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Marijuana Disciplinary Proceedings; Industrial Hemp for Marijuana Businesses; and Medical Marijuana Facilities (Rescinded) (collectively referred to as the "Proposed Rules") being promulgated pursuant to the Medical Marihuana Facilities Licensing Act ("MMFLA") and the Michigan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

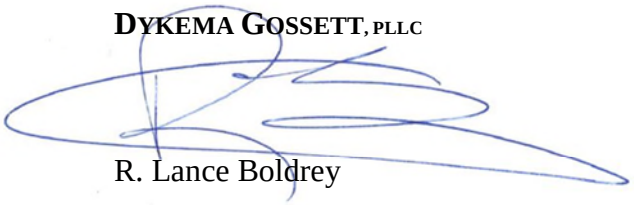
R 420.1003—Processing industrial hemp.

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

Robin Schneider
Executive Director
(517) 974-2265
robin@micannabisindustryassociation.org

MiCIA
216 N. Chestnut St.
Lansing, MI 48933
micannabisindustryassociation.org

MICIA COMMENTS ON DRAFT MARIHUANA RULES

(Rule sets # 2019-67 LR, 2019-68 LR, 2019-69 LR, 2019-70 LR, 2019-71 LR, 2019-72 LR, 2019-73 LR, 2019-74 LR, & 2019-75 LR.)

INTRODUCTION

The Michigan Cannabis Industry Association (MICIA) is the leading voice for Michigan's legal cannabis businesses. The association advocates for a responsible and successful medical and adult-use cannabis industry by promoting sensible laws and regulations and industry best practices among members. MICIA seeks to create a thriving industry for cannabis businesses in Michigan by developing opportunities for industry collaboration and partnerships and sharing industry knowledge and best practices among its membership.

MICIA supports many elements of the proposed rules. But MICIA offers the following constructive comments with the hopes of developing policies that promote both the growth of the industry and the establishment of good business practices. Moreover, MICIA seeks to ensure that the Marijuana Regulatory Agency (MRA) receives adequate stakeholder input prior to the adoption of its generally applicable policies, standards, and enforcement procedures consistent with the rule of law and the Michigan Administrative Procedures Act, MCL 24.201 *et seq*. Lastly, MICIA notes that, though it has not exhaustively commented on all of the rules, its silence on some rules should not be understood as either approval or disapproval of those particular provisions.

COMMENTS

1. Licensing Rules (R 420.1 *et seq.* and R 420.101 *et seq.*)

Licensing Prequalification Application Procedures

Proposed Rule 420.3(2) provides, in part, that prequalification status for a pending application is valid for 1 year after the agency issues a notice of prequalification status unless otherwise determined by the MRA. After 1 year has expired, the proposed Rule authorizes the MRA to require the applicant to submit a new application and pay a new nonrefundable application fee. While the permissive language of the proposed Rule provides that MRA with a great deal of flexibility, MICIA suggests that the MRA extend the period under which an incomplete, pending application may be held in prequalification status from a one-year or a two-year period. Oftentimes prequalified applicants who are actively under construction require more than one year to complete the final application due to circumstances beyond their control such as delay or inaction by contractors and/or local or county governments. To require those applicants to redo their

application and pay a new nonrefundable application fee under those circumstances can be unduly burdensome during the startup phase of a new business.

Licensing Application Procedures – Control

Proposed Rule 420.4(2)(*iv*)(B) requires applicants to disclose "any other person who . . . [i]s controlled, directly or indirectly, by the applicant or by a person who controls, directly or indirectly, the applicant." This cumbersome requirement has been difficult to understand and could theoretically require disclosure of a string of persons far removed from the applicant. MICIA suggests that this language be removed, limited, or further clarified.

Application Deficiencies – Opportunity to Cure

Proposed Rule 420.5(4) and (5) provides an applicant 5 days to correct any deficiency in the application. Failure of an applicant to correct a deficiency within 5 days of notification by the agency may result in the denial of the application. MICIA suggests that this timeframe be extended to ten days or, at least, be revised to provide five "business days" excluding holidays to cure application deficiencies.

Mandated Labor Peace Agreements

MICIA is opposed to the rules' mandate that licensees enter into and abide by labor peace agreements. R 420.5(6), R 420.13(1)(e), R 420.14(3)(h), & R 420.21(2)(m), R 420.801(1)(e), & R 420.802(3)(h). A legal mandate forcing a unionized workforce on applicants is both wholly unnecessary and unrelated to an applicants' qualifications to operate a marijuana establishment. The mandate also raises a number of significant legal concerns, including but not limited to whether it conflicts with federal law governing private-sector labor relations and state law preventing forced unionization. MICIA further believes such requirements are beyond the agency's delegated rulemaking authority under MCL 333.27206, MCL 333.27957, & MCL 333.27958. Additionally, the MRA has failed to engage in any cost-benefit analysis related to this requirement and its impact on the industry. See generally MCL 24.245(3).

Civil Lawsuit Reporting Requirement

Proposed Rule 420.14(5) requires applicants to notify the agency within 10 days of the initiation or conclusion of any new civil lawsuits or legal proceedings that involve the applicant. To the extent such actions are unrelated to any criminal or regulatory actions, this requirement is unnecessary and should be removed. The reporting requirement provides an incentive for third parties to target and seek to obtain leverage over licensees by threatening non-meritorious litigation. MICIA, however, continues to support reporting for civil judgments entered against licensees.

Excess Marihuana Grower Licenses

MICIA supports the MRA's inclusion of excess marihuana grower licenses. R 420.20(1)(b); & R 420.22. MICIA views this license as a significant means of addressing a market shortage of available product by permitting larger scale cultivation.

Marihuana Event Organizer Licenses and Temporary Event Licenses

MICIA supports the MRA's inclusion of marihuana event organizer licenses and temporary event licenses. R 420.20(1)(c), (1)(d), & (3); R 420.23; & R 420.24. MICIA sees both as a positive means of facilitating industry development and social consumption.

