eliminate the need for costly "mantraps" in co-located and integrated grower and processor facilities.)

Although the language of 420.203(2)(c) appears in the current rules, we believe that the MRA should remove the requirement that marihuana businesses must be contiguous. To date, MRA has allowed licensed activities to be in out-buildings on the same parcel as primary buildings (e.g., for grinding of waste). At a minimum, the MRA should at least define contiguous to mean structures located on one parcel.

Dykema suggests removing the prohibition against drive through operations in 420.203(2)(g).

R 420.204—Operation at same location

Dykema suggests amending 420.204(2)(d)(iii) to read "Have separate entrances, exits, inventory, record keeping, and point of sale operations ***other than for growers and processors at the same location***."

As noted above, in 420.204(2)(d)(ii) MRA should remove the requirement that marihuana businesses must be contiguous.

Dykema suggests adding a subsection (4)(d) under 420.204 that makes clear that a laboratory co-located with an existing non-marijuana testing laboratory must comply with all building security, design, and other MRA operational rules.

R 420.205—Equivalent licenses; operation at same location

Under 420.205(2)(c) to operate equivalent licenses at the same location, the operation cannot "circumvent a municipal ordinance or zoning regulation that limits the marihuana business under the acts." MCL 333.27956, however, provides that "[a] municipality may not adopt an ordinance that . . . prohibits a marihuana grower, a marihuana processor, and a marihuana retailer from operating within a single facility or from operating at a location shared with a marihuana facility operating pursuant to the medical marihuana facilities licensing act." Dykema suggest that this exact language be added to the end of (2)(c) after a "provided, however," in order to comply with the statutory requirements and prevent municipalities from sidestepping them.

R 420.206—Marihuana business; general requirements

Under 420.206(1)(b)(ii), cultivation may occur outdoors if "all drying, trimming, curing, or packaging of marihuana occurs inside the building meeting all the requirements under these rules." Dykema suggests adding "Provided, however, that marihuana may be transported to a grower or processor without drying, trimming, curing, or packaging of marihuana."

Under 420.206(8)(b), Dykema suggests defining the term "supervisory analyst."

Under 420.206(11), the term 'inactive ingredients' is a pharmaceutical product term. While the term and this requirement is sensible with respect to distillate blended with other products and intended for inhalation through vaping, to the extent that edibles or other supplements have ingredients that may be on the FDA inactive ingredient list, they are not intended to "facilitate the transport of marihuana in the body" and therefore the regulation makes no sense as applied to edible or ingestible marihuana products. As non-pharma products or supplements, such products should simply be required to list the ingredients pursuant to FDA labeling regulations (for food products).

420.206(14) requires marihuana businesses to comply with updated standards issued by the agency within 60 days of their adoption. However, for growers, 60 days does not provide enough time for a grow cycle to occur and product to be tested to comply with any changes. Therefore, Dykema suggests adding "Except in cases of public health emergencies, a lab must validate new tests within 60 days of adoption by the agency and growers and processors must meet the standards adopted by the agency within 150 days of adoption."

420.206(16)(a)-(b) quite simply amounts to a regulatory taking and must be removed. The agency has no statutory authority to force a sale of product to a third party "to ensure that all marihuana businesses are properly serviced." Such a regulation amounts to a regulatory taking and forces marihuana businesses to eliminate their competitive business advantage. By ***mandating*** sales in certain circumstances, it also puts the MRA itself in direct violation of the federal Controlled Substances Act, eliminating the defense to pre-emption challenges to the MMFLA (and, by extension, to MRTMA) relied upon by the Michigan Supreme Court in *Ter Beek v City of Wyoming*, 495 Mich 1 (2014). This step would thus threaten to undermine Michigan's entire statutory framework for the industry.

R 420.207—Marihuana delivery; limited circumstances

Under 420.207(3), Dykema suggests changing "shall establish procedures" to "***may*** establish procedures." (Otherwise, this could be read as mandating delivery for businesses that may choose not to engage in this practice.)

Under 420.207(4)(c), Dykema suggests amending the language to read: "All marihuana delivery employees meet the requirements in R 420.602 and are employees, ***as defined in R 420.601(1)(d)***, of the marihuana sales location.

R 420.208—Building and fire safety

Under 420.208(5), we believe that the MRA and Bureau of Fire Services needs to re-assess whether growers should be treated as an industrial use. This unique Michigan treatment has led to numerous requirements that are not present in any other state, including such absurdities as mandating sprinklers and specific paths and distances for marijuana planted outdoors under plastic high tunnels.

R 420.209—Security measures; required plan; video surveillance system

Under 420.209(3) Dykema suggests adding "***or other electronic or keypad access***" after "door locks." (The current mandate for commercial grade locks has been interpreted by some in MRA Enforcement to require low-tech deadbolt style locks, when electronic access controlled doors are more secure.)

5. Marijuana Sampling and Testing 2019-70 LR

R 420.301—Definitions

Under 420.301(1)(h) "Final Package" is defined as "the form a marihuana product is in when it is available for sale by a marihuana sales location." We believe the definition is ambiguous because it references the "form" of the product itself. The definition should reference the packaging, not the form of the product. Therefore, we suggest the definition be amended to read: "Final Package means the outermost container or box the marihuana product is house in when it is available for sale by a marihuana sales location."

R 420.303—Batch; identification and testing.

Dykema suggests that MRA clarify in 420.303(1) that each immature plant counts as one plant toward the grower plant count. As the MRA and others have determined, this is the count methodology required by the wording of the MMFLA. However, this provision for batch tagging in Metrc, while correct, continues to be misinterpreted, especially by new market entrants.

420.303(5) currently allows marihuana product that fails testing and is remediated to be sold or transferred once approved by the agency. We believe that agency approval should not be required for marihuana product that passes (under R 420.306) two subsequent re-tests following remediation.

Under 420.303(9), the MRA should change the language "anytime the marihuana product changes form" to read "anytime the marihuana product changes ***state***."

R 420.304—Sampling; testing

Under 420.304(2)(b)-(c), the MRA should amend section (2)(b) to read "The agency may publish sample sizes for other marihuana products being tested, ***and may provide for a maximum harvest batch size***." Additionally, the MRA should move the language at the end of section (2)(c) to the end of (2)(b) to now read "The laboratory must have access to the entire batch for the purpose of sampling and ***shall ensure that the sample increments are taken from throughout the batch***." (Sampling methodology should remain under the full control of the laboratory, not growers, and growers should not be held responsible for a laboratory's failure to take appropriate samples.)

In 420.304(2)(h), laboratories should be the parties responsible for uploading accurate data from the certificate of analysis into the statewide monitoring system. Certificates of analysis are not standardized, vary from lab to lab, and are commonly misunderstood.

Dykema suggests amending 420.304(2)(i) to read "This provision does not apply to a laboratory who engages another laboratory to perform certain safety tests on a subcontracted basis, ***or to a laboratory under common ownership***."

R 420.305—Testing; laboratory requirements

420.305(3) should be clarified so as to not interpret the section to mean a marihuana product needs to be tested every time it changes form (or state). Testing should be required before sale or transfer, but not when form changes due to processing.

