From:	Hendricks, Robert
To:	MRA-Legal
Cc:	Johnson, Matthew; Martin, Rodney; Hendricks, Robert; Sheets, Kaitlin; Nimphie, Benjamin; Hajali, Mazen; Chitwood, Alexandra
Subject:	Comments on proposed rule revisions
Date:	Monday, September 27, 2021 3:28:05 PM
Attachments:	image001.jpg 22355973_1 Proposed MRA Rule Comments (Combined)-c.DOCX

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

Attached please find our comments on the proposed revised rules.

Thank you for your attention and assistance.

Respectfully yours,

Robert A. Hendricks | Senior Counsel
Warner Norcross + Judd LLP
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Rule Citation	Rule Title	Page Number	Comments
MARIHUANA LICENSES			
R 420.1(1)(o)	Definitions	3	Rule adds definition of "Limited access area" meaning a "building, room, or other contiguous area of a marihuana business where marihuana is grown, cultivated, stored, weighed, packaged, sold or processed for sale and that is under the control of the licensee." This definition will add greater clarity of limited access areas for licensees. However, what if the licensee has multiple licenses operating at the same location and has a limited access area under the licensee's control, but is not contiguous to the marijuana business?
R 420.1(1)(dd)	Definitions	4	Rule adds definition of a "Restricted access area" meaning a designated and secure area at a marihuana business where marihuana products are sold, possessed for sale, and displayed for sale. The definitions do not define "secure area." I assume this definition adheres to the security requirements in R 420.209, but I would like to see more specific language here, e.g., "secured by four walls and a locking door."
R 420.3(3)	Application procedure; requirements	5	Rule states that partial applications to obtain prequalification status may be administratively withdrawn if application was filed and has been pending for more than 1 year. After a partial application has been withdrawn, the applicant may be required to submit a new application and pay a new nonrefundable application fee. If an application has been partially completed and the application fee paid prior to withdrawal, it seems excessive to make the applicant pay another application fee when they resubmit.
R 420.3(4)	Application requirements; financial and criminal background	5	Rule states that "an applicant who has been granted prequalification status may have that status revoked by the agency and a marihuana license denied should the agency determine that the applicant is no longer suitable or no longer qualifies for licensure under the acts and these rules. An applicant who has had its prequalification status revoked may request a hearing pursuant to R 420.703." This rule concerns me. It gives the MRA complete discretion to revoke prequalification status if "the applicant is no longer suitable." That is a very vague definition.
R 420.5(1)(d)(vii)	Application requirements; complete application	8-9	Rule states that the applicant must submit confirmation of municipal compliance, specifically an attestation "that the applicant will report any changes that occur with municipal ordinances or zoning regulations that relate to the proposed marihuana facility . . . ." This is very broad—any changes that occur with related municipal ordinances? What if an amendment is made but it is not publicly posted? Also, many municipal ordinances covering many topics may apply to the marihuana facility. It seems excessive to expect a licensee to monitor their municipality to report any ordinances that *may* apply. The rule should be written more narrowly to only reference "marihuana licensing or zoning specific" ordinances only.
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R. 420.305(16)(c)	Testing; laboratory requirements	10	Rule prohibits a lab from "Cherry pick, which means testing specific material from a batch. All sample increments must have the same chances of being selected." Practically, how can this even be enforced and it's unclear what procedures, if any, a lab can put in place to ensure samples have the same chance of being selected.
MARIJUANA SALE OR TRANSFER			
R 420.504(4)	Marijuana product sale or transfer; labeling and packaging requirements	4-5	New rule requires that both medical and retail sales location to provide customers with pamphlets that includes safety information related to marihuana use by minors and the poison control hotline number and that the pamphlet must substantially conform to the design published on the agency's website. This new requirement seems duplicative given that the products already have labels with a safety warning. It also raises numerous practical issues, such as when these pamphlets have to be issued; what information has to be included in the pamphlets; the added cost which will be passed down to the customer/patient; for sales made online or via telephone, will this require some sort of digital pamphlet and if the Agency makes changes to the required information, will that require a whole new set of pamphlets and discarding the old ones?
R 420.508(8) and R 420.509(6)-(7)	Trade samples Internal product samples	8-9	Rules limit the amount of internal product samples that can be given to an employee within a 30-day period to a total of 1 ounce of marihuana, a total of 2 grams of marihuana concentrate, and marihuana infused products with a total THC content of 2000 mgs. Further, R 420.509(7) requires that internal product samples be tested prior to transfer to its employees. This new limitation and testing requirement seem overbroad and limits the ability of licensee's to receive feedback from employees regarding the quality of the product/flower. Also, the testing requirement prior to transfer would mean that if a licensee is interested in knowing the quality of a product/flower before even deciding to put it to market, would have to pay the expensive testing requirements and would discourage product/flower improvement.
MARIHUANA EMPLOYEES			
Generally, the changes are stylistic and help make some of the rules with listed requirements easier to read. The substance of most of the rules in this section has not changed.			
R 420.602(1)	Employees; requirements	2-4	Rule has been modified to *require* employee training manuals to include detailed explanations for how employees can monitor and prevent over-intoxication, illegal distribution, etc. Previously, the rule only required such information to be in the employee manual *if applicable*. Generally, this isn't a major burden for most licensees, but it seems like the previous language should be considered here, as this seems unnecessary for certain types of cannabis businesses.
R 210.602a	Prohibitions	5	The major change is adding this rule, which prohibits employees of one type of licensee from being employees of another type. For example, employees of cultivators (growers) may not also be employed by transporters or labs. Do we know the reason for this addition? What is MRA trying to do here? The prohibition seems a little silly – are there similar prohibitions in the alcohol or tobacco industries?

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MARIHUANA HEARINGS			
As with Rule 601 et seq. above, most of the changes to these sections are stylistic and for readability purposes			
R 420.702(1)(d)	Hearing procedures; scope and construction of rules		The rule adds "the denial of the renewal of a marihuana license" to the situations where the "hearing" rules apply. This is an important addition.
R 420.703(3)	Public investigative hearing	2-3	Rule removes the specific requirements of what public investigators must provide in the contents of their notice to an applicant of an investigative hearing. It is unclear how often these public investigative hearings happen when a license is denied, and the degree to which this removal of specificity will impact applicants.
R 420.704a	Hearing on exclusion of individuals or employees	4	Rule has been added, which provides a procedure for a marijuana business to contest MRA's exclusion of a particular individual from the marijuana business. The procedures seem reasonable; however, subsection (1) allows the business only 21 days to contest MRA's decision to exclude an individual. From our client's perspective, this is not much time, and I would comment that maybe 45-60 days would be more helpful for our clients.
MARIJUANA DISCIPLINARY PROCEEDINGS			
R 420.802(7)	Notification and reporting	3	For clarity, R420.802(7) should indicate that the phrase "licensing, management, or other agreement" is as defined in R420.801(1)(j).

22355973

September 27, 2021 **VIA E-MAIL**

Marijuana Regulatory Agency
ATTN: Legal Section
E: MRA-Legal@michigan.gov

RE: Cannabis Law Section of the State Bar of Michigan's Special Committee on Administrative Rules
Public Comments on Proposed Administrative Rules

Disclaimer: The Cannabis Law Section of the State Bar of Michigan ("Cannabis Law Section") is not the State Bar of Michigan but rather a section whose membership is voluntary. The position expressed in this correspondence is that of the Cannabis Law Section's Special Committee on Administrative Rules only, and the State Bar of Michigan has no position on this matter. The Cannabis Law Section has approximately 911 members as of the date of this correspondence. The Special Committee on Administrative Rules of the Cannabis Law Section consists of six members of the Cannabis Law Section. All members of the Special Committee voted in favor of the positions contained in this correspondence.

To Whom It May Concern,

On behalf of the Cannabis Law Section, the undersigned members of its Special Committee on Administrative Rules had the opportunity to meet and discuss the proposed rule sets at significant length. Each member of the Special Committee is an attorney whose practice consists primarily on the focus of legal issues in the cannabis law space. Accordingly, the Special Committee is well suited to offer practical suggestions to assist the Marijuana Regulatory Agency ("MRA") as it navigates through many of the changes proposed in the draft rule sets.

The Special Committee engaged in thorough discussion and debate before reaching consensus on the comments presented herein. We thank the MRA in advance for its time and consideration of our comments.

2020-121 LR – Marihuana Licenses Rule Set

- R 420.4(2)(a)(i): The rule retains reference to required disclosure of deposit accounts, deeds, and other documents that the MRA no longer requires in its application process. The rule should be modified to be consistent with the MRA's current application practices and disclosure requirements.

- R 420.4(3): The revised disclosure requirements are ambiguous. It is unclear whether all members, shareholders, beneficiaries, etc. of various entities must be disclosed or whether the 2.5% threshold in the introductory language of this section operates to limit the disclosure requirements.

- R 420.6(2)(d): This provision disqualifies government employees/elected officials from holding an MRTMA license. There is no statutory authority within the MRTMA for this

provision. While the MMFLA has such language, it does not exist in the MRTMA. The MRA should consider whether the preservation of the regulated market requires such a broad prohibition. For example, is the public health and welfare of the State of Michigan negatively impacted by denying licensure to an applicant solely because his or her spouse is a public elementary schoolteacher?

- R 420.6(6)**:** The subject of this particular rule is a matter that is presently being litigated in a number of jurisdictions throughout the State of Michigan. Given the fact that the language presented in this rule appears in the MMFLA but does not appear in the MRTMA, the MRA should allow the judicial process to play out, as there is not clear and expressed statutory authority for this rule in the MRTMA. To the extent the MRA is concerned about pledges, loans, or liens against a state operating license, the MRA already has a regulatory framework that governs transfers of interests in licenses that these proposed transfers would be subject to.

- R 420.8(2)(b)(viii): Because drive-through transactions were previously prohibited, the MRA should expressly provide for the allowance of drive-through transactions. In the absence of express and explicit approval for drive-through transactions, it is possible that some municipal officials may interpret silence on this issues as the MRA's decision to continue the previous status quo of prohibiting drive-through transactions.

- R 420.21(3): The definition of "designated consumption establishment" may be overbroad, as the current rule, as written, would require licensure for private businesses where cannabis is privately consumed that is not part of any commercial activity of the business. For example, if a business owner privately offered a beer to his or her employees to celebrate a milestone achievement, no license would be required under the Michigan Liquor Control Code. However, under the present definition, it appears that a designated consumption establishment license would be required under that same example if "cannabis" was substituted for "beer." The MRA should give some consideration to the breadth of this definition.

- R 420.25(6): This rule should be clarified to make clear that temporary marihuana events could be held that allow (1) sales, (2) consumption, or (3) both. The present language of the rule suggests that only temporary events with both sales and consumption are allowed, which is inconsistent with the definition for "temporary marihuana event license" in the rules.

- R 420.27a(7): The MRA should re-consider the absolute prohibition on transfers contained in this rule, as an educational research licensee may develop and wish to license some unique genetics that have medicinal or other benefits for the general population and the market. Understanding that federal law and DEA restrictions may be implicated, we would suggest that the prohibition on transfers be modified to prohibit transfers "without the express written consent of the MRA."

- R 420.27a(9): Similarly, with respect to the prohibition on consumption and sampling, the MRA should consider adding language to prohibit consumption and sampling "without the

express written consent of the MRA." In the event that federal law or the DEA's position changes, this would give the MRA flexibility to respond to any such changes without having to re-engage the formal rulemaking process.

2020-120 LR – Marihuana Licensees Rule Set

- R 420.101(1)(ii)(m): This provision should only address participation in management, as the percentage of profits issue is covered in R420.112a. The provision in that latter section should be clarified that it applies to NET profit, and the rule needs clarification whether the threshold is particular only to a single license or whether it is to be calculated across the entire business entity.

- R 420.102(10): Any grower (not just small growers) should be allowed to accept transfer of plants upon licensure from any applicant for that license. There is no reason to prohibit licensed growers from obtaining plants, clones or tissue culture from any source, as genetics may be difficult to obtain and are critical supplies, but MRTMA prohibits sale unless licensed.

- R 420.103(3) is proposed for removal. This provision allows commonly owned processors to transfer product inventory between the establishments. There is no apparent justification for this change.

- R 420.105(a): This provision would allow a Class A Microbusiness to obtain a mature plant from persons including a registered primary caregiver, while the caregiver is prohibited from transferring anything to anyone except that caregiver's registered patients. This provision conflicts with the MMMA and case law (see McQueen case). All growers should have the same accessibility to genetics they can secure.

- R 420.105a(1)(c): This allows Class A Microbusinesses (but not regular microbusinesses) to purchase concentrates and infused products from any processor. This effectively will convert a microbusiness into a general retail store, but with limited flower availability. It could be expected that some of these entities will not even grow cannabis, but will use the license only as a retail store to sell everything else. Class A Microbusiness also would be prohibited from doing any processing, but allows purchase of processed products from a licensed processor. There is no reason for this prohibition.

- R 420.107(1)(a)(b)(c): Safety compliance facilities should be authorized to take, test, and return marijuana to any person or entity. Individuals are allowed to have their own product tested, but nothing obtained from a licensed business. There is no apparent good reason for this provision, and it would prevent a patient from having product tested which was obtained from their caregiver (or anywhere else). Testing prohibitions should be eliminated unless they can be justified.

2020-122 LR – Marihuana Operations Rule Set

- R 420.207a: The concept of "contactless and limited contact transactions" is introduced in this rule but, as written, the manner in which such sales may be effectuated is not expressly stated. The open-ended nature of the allowance is appreciated as it will enable the development of new, creative transaction methods among sales locations. However, it is presumed that this new rule was particularly drafted to allow for "drive-though" service, and yet the absence of any express statement to that effect (i.e. "including but not limited to drive-though service") is problematic because subsection (1) of the rule conditions the use of these new transaction methods upon their allowability under an applicable municipal ordinance. Without question, the lack of additional specificity in the rule will make it challenging to show municipalities that the MRA now allows "drive-through" service, as city attorneys will naturally interpret this rule cautiously. MRA should set out some examples of allowable "contactless and limited contact transactions" – including specifically drive-through service – to avoid unnecessary rule-parsing between industry participants and municipalities.

- R 420.206(11): In relevant part, this provision exempts "botanically derived terpenes that are chemically identical to the terpenes derived from the plant Cannabis Sativa L." from the mandate that inactive ingredients be approved for the intended use by the FDA. The botanical terpene exception is practical and necessary because to date, the FDA has not approved any substances utilized for a vapor-based inhalable. However, to ensure the exception works as truly intended, it should be amended to include "flavonoids" and "terpenoids" – not just terpenes – because all three are naturally occurring in cannabis and all three contribute to the smell and flavor of cannabis and other botanicals. Restricting the exemption to only terpenes drastically limits the botanically-based terpen formulations that are allowable for operators, as most contain at least minute amounts of the other two categories of organic compounds. It is presumed that many operators are not aware of that fact or their technical and unintentional violations of this provision relative to, most particularly, distillate-based inhalable products.