Marihuana Delivery Business License

MICIA opposes the MRA's development of rules allowing the licensure of standalone delivery businesses permitted to operate without a secured transporter license and without obtaining local approval. See R 420.20(1)(e) & R 420.27. MICIA believes that these services are more effectively regulated and tracked at licensed marihuana retail locations or when directly consummated by licensed marihuana retailers.

Research and Development License

MICIA proposes that the MRA develop and adopt rules to promote the growth of facilities specializing in genetic advancement of marihuana plant strains, seeds, and clones for sale via secured transporters to licensed growers.

Marihuana Plant Count – Female Flowering

MICIA supports the clarification in proposed Rule 420.102 that only female marihuana plants that flower may be included in the plant count referenced in subrule (1) of this rule. This treatment more accurately reflects marihuana growth and harvest cycles and should help alleviate the current supply shortage. MICIA further suggests replacing the phrase "female marihuana plants that flower" with the phrase "flowering marihuana plant" and defining that term as "a marihuana plant that has visible calices, stigma, or preflowers located at the node or a stem or branch."

Marihuana Transfers

MICIA supports the more flexible marihuana transfer provisions for licensed growers, processors, and retails in proposed Rule 420.102, 420.103, and 420.104.

2. Operations Rules (R 420.201 *et seq.*)

Orders Limiting Sales from Cultivators and Producers to Retailers Under Common Ownership

Proposed Rules 420.206(16)(a) & (16)(b) authorize the MRA to set orders limiting the sales from cultivators and producers to producers and marihuana sales locations under common ownership and establish sanctions and fines for violations of those orders. MICIA supports the concept of encouraging supply to licensed retailers who are not part of a vertically integrated operation and thus maintaining the value of separate license types. But MICIA believes that this issue can have a substantial impact on the industry and requires further study. Accordingly,

proposed rules should be withdrawn and a stakeholder workgroup should be established to provide more industry input on this issue before adoption of regulation on this topic.

Further, MICIA believes that, as part of that study, the MRA should identify either quantitative thresholds or qualitative standards for when the agency would exercise this authority. Although MICIA understands the MRA's position that these rules discourage stockpiling and promote adequate supply and distribution, MICIA requests that, to avoid inconsistent or arbitrary application of its authority, the MRA set standards to clarify the quantitative thresholds at which the agency may impose such an order or the limitations the agency intends to place on the amount of product that may be sold to entities under common ownership.

Prohibition on Sale of Fresh Food and Beverages

Proposed Rules 420.203(2)(b)(i) & (2)(b)(ii) prohibit marihuana businesses from allowing the onsite sale, consumption, or serving of food or alcohol unless designated as a consumption establishment and also prohibit the consumption, use, or inhalation of marihuana product without such license. See also R 420.201(1)(k) (defining "designated consumption lounge"). MICIA notes that MRA enforcement has interpreted this as prohibiting the sale or consumption of all kinds of beverages such as coffee, tea, or juice. MICIA recommends changing this rule to permit the sale of fresh food and non-alcoholic beverages at retail locations without additional approvals or licenses.

Access to Licensee Records

Proposed Rule 420.203(f) provides that "[l]icensee records must be maintained and made available to the agency upon request." MRA has taken the position that this language requires "immediate" access upon request. Many vertically integrated marihuana businesses maintain their records at a corporate headquarters and/or have security protocols that prevent immediate access to such records which presumably has a broad definition. MICIA recommends clarifying this language to provide access to records within 24 hours after a request.

Waste Removal Requirements

Proposed Rule 420.211(6) restricts a licensee's options for the disposal of marihuana product waste and marijuana plant waste to landfilling, composting, anaerobic digestion, and incinerator at a permitted, in-state municipal solid waste or hazardous waste incinerator. MICIA views these options for disposal as too restrictive. MICIA instead recommends that the MRA consider other innovative, sustainable, and/or environmentally responsible options for on-site disposal that may be more beneficial to the environment. MRA may thus amend the proposed rule to add the following language "or alternative method not listed with approval from the department." Along these same lines, MICIA further supports proposed Rule 420.211(13) which provides that "[n]othing in these rules prohibits a grower, with agency approval, from disposing of marihuana plant waste as compost feedstock or in another organic waste method at their marihuana business in compliance with part 111 of the natural resources and environmental protection act, 1994 PA 451, MCL 324.11101 to 324.11153."

Generic Adoption of the NREPA and Failure to Promulgate Rules Regarding its Application

Proposed Rule 420.203(3)(a) adopts entirely the application of the NREPA, MCL 324.101 to MCL 324.90106 to marihuana businesses without explaining which provision the MRA views as applying to particular circumstances and stating that "[t]he agency may publish guidance" to that effect at a later date.

MICIA and its members support good stewardship of the environment but oppose the imposition of new marihuana-specific environmental laws without the benefit of industry participation and other stakeholder's feedback through rulemaking. To the extent the MRA intends to set generally applicable policy on the environmental obligations of marihuana businesses that either the MRA or EGLE intends to enforce, such "guidance" must be promulgated. MCL 24.207; MCL 24.226.

Alternatively, MICIA requests that this new requirement not go into effect until one year after promulgation.

Broad Assertion of Agency Authority Unrelated to any Express Statutory Grant

Proposed Rule 420.203(3)(b) subtly assumes expansive authority to the MRA to require broad operational changes to marihuana businesses. The proposed rule states that "[a] marihuana business shall comply with . . . (b) *Any other operational measures requested by the agency that are not inconsistent with the acts and these rules*." (Emphasis added.)

MICIA opposes this assumption of broad and undelegated authority by the MRA. The agency's assertion of such broad power over marihuana businesses as to demand any operational changes "not inconsistent with" the law inverts the axiom that, as creatures of statute, administrative agencies can only assert the power expressly granted to them by law. See *York v City of Detroit*, 438 Mich 744, 767 (1991) ("While an administrative agency may make such rules and regulations as are necessary for the efficient exercise of its powers expressly granted, ''an administrative agency may not, under the guise of its rule making power, abridge or enlarge its authority or exceed the powers given to it by the statute, the source of its power.'")