420.305(10) currently sets a zero tolerance for chemical residue (pesticides). However, extremely low levels of pesticide residue is possible. We believe that chemical residue should have an action limit instead of a limit of quantification. Having an LOQ with a fail for even the slightest amount of chemical residue creates excess costs or production because potentially large batches must then be destroyed. At the very minimum we believe that R 420.306(3) should be amended to allow product that tests positive for chemical residue to be remediated to fall below the action limit allowable.

We believe that the accuracy thresholds for all licensed labs should be published by the department. This would allow other licensees to monitor and be aware of labs that are the most accurate.

The MRA should add a 420.305(2) stating that, "A marihuana business may have a failed batch R&D tested by a different laboratory to determine whether or not the laboratory that performed the initial test may have made an error. If an R&D test contradicts the failed result, the department will investigate the failed result and may have the item selected for random sampling by another licensed lab."

Finally, Dykema suggests adding a provision to Rule 420.305 that allows laboratories prelicensure possession of marihuana for the purpose of validating testing equipment. (With the passage of MRTMA, owners and operators of prelicensed laboratories have the legal authority to possess marijuana.)

R 420.306—Testing marihuana product after failed initial safety testing and remediation

Dykema suggests amending 420.306(2) to add a provision that prevents immediate destruction of product if the marihuana business is challenging the validity of testing. In this case, product would be required to be placed under an administrative hold as defined in R 420.501.

As discussed above, 420.306(3) is not ideal in practice. Currently, the rules propose a zero tolerance for chemical residue. However, ultra-low levels of chemical residue can be

attributable to accidental contamination rather than the use of a banned pesticide. Section (3) should be amended to allow processors to remediate the material to remove chemical residue. The implementation of the current section, as written, will result in exponential loses to licensees and a shortage of product for customers and patients. Growers are vulnerable to large losses as a result of accidental environmental contamination, while processors are vulnerable to large losses due to an accumulation of contamination during processing, even where no banned pesticide was utilized.

420.306(4) should be amended to specify that processors will be allowed to remediate any material that can be remediated. Additionally, this rule should allow processors to transfer material to another processor for remediation.

Finally, Dykema suggests amending section (4) to read "The agency ***shall*** publish a remediation protocol."

R 420.307—Research and Development

We believe that R&D testing should be allowed before or after final compliance testing.

6. Marijuana Infused Products and Edible Marijuana Product 2019-71 LR

R 420.403—Requirements and restrictions on marihuana-infused products; edible marihuana product

420.403(6) should be amended in accordance with our comment to R 420.206(11): The term 'inactive ingredients' is a pharmaceutical product term. To the extent non-medical marihuana products have ingredients which may be on the FDA inactive ingredient list, they are not intended to "facilitate the transport of marihuana in the body" and therefore the regulation makes no sense as applied to edible or ingestible marihuana products. As food or supplements, such products would be required to list the ingredients pursuant to FDA labeling regulations.

R 420.404—Maximum THC concentration for marihuana-infused products

420.404 should be amended to read "A marihuana sales location shall not sell or transfer marihuana infused products that exceed, ***by more than 15%***, the maximum THC concentrations established by the agency."

7. Marijuana Sale or Transfer 2019-72 LR

R 420.504—Marihuana product sale or transfer; labeling and packaging requirements

Under 420.504(1)(i), listing the name of the laboratory that performed ***any*** test, ***any*** associated batch number, and ***any*** test analysis date is very cumbersome and should be limited to certain laboratories, batch numbers, and analysis dates.

Under 420.504(1)(k)(iii), Dykema suggests amending the language to read: "For products being sold by a licensee under the medical marihuana facilities licensing act ***that exceed maximum THC levels allowed for products sold under MRTMA***, "For use by individuals 21 years of age or older only. Keep out of reach of children."

Additionally, under section (1)(k)(iv), Dykema suggests amending the language to read: "For ***all other*** products being sold by a licensee, "For use by individuals 21 years of age or older or registered qualifying patients only. Keep out of reach of children."

Together, the above changes would enable licensees to use the same labels for products that are allowed for both medical and adult-use customers, thereby reducing the costs incurred by growers and processors.

R 420.505—Sale or transfer; marihuana sales location

Dykema suggests amending section (1)(e) to read "A licensee ***selling marihuana product pursuant to*** the medical marihuana facilities licensing act."

R 420.507—Marketing and advertising restrictions

Under 420.507(6), Dykema suggests moving "under the medical marihuana facilities licensing act" to after "marihuana product" so that section (6) would read: "A marihuana product ***under the medical marihuana facilities licensing act*** must be marketed or advertised as 'medical marihuana' for use only by registered qualifying patients or registered primary caregivers."

Under 420.507(7), Dykema suggests moving "under the medical marihuana facilities licensing act" to after "marihuana product" so that section (7) would read: "A marihuana product ***under the medical marihuana facilities licensing act*** must not be marketed or advertised to minors aged 17 years or younger."

8. Marijuana Employees 2019-73 LR

R 420.602—Employees; requirements

Dykema suggests amending sections (6) and (7) to insert "***or professional***" after the word "trade".

9. Marijuana Hearings 2019-74 LR

R 420.706—Complaint by licensee

Dykema suggests adding a section that allows licensees to contest the standards set for testing.

10. Marijuana Disciplinary Proceedings 2019-75 LR

R 420.808—Citation

Dykema suggests amending section (7) to allow a licensee to provide "***a written response***" instead of limiting the response to one single page.

11. Industrial Hemp Rule for Marihuana Businesses 2019-88 LR

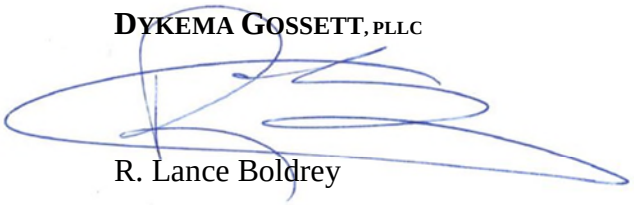
R 420.1003—Processing industrial hemp.

Sections (1), (2) and (5) of 420.1003 expressly require a medical or adult-use marijuana processor to comply with the Hemp Act and associated rules promulgated by the Michigan Department of Agriculture and Rural Development if the processor handles, processes, markets, or brokers industrial hemp. This would pose a serious compliance issue for marijuana processors that choose to process industrial hemp for several reasons. First and foremost, industrial hemp and marijuana are both defined as the plant Cannabis sativa L., with the only distinction between the two being the delta-9-tetrahydrocannabinol (THC) concentration of the plant. Under the Hemp Act, any cannabis in the processor's possession that exceeds .3% THC concentration would be considered non-compliant industrial hemp and would need to be destroyed. Thus, a marijuana processor that processes both industrial hemp and marijuana would not be in compliance with the Hemp Act because it would be processing and in the possession of cannabis with a THC concentration that exceeds the allowable limit under the Hemp Act. Similarly, a marijuana processor would be unable to use any industrial hemp-derived CBD or other ingredients in its finished marijuana products.