- R 420.206(14): This new subrule directs that "each form of marihuana or marihuana product [combined to make a new, single marihuana product] must have passing safety compliance test results in the statewide monitoring system prior to the creation of the new combined product." However, the MRA's August 18, 2021 Bulletin concerning the creation of "Inhalable Compound Concentrate Products" states that "compound concentrate products" must be "tested in final form" after they have "been created." (Bulletin at Pg. 2). There is tension between those two forms of guidance as the former new rule does not expressly say that the newly combined products must once again be tested in final form, and the absence of any such direction implies that, because the separate forms of marihuana products themselves each passes testing prior to being combined, a final-form test is not required. The Bulletin itself takes the opposite approach and commands final form testing in all settings other than "Raw Pre-Rolls without Kief Added" – which is a useful and supported exception. The MRA should consider building out this new subrule to incorporate the additional teachings of the Bulletin thereby ensuring that consistent, harmonized guidance is provided to operators on this important subject.

2020-124 LR – Marihuana Sampling and Testing Rule Set

- R. 420.305 Testing; laboratory requirements.

  (3) A laboratory shall conduct the required safety tests specified in subdivisions (a) to (i) of this subrule on marihuana product that is part of the harvest batch as specified in R 420.303, except as provided in subrule (4) of this rule. **The agency may publish minimum testing portions to be used in compliance testing.** After the testing on the harvest batch is completed, the agency may publish a guide indicating which of the following safety tests are required based on product type when the marihuana product has changed form:

  10) The agency shall publish a list of action limits for the 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 a passing sample.

  (11) 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 action limit is a failed sample.

The MRA is required to promulgate administrative rules that govern the testing and minimum action limit standards for safety compliance facilities as opposed to publishing ad hoc guidance. The current practice of the MRA in this regard violates the Administrative Procedures Act. The MRA should comply with the formalities of the Administrative Procedures Act, and should not publish the minimum standards for laboratory testing—giving those publications the force of law.

If and when MRA promulgates new testing rules, orderly operations of the markets dictate that MRA must allow for a phase-in or sell-through period before the new standards come into force, so as not to disrupt markets by requiring mass retesting of products, or leave processors or sales establishments holding significant volumes of products that can't be sold without additional testing. MRA should clarify whether the new rules apply to tested and approved product that is already packaged and labeled for sales establishments, and MRA should articulate a six-month phase-in period so that all market participants have sufficient time to adjust their operations.

- R420.107(1)(c): Although it is understood that MRA will not condone unlawful or underage possession or consumption of cannabis products, it is contrary to the interests of public health for MRA to raise barriers that discourage members of the public from having products tested. By creating an age bar for testing services, or by requiring testing licensees to verify age and retain documentation related to the identity of the person who desires to have product tested, MRA could be discouraging vulnerable Michiganders from accessing reliable safety and compliance information about marihuana products in their possession. MRA should make it clear that people in Michigan will not be penalized if they attempt to get their product tested—regardless of the owner's age.

2020-119 LR – Marihuana Infused Products and Edible Marihuana Products Rule Set

- R 420.403(7)(b): The rule uses the term "component ingredients," in subsection b, when describing the ingredients that must be listed on the label of marijuana-infused products. The term "component ingredients" is not defined, which could lead to confusion. The term "inactive ingredients" is defined and used elsewhere in these rules and would be a more suitable term. Another alternative would be to delete the term "component ingredients," entirely, and require all ingredients to be listed on the label.

2020-123 LR – Marihuana Sale or Transfer Rule Set

- R 420.504 (a) and (b) – This rule has resulted in sales establishment licensees attempting to push all label compliance obligations (and associated liability) upstream to processor licensees. This creates an operational problem for processors that are expected to satisfy requirements from multiple sales establishments with different understandings of what constitutes a compliant label. To promote consistency in the marketplace, MRA should clarify responsibility as between processor and sales establishment with respect to required label elements.

- R 420.504 (v) – This requirement specifies that the warning must be in "clearly legible type" – MRA should consider whether to require legibility for all mandatory label information.

2021-10 LR – Marihuana Employees Rule Set

- R 420.602 (2)(k) – This rule adopts the MRTMA position (10-year bar on hiring persons with convictions for sales to minors), but it excludes fewer people than the corresponding MMFLA prohibition on hiring employees with convictions. MRA should amend this rule to make it explicit that MRA will allow hiring of employees that would be barred by the MMFLA but not the MRTMA, without written permission or other additional hurdles, so long as the conviction is not for sale of a controlled substance to a minor.

- R 420.602 (6) – There is tension between the definition of "employee" in this rule and the definition of "employee" as provided elsewhere in other rules (for one example, R 420.401(1)(c)). Market participants have come to rely on the definition as it is stated here-that is, "employee includes, but is not limited to, hourly employees, contract employees, trainees, or any other person given any type of employee credentials or authorized access to the marihuana business." MRA should consider whether to make definitions in other Rule sections consistent with the definition as it is stated here.

2020-117 LR – Marihuana Disciplinary Proceedings Rule Set

- **R 420.808a:** The rule as drafted contains substantial ambiguity as to the criteria that constitutes conduct that could result in being excluded. Notions of due process require that there be fair notice of the types of conduct that would result in exclusion from the industry—particularly for conduct that has not resulted in a conviction.

On behalf of the Cannabis Law Section, this Special Committee on Administrative Rules respectfully submits the comments above to the Marijuana Regulatory Agency. We appreciate the opportunity to participate in the rulemaking process and are available to discuss should the MRA have any questions about the comments contained herein.

Sincerely,

Special Committee on Administrative Rules of the
Cannabis Law Section of the State Bar of Michigan

Matthew Abel, John Fraser, Steven Glista, Jordan Rassam, Marc Seyburn, and Benjamin Sobczak

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R 420.303(6)	Batch; identification and testing	4	Rule allows a cultivator to sell/transfer marihuana products without being tested by a lab to produce live resin, with agency approval but limits the sales/transfer to a producer under this rule if the package contains more than 1 harvest batch. The next line reads "This does not prohibit a cultivator from transferring multiple harvest batches for extraction." This reads as internally conflicting and does not make sense, that a cultivator cannot use the testing exemption under the rule if they sell/transfer a package with more than one batch, but still can sell/transfer multiple batches.

Rule Citation	Rule Title	Page Number	Comments
R. 420.305(16)(c)	Testing; laboratory requirements	10	Rule prohibits a lab from "Cherry pick, which means testing specific material from a batch. All sample increments must have the same chances of being selected." Practically, how can this even be enforced and it's unclear what procedures, if any, a lab can put in place to ensure samples have the same chance of being selected.
MARIJUANA SALE OR TRANSFER			
R 420.504(4)	Marijuana product sale or transfer; labeling and packaging requirements	4-5	New rule requires that both medical and retail sales location to provide customers with pamphlets that includes safety information related to marihuana use by minors and the poison control hotline number and that the pamphlet must substantially conform to the design published on the agency's website. This new requirement seems duplicative given that the products already have labels with a safety warning. It also raises numerous practical issues, such as when these pamphlets have to be issued; what information has to be included in the pamphlets; the added cost which will be passed down to the customer/patient; for sales made online or via telephone, will this require some sort of digital pamphlet and if the Agency makes changes to the required information, will that require a whole new set of pamphlets and discarding the old ones?
R 420.508(8) and R 420.509(6)-(7)	Trade samples Internal product samples	8-9	Rules limit the amount of internal product samples that can be given to an employee within a 30-day period to a total of 1 ounce of marihuana, a total of 2 grams of marihuana concentrate, and marihuana infused products with a total THC content of 2000 mgs. Further, R 420.509(7) requires that internal product samples be tested prior to transfer to its employees. This new limitation and testing requirement seem overbroad and limits the ability of licensee's to receive feedback from employees regarding the quality of the product/flower. Also, the testing requirement prior to transfer would mean that if a licensee is interested in knowing the quality of a product/flower before even deciding to put it to market, would have to pay the expensive testing requirements and would discourage product/flower improvement.
MARIHUANA EMPLOYEES			
Generally, the changes are stylistic and help make some of the rules with listed requirements easier to read. The substance of most of the rules in this section has not changed.			
R 420.602(1)	Employees; requirements	2-4	Rule has been modified to *require* employee training manuals to include detailed explanations for how employees can monitor and prevent over-intoxication, illegal distribution, etc. Previously, the rule only required such information to be in the employee manual *if applicable*. Generally, this isn't a major burden for most licensees, but it seems like the previous language should be considered here, as this seems unnecessary for certain types of cannabis businesses.
R 210.602a	Prohibitions	5	The major change is adding this rule, which prohibits employees of one type of licensee from being employees of another type. For example, employees of cultivators (growers) may not also be employed by transporters or labs. Do we know the reason for this addition? What is MRA trying to do here? The prohibition seems a little silly – are there similar prohibitions in the alcohol or tobacco industries?

Rule Citation	Rule Title	Page Number	Comments
MARIHUANA HEARINGS			
As with Rule 601 et seq. above, most of the changes to these sections are stylistic and for readability purposes			
R 420.702(1)(d)	Hearing procedures; scope and construction of rules		The rule adds "the denial of the renewal of a marihuana license" to the situations where the "hearing" rules apply. This is an important addition.
R 420.703(3)	Public investigative hearing	2-3	Rule removes the specific requirements of what public investigators must provide in the contents of their notice to an applicant of an investigative hearing. It is unclear how often these public investigative hearings happen when a license is denied, and the degree to which this removal of specificity will impact applicants.
R 420.704a	Hearing on exclusion of individuals or employees	4	Rule has been added, which provides a procedure for a marijuana business to contest MRA's exclusion of a particular individual from the marijuana business. The procedures seem reasonable; however, subsection (1) allows the business only 21 days to contest MRA's decision to exclude an individual. From our client's perspective, this is not much time, and I would comment that maybe 45-60 days would be more helpful for our clients.
MARIJUANA DISCIPLINARY PROCEEDINGS			
R 420.802(7)	Notification and reporting	3	For clarity, R420.802(7) should indicate that the phrase "licensing, management, or other agreement" is as defined in R420.801(1)(j).

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September 21, 2021
Marijuana Regulatory Agency
Legal Section
P.O. Box 30205
Lansing, MI 48909

Re: Comments on Proposed Administrative Rule Amendments

To Whom It May Concern,

We are writing to offer comments on the Marijuana Regulatory Agency's ("MRA" or the "Agency") proposed amendments to the current Administrative Rules, Mich Admin Code R 420.1 *et seq.* (the "Proposed Amendments") being promulgated under the Medical Marihuana Facilities Licensing Act ("MMFLA"), and the Michigan Regulation and Taxation of Marihuana Act ("MRTMA").

Our firm has served clients in the cannabis industry since before the MMFLA became law. We have collaborated extensively with the Agency to navigate the inevitable challenges of implementing each subsequent set of state regulations, including the current unified Administrative Rules (the "Rules") for medical and adult use marihuana businesses. Our comments are based on our collective experience. Pursuant to the rulemaking process and the request for public comments, please find below our comments and recommendations on the proposed rules.

1. General Global Comments

We appreciate the Proposed Amendments improved clarity and consistency—but believe additional clarity should be added to eliminate the enduring ambiguities we have encountered in the existing Rules to the greatest extent practicable. Moreover, we fear that many new provisions introduced in the Proposed Amendments may compound existing ambiguities. Finally, we believe many of the Proposed Amendments provide MRA with unfettered discretion to regulate by ad hoc Bulletin; a current practice of the MRA that at times has generated much consternation for attorneys, operators, and regulators alike.[1]

[1] The simple fact that MRA's Proposed Amendments clearly seek to codify the substance of numerous regulatory issues that were previously only contemplated in Bulletins as guidance or interpretative rules confirms that the substance of those Bulletins was *not* merely interpretative guidance but rule making. Two notable examples include the proposed addition of R 420.112a (regarding licensing, management, and other agreements), and the proposed changes to R 420.403 (regarding requirements and restrictions on marihuana-infused and edible marihuana products), each of which are substantively identical to the Bulletins MRA previously published on these topics—purportedly as mere interpretative guidance. If these prior Bulletins truly only provided interpretative rules or

The Proposed Amendments suggest that MRA will enjoy vast discretion to continue regulating Michigan's cannabis industry by Bulletin and bypassing the proper rulemaking procedures contemplated in the Michigan Administrative Procedures Act (MAPA). For instance, the Proposed Amendments seek to confer broad discretionary authority to MRA over (1) standard operating procedures for marihuana businesses,[2] (3) quality assurance and validation measures for safety compliance labs,[3] (4) material that must be distributed at a retail point of sale,[4] and numerous other matters, that will surely come out in piecemeal communications, analyst decree, and the aforementioned bulletins; all of which will avoid public review and comment. Rather than continuing the Agency's current practice of rulemaking by Bulletin we urge MRA to add additional substance and clarification to the Proposed Rules with the requisite public notice and comment period. Denying licensees the opportunity to take notice of—and provide feedback on—future substantive rules could lead to future legal action against the Agency.

We respectfully request that the Agency consider further revising the Proposed Amendments language to properly limit the scope and extent of discretionary authority MRA can deploy so the MRA, licensees, and applicants can operate under a concrete and well-defined set of new Final Rules. The Proposed Amendments could better achieve this objective.

2. Marijuana Licenses – R 420.1 et seq.

R420.1(1)(c)(i)—Definition of "Applicant"

"Indirect ownership interest" should be defined. Despite public comments on the originally proposed language for this Rule that specifically requested further clarification of the phrase "indirect ownership interest," the final adopted Rules did not further define or clarify this term. Countless hours of unnecessary confusion and frustration for both industry participants and Agency staff alike have resulted from the ambiguity of this undefined term. We accordingly re-iterate the importance of providing sufficient definitional clarity for critical operative phrases and terms throughout the Proposed Amendments.[5]

guidance, there would be no need to codify and promulgate them through the rulemaking process, as MRA now seeks to do.

[2] *See* Proposed R 420.206a.

[3] *See* Proposed R 420.305a.

[4] *See* Proposed R 420.504(4).

[5] The concept of an "indirect interest" or "indirect ownership" should also be used consistently both when determining which individuals or entities within the main applicant's organizational structure also count as supplemental applicants—and when determining what "other business interests" or "associated business" an applicant must disclose. However, this raises major administrability concerns—because any applicant who owns a single share of any exchange traded fund (ETF) that tracks a major stock index (e.g. the S&P 500, or Russell 2000) technically has an "indirect interest" in all 500 companies in the S&P, or all 2000 companies in the Russell. Attempting to disclose entire stock indices as "other business interests" or "associated businesses" would be entirely impracticable for both Agency analysts and applicants—but that is what consistent application of the phrase "indirect interest" in both the applicant identification and application disclosure contexts would require.

Other related examples of operational terms or phrases in R 420.1(1)(c) that require further clarification include, without limitation:

- "exercise control"
  - The Michigan Court of Appeals has held that "different percentages of control may be necessary to direct the management of different corporate entities."[6] To illustrate, the Court opines that "if an entity requires a supermajority to undertake an action, a mere majority of common shareholders would not be sufficient" to establish control thereof.[7] Thus, the Court concluded that "control" of a business entity depends "on the actual control of business" as structured in the entity's governing documents.[8]
  - We urge MRA to adopt a formal definition of "control" that is consistent with the case law cited above.
- "participate in the management of"
  - Like the "exercise [of] control"—MRA has never clearly established what constitutes participation "in the management of" an applicant entity. We urge MRA to adopt a definition of "management" that is consistent with the case law cited above.