Equivalent Licenses Operating at Same Location

MICIA supports the common-sense and efficient approach contained in proposed Rule 420.205 allowing equivalent licenses with common ownership to be operated at the same location.

3. Sampling and Testing Rules (R 420.301 *et seq.*)

Homogenizing of Samples

Proposed Rule 420.304(2)(b) requires the collection of samples of "not less than 0.5% of the weight of the harvest batch" and requires samples to be "homogenized for testing." This language seems to allow for unlimited batch sizes and marks a drastic departure from existing standard of 15-lb batches. MICIA suggests that, because contamination can spread out in a heterogeneous manner, it would be more appropriate to split samples up across batches with some

form of weight-based limitation in order to obtain a more representative sample of harvests. For example, under the proposed language, a 1,500 lb. summer "harvest batch" would require 7.5 lbs. to be tested and 50% of that homogenized. But sorting that harvest batch into smaller batches would provide better data on the quality of the product.

Scope of Laboratory Accreditation

Proposed Rule 420.305(1)(a) requires laboratories to be accredited within 1 year of licensing but do not clarify whether specific assays or analytes must be included within its accreditation. MICIA recommends that the MRA modify this rule to allow the MRA to approve and validate a Safety Compliance Facility's new method and to allow at least 6 months for a scope expansion within the Safety Compliance Facility's regular ISO surveillance period.

Good Manufacturing Practices Certification and Adoption

MICIA strongly supports the provision of the rules allowing for good manufacturing practices certification and adoption as applied to marihuana businesses. R 420.301(1)(i); R 420.305(4); R 420.602(2)(h).

Filing of Certificates of Analysis with the MRA for Failed Samples

Proposed Rule 420.305(12) requires laboratories to "enter the results into the statewide system and file with the agency within 3 business days of test completion" each laboratory test result "for any batch that does not pass the required tests." MICIA reads this requirement to unnecessarily mandate a duplicative "fil[ing]" of certificates of analysis with the agency after the results have already been entered into the statewide system. Because the laboratories will enter this information into the statewide system electronically, MRA should modify this requirement to clarify that it will not require a separate filing from laboratories. MICIA further seeks clarification regarding whether the language "test completion" refers to the completion of each individual test or when the full panel of tests per sample are completed.

Encouragement of "Laboratory Shopping"

Proposed Rule 420.306(2) prohibits laboratories that conduct an initial failed test of a sample from performing any retesting. The proposed rule has the perverse effect of encouraging laboratory shopping and discouraging the reporting of failed test results by laboratories. Rather than discourage accurate test reporting for failed samples, MICIA suggests that this language should be removed.

Retesting and Remediation

The MRA's proposed limitations on retesting and remediation, R 420.306(2) & (3), are unduly restrictive. The agency should broaden these provisions to allow for more extensive retesting and remediation. MICIA, however, supports R 420.306(4) which appears to allow quarantined product to be transferred between licensed processors for purposes of remediation as not all processors own applicable remediation equipment.

Failure to Promulgate Action Limits and LOQs

The rules require the agency to establish both action limits setting standards for "the permissible level of a contaminant in marihuana product" such as foreign matter, microbial screening, heavy metals, and residual solvents, R 420.301(1)(1)(a) and R 420.305(3)(b)–(3)(f), (6), & (9), and limits of quantification (LOQs) for chemical residue and target analytes. R 420.301(1)(n) and R 420.305(3)(i) & (10). Those action limits and LOQs are attended by significant consequences. Product failing to meet the standards "must be destroyed as provided in these rules or remediated" as permitted by the agency. R 420.306(2)–(4). The proposed action limits and LOQs thus set "agency regulation[s], . . . standard[s], . . . [and] polic[ies] . . . of general applicability that implement[t] or appl[y] law enforced or administered by the agency." MCL 24.207. As such, the action limits and LOQs are "rules" requiring promulgation in order to be enforceable by the agency. MCL 24.207; see also MCL 24.226; & MCL 24.232(5).

MRA's failure to include the proposed action limits and LOQs in the rules improperly circumvents the APA's rulemaking requirements. *Delta Co v Dep't of Natural Resources*, 118 Mich App 458, 468 (1982). Further, the failure to vet these standards through the rulemaking process and to allow the industry and other groups to have input into their development and their propriety for the purpose of establishing health-based standards will result in less technically accurate action limits and render them legally unenforceable.

Failure to Promulgate Remediation Protocol

Similarly, the rules delay to a later time the publication of a "remediation protocol." R 420.306(4). Like the action limits, this protocol sets "generally applicab[le]" agency policy "that implements or applies the law enforced or administered by the agency." MCL 24.207. Consequently, the remediation protocol is also a rule that needs to be promulgated.

Failure to Promulgate Safety Test Requirements

Additionally, the MRA has elsewhere circumvented the rulemaking process for safety test requirements, indicating that "the agency may publish a guide indicating which of the following tests are required based on product type when marihuana product has changed form." R 420.305(3). As noted above, such a decision sets an agency policy of general applicability concerning the law it enforces. MCL 24.207. Deciding which tests will be required for sampling and analyses must be vetted through rulemaking and included in this set of rules rather than via a later "guide" or bulletin. MCL 24.226; *Detroit Base Coalition*, 431 Mich at 183–84.

Vape Cartridge Testing

MICIA suggests the adoption of a rule to require vape cartridges to be tested for Vitamin E-acetate (ATA). Because of the recent outbreak of injuries associated with vape cartridges containing ATA, such a rule would promote the public health.