Therefore, the rule should be clarified to exempt marijuana processors from complying with the Hemp Act if and when the marijuana processor handles, processes, markets, or brokers cannabis with a delta-9-THC content greater than 0.3% on a dry weight basis.

Regards,

DYKEMA GOSSETT, PLLC



R. Lance Boldrey

Draft Rules Comments 2.10.20

We commend and agree with the following proposed changes:

- Unlimited remediation and testing on final product
- 6 month lead time on implementing changes to testing protocols
- Common definitions
- Independent, third-party consultation and confirmation of new testing protocols

Our feedback and proposed recommendations:

R 420.504
Rule 4. 1. (i) Name of the laboratory that performed any test, any associated test batch number, and any test analysis date

Comment: Written in a way that would require any future test dates to be affixed to the products. The Issue with this is if products are at a retailer and the processor has additional tests run (such as what happened with additional Vitamin E tests) retailers will defer to the processor who would have this info, but if it's already in the retailer's METRC system the processor is locked out of this information.

Recommendation: Tests done to product batches after they have been sold to provisioning centers do not need amended stickers.

R 420.507
Rule 7 (5) A person receiving reasonable payment under a licensing agreement or contract approved by the agency concerning the licensing of intellectual property, including, but not limited to, brands and recipes, is responsible for any marketing or advertising undertaken by either party to the agreement.

Comment: This adds undo stress on distributors, making it difficult for brands to move into the licensed market. Processors can't be held liable for the choices and spending habits of out of state partners.

Recommendation: If there is reasonable evidence that processors did were not aware of marketing campaigns that are non-compliant, they may appeal.

R 420.705
Rule 5. (1) If the agency summarily suspends a marihuana license without notice or hearing upon a determination that the safety or health of patrons or employees is jeopardized by continuing the marihuana business's operation, a post-suspension hearing must be held

promptly to determine if the suspension should remain in effect, in accordance with section 92 of the administrative procedures act, MCL 24.292, and MAHS general hearing rules.

Comment: If a licensee has their license suspended improperly, they are being caused an undo amount of stress with no foreseeable time limit in which their business will be shut down.

Recommendation: Ensure the issue will be reviewed within 3 days of suspending the license to ensure prompt response.

R 420.803
Rule 3. (1) ...Any material change or modification to the marihuana business must be approved by agency before the change or modification is made

Comment: Unclear about what kind of changes need to be reported

Recommendation: Define “material change”, possibly with a monetary threshold for reference.

R 420.404
Rule 4. A marihuana sales location shall not sell or transfer marihuana infused products that exceeds the maximum THC concentrations established by the agency. For the purposes of maximum THC concentration for marihuana infused products, the agency shall publish a list of maximum THC concentrations and serving size limits

Comment: This does not explicitly account for variability due to the lack of precise testing availability. For example, an infused product could have 100mg of THC which is the maximum allowable, but due to the margin of error in testing, the tests can report THC levels at 115mg, and lead to the unnecessary destruction of product.

Recommendation: Allow a +/- 15% THC limit to account for testing variance.

R420.1
C) i. “Managerial Employee”

Comment: “Managerial employees” are considered applicants, and must be disclosed to the state and thoroughly vetted. While it is understandable that this information be disclosed to the state for majority owners, the term “managerial employee” leaves room for confusion and error in the application and renewal process. Additionally, “managerial employee” can easily be confused with “managers” who are typically general administrators and have no ownership interests but oversee employees and operations.

Recommendation: The term “applicant” should only refer to those who have above 10% vested ownership in the company. The term “managerial employee” should not be used.

R 420.6

"Marijuana Delivery Business"

Comment: Allowing for standalone "Marijuana Delivery Businesses" is a threat for to the entire licensed industry and helps strengthen and allow for easier access to the black market. Nothing will prevent a "Marijuana Delivery Business" from smuggling black market contraband into the licensed market while they make deliveries. Established marijuana retailers who provide home delivery have their license and entire brick and mortar operation and investment at risk, whereas a "Marijuana Delivery Business" has the cost of the license ($4,000) and the investment of the delivery vehicles at risk. This license is a threat to the public health and safety of our communities.

Recommendation: Do not allow for standalone "Marijuana Delivery Businesses"

420.206
(b) (i) The outdoor area containing the cultivation of marihuana plants is contiguous with the building, fully enclosed by fences or barriers that block outside visibility of the marihuana plants from the public view, with no marihuana plants growing above the fence or barrier that are visible to the public eye, and the fences are secured and comply with the applicable security measures in these rules, including, but not limited to, locked entries only accessible to authorized persons or emergency personnel.

Comment: Outdoor grows are the most needed for stabilizing the industry. However, it is virtually impossible on many properties to completely block outside visibility of the marijuana plant due to the plants' possible heights and dips and valleys in properties. Outdoor grows will be the key in the industry rebounding from the caregiver cutoff. Outdoor grows are needed to produce distillate that previously would've been purchased from caregivers. Removing this requirement greatly increases the properties that can be feasibly used as outdoor grows. Moreover, because marijuana is indistinguishable from hemp when grown outdoors, removing the barriers and walls will make it less of a target, and not more of one.

Recommendation: Remove "block outside visibility of the marihuana plants from the public view"

R420.301
(g) "Final Package"

Recommendation: Products in their "Final Package" should be tested as such. Processors should not need to have every stage of a product tested, in addition to testing in its final product. This change would save time and money for processors without compromising the safety of patients. The greatest risk and liability would also be on the processor, as tainted distillate or other raw ingredients would cause the item in final packaging to fail, rendering it unusable and the entire process

R 420.403(10) [Product Expiration Dates]
(10) A producer shall not produce an edible marihuana product that requires time and temperature control for safety. The agency may publish validation guidance for shelf stable edible marihuana product. The agency may request to review the validation study for a shelf stable edible marihuana product. The end product must be a shelf stable edible marihuana product and state the following information:
(a) A product expiration date, upon which the marihuana product is no longer fit for consumption. Once a label with an expiration date has been affixed to a marihuana product, a licensee shall not alter that expiration date or affix a new label with a later expiration date.

Comment: The old language included more of a "best by" date that permitted sale after the best by date. Deletion of the language: "or a use-by date, upon which the marihuana product is no longer optimally fresh" presumably requires destruction after that date.

Recommendation: I'll lean on the manufacturing experts for a recommendation.

R 420.506 [Monthly v Rolling Calendar Days]
(2) Before the sale or transfer of marihuana product to a registered qualifying patient or registered primary caregiver, under the medical marihuana facilities licensing act, the licensee shall verify in the statewide monitoring system that the sale or transfer does not exceed the monthly purchasing limit of 10 ounces of marihuana product per month to a qualifying patient, either directly or through the qualifying patient's registered primary caregiver.

Comment: This is enforced as a rolling 30-day period.

Recommendation: If the intention is rolling 30-day period than mentions of "per month" should be changed to "per rolling 30-day period."