R420.1(1)(c)(i)(I)—Definition of "Applicant" for a trust

The proposed amendment for a trust application is impractical and potentially impracticable. The definition of "Applicant" for a trust seeks to add "trustees" and "any individual or body able to control and direct the affairs of the trust" without offering any further explanation of how this proposed expansion to the definition of a trust Applicant would apply to institutional trustees (e.g. large trust companies, financial institutions, law firms, etc.). Institutional trustees often assist in administrative matters necessary for the operation and maintenance of a trust with substantial assets—but typically do not make 'managerial' or 'business' decisions for the trust. If the Proposed Amendment to this Rule is not further revised to provide a safe harbor or other exemptions for institutional trustees, organizations including national banks—nearly all of which offer a variety of trust administration and management services[9]—would have to be treated as Applicants, even if the bank or other comparable institutional trustee does not participate in the operations or management of the prospective licensee in any conceivable manner.

[6] *TRJ & E Props v City of Lansing*, 323 Mich App 664, 673 (2018).
[7] *Id.*
[8] *Id.*
[9] *See e.g.* https://privatebank.jpmorgan.com/gl/en/services/trusts-and-estates/us-trust-services; https://www.privatebank.bankofamerica.com/solutions/individuals-families/trusts-estates.html; https://www.wellsfargo.com/the-private-bank/solutions/trust-services/; https://www.city.bank/personal/wealth/trust

R 420.4—Application requirements; financial and criminal background

- To the extent that MRA no longer requires applicants for licensure under the MMFLA to provide the financial statements contemplated in RR 420.4(2)(a)(i) and (ii)—these Rules should be updated or eliminated.
- The phrase "Controls, directly or indirectly" is susceptible to the same ambiguities noted above for R 420.1(1)(c)(i).
- The current language in R 420.4(2)(b)(ii) is impermissibly broad—insofar as it does not provide any standard for evaluating whether information is "required by the agency."
- The phrase "ownership interest" in the Proposed Amendment for R 420.4(3) is susceptible to the same ambiguities noted above for R 420.1(1)(c)(i).
- The Proposed Amendment for R 420.4(3)(b) directly contradicts the general 2.5% threshold for disclosing ownership interests in an applicant established in R 420.4(3) by mandating disclosure of "all shareholders"—which presumably includes those who own less than 2.5% of a private corporation applicant.
- The use of the phrase "shareholders holding a direct or indirect interest" in the Proposed Amendment for R 420.4(3)(c) requires further clarification. By definition, a "shareholder" is any entity or individual who owns shares of a corporation. Just as one cannot "indirectly" hold title to real or personal property—one cannot "indirectly" own shares of a corporation. Using the phrase "any individual or entity" in place of "shareholders" could eliminate this ambiguity.
- The Proposed Amendment for R 420.4(3)(f) directly contradicts the general 2.5% threshold for disclosing ownership interests in an applicant established in R 420.4(3) by mandating disclosure of "all members"—which presumably includes those whose membership interests consists of less than 2.5% of an LLC applicant.

R 420.5—Application requirements; complete application

- The Proposed Amendment to R 420.5(1)(c)(ii) directly contradicts the general 2.5% threshold for disclosing ownership interests in an applicant established in R 420.4(3) by mandating disclosure of all "persons who have a direct or indirect ownership interest in the marihuana establishment."
- The phrase "direct or indirect ownership interest" as used in the Proposed Amendment to R 420.5(1)(c)(ii) is susceptible to the same ambiguities noted above for R 420.1(1)(c)(i).

R 420.14—Notification and reporting

- It is unclear how an applicant could report the "appointment of a court-appointed personal representative, guardian, conservator, receiver, or trustee of the applicant" before such an appointment is made. At best, it seems that an applicant could report the possibility of a court ordering such appointments before they occur—but MRA cannot reasonably expect applicants to report a court order before the order has been issued.

3. Marijuana Licensees – R 420.101 et seq.

R 420.101—Definitions

- All references to "industrial hemp" throughout the Rules and Proposed Amendments (including the Proposed Amendment to RR 420.101(1)(i) and (j)) should be updated to include reference to the Industrial Hemp Growers Act.[10]
- The phrases "exercise control over" and "participate in the management of" are susceptible to the same ambiguities noted above for R 420.1(1)(c)(i).
- The definition of "Managerial employee" provided in Proposed Amendment for R 420.101(1)(m) includes ambiguous terms and phrases like "ability to control and direct the affairs of" and "ability to make policy concerning" a marihuana business that are susceptible to the same ambiguities noted above for R 420.1(1)(c)(i).

R 420.112a—Licensing, management, or other agreements

- Though we support MRA's decision to formally promulgate substantive rules pertaining to these agreements, we respectfully re-iterate the concerns noted in our General Global Comments above regarding MRA's historical practice introducing these regulatory obligations through Bulletins or other "guidance" documents that it routinely seeks to enforce as binding legal authority.
- The difference between "gross" and "net" profits is substantial, however, MRA treats them as equivalent synonyms throughout the Rules and Proposed Amendments (including R 420.112a(4)(ii)).
    - "Gross Profit" is traditionally defined as total revenue (sales) minus the cost of goods sold (COGS).
    - "Net Profit" is traditionally defined as Gross Profit minus operating expenses and all other expenses (e.g. taxes, interest paid on debt, etc.)[11]
- Proposed R 420.112a(5) would create an unreasonable burden on licensees that seek to use an assumed name or dba as authorized by another party to a licensing agreement—insofar as the mechanics of registering the assumed name when it is already registered to another entity is unduly cumbersome and time consuming. Under the statutory authority referenced in the Proposed Rule, if an unlicensed Michigan LLC (Entity A) registers the assumed name "ABC Cannabis" and enters into an agreement with a licensed Michigan entity (Entity B) that provides non-exclusive rights to use the assumed name "ABC Cannabis"—Entity A would have to withdraw its original assumed name registration and refile a new assumed name registration listing itself *and* Entity B on the registration. If Entity A subsequently entered into another agreement with licensed Entity C that provides the same non-exclusive use rights for the assumed name "ABC Cannabis"—it would have to withdraw the updated assumed name registration (listing Entity A and B) and refile a new assumed name registration listing Entities A, B, and C. While MRA could reasonably request copies of the licensing agreement as executed by the parties to verify that a given licensee has received proper authority from the party holding legal rights to an assumed

[10] Public Act 220 of 2020.

[11] The formula for calculating Net Income is traditionally stated as NI = R – COGS – OE – O – I – T; where NI = Net Income, R = Revenue, OE = Operating Expenses, O = Other Expenses, I = Interest, and T = Taxes.

name or dba—there is no rational basis for requiring non-licensees to amend their assumed name filings every time they execute a new licensing agreement assigning use rights of their assumed name(s).

4. Marijuana Licensees – R 420.201 et seq.

R 420.201—Definitions

- The definition of "Applicant" provided in R 420.201(d) is inconsistent with the definition of "Applicant" provided in R420.1(1)(c)(i).
- The definition of "Applicant" for a trust provided in R 420.201(1)(d)(i)(I) is inconsistent with the definition of "Applicant" for a trust provided in the Proposed Amendment to R420.1(1)(c)(i)(I).
- The phrase "direct or indirect ownership interest" is susceptible to the same ambiguities noted above for R 420.1(1)(c)(i).
- The language in RR 420.201(1)(d)(i)(E) and (F) has not been amended to eliminate the incoherent reference to "indirect stockholders" discussed above in the Proposed Amendment for R 420.4(3)(c).

R 420.204—Operation at same location

- The phrase "combined space" as used in the Proposed Amendment to R 420.204(4) should be further clarified or defined.

R 420.206 Marihuana business; general requirements

- We implore MRA to expedite its work with MDARD to develop a pathway for licensed hemp growers and processors to enter cannabinoid biproducts into METRC.

R 420.206a Standard operating procedures

- This newly proposed Rule seems duplicative of the existing requirements for applicants to submit a business plan—which licensees must maintain and update with MRA—including the applicant's plans for maintaining inventory and other business records, staffing and training employees, securing and otherwise operating the proposed marihuana business, etc.
- The language proposed in R 420.206a(4) seeks to delegate substantive rulemaking authority over "standard operating procedure requirements" to MRA, which would likely be issued in the form of Bulletins or other guidance. Under the MAPA, any new compliance obligations pertaining to the "standard operating procedures" contemplated throughout this proposed Rule would likely constitute substantive rulemaking that must be promulgated with an opportunity for public notice and comment. Since Agency guidance "does not have the full effect of law,"[12] a licensee could possibly challenge the use of Bulletins or other

[12] *See* MCL § 24.203(7) (defining "guideline" as "an agency statement or declaration of policy that the agency intends to follow, that does not have the force or effect of law, and that binds the agency but does not bind any other

guidance issued under this proposed Rule in any future enforcement action or proceedings.[13]

R 420.207 Marihuana delivery; limited circumstances.

- R 420.207(2)'s restriction of delivering medical marihuana product only to a patient "at the patient's residential address" raises numerous questions and concerns about the measures medical licensees and their delivery employees must take to prevent mis-delivery to an address that reasonably appears to be the patient's bona fide residential address but is later determined not to be the bona fide residential address. We respectfully request further clarification of this topic.

5. Marijuana Sampling and Testing – R 420.301 et seq.

R 420.304 Sampling; testing

- R 420.304(2)(d) should specifically set forth standards for the "statistically valid sampling method" that safety compliance licensees must have "approved by the agency." When MRA's scientific department has been given discretion to issue interpretative guidance—they have produced new substantive rules that impose unduly draconian standards that are treated by MRA as binding legal authority.

R 420.305 Testing; laboratory requirements

- Please list the mycotoxins that licensees must test for. MRA's scientific department has had ample opportunity to develop a list of the mycotoxins that licensees should be required to test for. Since Agency guidance "does not have the full effect of law," a licensee could possibly challenge the use of Bulletins or other guidance issued under this proposed Rule in any future enforcement action or proceedings.[14]
- The definition of "Cherry pick" provided in proposed R 420.305(16)(c) should be moved to the definitions section of this rule set.

R 420.305a—Validations

- Without including clear standards for receiving agency approval of the "validations" and "validated methodologies" contemplated in this newly proposed Rule, MRA is self-delegating substantive rulemaking authority. We would request that the approval methods be included in the rules for public review and comment. Since Agency guidance "does not have the full effect of law," a licensee could possibly challenge the use of Bulletins or other

person."). *Cf.* MCL § 24.207(1) (defining "rule" as "an agency regulation, statement, standard, policy, ruling, or instruction of general applicability that implements or applies law enforced or administered by the agency or that prescribes the law enforced or administered by the agency.").

[13] *See AFSCME v Mich Dep't of Mental Health*, 452 Mich 1 (1996); *Detroit Base Coalition for Human Rights of Handicapped v Dir, Dep't of Social Servs*, 431 Mich 172 (1988).

[14] *See* notes 12 and 13, *supra*.

guidance issued under this proposed Rule in any future enforcement action or proceedings.[15]

6. Marihuana-Infused Products and Edible Marihuana Product–R 420.401 et seq.

R 420.403—Requirements and restrictions on marihuana-infused products

- The phrase "appropriately descriptive" as used in the Proposed Amendment to R 420.403(7)(a) should be further clarified to give licensees adequate notice of their obligations under the rule.
- The phrase "component ingredients" as used in the Proposed Amendment to R 420.403(7)(b) should be further clarified so licensees can prepare to make the necessary changes to their current packaging labels.
- The phrase "in charge" as added in the Proposed Amendment to R 420.403(8)(d) should be further clarified—particularly since this language seems to implicate a form of policy making authority or "control" of the licensee that could make this employee a "managerial employee" and thus, an "applicant."
- Insofar as the Proposed Amendments to R 420.403(9) principally introduce new negative restrictions—the structure of the Rule could be clearer if R 420.403(9) was amended and reorganized to read "A producer of edible marihuana products *may not*…"
- The Proposed Amendment to R 420.403(9)(a) should be further clarified to provide a standard for determining whether the "shape" or "label" of a marihuana product "would appeal to minors aged 17 or younger." To date, MRA has issued guidance that does not provide any evidence or explanation for its determination that certain product label or package designs "appeal to minors"—and used this guidance as binding legal authority to impose transfer restrictions on products with purportedly non-compliant packaging. These restrictions could also possibly be challenged as an unconstitutional infringement of protected commercial speech rights.
- The Proposed Amendment to R 420.403(9)(a) should be further clarified to provide a standard for determining whether a proposed edible marihuana product "can be easily confused with a commercially available food product." As written – this language would appear to prohibit the production of all edible marihuana products, since all edible marihuana products could arguably be confused with a "commercially available food product" with some degree of relative ease. Licensees need clarity on what is "easily confused" and not "easily confused with a commercially available food product."
- The Proposed Amendment to R 420.403(9)(e) could be challenged as an unconstitutional restriction of licensee's commercial speech rights. In the parallel context of advertising restrictions for alcoholic beverages, the Federal Trade Commission has properly noted "[t]he First Amendment provides substantial protections to speech, and thus substantially limits the government's ability to regulate truthful, non-deceptive alcohol advertising based on concerns about underage appeal. For this reason, the Federal Trade Commission has long encouraged the alcohol industry to adopt and comply with self-regulatory

[15] *See* notes 12 and 13, *supra*.

standards to reduce the extent to which alcohol advertising targets teens, whether by placement or content."[16]

7. Marihuana Sale or Transfer–R 420.501 et seq.

R 420.502—Tracking identification; labeling requirements; general

- The Proposed Amendment to R 420.502(2) seems intended to give MRA the authority to require licensees distribute informational materials at the point of sale, as contemplated in proposed Rule 420.504(4). However, by moving the modifier "material" from its original position *after* the word "information" to its position *before* the word "information"[17]—the Proposed Amendment implicates the legal term of art "material information." This term of art does not refer to physical informational materials—but rather, to information that is 'material' (i.e. important or relevant to) making a particular decision. Further clarification is requested.

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

- The proposed addition of R 420.504(4) could possibly be challenged for lacking a rational relation to MRA's statutorily defined policy objective. Insofar as licensees must already provide the national poison control hotline number, and express age or patient-status use-restrictions on the product label under existing rules, it is largely redundant to provide the same information in the form of 3.5 x 5-inch pamphlet. We respectfully remind MRA that licensees would principally bear the cost for producing and updating these pamphlets in accordance with any subsequent changes MRA may later propose as mandatory content for said pamphlets—which may add unnecessary strain to already tight operating budgets. Since Agency guidance "does not have the full effect of law," a licensee could possibly challenge the use of Bulletins or other guidance issued under this proposed Rule in any future enforcement action or proceedings.[18]

R 420.507—Marketing and advertising restrictions

- The Proposed Amendment to R 420.507(2) is narrowly tailored to advance a substantial government interest in preventing the dissemination of false, deceptive, or misleading advertising—and is thus a constitutionally permissible restriction on commercial speech.[19] Any restrictions on the packaging or labeling designs of a marihuana product beyond the prohibition of false, deceptive, or misleading advertising contemplated in this Rule could possibly be challenged as an unconstitutional restriction of licensees' protected commercial speech.[20]

[16] https://www.consumer.ftc.gov/articles/0391-alcohol-advertising
[17] "require a marihuana business to provide *material information* or notifications…"
[18] *See* notes 12 and 13, *supra*.
[19] *See Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980). *Cf.* R 420.403.
[20] *See e.g.* R 420.403.