4. Sales and Transfers (R 420.501 *et seq.*)

Internal Product Sampling by Employees

Proposed Rule 420.509(5) permits cultivators to provide internal product samples to their employees but limits those samples to 2.5 ounces in a 30-day period. MICIA supports the rules' encouragement of employees' product sampling. Employee product sampling can foster familiarity with and develop their expertise concerning the product, which facilitates better operations and encourages sales. But the MRA's proposed limitation is too stringent and improperly sets a limitation that does not take into account the size of or number of employees at an operation. MICIA instead proposes that the MRA extend this provision to allow cultivators to provide internal product samples of up to 1 ounce per employee per month. MICIA further seeks clarification of what level of documentation will satisfy the requirement that "[t]he results of internal product sampling must be documented . . . ."

5. Non-compliance with APA Procedures (all sets)

MICIA also notes that the MRA has improperly failed to comply with APA procedural requirements for this set of rules in several respects. Per MCL 24.245(3)(*l*), (3)(*m*), & (3)(*n*) the MRA was required to include in its Regulatory Impact Statement and Cost Benefit Analysis (RIS-CBA) "an estimate of the actual statewide compliance costs of the propose rules on individuals" and "an estimate of the actual statewide compliance costs of the proposed rules on business and other groups" as well as "a demonstration that the proposed rule is necessary and suitable to achieve its purpose in proportion to the burdens it places on individuals." The RIS-CBAs in support of the rules do not engage in any significant substantive analysis of the economic impacts of the proposed rules on individuals and businesses nor include any numerical estimates of these impacts.

Additionally, MCL 24.245(3)(*o*)–(3)(*s*) require detailed analysis of and estimates of the financial impacts of the rules on small businesses. The RIS-CBAs do not provide any such estimates nor any substantive analysis and simply state that "[i]t is uncertain how many small businesses may be affected by the proposed rules" but that "the belief is that these proposed rules will make it easier for small businesses to enter the regulated market." The RIS-CBAs make such a statement without analyzing the barriers to entry imposed on small businesses as a result of the licensing and operational costs associated with the rules.

The rules also fail to estimate the impacts to state and local revenues as a result of the rules. MCL 24.245(3)(*z*) & (3)(*dd*). In response to question # 13 posed by the RIS-CBA requiring an "[e]stimate [of] any increase or decrease in revenues to other state or local governmental units . . . as a result of the rule," the agency merely states that "[t]here are no anticipated increases or decreases in revenues or costs to other state or local government units as a result of the proposed rules." This suggestion is not credible. Given the various direct compliance costs and other regulatory burdens imposed by the rules, the agency's failure to estimate the impacts of these burdens on marihuana businesses' sales and the resultant impact on state and local revenues through the State's corporate income tax, MCL 206.601 *et seq*, local income tax paid by both the businesses and their employees, MCL 141.501 *et seq*, sales tax, MCL 205.51 *et seq*, use tax, MCL

205.91 *et seq*, the General Property Tax Act, MCL 211.1 *et seq*, and of course, the Michigan Regulation and Taxation of Marihuana Act, MCL 333.27951 *et seq*., is unsupportable.

As one example, the testing and sampling rules' requirement to test "not less than 0.5% of the weight of the harvest batch," R 420.304(2)(b), means that at least 0.5% of such a harvest is not being sold. That cost has not been calculated and weighed against the alleged benefit of the sufficiency of that sample size to conduct required tests, the impact of sample size on sampling accuracy, and whether a smaller sample size would achieve the same goals. Nor has the agency calculated the impact of its proposal limiting the ability to remediate and retest (and ultimately requiring the destruction of) marihuana that does not meet action limits. See generally R 420.306. Recent market values of marihuana have averaged over $500 per ounce through licensed operations. See https://www.mlive.com/public-interest/2020/02/major-marijuana-website-bans-advertisements-from-black-market-companies-in-michigan.html. Consequently, small alterations to the scope of such requirements can impose a substantial cost on large volumes of sales as well as attendant costs state and local revenues of a minimum of 16% in sales and marihuana excise taxes. MCL 205.52(1); MCL 333.27963(1).

These procedural defects deprive stakeholders, the Legislature, and the agency of a more substantive debate regarding the costs and benefits of individual proposed rules. Additionally, the defects can render the rules invalid through an APA procedural challenge. MRA should therefore resubmit the rules with these legislatively required analyses.

CONCLUSION

MICIA appreciates the opportunity to comment on the MRA's proposed rules and the MRA's efforts to develop a sound regulatory structure for the cannabis industry. MICIA believes that, with the changes suggested above and with greater industry feedback and more thorough vetting of the costs and benefits of proposed regulations, Michigan can be a leader both economically and in its promotion of good business practices for the industry.

Respectfully submitted,

Robin Schneider, Executive Director
Michigan Cannabis Industry Association
www.MICannabisIndustryAssociation.org

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.

February 17, 2020

Marijuana Regulatory Agency
Legal Section
P.O. Box 30205
Lansing, MI 48909
Re: Comments on the Proposed Combined Topic-Based Rule Sets

To Whom it May Concern:

R 420.201 (a) defines “active ingredient” as marihuana, as defined in section 7106 of the public health code, 1978 PA 368, MCL 333.7106.”

The proposed definition of “active ingredient” excludes industrial hemp. If this definition is adopted, we will find ourselves in a situation where the same chemical compounds—from the same genus and species of plant—are considered either “active ingredients” or “inactive ingredients” depending on the percentage of THC in the plant.

For example, CBD from a Cannabis Sativa L plant with more than .3% THC would be considered “active ingredient”. This CBD could be added to products under the proposed definition. On the other hand, Chemically identical CBD from a Cannabis Sativa L plant with less than .3% THC would be considered “inactive ingredient”. This CBD could not be added to products under the proposed definition because “inactive ingredients” must be approved by the FDA under 420.206 (11).

As a second example, a terpene from a Cannabis Sativa L plant with more than .3% THC would be considered “active ingredient”. This terpene could be added to products under the proposed definition. On the other hand, a chemically identical terpene from a Cannabis Sativa L plant with less than .3% THC would be considered “inactive ingredient”. This terpene could not be added to products because inactive ingredients must be approved by the FDA under 420.206 (11).