R 420.27(19), R 420.207(14), R 420.804(1), R 420.15(1) [Criminal Activity Reporting, consistency]

-agency, state police, or local law enforcement (R 420.27(19) - delivery)
-agency, state police, or local law enforcement (R 420.207(14) - delivery)
-agency and local law enforcement authorities (R 420.804 (1) - at business)
-agency and local law enforcement authorities (R 420.15 (1) - at the marihuana business)

Comment: Consistency will make for better compliance.

Recommendation: Make criminal reporting more clear across these 4 rules. No real preference just want consistency so we know exactly what to do when there's criminal activity no matter if related to delivery or at the facility.

R 420.205(2)(d)(i) [Fees]
(2) To operate equivalent licenses at the same location, all of the following requirements must be met:
(d) The person operating the equivalent licenses at the same location under this rule shall do all the following:
(i) Apply for and be granted a separate state license and a state operating license and pay the required fees for each license.

Comment: medical license fees should be reduced for holders of equivalent licenses.

Recommendation:

Other:
-Aside from CPA attestation, not requiring any more SA information for Persons who are prequalified and applying for new entity.
-making renewal date a single date in the year (e.g. Liquor May 31). Any information that would otherwise be required of the SA when applying for a new application, will be provided at time of renewal.

MICHIGAN CANNABIS MANUFACTURERS ASSOCIATION
DUAL RULE COMMENTS
(Feb. 2020)

SET #1 LICENSES

- **Definition of "Same Location" (R 420.1(1)(ai); R 420.203(2)(a))**: The continued inclusion of a "partition" as the minimum standard of division for more than one license operating at the same location is appreciated. Further direction from the Enforcement Division on the minimum requirements of a "partition" would be helpful. Doing so would standardize this issue and avoid subjectivity on the part of operators and field inspectors.

- **Typo (R 420.4(1))**: Seems like the word "either" is a mistake.

- **Disclosure of Persons "Controlled" by a Person who Controls the Applicant (R 420.4(2)(iv)(B))**: Among other things, the MMFLA conditions suitability for licensure upon the "integrity, moral character, and reputation" of any person who "[i]s controlled . . . by a person who controls, directly or indirectly, the applicant." MCL 333.27402(3)(a)(ii). The MRTMA does not contain a similarly detailed provision, but instead merely entrusts the MRA to "promulgat[e] rules . . . that are necessary to implement, administer, and enforce [the MRTMA]," and to "grant[] or deny[] each application for licensure . . . ." MCL 333.27957 (1)(a-b). Based upon these provisions, proposed Rule 420.4(2)(iv)(B)) requires the disclosure "any other person who . . . [i]s controlled, directly or indirectly, by . . . a person who controls, directly or indirectly, the applicant." This has been confusing and cumbersome since the inception of the MMFLA application process. The requirement is difficult to understand and, taken to its furthest extreme, creates an endless string of attenuated control relationships. Propose doing away with the requirement via legislative amendment to the MMFLA and by extension, the Proposed Dual Rules, so as to avoid (i) unnecessary expenditure of attention and resources on the part of the MRA, and (ii) unintentional non-disclosures by applicants. [*REQUIRES STATUTORY AMENDMENT*]

- **60 Day Inspection Window & Need for Preliminary Plan Approval (R 420.4(13))**: It is understood that this 60 day window is necessary to comply with the 90 day application review period required by the MRTMA. (MCL 333.27959(1)). However, only being able to access MRA field inspectors after a Step II application is filed, which itself requires substantial completion of an establishment build-out by virtue of this limited timeline, creates great risk for prospective operators. It is suggested that MRA develop an interim, consistent process for prospective licensees to get preliminary site plan approval before filing a Step II, and before assuming the expense of the establishment build-out, to lessen the risk otherwise borne by those prospective operators.

- **Adjusting the NOD Correction Window to "Business Days" Excluding Holidays (R 420.5(4-5))**: While the reasons for this limitation are fully understood, often, correction of NODs will involve the input of third-party professionals (architects, CPAs, lawyers, etc.), and depending upon the timing of same, weekends and holidays can place unnecessary strain on an application who is attempting to comply and address NODs in good faith. It is suggestion that the language of this rule should be modified to operate upon "business days," and to exclude national holidays, thus ensuring that applicants do not fall victim to timing circumstances outside of their control.

- **Express Cure Right for Renewal NODs (R 420.13)**: Suggest adding an express NOD cure right for renewal applications in line with the above comment re: NOD Correction Window for lead applications. This is already being done in practice, but is not expressly set forth in the rules.

- **Reporting New Civil Lawsuits (R 420.14(5))**: In the MMFLA Rules, a licensee needs to update the MRA when it is the subject of a new civil judgment. The Dual Rules have expanded that reporting requirement for "new . . . lawsuits" that are civil in nature. This is problematic, as it creates an incentive for non-licensed contracting parties to leverage the litigation threat against a licensee whether or not the actual claims are meritorious. That new requirement should be removed or carved out for non-criminal, non-regulatory actions. Only when a judgment is obtained should the matter need to be reported. If a case is settled, the MRA does not need to be informed at all – as its just business at that point.

- **Delivery Business (R 420.20(1)(e); R 420.27)**: Suggest removing as the service is not needed in light of home delivery allowed by licensed Provisioning Centers and Retailers. Also, maintaining delivered sales within the seed-to-sale tracking system seems untenable as it is unclear who is obligated to "record[] [confirmed sales] in the statewide monitoring system." (R 420.27(11)(d)). These license types are not allowed to "sell" the products (R 420.27(11)(f), as they are only allowed to take "physical," rather than "legal" custody of the marihuana or money (R 420.27(8)), and yet deliveries must be recorded after being made in compliance with applicable regulations (R 420.27(11(d)), including verifying age and other delivery requirements (R 420.27(11(e)), and in instances when delivery business employees are unable to do so, or in certain other cases, these license types must return the products to the marihuana retailer (R 420.27(11(g)). This requires a great deal of interaction and follow up with the retailer. Since the delivery business employee is not an employee of the retailer, limited access area restrictions and visitor log concerns come into play, further complicating the situation for no apparent reason. Given the amount of oversight and logistics required (R 420.27(12)), it is unlikely that this license type will be viable for small business scales, so it will not further the MRA's social equity initiatives in any meaningful way. As such, it is an added complication without a reason. Alternatively, these licensees should be required to obtain local approval to increase the controls placed upon this new license type.

Set #2 LICENSEES

- **Only Female Flowering Plants Count in AU (R 420.102(2))**: It is suggested that greater consideration be given to this standard before formalization. While it is not immediately objectionable on its face, the long-term market implications of the loosened standard, coupled with the possibility for abuse by bad actors, should be carefully considered by cultivation and operations experts to ensure the immediate apparent benefits of the altered standard are not outweighed by longer-term negative implications.

- **Sale of Seeds, Seedlings, Tissue culture Authorized and No Secured Transporter Needed. (R 420.102(3, 9))**: A good development in the rules. This entire subject matter was very unclear in previous renditions of the medical and AU rules.

- **Transfer of Inventory Between Commonly Owned MRTMA Processors (R 420.103(3))**: Very important and necessary development in the rules. Note, the MMFLA processor rule (R 420.109) does not include a similar allowance. Why not? Can it?