8. Marihuana Hearings–R 420.701 et seq.

R 420.704a—Hearing on exclusion of individuals or employees

- Insofar as the exclusion of an individual or employee from participation in Michigan's marihuana industry amounts to a restriction of individual liberty—we believe MRA's burden of proof should be higher than the "preponderance of the evidence" standard contemplated in proposed R 420.704a(5) as individuals liberty and pursuit of happiness may include working for a Marijuana establishment or facility and that type of restriction should not be taken lightly

9. Marihuana Disciplinary Proceedings–R 420.801 et seq.

R 420.802—Notification and Reporting

- The Proposed Amendment to R 420.802(3)(g) implicates the same concerns noted above in our comments regarding the Proposed Amendment to R 420.14. It is unclear how an applicant could report the "appointment of a court-appointed personal representative, guardian, conservator, receiver, or trustee of the applicant" before such an appointment is made. At best, it seems that an applicant could report the possibility of a court ordering such appointments before they occur—but MRA cannot reasonably expect applicants to report a court order before the order has been issued.
- The Proposed tattletale Amendment to R 420.802(4)(c) creates an unrealistic burden for licensees.

R 420.808a—Exclusion

- The phrase "valid and current exclusion list from another jurisdiction in the United States" as used in proposed R 420.808a(1)(e) should be further clarified, as it is presently unclear what "exclusion lists" would potentially implicate this proposed Rule.

Regards,

BENJAMIN D JOFFE, PLLC

Benjamin D Joffe
Ari D Goldstein

MEMORANDUM

TO: **Marijuana Regulatory Agency**
FROM: **Pollicella, PLLC d/b/a Cannabis Attorneys of Michigan**
DATED: **September 27, 2021**
RE: **Comments to Draft Joint Administrative Rules**

In no particular order:

420.3(4) We disagree with the ability of the MRA to revoke a prequalification approval because there are not sufficient due process protections built into this process to protect the prequalified applicants.

420.13(5) Failure to file an AFS should be one factor in license renewal but should not, by itself, be a barrier to renewal. Additionally, there needs to be a defined time for what is considered a "failure to renew". 30 days late? 90? 120?

420.4(3):
The language needs to be clarified. The initial sentence of the rule says an applicant only has to disclose person's having 2.5% or more ownership interest. But the subdivisions a-f (except for c) say applicants shall disclose the names of ALL members and managers, etc., for an LLC.

420.6(6):
Language that states a license is not a property right should be removed. A license is a property right. This is long-established law in Michigan and this provision is de facto invalid. (It was inserted on the Senate floor in 2015 by a staffer in exchange for a vote and never properly sent through LSB.)

420.801 set:
Not renewing a license due to a violation would be unconstitutional. It is akin to a revocation but would subvert (or try to subvert) the due process protections owed a licensee when the government agency wants to revoke a license.

420.806 - Penalties:
Under the current and proposed rules, one single "violation" of the act can be fined multiple times under (if applicable) multiple sections of the joint rules. It would be preferable to everyone to have some type of limit/cap of the number of fines per violation. This would give

predictability to both the MRA and to persons/applicants/licensees subject to possible fines, and it would provide fairness and consistency in the MRA's deliverance of penalties.

420.808a(1)(c):
One of the reasons for being put on the exclusion list for employees is if the person has been found ineligible for licensure under the acts or rules. This is problematic and needs to be removed. An individual can be ineligible for licensure for a large variety of reasons unrelated to criminal history and those reasons are wholly unrelated to their ability to be employed by a licensed company. This prohibition goes beyond what is contemplated by both acts.

420.8(2)(b)(viii):
This requires that architectural plans include areas designated for contactless and limited contact transactions. This should just be for retail sales locations.

What is missing:

There needs to be a limit on the amount of time that:

- A product can be placed on administrative hold, particularly if the product has already passed testing. Placing products on hold indefinitely is an unconstitutional regulatory taking, and can result in the MRA effectively putting a company out of business. We recommend 90 days total.
- A compliance complaint can be brought after a known violation. Licensees have received compliance complaints many months both after the alleged violation happened and after it was discovered. Bringing a compliant more than 9 or 12 months after an alleged violation leaves the Licensee without the ability to adequately respond to the complaint due to the time lapse. We recommend 6 months after the violation became known or 12 months after it happened, whichever is earlier.

The MRA needs an independent (civilian or non-civilian) emergency review board to deal with summary suspensions and revocations. Because there is no licensing board as in other regulatory agencies, licensee-respondents are left to the slow and bureaucratic MOAHR process, which is also not equipped to deal with complex marijuana licensing or compliance matters, and does not provide hearings in a timely manner that meets the due process requirements of a summary suspension or revocation review. An emergency review board's sole responsibility would be determining whether a summary suspension or revocation by the MRA is supported by enough evidence to permit it to continue during the complaint process. This is the right of every licensee who suffers hundreds of thousands of dollars in product, productivity, staffing and PR losses when a summary suspension or revocation action is taken by the MRA.

The definition of "Managerial Employee" needs to include a manager of a Management Agreement. It needs to be very clear that a Management Agreement is a contract subject to MRA review and prequalification approval and that the manager in a Management Agreement meets the definition of "Applicant".

From: Rick Thompson
To: MRA-Legal
Subject: Comments on the proposed topic-based rules- Administrative Rules hearing Sept 27
Date: Sunday, September 26, 2021 10:37:10 PM

Please add these comments to the official record for the proposed rule changes. Thank you.

Rick Thompson
Executive Director, NORML of Michigan
--
To MRA:

In regards to the proposed Administrative Rule changes, these are our concerns and wishes:

2020-117 LR:

420.802 Rule 2, section 4 sub a
Eliminating the requirement to report any adverse reaction to cannabis products is detrimental to the purpose of Marijuana Regulatory Agency oversight of the MMFLA and MRTMA programs. Without safety reporting, retailers will behave in a less safe manner and this disadvantages consumers. We oppose this change.

420.803 Rule 3 sub 3

Eliminating this reporting requirement means the MRA is not in a position to know if a proposed business has actually satisfied all the requirements for operations in the municipality in question. This seems not to be a burdensome requirement on business. We oppose this change.

420.805 Rule 5 sub 2

Issuance of these notifications of violation is the only way consumers can track how the MRA is disciplining their regulated businesses. This is an important aspect of consumer protection and is part of the transparency mission the MRA continues to maintain. We are opposed to this change.

Rule 5 sub 10 and 11

Giving the MRA additional powers to take action against companies which violate the rules is consistent with greater consumer safety. We support this change.

R420.806 Rule 6 sub f

If this has never been clearly expressed in the language of the MRTMA or MMFLA, then it is welcome as an addition here. Businesses which violate the MRA rules are likely to perform

acts which compromise consumer safety. Denial of license renewal is an appropriate tool for the MRA to have available, in their effort to secure licensee compliance. We support this change.

R420.808a

We oppose this entire rules section. This codifies the ability for the MRA to apply subjective evaluations of individuals and apply differential standards toward two people striving for the same task. This is the same tool used by Rick Johnson and the Marijuana Regulatory Board to discriminate against caregivers and other individuals with a history in the cannabis industry. The current MRA regulations are strict enough regarding ownership, employability and fitness to operate within the industry. We oppose this change.

R2020-118 LR

Rule 420.704 sub a

We stand opposed to the entire idea of subjective decisions made by the Agency regarding a person's fitness to participate in the industry. Hard and clear guidelines are the only way to ensure bias and favoritism are not used in determining who can participate in the industry, and who cannot. We stand opposed to this series of subjective and discriminatory changes.

2020-119 LR:
R420.401 Rule 1d

This change is appropriate as it tests the product in final form, instead of testing components. Devices sometimes contribute to the chemical profile of the cannabis concentrate, and testing while product is in the dispensing device is justified. We support this change.

Rule 1 o

Requiring the formulation and proofs of shelf stability is reasonable from a regulatory standpoint. Any recall issues might be facilitated by a knowledge of internal ingredients, especially if additives are banned by future action of the MRA. We oppose this change.

R420.403 Rule 7 sub a

Without transparent packaging, the consumer has to be able to accurately identify what's in the sealed package prior to purchase. An appropriate description of contents will remove ambiguity and clarify purchase decisions for consumers. We support this change.
Same, sub e

This is valuable information. Consumers will benefit from knowing when a product was manufactured. We support this change.

Same, Rule 10 sub a

This is a responsibility dodge by the MRA. If two companies produce the exact same gummies, but each is allowed to figure their own expiration date, there is unacceptable variance in the industry and consumers could potentially suffer. The MRA needs to establish

expiration periods for ALL consumable products and all manufacturers will have to adhere to the standard, instead of composing their own product life expectancies. We support the intent of the changes made, but oppose the lack of specificity and industry ambiguity.

2020-120 LR:

R420.102 Rule 12
also
R420.105 Rule 8
R420.108 Rule 10

This rule defies explanation. It seemingly is covered under other rules within this regulatory framework, and therefore seems redundant. In the absence of an explanation for this change, we are opposed to the provision barring cannabis cultivators from acquiring cannabis from sources outside the regulated market.

420.103 Rule 3 sub 3
also
420.104 Rule 4 sub 4

We support the removal of this clause from the Administrative Rules. This loophole gives processors and retailers with multiple licenses an unfair advantage over single-licensed entities, and therefore is potentially detrimental to a fair market and consumer benefit. We support this change.

R420.105a

We support the creation of this new license type. We specifically support the addition of sub 8 to the language of the proposal. We support this change.

R420.107 sub c

Preventing common citizens from cross-checking the results of lab analysis of cannabis from the regulated system is highly detrimental to the cannabis industry as a whole, and consumer safety in particular. Having a double-check on lab results is essential to ensuring consumers have trust in the products you take to market. This seems to be blatant industry protectionism and is at its core, anti-consumer, as it limits what we can do with our medicine. We stand opposed to this change, with great vehemence.

Rule 420.112a

This entire section is new and seems to include MRA approval of partnerships, ownership stakes, licensing deals and other internal corporate information, which must be sent to the MRA and held in their files. The proposed level of scrutiny seems less regulatory and more investigatory, which is a stage usually reserved for entities which have violated agreements. We stand neutral on this change.

2020-121 LR

R420.4 Rule 4 sub 3

There seems no logical reason for the MRA to reduce the revealed percentage share from 5% to 2.5%. In the absence of clear and compelling reasoning, we oppose this change.

R420.5 Rule 1 sub e

This is a clear definition of what is required for municipal approval of potential licensed facility locations. We support this series of changes.

R420.25 sub 6

A temporary event can only be authorized if the municipality has approved on-site sales AND consumption of cannabis? Some communities would approve one or the other. This rule is off-target and puts unnecessary restrictions on the event license holder. We stand opposed to this change.

Additionally, the regulations regarding temporary events gives attendance permission to people over 21, but fails to include registered medical marihuana patients. We suggest including them in the language everywhere, alongside the over 21 designation.

R420.27a

The research grant funding was approved this year under current rules, as contained in the MRTMA, and these regs seem to restrict the execution of that mandate. For example, the need for a floor plan of the research location is unclear. We stand neutral on these changes, although the intent of the voter-directed initiative is supported by consumers everywhere.

2020-122 LR

R420.206 sub 13 and 14

--
Rick Thompson
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Named **Citizen Activist of the Year 2015** by national media source
Crystal Trichome Award winner- **Journalist of the Year** 2016
Radio: Jazz Cabbage Cafe, The Planet Green Trees Radio Show, *more*
Activism: MiNORML and MiLegalize, Board member of both
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September 27, 2021

Marijuana Regulatory Agency
Legal Section
P.O. Box 30205
Lansing, MI 48909
Via Email: MRA-Legal@michigan.gov

Dear Marijuana Regulatory Agency ("MRA"):

Thank you for the opportunity to comment on the proposed rule sets intended to promote clarity and consistency in Michigan's medical and adult-use markets. Cresco Labs Michigan, LLC ("Cresco") holds grower and processor licenses, operating a facility in Marshall. Cresco respectfully submits the following comments to the amended rule sets (proposed additions underlined in blue, proposed deletions in strikethrough red), which balance the clarity and flexibility necessary for operators with the interests of the program's customers and patients and the other objectives essential to the implementation of a safe, secure and effective program:

MARIHUANA DISCIPLINARY PROCEEDINGS

R 420.802 Notification and reporting.
[. . .]

Rule 2.

[. . .]

(4) A licensee shall notify the agency within ~~1~~ 3 business days of becoming aware or within ~~1~~3 business days of when the licensee should have been aware of any of the following**:**;

~~(a) Adverse reactions to a marihuana product sold or transferred by any licensee.~~

(~~b~~**a**) Criminal convictions, charges, or civil judgments against a licensee in this state or any other state, federal, or foreign jurisdiction.

(~~c~~**b**) Regulatory disciplinary action taken or determined against a licensee by this state or any other state, federal, or foreign jurisdiction, including any pending action.

(c) Action by another party in actual or alleged violation of the acts or these rules.

[. . .]

Comment:

Cresco respectfully urges the MRA to consider the above changes, which would afford operators a more reasonable period in which to report certain events. Allowing three businesses days rather

than a single day would not be burdensome on the MRA and presents no risk to the public. Allowing license holders a small amount of additional time to understand whether an event must be reported, including with respect to new subsection (c), simply provides licensees with a fair amount of time in which to report events to the MRA.

R 420.808a Exclusion.
Rule 8a.
Rule 8a. (1) A person may be excluded from employment at, or participation in, a marihuana business upon a finding of any of the following:

[. . .]

(e) The person is included on any valid and current exclusion list from another jurisdiction in the United States if the basis for the person's inclusion on the exclusion list would also be grounds for exclusion as set forth in this Rule.

[. . .]

Comment:

Cresco proposes to clarify the language set forth in the above rule, which would permit a person from being excluded from employment at, or participation in, a marihuana business based on that person's exclusion from the cannabis industry in another state. Cresco submits that a person should only be excluded from participating in the cannabis industry in this state if the conduct or grounds for the person being excluded in another state would result in exclusion in this state. Absent clarification such as the above, an otherwise qualified individual may be prevented from participating in the Michigan cannabis industry for conduct that may acceptable under Michigan law.

MARIHUANA-INFUSED PRODUCTS AND EDIBLE MARIHUANA PRODUCT

R 420.403 Requirements and restrictions on marihuana-infused products; edible marihuanaproduct.
Rule 3.

[. . .]

(7) A producer shall label all marihuana-infused product with all of the following:
(a) The name of the marihuana-infused product. **The name of the product must be an appropriately descriptive phrase that accurately describes the basic nature of the product.**

[. . .]

(2) A producer of edible marihuana product shall comply with all the following:

(a) ~~Edible marihuana product packages shall~~ ~~n~~**N**ot ~~be in~~ **produce an edible marihuana product in** a shape or **with a** label~~ed in a manner~~ that would appeal to minors aged 17 years oryounger. ~~Edible marihuana products shall not be associated with or have cartoons, caricatures,toys, designs, shapes, labels, or packaging that would appeal to minors.~~

(b) Not produce an edible marihuana product that is associated with or has cartoons,caricatures, toys, designs, shapes, labels, or packaging that would appeal to minors.