Dual treatment of the same ingredient from the same genus and species of plant would be confusing and misleading to patients and customers. The cannabinoids and terpenes in marijuana products have the same medicinal properties regardless of the THC content in the Cannabis Sativa L plant from which they were extracted. The common usage definition of “active ingredient” carries the connotation of medicinal effect. A product label that listed a biologically active ingredient as an “inactive ingredient” would be misleading.

This is important because listing “inactive ingredients” is a labeling requirement in 420.206 (11). “All non-marihuana inactive ingredients must be clearly listed on the product label.” Listing the same cannabinoid or terpene ingredient as an “active ingredient” on one package and an “inactive ingredient” on another package would confuse customers, and it has the potential to cause customers to take the wrong dose of the ingredients they are seeking. It’s easy to imagine a patient or customer taking too large a dose or serving of a marijuana product because he or she was over-compensating for an ingredient that was listed on the product label as “inactive”.

We ask that MRA solve the problems described above by updating the definition of “active ingredient” to include industrial hemp.

R420.305 (1) (h) defines “final package” as “the form a marihuana product is in when it is available for sale by a marihuana sales location.”

It appears this definition of final package is attempting to conflate two independent and important concepts, “final package” and “final form”.

We believe “final form” should be defined in the rules in addition to “final package”.

“Final form” should be defined as the “final set of ingredients, after all processing, mixing, curing, filling, quality control, and other preparatory processes have been completed, such that the product is in the same state it will be in when sold by a retailer”.

“Final package” should be defined as “the final retail-ready protective packaging that houses and protects a product that is in final form, so it can be sold by a retailer”.

We worry that conflating the concepts of “final package” and “final form” could lead us to a situation in which processors are not allowed to produce marijuana-infused products in a way that allows for remediation and/or retesting because any product produced would be considered a product in “final package” as soon as it was in “final form”.

We hope to be able to produce an item and have it tested in “final form” before we place it into a “final package”. We hope to have the opportunity to remediate an item like a cartridge or edible after a failed test, before it is placed into retail-ready packaging. Remediation is technically possible and completely safe in situations like a potency fail in an edible or a residual solvent fail in a cartridge. We ask that remediation and retesting be allowed in all situations where full compliance testing can be performed after remediation, to ensure patient safety is in no way put at risk.

R. 420.303 (10) says, “After a package is created by a producer of the marihuana product **in its final package**, the producer shall have the sample tested pursuant to R 420.304 and R 420.305.

We believe this rule should be changed to say, “After a package is created by a producer of the marihuana product **in its final form**, the producer shall have the sample tested pursuant to R 420.304 and R 420.305.

This change requires the addition of a definition of “final form”, which we believe will remove the ambiguity from the definition of “final package”.

R. 420.304 (h) says, “a marihuana business that receives a certificate of analysis stating that the sample meets specifications required by the agency shall ensure that the test results entered into the statewide monitoring system matches the information provided on the certificate of analysis received from the laboratory prior to transportation, sale, or transfer of the marihuana product.”

We believe safety compliance facilities should be responsible for uploading accurate data to the statewide monitoring system. We are unclear why the responsibility of uploading accurate test data to the statewide monitoring system should extend to a grower, processor, or retailer. If an audit step or additional redundancy is needed because a laboratory doesn’t have an automated, error-free way of uploading results from their internal system to Metrc, this redundancy should be provided by a second laboratory employee doing an audit of the certificate of analysis to make sure accurate results have been uploaded to Metrc.

Growers and processors should not be responsible for laboratory mistakes. The statewide monitoring system provides test results in a standardized format. On the other hand, each certificate of analysis is formatted differently, and it’s often difficult to tell whether a product passed or failed testing when looking at a certificate of analysis.

The statewide monitoring system should continue to be the system of record for test results. Growers, processors, and retailers should be able to rely on the test results in Metrc. Growers, processors, and retailers should not have to check a COA to verify the data in Metrc is accurate.

R420.305 (10) says, "For the purposes of chemical residue testing and target analyte testing, the agency shall publish a list of quantification levels. Any result that exceeds the LOQ is a failed sample."

We understand and support the requirement in the MMFLA that marijuana be **reasonably free** of chemical residues. MMFLA Sec. 505. (4) says: "A safety compliance facility shall… ...Perform tests to certify that marihuana is **reasonably free** of chemical residues such as fungicides and insecticides."

The concern we have is that the proposed rule goes beyond the "reasonably free" standard. Under the proposed rule, a marijuana product must be absolutely free of chemical residues in order to pass testing. Any amount of chemical residue detected would result in a fail, and—if remediation and retesting are not allowed—an order from MRA to destroy the material.

Modern laboratory equipment is so sensitive that it can pick up contamination into the single-digit parts per billion. There must be some level at which a product can be considered **reasonably free** of the chemical residue.

Extremely low levels of chemical residue in test results indicate contamination in the environment or in the equipment, rather than use of a banned pesticide.

Growers are vulnerable to environmental contamination from neighboring farms. Processors are vulnerable to low levels of contamination when they process material on equipment that has previously been used to process caregiver material or industrial hemp.

In cases of low-level environmental or equipment contamination where the licensee has not used a banned pesticide, we believe MRA should allow material that fails testing for chemical residue to be remediated or used in edibles (assuming the level of chemical residue is below the EPA's Maximum Residue Limit for food).

We have an additional concern that MRA's suggested approach of setting "Limits of Quantitation", rather than action limits, incentivises laboratories to use older testing equipment so as not to detect contamination below the LOQs set by MRA.

This approach is akin to closing our eyes and hoping the problem isn't there. It's not the right approach. Growers, processors, and regulators need more data—not less data—in the event of low-level environmental contamination, so the problem can be understood and corrected. Instead of reporting a result as "not detected" (below the LOQ), laboratories should be incentivised to calibrate their equipment as accurately as possible and report the actual result detected. Accurate residue data is crucial to the grower, the processor, and the regulator. All three parties are aligned in their goal of eliminating the source of the contamination and removing the residue contamination from the material.