- **Transfer of Inventory Between Commonly Owned MRTMA Retailers (R 420.104(4))**: Also a good development. Query: If the amount of product to be transferred is under the limits for home delivery carriers, can this sort of a transfer be accomplished without use of a secured transporter, similar to the rule to transport to temporary events noted above? As presently written, these rules would indicate that the answer is "no." Note, the MMFLA provisioning center rule (R 420.111) does not include a similar allowance. Why not? Can it?

- **Standards for Heavy Metals are Prohibitively High and Should Established through the Scientific Process (R 420.107(3); R 420.206(12))**: There have been reports that the maximum levels for heavy metals established in October are causing hundreds of pounds of flower to only be usable in oils, further contributing to the current shortage. There needs to be a 6 month+ runway for licensed cultivators to meet these standards, so that a root cause analysis can be performed on operating facilities/establishments to determine the source of these heavy metals (water, soil, etc.). Also, established standards should be the product of an evaluation by a science-based panel of impartial experts. The delayed implementation of the current testing requirements for copper and nickel announced on Feb. 5, 2020, is appreciated, but it will only delay the negative repercussions of the present standards, rather than alleviating them.

Set #3 OPERATIONS

- **RFID Cards and Logs for Facilities/Establishments (R 420.203(e); R 420.209(4-5))**: This could be a mandatory requirement under the referenced rules. Alternatively, if deemed to be cost-prohibitive as a mandatory requirement, the MRA should make the installation and operation of a facility/establishment-wide RFID Access Card and Log system a mandatory requirement of GMP/GACP certification as set forth in later rule sets. Doing so will improve safety and recordkeeping functions, among other indirect benefits.

- **Access to Licensee Records (R 420.203(2)(f))**: Right now, the rule says licensee "records," presumably meaning, records of any sort, must be available to the Agency "upon request," which Enforcement has previously clarified means "immediately upon request" in the context of the prior MMFLA Rules. Given that many vertically integrated operators will have a corporate headquarters and various access limitations/security protocols on certain sorts of "records," this rule needs to clarify which records must be immediately accessible to the Agency, and/or provide a 24 hour request window to ensure operators can always comply with such requests.

- **Compliance with Natural Resources and Environmental Protection Act (R 420.203(3)(a))**: This is an expansion of the prior MMFLA Rule's obligation, which was limited to compliance in the context of "waste disposal." The implications of this expanded requirement could be substantial, and the MRA should give operators a 1 year running start at this, similar to the Dual Rule's requirement that a safety compliance facility be "accredited" within a year of assuming operations (R 420.107(2); R 420.305(1)(a)).

- **No Distinction of Separation for Equivalent Licenses (R 420.205(5))**: This is a great rule, and exactly what should be done.

- **Structure of Rule 6 in Set #3 (R 420.206)**: This rule spans nearly three pages, and contains various operating requirements, some applicable to all classifications of licenses, and some specific to certain licenses. There are no sub-titles in the rule and the placement of various sub-parts appears somewhat random. Recommend breaking this into separate rules per facility classification for ease of understanding and use.

- **Incorporation of Good Agricultural Collection Practices for Cultivators (R 420.206(2); R 420.212(5); R 420.301(i); R 420.305(4); R 420.602(2)(h))**: Current rules incentivize growers to obtain GMP certification. This is ideal, but GMP does not, by its nature, operate upon the "cultivation" of plant products in a meaningful way. To truly achieve the intended result here – standardized, repeatable cultivation practices with consistent, safe results – growers must meet Good Agricultural Collection Practices ("GACP"). For instance, the definition of "Good manufacturing processes" in Set #4 is limited to "manufacturing processes and facilities," and "manufactured" products. The equivalent "cultivation" standards need to be incorporated into these rules. Properly incorporating GACP standards into cultivation operations requirements will help the State of Michigan effectively compete in the interstate commerce post-Federal decriminalization. Potential particulars include: (i) Inclusion of a GMP/GACP Plan requirement that can (ii) serve as a basis for MRA benchmark inspections tied to the license renewal process or, perhaps, more frequently. The specific incentives provided for achieving certification include no testing and/or increased batch sizes. See above discussion re: "Plant Counts" and below discussion re: "Harvest Batches." In the future, depending on development of the matured market, this could be changed to require a cultivator achieve GACP certification within two years of initial licensure, and GMP/GACP Plans could become mandatory Step-II submissions.

- **General Incorporation of GMP for Manufacturing, Packaging and Food (R 420.206(10))**: This is a great rule, and was part of the prior MMFLA Rules. The question now is how this standard will be enforced? It only matters if it is policed properly.

- **Forced Sharing Rule (R 420.206(16))**: This rule does not appear to be expressly authorized by the MRTMA, and does not efficiently serve its own stated purpose, which itself may turn out to be a non-issue as the recreational market assumes its final form. Moreover, regardless of the rule's foundation, necessity or effectiveness, the Forced Sharing Rule as presently drafted is susceptible to Constitutional challenge because it does not provide an objective standard of compliance or enforcement.

- **Home Delivery as it Relates to Consumption Lounges (R 420.207)**: Certain provisions here, specifically subsection 7(c-d, h, l), contemplate use of a motor vehicle for deliveries. However, the most ideal situation is one where a Retailer is located directly next to a Consumption Lounge so that real-time delivery on foot is possible. While there is nothing in this rule that expressly disallows such that scenario, greater clarity on that point, and perhaps a relaxed list of requirements for such a process, would be ideal.

- **Mandatory Installation of Backup Generator Power System (R 420.209)**: The MRA should consider making the installation and operation of a backup generator/power system a mandatory requirement under the rules. Alternatively, if deemed to be cost-prohibitive as a mandatory requirement, the MRA should make the installation and operation of a backup generator a mandatory requirement of GMP/GACP certification as discussed elsewhere in the rule sets. Doing

so will improve safety and security and avoid product losses that will impact the market and pricing, among other indirect benefits.

- **Other Composting/Feedstock Disposal Methods (R 420.211(13))**: This is a good rule and allows operators to come up with more efficient ways to reuse/repurpose cannabis waste in the future.

- **Common Ownership MM to AU Transfers (R 420.214)**: It is suggested that the inverse of this process be permanently allowed in the rules. As the market matures, recreational marijuana and marijuana product generation will be the primary focus of cultivators and processors, and allowing the transfer of AU products to the MM market, as needed, will ensure ample supply for the MM market without requiring those operators to dedicate floor space and resources to MM licenses that may be better utilized for AU operations.

Set #4 SAMPLING AND TESTING

- **No Limits on Harvest Batches (R 420.301(j); R 420.304(2)(b))**: There no longer appears to be an express limitation on the size of a "harvest batch." Prior MMFLA Rules (R 333.248(2)(b)) and the Emergency MRTMA Rules (R 42(2)(b)) were limited to 15 pounds. Now the issue seems to be limited to the dictates of the definition of "batch," meaning "same variety that has been processed together and exposed to substantially similar conditions." (R 420.301(1)(e)). While this is an ideal situation for operators from a COGs standpoint, it should be offered as an incentive for GMP/GACP certification rather than being the general standard. Doing so will incentivize such certification, strike a balance between safety and efficiency, and quell work-flow concerns from the Safety Compliance operators.