(~~b~~**c**) **Not produce** ~~E~~**e**dible marihuana products ~~shall not be~~ **that can be** easily confused with **a** commercially ~~sold candy~~ **available food product**. The use of the word candy or candies on the packaging or labeling is prohibited. ~~Edible marihuana products shall not be in the distinct shape of a human, animal, or fruit, or a shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings. Edible marihuana products that are geometric shapes and simply fruit flavored are permissible.~~

[. . .]

(9) A producer of edible marihuana product shall comply with all the following:

(a) ~~Edible marihuana product packages shall~~ ~~n~~**N**ot ~~be in~~ **produce an edible marihuana product in** a shape or **with a** label~~ed in a manner~~ that would primarily appeal to minors aged 17 years oryounger. ~~Edible marihuana products shall not be associated with or have cartoons, caricatures,toys, designs, shapes, labels, or packaging that would appeal to minors.~~

(b) Not produce an edible marihuana product that is associated with or has cartoons, caricatures, toys, designs, shapes, labels, or packaging that would primarily **appeal to minors.**

[. . .]

(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 shelfstable 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 **and after which it must be destroyed**. 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 newlabel with a later expiration date. **The expiration date must consider all the following:**

(i) The quality and characteristics of the edible marihuana product.

(ii) The packaging of the edible marihuana product.

(iii) The customary conditions encountered by the edible marihuana product from product to sale.

[. . .]

Comment:

With regard to the proposed amendment to subsection (7)(a) above, which would require operators to label products in a descriptive manner that accurately describes the basic nature of the product, Cresco respectfully asks the MRA to provide further clarify to operators. While Cresco understands the proposed rule to echoes recent packaging guidance issued by the MRA, the proposed rule is not precise and leaves operators to interpret the MRA's intent with this additional language. Packaging and labeling changes take substantial time to design, implement, and purchase and changes cannot be made easily. Accordingly, to the extent the MRA can provide more specificity, codified in the rule, such would be to the benefit of both operators and the agency and would avoid costly changes to packaging that take considerable time to effectuate.

Regarding subsections (9)(a) and 9(b), Cresco suggests the above change that more accurately reflects the intent of the rule and balances an operator's ability to build brands and design packaging creatively while ensuring that such packaging is not aimed to the appeal of minors. Employment the qualifier "primarily" or "likely" is in line with other adult use jurisdictions and serves to accomplish the aim of the rule change.

Additionally, related to subsection (10)(a)(i), Cresco seeks clarity from the MRA as to what is meant by the phrase "quality and characteristics of the edible marihuana product." As drafted, this new language is subject to interpretation and is not defined within the amended rules. As a result, Cresco asks the MRA to consider providing further clarifying language to provide operators the necessary transparency to comply with the new rule.

MARIHUANA LICENSEES

R 420.106 Marihuana secure transporter license.

Rule 6. (1) A marihuana secure transporter license authorizes the licensee to store and transport marihuana and money associated with the purchase or sale of marihuana between marihuana establishments for a fee upon request of a person with legal custody of that marihuana or money.It does not authorize transport to a registered qualifying patient or registered primary caregiver. If a marihuana secure transporter has its primary place of business in a municipality that has notadopted an ordinance under section 6 of the MRTMA, MCL 333.27956, prohibiting marihuana establishments, the marihuana secure transporter may travel through any municipality

[. . .]

Comment:

Cresco respectfully asks that the MRA consider permitting operators to self-distribute to entities under common ownership if an operator meets the requirements set forth in the secure transporters Rule 420.106, set forth in part above.

R 420.101 Definitions.
[. . .]

(~~c~~**d**) "Applicant" means a person who applies for a marihuana license, subject to paragraphs (i) and (ii) **of this subrule**:

(i) For purposes of this definition, an applicant includes a managerial employee of the applicant, a person holding a direct or indirect ownership interest of more than 10% in theapplicant, and the following for each type of applicant:

[. . .]

(F) For a publicly held corporation: all corporate officers or persons with equivalent titles ~~and their spouses~~, all directors ~~and their spouses~~, all stockholders, not including those holding a direct or indirect ownership interest of 10% or less~~, and their spouses~~.

[. . .]

Comment:

Cresco urges the MRA to consider the above changes to remove "spouses" from the definition of applicant with respect to publicly held corporations. Simply stated, the spouses of corporate officers, persons with equivalent titles, directors, and certain stockholders should not be construed as applicants under the law. Indeed, Michigan stands as an outlier in making such a determination, which only serves to burden applicants with additional disclosures not required in other similarly situated jurisdictions and does not advance any goal the state may have with regard to transparency.

PART 3. AGREEMENTS
R 420.112a Licensing, management, or other agreements.
Rule 12a. (1) A licensee may contract with another party to use the other party's intellectual property or for the other party to provide management or other services necessary for the operation of the licensee pursuant to a licensing, management, or otheragreement approved by the agency.

(2) A licensee shall submit a complete, unredacted, signed copy of the licensing, management, or other agreement to the agency for review and approval prior to performance under the agreement. Approval by the agency indicates an agency determination that it does not appear based upon the information provided that the otherparty meets the definition of applicant.

~~**(3) The agreement must include, but is not limited to, all of the following:**~~

[. . .]

Comment:

While Cresco understands the intent behind the MRA's propose rule, set forth above, and takes no issue with providing a licensing, management, or other agreement to the MRA for review to confirm that any third party does not meet the definition of an applicant, Cresco respectfully urges the MRA to take another approach with respect to the requirements set forth in the proposed rule. As currently drafted, the MRA's requirements come close to dictating the terms of a business agreement, which Cresco respectfully suggests goes beyond the role of a regulator and is not the ultimately intent here. As an alternative approach, Cresco proposes the above rule be amended to plainly set forth what is prohibited from inclusion in such agreements rather than a list of required terms. Such an approach would still provide the MRA discretion over agreements but would not otherwise restrict the terms of such agreements (other than that certain terms cannot be included in such agreements).

MARIHUANA LICENSES

R 420.1 Definitions.
Rule 1. (1) As used in these rules:

[. . .]

(a) "Applicant" means a person who applies for a marihuana license, subject to paragraphs (i)and (ii) **of this subdivision**:
(i) For purposes of this definition, an applicant includes a managerial employee of the applicant, a person holding a direct or indirect ownership interest of more than 10% in theapplicant, and the following for each type of applicant:

[. . .]

(F) For a publicly held corporation: all corporate officers or persons with equivalent titles ~~and their spouses~~, all directors ~~and their spouses~~, all stockholders, not including those holding a direct or indirect ownership interest of 10% or less~~, and their spouses~~.

Comment:

Once again, as set forth above, Cresco urges the MRA to consider removing "spouses" from the definition of applicant with respect to publicly held corporations. The spouses of corporate officers, persons with equivalent titles, directors, and certain stockholders should not be construed

as applicants under the law. Indeed, Michigan stands as an outlier in making such a determination, which only serves to burden applicants with additional disclosures not required in other similarly situated jurisdictions and does not advance any goal the state may have with regard to transparency.

R 420.4 Application requirements; financial and criminal background.

Rule 4. (1) Each applicant shall disclose the identity of any other person who controls, either directly or indirectly, the applicant, including, but not limited to, date of birth, government issued identification, and any other documents required by the agency.

(2) Each applicant shall disclose the financial information required in the acts and these rules ona form created by the agency, including the following:

(a) For an applicant seeking licensure under the ~~medical marihuana facilities licensingact~~**MMFLA**, required information includes, but is not limited to, all of the following:

(i) Financial statements regarding all of the following:

(A) A pecuniary interest.

(B) Any deposit of value of the applicant or made directly or indirectly to the applicant, orboth.

(C) Financial accounts including, but not limited to, all of the following: funds, savings, checking, or other accounts including all applicable account information, such as the name of thefinancial institution, names of the account holders, account type, account balances, and a list of all loan~~s~~ types specified by the agency, amounts, securities, or lender information.

(ii) Property ownership information, including, but not limited to, deeds, leases, rentalagreements, real estate trusts, or purchase agreements.

(iii) Tax information, including, but not limited to, W-2 and 1099 forms, and any otherinformation required by the agency.

(iv) Disclosure by the applicant of the identity of any other person who meets either of thefollowing:

[. . .]

(b) For an applicant seeking licensure under the ~~Michigan regulation and taxation of marihuanaact~~ **MRTMA** ~~required information includes, but is not limited to,~~ **all of** the following **is required**:

(i) Tax information, including, but not limited to:

(A) W-2 forms for the most recent tax year.

(B) 1099 forms for the most recent tax year.

(ii) Any other information required by the agency.

[. . .]

(3) ~~Each applicant shall disclose all shareholders holding a direct or indirect interest of greater than 5%, officers, and directors in the proposed marihuana establishment.~~ **Each applicant shall**

disclose the identity of every person having a 2.5% or greater ownership interest in the applicant with respect to which the license is sought.

[. . .]

(c) If the disclosed entity is a publicly held corporation, the names and addresses of all shareholders holding a direct or indirect interest of greater than 5%, officers, and directors.

Comment:

As an initial matter, Cresco seeks clarification regarding subsections (2)(a) and (2)(b) of Rule 4, which appear to set forth different requirements for applicants in the medical and adult use programs in terms of financial information required to be disclosed. Cresco respectfully proposes that the MRA seek to align these requirements for consistency and to create parity between the programs. Further, to the extent disclosures are not accompanied by any temporal limitations, Cresco proposes that the MRA take steps to limit the information required to be produced. For example, an applicant under the MMFLA must produce tax information (*see* subsection (2)(a)(iiii)) whereas an applicant under the MRTMA must produce tax information for the most recent tax year (*see* subsection (2)(b)(i)).

Further, Cresco seeks clarity from the MRA as to the required disclosures applicable to a publicly held corporation. The definition of applicant in Rule 420.1 defines an applicant as a person holding an interest of more than 10% in the applicant while subsection (3) of this rule mandates disclosure of the identity of every person having a 2.5% or greater ownership interest and subsection (3)(c) requires a publicly held corporation to disclose certain persons holding a 5% of greater interest in the business.

R 420.13 Renewal of marihuana license.
Rule 13.

[. . .]

(c) For an applicant seeking renewal of a license under the MMFLA, confirmation of municipal compliance on an attestation form provided by the agency that includes all of the following ~~A**a**ttestation by the municipality on a form created by the agency regarding a licensee who submits an application for marihuana license renewal which shall include, but not be limited to, both of the following~~:

(i) A description of any violation~~, if applicable,~~ of an ordinance or a zoning regulation adoptedpursuant to section 205 of the ~~medical marihuana facilities licensing act~~**MMFLA**, MCL 333.27205~~, or section 6 of the Michigan regulation and taxation of marihuana act, MCL 333.27956,~~ committed by the licensee, but only if the violation relates to activities licensed underthe act~~s~~ or these rules.

(ii) Whether there has been a change to an ordinance or a zoning regulation adopted pursuant to section 205 of the ~~medical marihuana facilities licensing act~~**MMFLA**, MCL 333.2720~~5, or section 6 of the Michigan regulation and taxation of marihuana act, MCL 333.27956,~~ since the marihuana license was issued to the licensee and a description of the change.

(iii) The date and signature of the clerk of the municipality or his or her designee.

(iv) The date and signature of the applicant.

(v) The name and address of the marihuana facility.

(vi) The license type of the marihuana facility.

(d) For an applicant seeking renewal of a license under the MRTMA, confirmation of municipal compliance on an attestation form provided by the agency that includes all of the following:

(i) A description of any violation, if applicable, of an ordinance or a zoning regulation consistent with section 6 of the MRTMA, MCL 333.27956, committed by the licensee, butonly if the violation relates to activities licensed under the act or these rules.

(ii) Whether there has been a change to an ordinance or a zoning regulation consistent with section 6 of the MRTMA, MCL 333.27956, since the marihuana license was issued tothe licensee and a description of the change.

(iii) The following information for the municipality where the marihuana establishmentis located, including, at a minimum, all of the following:

(A) The name and address of the marihuana establishment.

(B) The license type of the marihuana establishment.

(C) The municipality where the marihuana establishment is located.

(D) The contact information for the municipality, including, at a minimum, all of thefollowing:

(I) The name of the clerk of the municipality or his or her designee.

(II) The telephone number of the clerk of the municipality or his or her designee.

(III) The email address of the clerk of the municipality or his or her designee.

(IV) The mailing address of the clerk of the municipality or his or her designee.

(iv) Confirmation that the municipality has not adopted an ordinance prohibiting theproposed marihuana establishment.

(v) Confirmation that the applicant is in compliance with any ordinance the municipalityhas adopted relating to marihuana establishments within its jurisdiction, including zoning regulations.

(vi) Attestation that the applicant will report any changes that occur with municipal ordinances or zoning regulations that relate to the marihuana establishment, any municipal establishment approvals, or any violations of a municipal or zoning regulation.

The date and signature of the applicant.

[. . .]

Comment:

With respect to the requirements of the above Rule, Cresco asks that the MRA consider the scope of information required of municipalities and how to address situations where a licensee may be unable to procure the necessary information in a timely fashion from a municipality so that the licensee may continue to serve patients and customers without disruption.

R 420.14 Notification and reporting.
[. . .]

(4) An applicant shall notify the agency within ~~1~~3 business days of becoming aware of or within ~~1~~3 business days of when the applicant should have been aware of any of the following:

[. . .]

Comment:

Cresco respectfully urges the MRA to consider the above change, which would afford operators a more reasonable period in which to report certain events. Allowing three businesses days rather than a single day would not be burdensome on the MRA and presents no risk to the public. Affording license holders a small amount of additional time to understand whether an event must be reported simply provides licensees with a fair amount of time in which to report events to the MRA.

MARIHUANA OPERATIONS

R 420.1 Definitions.
Rule 1. (1) As used in these rules:

[. . .]

(d) "Applicant" means a person who applies for a marihuana license, subject to paragraphs (i) and (ii) **of this subdivision**:

(i) For purposes of this definition, an applicant includes a managerial employee of the applicant, a person holding a direct or indirect ownership interest of more than 10% in the applicant, and the following for each type of applicant:

[. . .]

(F) For a publicly held corporation: all corporate officers or persons with equivalent titles ~~and their spouses~~, all directors ~~and their spouses~~, all stockholders, not including those holding a direct or indirect ownership interest of 10% or less~~, and their spouses~~.

Comment:

As stated above, Cresco respectfully asks the MRA to consider removing "spouses" from the definition of applicant with respect to publicly held corporations. The spouses of corporate officers, persons with equivalent titles, directors, and certain stockholders should not be construed as applicants under the law. As noted above, Michigan stands as an outlier in making such a determination, which only serves to burden applicants with additional disclosures not required in other similarly situated jurisdictions and does not advance any goal the state may have with regard to transparency.

R 420.206 Marihuana business; general requirements.
Rule 6.

[. . .]

(13) All ingredients containing cannabinoids, whether naturally occurring or synthetically derived, that are added to marihuana or marihuana products must be from a source licensed to grow, handle, and produce cannabinoids under a license issued by a governmental authority and entered into the statewide monitoring system.