We feel strongly that the LOQ approach is the wrong path forward for Michigan and the Cannabis Industry. This standard goes far beyond the statutory requirement that marijuana be **reasonably free** of chemical residue. And, it creates a situation where growers and processors can have massive financial losses due to 1 or 2 parts per billion of chemical residue.

We ask that MRA use an approach more similar to the EPA's approach in setting Maximum Residue Limits for food, and/or the FDA's approach in setting Maximum Residue Limits for tobacco products.

R. 420.307 (1) defines “research and development testing” as “optional testing performed before final compliance testing.”

Expanding the definition to allow for R&D testing **before or after** final compliance testing would provide valuable data to growers, processors, and regulators.

When material fails a final compliance test, the grower or processor has no way to know whether the failed result was accurate or due to laboratory error. Having an R&D test performed after the failed compliance test would allow the grower or processor to gather additional data. If the R&D test result conflicted with the final compliance test, the grower or processor would then have data to provide MRA when asking MRA to investigate the accuracy of the final compliance result.

Accurate results and clean, safe products are in everyone’s interest. We see no downside to allowing R&D testing after final compliance testing.

If MRA is concerned growers or processors may use R&D testing for “lab shopping”, we would point out that lab shopping would more likely occur prior to final compliance testing.

Additionally, we’d point out that R&D testing after final compliance testing would give MRA access to valuable data about disparities between safety compliance facilities. To the extent there are disparities in results issued by different laboratories, MRA would surely want to identify and fix these issues as quickly as possible.

R&D testing after final compliance testing is an important tool for growers and processors to help MRA identify false positives and other laboratory errors.

R. 420.306 (3) A marihuana product is prohibited from being retested if a final test for chemical residue failed pursuant to these rules. If the amount of chemical residue found is not permissible by the agency, the marihuana product is ineligible for retesting and remediation, and the product must be destroyed. This subrule does not apply to marihuana product that has been obtained under a Resolution on Marijuana Product Access for Patients adopted by the medical marihuana licensing board.

This rule is problematic for several reasons:

1. In the past 12 months we've learned that safety compliance facilities do make errors from time-to-time. The Choice Labs Processor Facility has had at least three false positives where material failed testing for chemical residue, and that failed result was later updated in Metrc when the lab acknowledged their mistake. We had an additional 8 samples where the lab admitted mistakes that amplified the result, but was unwilling to correct the results in Metrc without permission from MRA, which was not granted.

This rule is written under the assumption that labs don't make errors, and that just isn't the case.

What is the statutory justification for denying a facility the ability to retest an item that failed testing for chemical residue? Are the labs so unreliable that a contaminated item could pass two subsequent retests? If yes, that underscores the importance of allowing retests.

In fact, the labs do make mistakes. Samples are prepared by humans. There is always the potential for contamination within the lab equipment, glassware, utensils, or elsewhere in the facility. Retesting is the best way to find out whether the lab made an error. Why is retesting prohibited? Retesting should be encouraged. Confirmation and reproducibility of data are cornerstones of the scientific process.

2. The rule does not distinguish between growers who intentionally sprayed banned pesticides on their plants, and growers or processors who suffered extremely low-level (but detectable) environmental contamination.

Ultra-low levels of chemical residue indicate accidental contamination rather than use of a banned pesticide. In the event of accidental contamination, processors should be allowed to remediate the material to remove the chemical residue. The rule as written will result in needless financial losses for licensees, and needless shortages of material for patients and customers.

Growers are vulnerable to large losses from environmental contamination.

Processors are vulnerable to chemical residue contamination or accumulation during processing, even though the processor never has used a banned pesticide.

Consider a processor who purchases trim from an outdoor grower intending to process the trim into THC Distillate. The grower's crop passes chemical residue testing. The processor takes that material, extracts it, and concentrates it into THC Distillate. When the processor sends the THC Distillate for testing, he discovers the concentrated material has failed testing. In other words, the trim was below the LOQ, but the concentrated material is now above the LOQ.

Under the proposed rule, the material would be ordered destroyed. No retest would be allowed. The parties negatively impacted by the failed test result would not even be able to verify that the result was in fact accurate through an R&D test after the final compliance test.

We urge MRA to differentiate between banned pesticide use and accidental environmental or equipment contamination. Licensees that haven't used banned pesticides should be allowed to remediate and/or retest in the event of low-level fails.

R. 420.306 (4) says, “The agency may publish a remediation protocol including, but not limited to, the sale or transfer of marihuana product after a failed safety test as provided in these rules.”

We’ve been told by MRA that they’re currently not allowing a processor to transfer failed material to another processor for remediation. We cannot see any way in which this policy benefits licensees, regulators, or patients. A processor is unlikely to have every piece of remediation and processing equipment.

We believe the rules and remediation protocol should allow a processor to transfer material to another processor for remediation. As a processor, we intended to offer remediation services to other processors who may not have the equipment we have. We were disappointed not to be able to offer this service.

R 420.404 says, “A marihuana sales location shall not sell or transfer marihuana-infused products that exceed the maximum THC concentrations established by the agency. For the purposes of maximum THC concentrations for marihuana-infused products, the agency shall publish a list of maximum THC concentrations and serving size limits.”

The maximum THC concentrations and serving size limits—as currently enforced by MRA—are hard ceilings.

Given that potency results themselves have a margin of error, we ask that MRA allow for a +/- range above the maximum THC concentrations and serving size limits that mirrors the acceptable laboratory margin of error.

One additional suggestion:

Throughout the past year, we’ve seen potency variations of approximately 10% between labs.

It is our understanding that there is currently no mechanism in the rules to ensure that two different labs would give the same (or nearly same) result.

We encourage MRA to create a rule or internal process designed to reduce variations in results between labs.

It is our view that growers and processors should be able to have their products sampled by any licensed lab and receive the same results within a very tight tolerance.

Sincerely,

Maxwell Murphy
Compliance Department
Choice Labs, LLC

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.