- **Skipping Testing for Plant Material Converted into Live Resin or Concentrate (R 420.303(6))**: In the Emergency MRTMA Rules (R 41(6)), the ability to skip testing until after the finished product was produced was limited to 60 pound batches for live resin. Now, the same can be done for "concentrates, with agency approval," and there are no express weight limits. This seems to be a good rule, but would be interested in knowing more about what will be required to receive "agency approval." Note, "concentrate" is not defined in this rule set. "Concentrate" is also not defined in the MMFLA, but it is included under the MRTMA definition of "Marihuana" (MCL 333.27953(e)), and has its own definition there as well (MCL 333.27953(g)). Accordingly, a defined term for "concentrate" in this rule set would be useful. The rule also says that the Agency may publish "guidelines" in this regard.

- **Allowance for Transfer of Remediation Product (R 420.306(4))**: Quarantined product must be able to be transferred between processors for remediation purposes, as there will be certain remediation methods that only some processors will have equipment to perform. As it currently stands, this is not considered or enabled under the rules and guidance published to date.

Set #5 MARIHUANA-INFUSED PRODUCTS AND EDIBLE MARIHUANA PRODUCT

- **Reference to "Address" on Infused Product Labels (R 420.403(7)(a)**: Infused products must be labeled with the "address" of the marihuana business that processes or packages the product. This notation of an address is not a part of the general labeling requirements for marihuana itself. (R 420.504). Given that fact, coupled with the amount of other information that must be included

on labels and the safety concerns brought about by noting the facility/establishment's address on packaging, it is suggested that this requirement be omitted. If patrons want to find a facility/establishment's address, they can look up the license number on the MRA website.

Set #6 MARIHUANA SALE OR TRANSFER

- **Different Warnings for MM and AU Products (R 420.504(k))**: Currently, there are different warnings required for MMFLA and MRTMA products. This requires the generation and application of different labels for the different products, which will otherwise be identical. Enforcement has previously instructed that, under the current rules, operators cannot combined the warnings ("For use only by registered qualifying patients or individuals 21 years of age or older") to streamline the labeling process. This should be reconsidered in the Dual Rules.

- **Prohibits Health Claims in Marketing (R 420.507(3))**: This is a new marketing limitation, which runs head first into the concept of "medical marijuana" itself, as embodied by the MMMA and MMFLA. In fact, as the MRA is well aware, there is a LARA/Medical Marihuana Review Panel made up of experts who are responsible for approving debilitating conditions for which a patient might be eligible under the MMMA. Yet, the FDA is not supporting any cannabis-based health claims right now, so any such marketing statements will constitute regulatory violations. Further clarity on what constitutes a health claim ("wellness," "holistic," "calming," "pain management," etc.) should be provided by the Agency to avoid inconsistent compliance and enforcement efforts.

- **What Does it Mean to Advertise a "Marihuana Product?" (R 420.507(4, 6-9))**: There have already been several instances where the Agency, and an operator, disagreed as to whether or not the latter was advertising its brand generally, or advertising a "marijuana product" within the context of the limitations on public advertisements. The Agency should provide further guidance here, or disputes will continue to arise. Also worthy of note, in both the Emergency MRTMA Rules and here, the following prior limitation in the MMFLA Rules has been removed: "A licensee shall not advertise a marihuana product where the advertisement is visible to members of the public from any street, sidewalk, park, or other public place." (R 333.276(3)). This change is appreciated as that prior restriction was overly restrictive in many respects.

- **Trade Samples (R 420.508)**: This rule is identical to the one in the Emergency MRTMA Rules, but for the following provision, which has been deleted: "Except for a licensed designated consumption establishment, the samples may not be consumed or used on the premises of a licensed marihuana establishment." (R 53(3)). This is a good rule change.

- **Allowance of Internal Product Samples (R 420.501(1)(j); R 420.509)**: This was not allowed in the MMFLA Rules, and seems like a welcomed accommodation for testing new products. Note, the "results of internal product sampling" must be documented and kept on hand. Does this mean a survey of employees' impressions of the products? Also, the Trade Samples rule clarifies that those samples need to be tested and entered into METRC. This rule does not have similar language, so clarification on testing and recordation requirements for Product Samples under this rule would be helpful. Also, what is the difference between a Trade Sample and an Internal Product Sample for a Sales Location? Provisioning Centers and Retailers do not generate products, so they would either be given trade samples by up-stream operators, or purchase products and then circulate to their employees as Internal Product Samples before stocking on the sales shelf? Seems odd. More clarity should be provided on these issues.

- **Product Development Allotment (R 420.510)**: Per sub-2, up to 50 plants do not count toward the operators total plant count, which is great. R&D testing is allowed, as further explained in R 420.307. Generally, this is a good rule addition. These products to employees for market research, and can sell those products to a Sales Location, assuming they passed testing. The rule also allows operators to participate in research studies with prior Agency approval which is appreciated.

Set #7 EMPLOYEES

- **Operations Plan Requirement in Employee Training Manual (R 420.602(e))**: This is a new requirement not previously included in the MMFLA Rules. Must address policies to avoid over-intoxication, underage access, illegal sales and other potential criminal activity. The MRA should provide an initial 6 month runway to generate these Manuals to ensure they are based in operational fact rather than hypothetical speculation.

- **21+ for Dual Employees (R 420.602(2)(j)**: Because equivalent licensed operators have to comply with this limitation from the MRTMA, it basically makes it impossible to employ persons between the ages of 18 and 21, unless the operator is running a strictly MM facility. This is unfortunate, especially with regard to contractors and student interns. But, since the 21+ requirement is a part of the MRTMA itself, a statutory changes is required. [*REQUIRES STATUTORY AMENDMENT*]

- **Criminal History for Dual Employees under MMFLA/MRTMA (R 420.602(2)(k))**: Since nearly all Sales Locations will have "equivalent licenses" for MM and AU, the more restrictive prohibitions in the MMFLA ("past 10 years for a controlled substance-related felony," R 333.27405) will always apply, and the social equity initiatives of the MRTMA (disqualifying offenses limited to distribution of a controlled substance to a minor, R 56(2)(b)) will be thwarted. Under this bulletin, the Agency must provide prior approval if an operator under the MMFLA wishes to hire, or continue to employ, a person with a disqualifying offense, so it is possible that the Agency could alleviate the conflict between the hiring limitations in this way, but it would be preferable to align the two standards via amendment of the most restrictive MMFLA standard. [*REQUIRES STATUTORY AMENDMENT*]

Set #9 DISCIPLINARY PROCEEDINGS

- **Advanced Reporting re: Labor Peace Agreements (R 420.802(3)(h))**: Changes to Labor Peace Agreements must be reported in advance, which is odd if one assumes that, in most cases, changes will come due to unexpected breakdowns in renewal negotiations. This should be addressed in the context of the grander discussion on these Labor Peace Agreements generally.