(14) When combining more than 1 form of marihuana or marihuana product into a single marihuana product, each form of marihuana or marihuana product must have passing safety compliance test results in the statewide monitoring system prior to the creati on of the new combined product.

[. . .]

Comment:

Cresco respectfully seeks clarification from the MRA regarding the meaning of the above language. Specifically, does the MRA intend subsection (13) of Rule 6 to mean an operator can procure hemp-derived cannabinoids from outside of Michigan as long as the source of the cannabinoids is licensed in the state in which it operates and the product passes testing, as set forth in subsection (14).

R 420.207 Marihuana delivery; limited circumstances.
Rule 7.

[. . .]

(9) ~~To ensure the integrity of the marihuana sales location operation, a~~ **A** marihuana delivery employee shall comply with all the following:

[. . .]

(d) A marihuana delivery employee shall not carry marihuana product in the delivery vehicle with a value in excess of $5,000.00 (pre-tax retail value) at any time. The value of marihuana products carried in the delivery vehicle for which a delivery order was not received and processed by the licensed retailer prior to the delivery employee departing from the marihuana sales location may not exceed $3,000.00 (pre-tax retail value). For the purposes of this subrule, the value of marihuana products must be determined using the current retail price of all marihuana products carried by, or within the delivery vehicle of, the marihuana delivery employee.

[. . .]

Comment:

Cresco respectfully asks the MRA to consider the above change to clarify that value of products is measured before tax. Such is a reasonable clarification and would be easier for operators to navigate compared to determining product value post-tax.

R 420.214b Adverse reactions.

Rule 14b. (1) A licensee shall notify the agency within ~~1~~3 business days of becoming aware ~~or within 1 business day of when the licensee should have been aware~~ of any adverse reactions to a marihuana product sold or transferred by any licensee.

(2) A licensee shall enter into the statewide monitoring system within ~~1~~3 business days of becoming aware of ~~or within 1 business day of when the licensee should have been aware of~~ any adverse reactions to a marihuana product sold or transferred by any licensee.

Comment:

As an initial point, Cresco requests the MRA to consider the above change, which would afford operators a more reasonable period in which to report certain events. Allowing three businesses days rather than a single day would not be burdensome on the MRA and presents no risk to the public. Further, permitting license holders a small amount of additional time to understand whether an adverse reaction has actually occurred must be reported provides licensees with a fair amount of time in which to report adverse reactions.

Additionally, Cresco asks the MRA to consider eliminating language that would mandate a licensee to report (and enter information into the statewide monitoring system) within one business day of when the licensee "should have been aware" of an adverse reaction occurred. Licensees can only fairly report information they are aware of and it is unclear, as a general matter, how a licensee can report and enter information concerning an event which they were not aware of but "should have been." As a result, Cresco proposes the above changes to Rule 420.214b.

R 420.214c Product returns.

Rule 14c. (1) A marihuana sales location may accept the return of marihuana product that is reported to have caused an adverse reaction or is determined to be defective.

(2) A marihuana sales location must have a written policy for the return of marihuana product that contains, at a minimum, the following:

[. . .]

(g) A marihuana retailer may return a marihuana product that is past its expiration date to the marihuana processor who produced the marihuana product for destruction or retesting and/or remediation instead of destroying the marihuana product.

Comment:

Cresco respectfully asks the MRA to consider permitting operates to retest and remediate, as necessary, any product that has been returned as being past an expiration date. With appropriate testing and/or the application of remediation, a product can be assured as appropriately dispensed to the public. Such would avoid the unnecessary destruction of products to the expense of operators and ultimately to patients and customers who would not have that product available.

MARIHUANA SAMPLING AND TESTING

R 420.303 Batch; identification and testing.
Rule 3.

[. . .]

(6) A cultivator may transfer or sell **fresh frozen or dry** marihuana to a producer without first being tested by a laboratory in order to produce ~~fresh frozen~~ **live resin or rosin,** or if the marihuana product willbe ~~refined to a concentrate~~ **extracted**~~, with agency approval~~. **A cultivator may not transfer or sell marihuana to a producer under this rule if the package contains more than 1 harvest batch. This does not prohibit a cultivator from transferring multiple harvest batches for extraction.** After the producer has ~~processed~~ **extracted** the material, the producer shall have the sample tested **for all required safety tests** pursuant to R 420.30**4** and R 420.305. **A producer that received a package under this rule that has not been processed may transfer that package to another producer without having the package first tested by a laboratory to produce live resin or rosin or concentrate** ~~**with agency approval**~~**.** The agency may publish guidance **f**or fresh frozen and concentrate production, transfer, and sale.

Comment:

Cresco asks the MRA to consider the above changes which would provide operators with flexibility while continuing to ensure products meet testing standards before being dispensed to patients or customers. As drafted, the above rule would permit the transfer of fresh frozen

marijuana to a producer to make live resin or marihuana extract without first being tested, with MRA approval. Cresco proposes that rosin be included in the above amended regulation, as a reasonable expansion of this amended rule. Cresco further suggests that the ability to transfer biomass intended for extraction should not be limited to fresh frozen marihuana and should also include dry marihuana. And finally, Cresco proposes removing the requirement that an operator must request and receive approval before transferring materials that will be subject to extraction. The above modifications serve to reasonably expand the intent of the rule and would not result in untested product being offered for sale. Indeed, the above modifications further the purpose of the rule change, by permitting the transfer of biomass that will be subject to extraction without requiring that the marihuana be subject to a pre-transfer test and then tested again following extraction.

MARIHUANA EMPLOYEES

R 420.601 Definitions.
Rule 1. (1) As used in these rules:

[. . .]

(~~d~~**e**) "Employee" means, except as otherwise provided in these rules, a person performing work or service for direct compensation from the marihuana establishment. "Employee" does not include individuals providing trade or professional services who are not normally engaged in the operation of a marihuana establishment.

[. . .]

Comment:

Cresco proposes the above changes to the definition of employee in this rule set—and in other rule sets that employs the same definition of employee—as the current definition is overly broad. By enacting the above changes, the definition more clearly defines the term "employee."

Thank you for the opportunity to comment on these proposed rule sets. Cresco welcomes the opportunity to provide the MRA with any additional feedback or information.

Sincerely,

Cresco Labs Michigan, LLC

Comments on R. 420.101

- Add a definition for "Marihuana Educational Research Licensee" that includes:
    - That the educational institution applying for the license is the applicant under the rules rather than any individual professor, dean, or representative.

    - Indicates or clarifies the extent of background checks that would be needed and of which personnel within the university.

Comments on R. 420.1

- Add a definition for "Marihuana Educational Research License" that includes:
    - This license type is available only to accredited institutions within Michigan. Program accreditation is not necessary, however, the institution should be properly accredited to be eligible for the license.

- R420.1(s): Does the MRA intend for a Marihuana Educational Research Licensee to be a "marihuana establishment" under the rules? The educational licensee is not accounted for in that definition.

Comments on R 420.3

- Indicate whether the Marihuana Educational Research Licensee is subject to the same background checks as other Marihuana Establishments.

- Indicate who at the institutions would be subject to background checks and disclosure. It would be overly burdensome for each student or each professor in or running these programs to go through background checks. LSSU suggests that the MRA develop rules for how a Marihuana Educational Research Licensee would vetted in relation to background checks during the application process. The disclosures and background checks that are applicable to other license types will not be applicable to institutions.

Comments on R 420.27a

- R420.27a (2): The requirement that an educational research licensee would need to obtain a DEA license within 90 is not practicable given the long delays (upwards of two years) that institutions may be waiting on current DEA licensing decisions. Therefore, LSSU requests that the MRA strike the language related to "obtaining" and indicate only that the licensee must apply for the necessary DEA licensing within 90 days of issuance of the state license.

- R420.27a (3) b: LSSU is located near both churches and k-12 schooling. Protections within the rule set that would guarantee that the educational research licensee can be granted a license even if the institution is within the buffer zone of local ordinances is requested. LSSU recognizes it will need to work with the municipality to change the opt-in ordinance to specifically allow a Marihuana Educational Research Licensee, however, even if the municipality makes that change, intuitions may still run into buffer zone issues that are hard to escape.

  Assuming that the MRA cannot legally require municipalities to allow a Marihuana Educational Research Licensee within an area that violates a local zoning ordinance that contains standard buffer zones for how close a Marihuana Establishment can be to schools and places of worship, the MRA should address what the specific address on the application will be for a licensee of this type.

  For example, rather than having the licensee list 650 Easterday Avenue as the campus address (which is the all-encompassing address for campus), the licensee should be able to use the specific building address where the product will be kept so as to allow more ability to abide by buffer zones.

  If the entire campus property is considered the applicant location rather than one building, LSSU may not be able to take advantage of this license type unless the municipality reduced its buffer zone distances, which is unlikely.

- R420.27a (9): As stated this restriction is too broad. LSSU suggests the language be changed to "A marihuana educational research license shall

prohibit marihuana products obtained under the license to be consumed or sampled on the licensed premises." If the language is left as is, it is too broad and could be have the impact of limiting medical patients' access to marijuana.

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September 27, 2021

Marijuana Regulatory Agency
Legal Section
P.O. Box 30205
Lansing, MI 48909
Via E-mail: **MRA-Legal@michigan.gov**

Re: Proposed Marijuana Regulatory Agency Rules

Dear Marijuana Regulatory Agency Staff:

On behalf of the Michigan Cannabis Manufacturer's Association ("MCMA"), I write to offer public comments on the proposed changes to the Marijuana Regulatory Agency's ("MRA") administrative rule sets (the "Draft Rules"). The MCMA is an association of the largest business stakeholders in Michigan's cannabis industry. MCMA's members represent hundreds of millions of dollars of private investment and employ thousands of Michigan citizens, but the Number One priority of the MCMA is protecting the health and safety of Michigan citizens. The MCMA appreciates the opportunity to provide stakeholder feedback on the issues that directly impact the public and our members, and MRA's willingness to engage its stakeholders.

By way of introduction, MCMA finds much to praise in MRA's Draft Rules. In particular, MCMA believes that the Draft Rules will continue to advance product safety to the benefit of patients and customers. Revisions to facilitate internal testing, address the potential for the manipulation of testing results before we see such problems in Michigan (issues that have arisen in other states), and authorizing testing of homegrown adult-use cannabis are all extremely positive steps. So too are changes to allow drive-though and curbside service, and to simplify the fee structure to allow for greater predictability. The addition of a formal process for declaratory rulings is also welcome.

MCMA does nonetheless find some areas of the Draft Rules that could use some additional review and improvement. As explained in more detail below, the Draft Rules leave important terms and requirements undefined, and would improperly rely upon guidance and administrative bulletins, rendering important rule topics vulnerable to legal challenge. MCMA also strongly objects to the creation of a Class A Microbusiness License, a license that would violate the Michigan Regulation and Taxation of Marihuana Act ("MRTMA") and authorize activity that presently constitutes a felony under the Michigan Medical Marihuana Act ("MMMA"). MCMA also opposes efforts to

limit "non-marijuana" cannabinoid sourcing. And MCMA believes that there are a number of additional areas where the rules should be changed based on lessons learned, most especially with respect to the operation of co-located grower and processor facilities and the excess grow license. MCMA's comments follow.

Utilization of Guidance

As we all well know, the cannabis industry has been evolving at light speed since the first state licenses were issued just over three years ago. MRA has been evolving too, and we understand the need for MRA to be flexible and respond to new developments. That said, one significant over-arching concern for MCMA is MRA's practice of relying on the issuance of ad hoc advisory or technical bulletins in lieu of the formal rulemaking process of the Administrative Procedures Act, 1969 PA 306, MCL 24.201 to 24.328 ("APA"). While understandable in the very early days of the industry, we are concerned that in many places the Draft Rules appear intended to extend and expand that practice. By way of example, proposed R 420.304(2)(l) provides that licensees must comply with to-be-published guidance with respect to chain of custody documentation. Proposed R 420.206a(4) mandates that licensees have Standard Operating Procedures that "must comply with any guidance issued by the agency." There are numerous other instances.

While the objectives of the underlying rules may be laudable, MRA's reliance on such guidance—and imposition of that guidance on licensees—violates the APA. The APA defines a "rule" as "an agency regulation, statement, standard, policy, ruling, or instruction of general applicability that implements or applies law enforced or administered by the agency, or that prescribes the organization, procedure, or practice of the agency, including the amendment, suspension, or rescission of the law enforced or administered by the agency." MCL 24.207. Relying on a long line of precedent, the Michigan Court of Claims reiterated this principle earlier this year, ruling that, "A 'rule' not promulgated in accordance with the APA's procedures is invalid." *Genetski v Benson*, Ct. Claims Docket #20-000261-MM (March 9, 2021) at pp. 7-8, citing MCL 24.243; MCL 24.245; *Pharris v Secretary of State*, 117 Mich App 202, 205; 323 NW2d 652 (1982).

As the *Genetski* decision explains,

> An agency must utilize formal APA rulemaking procedures when establishing policies that "do not merely interpret or explain the statute or rules from which the agency derives its authority," but rather "establish the substantive standards implementing the program." *Faircloth v Family Indep Agency*, 232 Mich App 391, 403-404; 591 NW2d 314 (1998). "[I]n order to reflect the APA's preference for policy determinations pursuant to rules, the definition of 'rule' is to be broadly construed, while the exceptions are to be narrowly construed." *AFSCME v Dep't of Mental Health*, 452 Mich 1, 10; 550 NW2d 190 (1996).

Genetski at 8. Unlike a guideline, which "binds the agency but does not bind any other person", MCL 24.203(6), a rule, whether labeled as such or not, must involve notice, a public hearing, and review by the Legislature's Joint Committee on Administrative Rules. *AFSCME v Dep't of Mental Health*, 452 Mich at 9.

MCMA certainly appreciates and understands MRA's desire to be flexible to respond to new situations as data becomes available or new lessons are learned. MCMA is also thankful that MRA has regularly sought industry and public input, be it through public meetings or MRA workgroups and advisory boards. But however receptive to input today's MRA has been, enshrining the use of guidance in the rules creates the very real risk that future MRA leadership will attempt to regulate by fiat. And even more importantly, if MRA guidance is challenged in the courts, the result could easily be an environment where the regulated industry and market are left without legal standards on important topics, such as requirements for safety testing.

Accordingly, we recommend that MRA resolve these concerns by removing references to guidance in the rulesets and instead codifying any technical guidance and bulletins in the administrative rules themselves. If a new situation arose that required immediate action, the APA gives MRA the power to promulgate emergency rules to address matters that concern the preservation of public health, safety, or welfare. MRA has used emergency rules to great success and effect historically to combat and address matters of urgent public health, such as the Vitamin E Acetate vaping crisis. MRA should conform to the APA's requirements.

With respect the various proposed rulesets, the MCMA offers the following comments:

2020-121 LR – Marihuana Licenses Rule Set

- R 420.1(1)(c) – The definition of "Applicant" contains language covering both a direct "or indirect" ownership interest, yet does not define the terms. In interpreting "indirect ownership interest," MRA has looked primarily to the right of a party to receive any share of revenues or profits. Recently, though, uncertainty has been created by MRA relying on language in its Statement of Money Lender form to conclude that a lender has an interest for purposes of the rule prohibiting holding interests in both a safety compliance facility and other license types. "Indirect ownership interest" should be specifically defined to provide clarity to the industry as to what types of relationships constitute an "indirect ownership interest" for purposes of meeting the definition of "applicant."