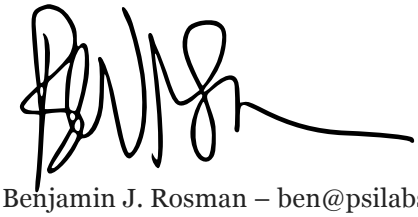
Thank you in advance for your consideration.

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>

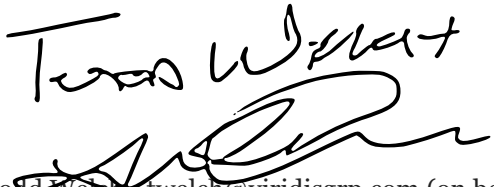
MICIL

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).**

Recommendations on Proposed Marijuana Rule Sets

Overview

The current regulation and interpretation of cannabis flower/cannabis concentrate remediation is significantly reducing the ability of safe cannabis to get to market, and in turn negatively effects patients, industry stakeholders, as well as the framework of the medical and adult-use cannabis programs. In addition to these negative impacts, the current rules significantly reduce scientific method development and innovation. Furthermore, the decreased product to the legal market as a result of these regulations will continue to raise the cost of licensed products and prolong the dependency on caregiver cannabis. These industry impingements will continue to drive down the cost of black-market cannabis products, forcing patients and adult-use consumers to the black/external market for cheaper cannabis products.

The overall success of the cannabis industry hinges on the success of the patients/consumers, licensed operators within the industry, and the MRA. Without the success of these three components together, the industry will seize to grow effectively and efficiently. The current regulation specific to remediation of cannabis flower/cannabis concentrate stands in the way of a successful cannabis industry. The below comments and suggestions provide specific detail to how to overcome these roadblocks. Which will in turn provide patients and consumers access to significantly more safe cannabis products, allow cannabis businesses to grow and operate efficiently, and the MRA/State of Michigan to maintain an efficient cannabis market.

Marihuana Sampling and Testing

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

Rule 6. (1-4)

Current verbiage: (1) A laboratory may test marihuana product that has failed initial safety testing, except as indicated under subrule (3) of this rule.

(2) A failed marihuana product must pass 2 separate tests with new samples consecutively to be eligible to proceed to sale or transfer. The laboratory that reported the initial failing results shall not perform the tests. If both samples pass, the batch is out of quarantine and eligible for sale or transfer. If 1 or both samples fail, the marihuana product must be destroyed as provided in these rules or remediated as described in subrule (4) of this rule.

(3) A marihuana product is prohibited from being retested if a final test for chemical residue failed pursuant to these rules. If the amount of chemical residue found is not permissible by the agency, the marihuana product is ineligible for retesting and remediation, and the product must be destroyed. This subrule does not apply to marihuana product that has been obtained under a Resolution on Marijuana Product Access for Patients adopted by the medical marihuana licensing board.

(4) The agency may publish a remediation protocol including, but not limited to, the sale or transfer of marihuana product after a failed safety test as provided in these rules.

Issues with current verbiage: The current regulation and interpretation of cannabis flower/cannabis concentrate remediation is significantly reducing the ability of safe cannabis to get to market, and in turn negatively effects patients, industry stakeholders, as well as the framework of the medical and adult-use cannabis programs. In addition to these negative impacts, the current rules significantly reduce scientific method development and innovation. Furthermore, the decreased product to the legal market as a result of these regulations will continue to raise the cost of licensed products and prolong the dependency on caregiver cannabis. These industry impingements will continue to drive down the cost of black-market cannabis products, forcing patients and adult-use consumers to the black/external market for cheaper cannabis products.

The overall success of the cannabis industry hinders on the success of the patients/consumers, licensed operators within the industry, and the MRA. Without the success of these three components together, the industry will seize to grow effectively and efficiently. The current regulation specific to remediation of cannabis flower/cannabis concentrate stands in the way of a successful cannabis industry. The below comments and suggestions provide specific detail to how to overcome these roadblocks. Which will in turn provide patients and consumers access to significantly more safe cannabis products, allow cannabis businesses to grow and operate efficiently, and the MRA/State of Michigan to maintain an efficient cannabis market.

Resolution to current verbiage: Based on the concerns described above, we suggest that cannabis processors are allowed to perform remediation without limitation for all failed cannabis concentrates, including those which have failed for chemical residue, residual solvents, metals, and other testing parameters which may define a cannabis product unsafe for consumption. Furthermore, we suggest that there should be no reason that a cannabis product should be forcefully destroyed as all residual impurities can be removed via scientific method and thus render said product safe for consumption. Product should only be destroyed voluntarily when the processor/producer decides is necessary per voluntary product destruction protocols that are already in place by the state. Failed cannabis product should also be able to be transferred from processor to processor for remediation if a processor does not have the capability to remediate for a specific toxicity.

Not allowing unlimited remediation of cannabis product until it is rendered safe for consumption significantly hurts the patients/consumers of Michigan, cripple's industry stake-holders and cannabis businesses, and hinders the ability of the MRA to manage a market that doesn't rely on external market product.

R. 420.305 Testing; laboratory requirements

Rule 9.

Current Verbiage: The agency shall publish a list of action limits for required safety tests in subrule (3) of this rule, except for potency. A marihuana sample with a value that exceeds the

published action limit is considered to be a failed sample. A marihuana sample that is at or below the action limit is considered to be passing sample.

Issues with current verbiage: Nowhere in the verbiage specific to the agency publishing required safety tests for marihuana products is there detail of lead time of when these regulations will be enforced. Historically, the state has added new testing regulations to the existing required tests without notice, immediate enforcement, and has attempted to retroactively enforce new regulation on product that has been produced prior to the addition of new regulation or has been submitted for testing prior to new compliance regulation. This has negatively impacted the industry by forcing product to be destroyed, significant immediate changes in infrastructure to accommodate new regulation, and overall restricted product to market which in turn negatively impacts the regulated market, the patients, industry stakeholders, and further bolsters the external market.