- **Reporting New Civil Lawsuits (R 420.802(5))**: As mentioned in the comments to Set # 1 regarding "Reporting New Civil Lawsuits," having to report the initiation of any civil case is inadvisable for a number of reasons.

MICIL

MICHIGAN COALITION OF INDEPENDENT CANNABIS TESTING LABORATORIES

January 8, 2020

Marijuana Regulatory Agency - Legal Section
P.O. Box 30205
Lansing, MI 48909
Phone: 517-284-8584
Fax: 517-284-8598
MRA-Legal@michigan.gov

SENT VIA EMAIL ONLY

Re: Response to MMFLA and MRTMA Draft Rules and Safety Compliance Facility Sampling and Testing Technical Guidance

Dear Sir or Madam,

The Michigan Coalition of Independent Cannabis Testing Laboratories (MICIL) – currently comprised of all six licensed Safety Compliance Facilities - has reviewed the MRTMA and MMFLA draft rules, as the most recently updated Technical Guidance Bulletins.

Our Coalition has a number of concerns outlined below, as well as suggestions to help amend issues that we have identified.

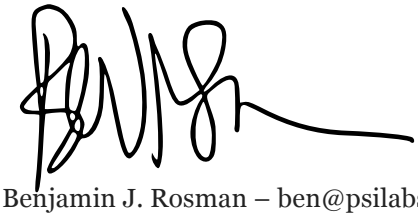
Thank you in advance for your consideration.

Benjamin J. Rosman, JD
CEO & Co-Founder, **PSI LABS**
Founder, **MICIL**
www.psilabs.org / ben@psilabs.org
office: (734) 369-6273
cell: (248) 703-6463

MICIL Member Labs
<Signature Page Follows>

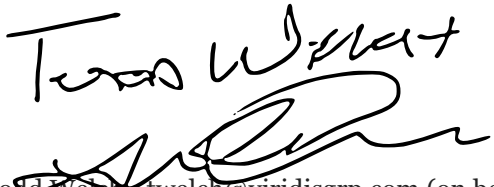
MICIL

MICHIGAN COALITION OF INDEPENDENT CANNABIS TESTING LABORATORIES



Benjamin J. Rosman – ben@psilabs.org (on behalf of PSI Labs, Ann Arbor)

Avram Zallen - safety@steadfastlab.com (on behalf of Steadfast Lab, Hazel Park)



Todd Welch - twelch@viridisgrp.com (on behalf of Viridis Group, Lansing)

Linda Palmatier - lindap@mispott.com (on behalf of The Spott, Kalamazoo)

Amy Brown – abkolabs@gmail.com (on behalf of ABKO Labs, Warren)

Michael Goldman - mike.g@IRONlaboratories.com (on behalf of Iron Labs, Walled Lake)

MICIL

MICHIGAN COALITION OF INDEPENDENT CANNABIS TESTING LABORATORIES

Response to Draft Rules and Technical Bulletin

R 420.304(2)(b) Unlimited Batch Size:

- *"Except otherwise required by the agency, the laboratory shall collect a sample size that is sufficient to complete all required analyses, and not less than 0.5% of the weight of the harvest batch. At least 50% of the sample taken must be homogenized for testing. The agency may publish sample sizes for other marihuana products being tested."*

- The draft rules remove the 15 lb. maximum flower batch size, leaving an **unlimited batch size** in its place. It will be extremely difficult for SCFs to obtain a truly representative sample if there is an unlimited batch size. Sampling will take longer, be more labor intensive, create more of a bottleneck in a system that is already stressed.

- For example, imagine an outdoor grow with a 1,500 lb. total harvest:

    - Draft Rules: 1,500 lb. batch
        - = 7.5 lbs. of 1,500 lb. batch required (0.5% minimum of the batch)
        - Rule 4(2)(b): "At least 50% of the batch must be homogenized for testing":
            - In the example above, this would mean needing to homogenize nearly 4 lbs. of flower for testing.
    - Current Rules: 100, 15 lb. batches
        - =100, 0.075 lb. samples required

- Contamination can often spread out in a heterogeneous manner – especially for microbiological contamination. Splitting samples up across 15lb. batches helps samplers (and facilities) identify areas of the harvest batch that may be more problematic.

- **Recommendation: Michigan should not change the 15 lb. maximum batch size.**

R 420.301(g):"Final Package"

- *"'Final Package' means the form a marihuana product will be in after fully complying with these rules. This is the form marihuana product is in when it goes from a marihuana sales location to a consumer, registered qualifying patient, or a registered primary caregiver."*

- This definition requires more clarity - especially since SCFs can be given citations for providing retests of a product that is in its "final package".

- As an example, it is unclear if the following would be considered final packaging:
  - Products in boxes/packaging, but without affixed test result labels.
  - Products in packages but without any labels whatsoever.
  - Products in packages that have failed, but were taken out of the packages and submitted for a retest?
  - Products in packages, but would be further packaged (e.g., gummies in a bag, but will be placed in an additional container) or would be repackaged.

- There is no clear scientific reason to suggest that once a product has reached a final package state it cannot be safely repackaged without compromising safety or quality. If a processor is able to package a product once safely it seems likely they would be able to unpack and repack product as needed.

- **Recommendation: the definition of "Final Package" needs an explicit, clarifying definition to help alleviate industry confusion.**

R 420.304(2)(e)(iv): "laboratory confirms"

- *"If the product test sample is obtained for a retest, the laboratory confirms that it is not accepting a product test sample that is prohibited from being retested."*

- The state has placed the responsibility on SCFs to monitor their clients, ensuring they are in compliance with the rules. In effect - an SCF must act as both a laboratory and a branch of MRA-Enforcement. However, in failure of those Enforcement duties, the SCF (whose most important duty, and expertise, lies with the testing of samples for compliance) faces penalties, including citation or even suspension.

- Should the onus not be on the sample-submitting facility itself? And because MRA regulates and monitors all traffic via Metrc, could MRA not take this on as their responsibility?

- For example, if a sample has failed for chemical residue, it should automatically be placed on hold and *not* be able to be transferred to another facility.

- **Recommendation: MRA should handle all aspects of enforcement, tracking and monitoring, rather than relying upon (and penalizing) licensed facilities, who should spend their time perfecting their own processes.**

MICIL

MICHIGAN COALITION OF INDEPENDENT CANNABIS TESTING LABORATORIES

R 420.305(1)(a): Scope of Accreditation

- A lab must be accredited within 1 year of licensing. However, there is no mention (and has never been mention in any previous rule set) that after 1 year a lab must have each specific assay (and analyte) in its scope of accreditation in order to perform that test.

- **Recommendation: The state should further clarify this verbiage to allow MRA to approve and validate a SCF's new method, and allow at least 6 months for a scope expansion (which should fall within the SCF's regular ISO surveillance period).**

R 420.305(12): COAs to MRA

- Sending COAs of all failing results to MRA is unreasonably burdensome - especially when all of the data is available to MRA in Metrc. However, upon request the SCF can send any and all COAs. The need to send *all* failing COAs will slow a SCF's turnaround time and, generally, negatively impact industry health.