- R 420.1(1)(f) – The definition of "common ownership" should be clarified to specify that "common ownership" includes 2 or more state licenses or 2 or more equivalent licenses held directly or indirectly by the same legal person, which among other effects would provide clear authority for transfers between the subsidiaries of a parent company.

- R 420.1(1)(o) and (dd) – MRA should consider clarifying the definitions of "limited access area" and "restricted access area" as there is overlap in these definitions—particularly with respect to marijuana sales locations.

- R 420.1(1)(s) – The definition of "Marihuana establishment" in the Draft Rule (and in the current rules) is inconsistent with the definition in MRTMA, MCL 333.27953(h). MRTMA defines an "establishment" as a "business," not a "location." While MCMA understands the desire to harmonize definitions in MRTMA with those in the Medical Marihuana Facilities Licensing Act ("MMFLA"), the definition of "marihuana establishment" in the rules should be consistent with the statutory definition.

- R 420.3 – The MCMA supports the changes proposed to provide clear guidance as to when applications may be administratively withdrawn or for prequalification approvals to be revoked for subsequent ineligibility.

- R 420.4(2) and (9) – The Draft Rules continue requiring information not requested on MRA's current applications, such as financial account statements. MRA progressed in easing the regulatory burden of the application process and focusing on information that is truly important for determining applicant suitability. The rule should be amended to conform to the MRA's current application disclosure practice, by "required information includes" with "may include" and making similar revisions elsewhere in R 420.4.

- R 420.4(3) – The proposed language as to who meets the disclosure requirement is internally inconsistent. It starts with a statement that every person having an interest of 2.5% or greater must be disclosed. It then specifies by entity type who must be disclosed, varying from the 2.5% threshold. This could be readily clarified by changing the introductory language as follows: "Each applicant shall disclose the identity of all persons having an ownership interest in the applicant with respect to which the license is sought as follows:". Also, it should be noted that the definition of applicant is proposed to be changed with respect to trusts, but the disclosure requirement does not reflect that.

- R 420.5(1) – This rule should be modified to conform to the current application requirements of the MRA. For example, the reference to a business plan in Subsection (1)(ii) should be modified to reflect a marketing plan, technology, plan, and staffing plan.

- R 420.5(1)(e) – The MCMA applauds and supports the proposed rule change with respect to MRTMA municipal attestations, as the proposed change conforms to MCL 333.27959(3)(b).

- R 420.6(2)(d) – This subrule should be either removed or revised. While this prohibition on holding any governmental office or position of employment appears in the MMFLA, this statutory prohibition does not appear in the MRTMA. This prohibition should be either stricken or narrowed to focus on addressing true issues of concern as opposed to importing the broad exclusion from the MMFLA. The public health, safety, and welfare of the State of Michigan is unlikely to be implicated if the spouse of a marijuana licensee happens to be a public elementary schoolteacher or an appointee on the Ski Area Safety Board. If this rule is maintained, then "regulatory body" should be defined and exclude Boards and Commissions that do not issue licenses or promulgate regulations governing the activities of third parties. (Relatedly, MCMA recommends that "regulatory body" also be defined for MMFLA applications, and that the rules expressly incorporate the bases for license denial contained in the MMFLA.)

- R 420.6(2)(h) – This rule prohibiting an ownership interest in more than 5 adult-use Class C Grower licenses is inconsistent with the definition of "marihuana grower" in the MRTMA. A "marihuana grower" is defined as a "person licensed to cultivate marihuana and sell or otherwise transfer marihuana to marihuana establishments." MCL 333.27953(i). In the context of MCL 333.27959(3)'s prohibition on holding an interest in more than 5 "marihuana growers," there is *not* a prohibition on the number of licenses. Instead, the statute prohibits a "person" from holding an ownership interest in more than 5 different businesses that hold Grower licenses, as opposed to 5 or more licenses. Accordingly, the rule should be modified to conform to the statute by prohibiting an applicant from holding an interest in more than 5 different entities that hold Grower licenses as opposed to restricting the number of licenses that any individual entity may hold. This change would not only reflect the actual statutory language, but would also eliminate what has become an impediment to capital investment.

- R 420.6(6) – This added subsection, which imports for MRTMA licenses the language from the MMFLA, MCL 333.27409, stating that a license is a revocable privilege and not a property right should be stricken, as the same statutory language does *not* appear in MRTMA. Whether a MRTMA license is a revocable privilege or a property right is the subject of ongoing litigation. Absent express statutory authority, MRA should not promulgate a rule to opine on an open question of law. Indeed, the determination of whether a license is a property right and the definition of the scope of that right is a legislative determination, not one delegated to the MRA.

- R 420.7 – The MCMA applauds the MRA's decision to reduce prequalification application fees and licensing fees across the board. The MCMA also applauds the MRA's decision to provide uniform fees for renewals, which gives clarity and certainty to the regulated industry for purposes of budgeting the costs of licensure.

- R 420.8 – The MCMA applauds MRA's decision to allow limited contact and contactless options for marijuana sales locations. The COVID-19 pandemic has shown that the industry can safely and securely provide limited contact and contactless options to customers. While we recognize that the Draft Rule strikes the prohibition on drive-thru transactions, MCMA recommends that the MRA be explicit in authorizing drive-through, so that no municipalities are confused and claim that drive-through's are not allowed because they are not specifically authorized.

- R 420.12(2)(s) – The denial of a license for failure to pass a pre-licensure inspection should be clarified to indicate that this means the failure of a MRTMA applicant to pass a pre-licensure inspection within 60 days of the submission of its establishment license application. The current proposed language simply states that a failure to initially pass a pre-licensure inspection could be grounds for denial of the application, which is contrary to MRA's practice. It is typical in a pre-licensure inspection for an applicant to add additional security cameras or make other minor changes to the facility in response to concerns or direction from the MRA field agent. These types of corrections to ensure compliance and to respond to the direction of the field agent—even if initially a failing pre-inspection report is issued—should not be grounds for denial of a license if the applicant cures any noted deficiencies.

- R 420.12(2)(t) – The proposed rule seeks to give MRA authority to deny an applicant's application if they submit an amendment to add an individual or entity that MRA then determines is not eligible for licensure. It is unclear what issue this rule is seeking to fix, as the amendment application would be denied if it was determined that an individual or entity proposed to be added was ineligible or unsuitable. In practical terms, applicants could be expected to cause any and all individuals or entities they wished to add to ownership first be separately prequalified. Only then would applicants be able to add new parties without fear of possibly jeopardizing the original applicant's status by attempting to add an unsuitable partner. This would create inefficiencies in the process and inhibit the ability of applicants to raise capital after they have been prequalified. MCMA proposes striking this proposed addition to the rules.

- R 420.14 – The reporting requirements for licensees should be consistently changed from "calendar days" to "business days" to conform with the proposed changes in R 420.802, which exclusively uses "business days." The timelines for reporting to the MRA should be consistent to avoid inconsistency or misunderstandings.

- R 420.18(2) – The MRA should clarify and make explicit the fees that will be required for a change of location. The current rule uses permissive language by using the word "may" as to whether additional fees will be required, yet our experience has been that MRA charges a full new licensure fee or regulatory assessment even when a licensee is moving

from a facility that has been licensed for a short period of time. MCA recommends that MRA charge a specific transfer fee limited to MRA's actual expense in reviewing a new facility application and inspecting a new location.

- R 420.20 – MCMA wholeheartedly supports MRA reviewing financial records of licensees for critical compliance matters. Nevertheless, in its application of the MMFLA's Annual Financial Statement to MRTMA licensees, MCMA believes that the AFS has metastasized to become something it was never intended to be. There is nothing to suggest that the Legislature intended the AFS to be anything other than what is commonly understood to be financial statements, i.e., a balance sheet, income statement, and a statement of cash flows. Instead, what MRA has turned into a searching audit takes enormous amounts of time and expense. For smaller businesses (e.g., stand-alone provisioning centers or retailers, microbusinesses), the cost is extreme enough that a credible argument can be made that the AFS constitutes an "unreasonably impracticable" mandate in violation of MCL 333.27958(3)(d). The MRA should provide definitive clarity as to the breadth and scope of the AFS mandate, and should strongly reconsider its current practice to focus on requiring applicants to provide only those financial documents that are necessary for the MRA to confirm regulatory compliance. Relatedly, MCMA recommends that a rule be added to define the AFS requirement under the MMFLA.

- R 420.23 – Again, MCMA believes that MRA should conform its definition of "marihuana grower" in R 420.6(2)(h) to the language of the statute. This would obviate the need for excess grower licenses. If MRA keeps the excess grow license, MRA should re-evaluate the ratio of Medical Class C Grower Licenses that are required to secure each excess grower license. Medical product is now only 25% of the marijuana market and likely to become an even smaller share. A ratio of 1 medical Class C license to 4 excess grow licenses would much better reflect the market.

2020-120 LR – Marihuana Licensees Rule Set

- R 420.101(c) – The definition of "another party" becomes unclear in certain contexts, such as the obligation to report misconduct of "another party" being limited to parties to a contract rather than other licensees. "Outside party" or "unlicensed third party" may be preferable.

- R 420.101(1)(m) – The definition of "management or other agreement" should be clarified to provide clear definitions for the terms "gross profit" and "net profit." "Gross profit" should be defined as "Revenue less Cost of Goods Sold." "Net Profit" should be defined as "Gross profit less expenses." These terms would eliminate ambiguity that exists in the context of licensing agreements today. Additionally, the definition for management or other agreement states that such an agreement is one by which an outside party either can

exercise control or receive more than 10% of gross or net profit. Consequently, the other party would be an applicant under both the statutory definitions and the provisions of proposed new rule 420.112a(4). That being the case, the management or other agreement definition should also include the fact that the outside party will be a supplemental applicant and must be reviewed by MRA as such.

- R 420.102(1) – MCMA recommends that the broader term "cultivate" should be used in this rule as opposed to the term "grow." This would mirror the language used in Section 10 of MRTMA, MCL 333.27960(1)(a) and also the language used in R 420.105(1)(a) for microbusinesses with respect to the authorization to cultivate marijuana plants.

- R 420.102(3) and (5) –The rule allows growers to acquire mature plants, seeds, seedlings, tissue cultures, and immature plants from other adult-use growers, but does not authorize acquiring harvested marijuana from another adult-use grower. MRTMA, however, expressly allows a grower to sell marijuana, broadly defined, to other licensed establishments. MCL 333.27960(1)(a). The rule should be modified to track the statute and also allow growers to acquire "marihuana" from other growers.

- R 420.102(9) – By providing that a grower may obtain from another grower "seeds, tissue cultures and clones *that do not meet the definition of marihuana plant*," this subrule conflicts with subrule (3), which explicitly allows an adult-use grower to transfer mature plants to another adult-use grower. It also conflicts with MRTMA. To reflect the language of MRTMA, the subrule should either broadly grant authority to acquire "marihuana" from another grower, or simply be deleted in favor of reliance upon subrule (3). If the intent of this subpart is to address the acquisition of seeds, tissue cultures and clones by an adult-use grower from a *medical* grower, then the subrule should be limited to such acquisitions. Finally, the entirety of R 420.109 fails to recognize that MRTMA authorizes adult-use growers "acquiring marihuana seeds or seedlings from a person who is 21 years of age or older." MCL 333.27960(1)(a). In the interests of clarity, this statutory authorization should be placed into the rule.

- R 420.103 – Subrule (1) allows processors to purchase from or sell to adult-use establishments, which would obviously include other processors. The proposed rule would delete subrule (3), which permits a licensee who holds processor licenses at multiple locations to transfer inventory between locations. This would appear to still be allowed under subrule (1), but it would be helpful for MRA to confirm that. Furthermore, when the present rules were adopted, they were for a brief time misinterpreted as allowing microbusinesses to acquire processed product, which contravenes MRTMA's requirement that microbusinesses sell only "marihuana cultivated or processed on the premises." MCL 333.27960(1)(f). To avoid such a misinterpretation arising again in the future, MCMA

recommends that subrule (1) expressly exclude microbusinesses from the establishments to which a processor may sell or transfer marijuana.

- R 420.104 – MCMA's comments regarding R 420.103 apply to R 420.104 as well.

- R 420.105 – As noted above, R 420.105(7) provides that microbusinesses are subject to all "applicable" rules that govern the activities of growers, processors and retailers. The rule also notes the obvious that microbusinesses are subject to the provisions of MRTMA pertaining to this license type. This includes that activities related to cultivation, processing and sale of marijuana must take place solely on the premises of the microbusiness. MCL 333.27960(1)(f). Because subrule (7) was for a brief time misinterpreted as allowing microbusinesses to participate in the full range of activities permitted for growers, processors, and retailers, MCMA recommends that the rule more clearly incorporate the limits of MRTMA. This could be accomplished by:

    - Inserting "All marijuana must be cultivated solely on the premises" at the end of subrule (1)(a);
    - Inserting the phrase "cultivated on the premises" after the word "marihuana" in subrule 1(b); and
    - Inserting the phrase "cultivated or processed on the premises" after the word "marihuana" in subrule (1)(c)."

  To align the rule with the statutory language, MCMA recommends that proposed subrule (8) read "A marihuana microbusiness may not purchase or accept a ~~mature~~ plant from another establishment, an individual, a registered qualifying patient, or a registered primary caregiver." (Should pending House Bills 5300 and 5301 be enacted, "specialty medical grower" should be added to the above, as well as in other applicable rules.)

- R 420.105a – **This new proposed license should be stricken entirely from the rule set.** The proposed "Class A microbusinesses" would be the farthest thing from any conception of a "microbusiness," and completely disrupt the market and settled expectations of incumbent businesses at every level. Instead, these so-called microbusinesses would be full-fledged retailers able to acquire unlimited just-harvested plants from multiple sources including caregivers and individuals, acquire and sell unlimited amounts of concentrate and infused product, and to still operate as a grower and retailer, all for a lower license fee.

  The suggested authorization to allow mature plants to be acquired from patients, caregivers, and anyone over the age of 21 would without question lead to microbusinesses that would be based on mature plants collectively grown by unlicensed individuals, greatly exacerbating current problems with caregivers and unlicensed individuals functioning as de facto commercial growers in neighborhoods throughout the state. MRA would

effectively be blessing and encouraging the movement of cultivation activities outside of MRA licensed and regulated facilities. Even worse, the conduct that would be authorized by rule is flat-out illegal and would blatantly violate both MRTMA and the MMMA. MRTMA is explicit that adults *cannot sell* marijuana, but can only gift marijuana to individuals (not businesses). MCL 333.27955(1)(d). Our Supreme Court has ruled that the only transfers of medical marijuana authorized by the MMMA and that are lawful are transfers from caregivers to their maximum of five patients connected to them through the medical marihuana registry. *People of the State of Michigan v McQueen*, 493 Mich 135 (2013). Indeed, a caregiver or patient selling their marijuana cultivated under the MMMA is committing a *felony*. MCL 333.26424(l). Patients and caregivers are authorized only to transfer or sell marihuana *seeds or seedlings* to MMFLA growers. MCL 333.26424a(2)(b). Quite simply, this proposed new license type would facilitate and reward the illicit market and unregulated actors.