Resolution to current verbiage: Considering there is no specific time frame established for the agency to implement new regulation, we suggest that a period of 9 months be put into place prior to any new compliance testing regulation being enforced. This lead time will allow both cannabis cultivators and producers enough time to make changes to processing and cultivation protocol and infrastructural changes to accommodate new regulation. Considering the lifecycle of a cannabis plant at scale, this lead time will allow cultivators to make changes as needed in their protocols to be in line with new regulation without negatively impacting the plants at various stages of growth or while in testing. Furthermore, this lead time allows for cannabis processors to source new equipment, onboard and train new processes that may be required to accommodate for new regulation, make changes to internal processes, and protect any product which is in process or in testing when new regulation is announced. Additionally, we suggest that a scientific review board be established with members of the agency and active industry stakeholders/license holders to meet on a monthly basis to review new suggestions to compliance testing regulation as to fully understand and communicate the scientific reasoning behind any new compliance regulation and the economic impact of such changes.

Marihuana Sale or Transfer (2019-72-LR)

R 420.509 Internal Product Samples

Rule 9. (6)

Current verbiage: “A producer is limited to providing a total of 5 grams of marihuana concentrate of internal product samples to their employees in a 30-day period.”

Issue with current verbiage: The allotment of a total of 5 grams of concentrate as internal product samples for all employees in a 30-day period does not provide for enough available concentrate to effectively be sampled based on volume of production in a processing facility. It is not uncommon for more than 30 production batches of one type of concentrate product (ie.

Live resin concentrate) to be submitted to testing in a 30-day period. A maximum of 5 grams in a 30-day period for all employees inhibits the ability to effectively perform quality assurance on manufactured goods to ensure they meet the standard of the manufacturer prior to going to market. Furthermore, it is common for a producer to make multiple types of cannabis concentrate products which include but are not limited to shatter, crumble, cured resin, live resin, THCA isolate, sauce, vape carts, rosin, dry sift, batter, RSO, and distillate which are all commonly packaged in 0.5g-1g units. Considering the significant number of products which can be produced in a processing facility, a limit of 5 grams total to all employees as samples in a 30-day period does not reflect the actual amount needed to effectively sample the products produced to ensure the product meets the standards of the producer. Additionally, the employee population of licensed producers varies from location to location as some facilities are significantly smaller or larger than one another. A limit of 5 grams for all employees in a 30-day period does not account for the difference in employee population from producer to producer and thus further restricts the number of samples which can be provided.

Resolution to current verbiage: Considering the above concerns with the proposed regulation that a producer is limited to providing a total of 5 grams of marihuana concentrate to their employees in a 30-day period, we suggest that a producer should be allowed to provide 5 grams of marihuana products to each individual employee in a 30-day period. This will effectively allow for employees to sample a representative amount of product produced by a facility, as well as account for the difference in employee population between licensed facilities. In addition, this will help account for the various number of products produced by a cannabis producer to effectively be samples (ie. Vape carts, live resin, cured resin, isolate, crumble, shatter, etc.).

R 420.510 Product Development

Rule 10 (3,6,9)

Current Verbiage: (3) A producer may designate up to 5 grams of marihuana concentrate for product development in a 30-day period. Any marihuana concentrates designated for product development must be tracked in the statewide monitoring system. **(6)** A licensee authorized under this rule to engage in product development may transfer its product development inventory to its employees for consumption. A licensee shall have product development inventory tested pursuant to R 420.304 and R 420.305 before transfer to its employees. The licensee shall not transfer or sell product development inventory to a marihuana sales location until after test results in the statewide monitoring system indicate a passed test. Any product development inventory that is not properly transferred to an employee must be destroyed pursuant to these rules. **(9)** A licensee authorized under this rule to engage in product development may also engage in a research study with a college, university, or hospital approved by the United States Food and Drug Administration and sponsored by a non-profit organization or researcher within an academic institution researching marihuana. A licensee's participation in a research study must be approved by the agency.

Issues with current verbiage: The limitation of only being able to designate 5 grams of cannabis concentrate in a 30-day period for product development is a major concern. Any limitation on cannabis concentrate being designated for product development only inhibits innovation and reduces new products to market which in turn constrict the regulated market. Furthermore, this restriction on product development does not allow for enough cannabis concentrate to be allocated for any type of research study and/or observational trial. Overall, the suggestion of restricting product development to only 5 grams of cannabis concentrate per month inhibits the scientific endeavor and our ability to understand proper dosage from a clinical perspective.

Resolution to current verbiage: Considering the above stated issues with the current verbiage, we suggest that an unlimited amount of cannabis concentrate be allowed to be allocated for product development as deemed necessary by the license holder. This will allow cannabis producers to participate in unrestricted innovation to develop new, unique, and more safe/accurate methods of consuming cannabis concentrate. Furthermore, we suggest that these products assigned to product development in line with a research study/observational trial alongside a college, university, or hospital approved by the FDA and sponsored by a non-profit organization or researcher within an academic institution research marihuana are to be allocated without restriction to the patient population of the study in line with the design of the approved study. The unrestricted amount of cannabis concentrates to be used as product development will enable a research study to progress in an effective and efficient manner as restriction of the drug being investigated will only restrict the study.

As licensed operators drawing on years of experience both inside and outside the industry, we feel strongly that our recommendations will streamline the Michigan cannabis industry's ability to deliver more product to market, ensure all products are safe for consumption and allow Michigan's rules and regulations to be a best practice for other states.

These suggestions are supported with signature permission by the following industry stakeholders.

Sincerely,

Ryan Ratzloff
President/Founder – Lion Labs Ltd

Jonathan Kane
Chief Scientific Officer – Lion Labs Ltd

Robin Schneider – MICIA
On behalf of MICIA's members

Ben Rosman + Lev Spivak-Birndorf
PSI Labs

Adam Goldberg
Evergreen Transport

James Fisher
New Standard/Canterra Cannabis

Gene Simon
Griffin Transport

Brad Chenoweth
BlueSol Biomedical

Emily and Jay Elms + Team
Organic Healing Garden

Alex Ditton
Green Tree Relief