- **Recommendation: MRA should rely upon Metrc-submitted lab data, and request COAs on an as-needed basis.**

R 420.304(2)(f): Three Day Rule:

- *"The laboratory shall enter into the statewide monitoring system the test results within 3 business days of test completion."*

- Mandating a testing facility to meet deadlines, imparts undue pressure on the analytical staff that will ultimately lead to quality assurance issues within the laboratory. The very standard that the MRA requires the Safety Compliance Facilities to meet for accreditation purposes (ISO 17025), specifically addresses these pressures that have a negative impact on the impartiality of the test results and the laboratory's quality management system governing those results.

- **Recommendation: MRA needs to narrowly define "test completion", given that technical and administrative reviews are a standard, necessary practice.**

R 420.305(4): GMP Certification to Replace Aspects of Safety Compliance Testing:

- *"All marihuana businesses may become certified to GMP by an ISO 17065 accreditation body. This accreditation may enable the licensee certain allowances with testing. The agency will publish those allowances and information on how to obtain approval for*

allowances."

- The ISO 17065 standard is what *certification bodies* become accredited to which brings higher credibility to their product certification operations. They are not an *accrediting body* and subsequently cannot offer accreditation, rather they certify the quality of a product being manufactured. Nowhere in the FDA's Code of Federal Regulations Title 21, where Good Manufacturing Practice is addressed, does it suggest allowances can be made from regulated testing requirements.

- **Good Manufacturing Practice (GMP) is internal to one's processes and should not be used as a measure to avoid testing requirements that ensure the health and safety of consumers.**

R 420.306(2): MRA-enforced lab shopping

- *"The laboratory that reported the initial failing results shall not perform the tests".*

- This is arbitrary and there is no scientific evidence to support the practice. The test should be performed the same way each time, if a failed product is remediated and sent for retesting, there is no reason why it could not be tested at the same SCF to confirm whether the remediation was successful.

- Lab shopping is already a known problem within the cannabis industry. This rule mandates that a facility *must* attempt to find another lab that will pass their product.

- Pursuant to Rule 5 (13), the state already mandates proficiency testing in an attempt to ensure standardization across labs. Further, in order to perform the assay, the lab's methods must have already been approved by both the state and an ISO 17025 accreditation body.

- **Recommendation: MRA should not promote doubt and a lack of confidence in its licensed SCFs. MRA must not force facilities to shop for a lab that will give them the most favorable results. Simply put, MRA should not mandate lab shopping.**

Vape Cartridges - required ATA tests, additives and copper test

- ATA Testing:

    - We want to ensure that moving forward (post-emergency rules), Vitamin E-acetate (ATA) will be a *required* test for *all* newly manufactured vape cartridges -

not merely something notated on a waiver/attestation form, signed off by processors. The recent outbreak of lung injury associated with vape cartridges (EVALI) is becoming a serious health crisis.

- **Recommendation: Michigan must enact a mandatory ATA test for all vape cartridges. Anything less would be irresponsible.**

- Additives:
  - It is currently unclear if botanical terpenes are allowed as an additive, though they are chemically indistinguishable from cannabis-derived terpenes. All vape cartridges (and other marihuana products) are tested for pesticides, metals, solvents (and hopefully ATA) under MRA.
  - **Recommendation: MRA should allow processors to use botanical terpenes as additives, since they are chemically indistinguishable from cannabis-derived terpenes, and they will ultimately undergo the same level of testing scrutiny as all other marihuana products.**

- Required copper test:
  - Copper is now a required test - for vape cartridges only. This was amended, where copper was first required for all marihuana products. Because copper-based fungicide is a safe (approved by MRA) and effective tool in eliminating fungal contamination, a vast majority of flowers we've tested are "contaminated" by copper at high levels. MRA's indifferent knowledge of the fact that patients and adults will be smoking plants "contaminated" with copper - but requiring a health and safety copper test, solely for vape carts, is unusual and illogical.
    - One exception could be if there is scientific data to support the idea that inhaling vaporized copper is more harmful than inhaling copper during combustion of plant material.
  - **Recommendation: Copper should either be a mandatory test for all inhaled products, or be removed entirely as a required test.**

Potency Test

- Reported variance:

- Scientific measurements are reported as ranges or with the ± sign rather than as single values because ***every measurement*** has some degree of variance, which must be reported

- e.g., a cannabis lab may report the variance at 10% relative - an industry standard.

- Statistically speaking, an infused marihuana product reported at 200 mg is equivalent to 180 - 220mg.

- The potency action limit for certain infused marihuana products is 200mg. If a processor yields a "fail" with a test result of 205mg ± 20.5mg (which is statistically equal to 184.5mg), it should not result in a "fail".

- Conflicting information currently exists for this guideline.

    - There is no mention of variances or error tolerances in a recent bulletin on infused product limits, however, a separate webpage for "Rule 34" says that all limits have a variance of +/-10%

- **Recommendation: MRA should account for a lab's reported variance – possibly rewriting the "error" section of the testing guide in ISO terms.**

Homogeneity and Potency Test:

- The Homogeneity Test was recently described to our lab by MRA as an optional test for processors, though the technical bulletins read as it being mandatory for the first batch and every 6 months thereafter.

    - **Recommendation: A Homogeneity Test should be mandatory, and MRA should clarify same to SCFs and Processors.**

- A related issue has to do with the difference between **Precision** and **Accuracy –** in this case, the difference between the homogeneity of a batch of infused products (**precision**) and the variance from the target dose (i.e., **accuracy**).

    - **Precision** is the variability from unit to unit within the batch which is covered by the +/-15% variance allowed in Homogeneity Tests.

- e.g**.,** if each individual increment tested was within +/-15% of each other (e.g., 10 mg, 11 mg., 10.5 mg, 12 mg.) - the product would **pass homogeneity**. If the doses were significantly different (e.g., 10mg, 50mg and 100 mg), the product would **fail homogeneity.**

- **Accuracy** is how close the actual measured potency is to the target dose.

- While it is very important to establish that tested products are homogenous (to ensure the end user gets the same expected dose each time, that only addresses the **precision** of the edible dosing. **Accuracy** is *not* being addressed with the current iteration of Homogeneity Testing, and has thus far been ignored for Potency Testing, possibly as an oversight.

  - Example: Target dose of 200mg, and actual potency of:

    - 201mg - **fails** Potency Test.

    - 6 mg - **passes** Potency Test.

      - Increments tested w/in +/- 15% of each other – 6 mg, 6.4 mg, 6.1 mg, 6.3 mg – **passes** Homogeneity Test.

- **Recommendation: MRA should mandate the Homogeneity Test (Precision), and also flag products as Potency Test failures if the tested potency is not +/- 15% of the target dose (Accuracy). Remediation can include repackaging with a different label to reflect the lower/higher dose.**

- **Measuring both Precision and Accuracy is crucial for establishing the consistency of the products from package to package and dose to dose, and will also help ensure that the dose is within +/- 15% of the target dose (often permanently printed on packages as part of branding).**