It is also worth noting that this concept originated with MRA's Racial Equity Workgroup, yet the proposed rule is not in any way tied to social equity. MCMA has in the past supported legislative changes to authorize a higher plant count for social equity applicants (as well as improvements to MRA's determination of what makes up definition of "disproportionately impacted communities.")

- R 420.106 – MCMA recommends that this rule be revised to simply require ongoing reporting to MRA Compliance of any off-site addresses where vehicles may be stored, not require these locations to be identified by address in a secure transporter's staffing plan. This would alleviate any need for a secure transporter to constantly update a plan that would need to be sent through MRA Applications.

- R 420.107 – MCMA strongly supports the proposal to allow MRTMA safety compliance facilities to test marijuana from individuals who are home growing under MRTMA.

- R 420.108 – Unlike MRTMA, the MMFLA does not allow growers to accept returns of product from processors or provisioning centers. As you know, MRA has taken disciplinary action against MMFLA licensees for product returns to growers. To parallel other rules and make the prohibition more clear, MCMA recommends placing that prohibition in the rule.

- R 420.110 – While the MMFLA limits to whom some license types may transfer product, this is not the case for secure transporters, who may "transport marihuana and money … between marihuana *facilities*." MCL 333.27503(1). Although a secure transporter's place of business is a "facility," there has been some confusion over whether secure transporter to secure transporter transfers are permissible. MCMA recommends that the rule expressly state that such transfers are lawful. As with R 420.106, MCMA also recommends that this

rule be revised to require ongoing reporting to MRA Compliance of any off-site addresses where vehicles may be stored, not require these locations to be identified by address in a staffing plan.

- R 420.112 – This rule today states that safety compliance facilities are authorized to "Take marihuana from, test marihuana for, and return marihuana to *only* a marihuana facility." R 420.112(1)(a) (emphasis added). Although the rule tracks the statutory language of the MMFLA, it must also account for the fact that the MMMA allows patients and caregivers to transfer "marihuana for testing to and from a safety compliance facility licensed under the medical marihuana facilities licensing act." MCL 333.26424a(2)(c). This provision of the MMMA was enacted at the same time as the MMFLA, via a tie-barred bill, and was contingent upon the MMFLA being enacted. The two statutes, therefore, should be construed *in pari materia*, and the rule should therefore reflect that safety compliance facilities may also test patient and caregiver medical marihuana.

- R 420.112a – MCMA appreciates MRA placing the standards for licensing agreements in the rules and recognizing the need to address management agreements and other similar agreements. MRA is also pleased that the rule removes the current Advisory Bulletin requirement that licensing royalties be based on the number of units sold or a monthly rate. As the Advisory Bulletin provisions are being enshrined in the rules, though, MCMA believes that there are aspects that should be made more clear.

  First, the definition of "other agreement" and the test for whether another party meets the definition of "applicant" both depend on whether the other party could receive "more than 10% of the gross or net profit from the licensee." As with proposed R 420.101(1)(m), this rule should provide clear definitions for the terms "gross profit" and "net profit." ("Revenue less Cost of Goods Sold" and "Gross profit less expenses" respectively.) Second, "profit from the licensee" should be defined as being based on the licensee's total revenues, not just the revenues attributable to the products that are the subject of the licensing agreement. This would then track the statutory definition of applicant. Third, it should be made clear that the 10% payment cap does not include payments for services, equipment, packaging, etc. so long as they are provided at fair market value and the contract shows how that is calculated. (This is MRA's current practice.)

  In addition to these points of clarification, MCMA recommends striking the provision on how and by whom payments may be made (the second sentence of subrule 3(i)), as payment flow should not be an issue unless the other party is being given the ability to control or participate in the management of the licensee. For the same reason, MCMA recommends striking subrule (3)(iii). Finally, MCMA asks that the rule be applied only prospectively or to agreements that have not previously been approved by MRA. This would avoid what would be the unconstitutional impairment of contracts.

2020-122 LR – Marihuana Operations Rule Set

- R 420.203 – MRTMA prohibits MRA from adopting any rule requiring a "marihuana retailer to acquire or record personal information about customers other than information typically required in a retail transaction." MCL 333.27958(3)(b). In requiring that licensees maintain sales records and receipts, MRA should make clear, at least for adult-use, that personal information about customers at the retail level need not be provided to MRA.

- R 420.204 – MCMA supports the accommodation that would permit internal analytical testing space to be utilized by co-located licensees. Based on the experience MCMA members have in numerous other jurisdictions, however, MCMA discerns no regulatory purpose that is being achieved with the artificial separation of grower and processor spaces within co-located facilities. In other states, no such separation is required, and licensees are free to design facilities that are far more efficient. MCMA strongly recommends eliminating the separation requirements altogether, at least as pertains to grower and processor activities. METRC tags are sufficient to determine if marijuana or marijuana products that are in progress or finished are associated with the grower license or processor license, just as with adult-use and medical marijuana and products being in the same grower or processor space. For co-located growers and processors, MRA should permit inventory, record keeping, and point of sale operations to be shared, and there is no reason to mandate that licenses be posted in separate spaces. If MRA does, for some reason, believe that the separation of these operations is necessary, MRA should at a minimum allow both licenses to use some areas simultaneously (e.g., shipping and receiving).

- R 420.206(4) – This rule presently provides that MRA is to publish lists of approved and banned chemicals, but the rule is silent about the use of chemicals that are on neither list. MRA's present stance is that if a cultivator wishes to use an unlisted chemical, they must ask MRA, which will first work with MDARD to determine if use should be allowed. This should be spelled out in the rule.

- R 420.206(8)(b) – This rule currently provides that when a lab manager leaves and an interim is designated, that interim must meet the qualifications of a "supervisory analyst." These qualifications should be set out in the rule.

- R 420.206(13) – MCMA believes that the ability of licensees to utilize hemp-derived inputs would be unnecessarily hampered by mandating that all ingredients containing cannabinoids, whether naturally occurring or synthesized, be sourced from an entity that is licensed by a governmental authority and entered into METRC. First, there is not presently any mechanism for MRA licensees to add ingredients to METRC, and there is no METRC access for hemp producers. Second, the function of protecting patient and customer safety would be better served by requiring Certificates of Analysis to be provided by all suppliers

of cannabinoids that do not meet the definition of "marihuana" than by requiring that all come from licensed sources. Testing of the resulting product then will further confirm safety.

If MRA is to retain the proposed requirement, at a minimum it should be modified to clearly provide that the licensing authority is not restricted to MDARD or other Michigan agencies, as interstate commerce in hemp-derived products is now federally legal. Any hemp-based ingredients originating from a producer operating under a USDA approved hemp plan should be acceptable. Additionally, there should be some phase-in of this rule so that it does not take effect until (1) the necessary functionality is added to METRC, and (2) MDARD has provided a clear pathway for Michigan hemp growers and processors to transfer hemp and derivatives to MRA licensees. In the interim, MRA could require that all COAs and licenses of suppliers be kept on file for inspection, and that they be uploaded to MRA once MRA creates a way to do this.

- R 420.206a – While requiring written standard operating procedures is appropriate and welcome, the proposed rule provides no clarity or definition to permit a licensee to identify the specific processes for which SOP's are required. The rule lacks any description about the level of detail that SOP's must contain. The rule leaves all this and more to "any guidance issued" by MRA. Again, the use of binding guidance documents rather than notice and comment rulemaking violates the APA. MRA should also recognize the value of industry operational experience being considered when developing required parameters for SOP's. For both legal and practical reasons, SOP requirements should not be produced without industry input.

- R 420.207 – MCMA recommends eliminating the current restriction that a delivery employee may only be employed for one sales location. At a minimum, MRA should allow drivers to be employed by multiple sales locations if those locations are under common ownership. It serves no regulatory purpose to require companies that have multiple stores to have employees be restricted to working at only one location.

- R 420.207a – MCMA is highly supportive of permitting sales locations to designate an area for contactless or limited contact transactions, unless prohibited at the municipal level. To avoid uncertainty, MCMA recommends that the rule state explicitly that drive-through and curbside sales are acceptable. MCMA also recommends that subrule (7), which would direct that the area for contactless or limited contact transactions meet the security requirements of R 420.209, be modified to exclude R 420.209(3)'s mandate for locks.

- R 420.208 – Michigan is an outlier, perhaps the only state in the nation, in classifying marijuana grow facilities as "industrial uses." The sprinkler systems, minimum aisleway widths, and other requirements for manufacturing facilities simply make no sense for

buildings used for the cultivation of marijuana. MCMA recommends that MRA and the Bureau of Fire Services work with industry to adopt or develop standards that are more appropriate to the actual use of facilities. Also, as MRA and BFS are no doubt aware, the National Fire Protection Association is currently developing new standards for cannabis facilities. MCMA recommends that the rule provide for re-evaluation of fire protection standards once the NFPA process is complete.

- R 420.212 – MCMA recommends that co-located facilities be permitted to store marijuana product in a common area.

- R 420.214 – MCMA suggests that "common ownership" be broadly defined such that transfers among subsidiaries of the same company are more clearly authorized. MCMA also recommends that the requirements and parameters for transfers be set forth in the rule, and not by "guidance," which violates the APA. MCMA also recommends providing clear authority for transfers of all from expiring licenses that are not being renewed.

- R 420.214a – MCMA is strongly supportive of the express authorization of internal analytical testing, and suggests only that licensees be allowed to have product from more than one license in the space the same time.

- R 420.214b – MCMA recommends that the term "adverse reaction" be defined. MCMA also recommends that the reporting requirement be placed into R 420.14, which contains all of the other event reporting mandates.

- R 420.214c – MCMA recommends that the term "defective product" be defined.

2020-124 LR – Marihuana Sampling and Testing Rule Set

- R 420.305 – MCMA strongly supports this proposed rule, which would give consumers and patients (as well as industry) greater confidence in the reliability of safety testing.

- R 420.307 – MCMA recommends striking the mandate that all marijuana businesses must follow guidance that may be published and instead set forth standards in the rules. By law, guidance cannot bind those outside of the agency; this rule should be modified to conform to the requirements of the APA.

2020-119 LR – Marihuana Infused Products and Edible Marihuana Products Rule Set

- R 420.403(6) – "Inactive ingredients" is defined in the rules in a manner that excludes from the definition ingredients "not derived from the plant *Cannabis sativa L*." R 420.102(1)(e). By requiring "All *non-marihuana* inactive ingredients" (emphasis added) to be listed and approved, ambiguity is introduced. "Inactive ingredients" are by definition "non-marihuana," so it is unclear what is accomplished by the addition of "non-marihuana" to the term. Because of the general interpretive rule that words in a rule should be interpreted so that they are not surplusage, licensees will be left to attempt to interpret the meaning. One implication could be that hemp-derived products and compounds (CBD, etc.) fall within the rule's ambit. If this is the case, then virtually all such ingredients would be prohibited, because the FDA has not included them in the FDA Inactive Ingredient database. MCMA recommends that the words "non-marihuana" be deleted.

- R 420.406(7)(a) – MCMA recommends that MRA not adopt its proposed mandate that product names "must be an appropriately descriptive phrase that accurately describes the basic nature of the product." This significant change seems to imply that products must be named "gummies" or "chocolate bars" and would undermine the value of branding.

- R 420.406(8)(d) – MCMA recommends that MRA not adopt the addition of "in charge" as that could be interpreted as requiring the certification of all managerial employees. MCMA recommends a more targeted requirement that "an employee who is certified as a Food Protection Manager must supervise the production of edible marihuana product."

- R 420.406(9)(e) – MCMA recommends that this new proposed provision be deleted, or at the minimum, made more clear. It is not clear from the text of the rule what prohibiting edible marijuana packaging from containing "the characteristics of commercially available food products" means. Would this prohibit packaging like that used for a candy bar? Clarity should be provided.

2020-123 LR – Marihuana Sale or Transfer Rule Set

- R 420.501 – MCMA recommends that "administrative hold" be expanded to also expressly encompass "potential health hazards." Prior to the MRA's emergency rules during the EVALI crisis, it was not a violation of either the acts or the rules to produce vape cartridges containing Vitamin E Acetate (although fortunately, there is no record of such products being manufactured by MRA licensees). MRA therefore arguably lacked legal authority at that time to impose an administrative hold. The rule should explicitly give MRA the authority to do so when public health is in jeopardy.

- R 420.504(1)(f) – MCMA strongly believes that the requirement that product containers or bags include net weight in "United States customary" units should not be removed from the rules. Quantity limitations for products sold to patients and customers are virtually all expressed in ounces. See MCL 333.2424(c). Ounces and pounds have been customarily used in reference to cannabis since before the invention of the metric system and are widely understood by customers and patients.

- R 420.504(4) – By requiring that safety information pamphlets "substantially conform to the design published on the agency's website," MRA is again sidestepping the requirements of the APA. In addition, this approach violates the Acts. In the MMFLA, the Legislature mandated that the MRA "promulgate *rules*" that "must include *rules* to … [e]stablish informational pamphlet standards…" MCL 333.27206(u) (emphasis added). MRTMA also mandates the inclusion of informational pamphlet standards in promulgated rules. MCL 333.27958(1)(l). MCMA recommends that MRA conform to the requirements of the APA, MMFLA, and MRTMA and incorporate the pamphlet standards into the rules themselves. MCMA also recommends that MRA provide lead time for new pamphlet requirements (which would occur naturally under the framework of the APA).

2021-10 LR – Marihuana Employees Rule Set

- R 420.602(2)(e) – MCMA believes that the requirement for "responsible operations plans" should be limited to designated consumption establishments, marijuana events, microbusinesses, and retailers. These are the only license types that deal directly with customers and patients. While MCMA recognizes that responsible operations plans are also to detail how employees will prevent underage access to the establishment, illegal sale of marihuana in the establishment, and potential criminal activity, each of these must be addressed in the establishment's security plan. Having duplicative plans invites confusion.

- R 420.602(2)(j)-(k) – MCMA recommends that MRA include the statutory disqualifier for MMFLA employees, and the ability to obtain a waiver from MRA.

- R 420.602a – MCMA believes that extending to the employment context the prohibition on holding an interest in a secure transporter or safety compliance facility while holding an interest in any other license type is unnecessary and over-reaches. MCMA does not believe that there is an adequate rationale to provide that an employee of a secure transporter or laboratory may not also be an employee of any other licensee. MCMA is also concerned that a licensee could face regulatory discipline for unknowingly employing or continuing to employ someone who also has a job with a prohibited license type.

2020-118 LR – Marihuana Hearings Rule Set

- R 420.703 – MCMA is pleased to see the specific inclusion of authority for ALJ's to subpoena witnesses.

2020-117 LR – Marihuana Disciplinary Proceedings Rule Set

- R 420.801(1)(g) – MCMA recommends that the subrule read that contested case hearings be conducted "pursuant to the APA, the acts and these rules."

- R 420.802 – MCMA asks that subrule (4)(c) be clarified to provide that reporting of violations of "another party" means the defined term "another party." Otherwise, this rule could easily be misinterpreted as requiring notification to MRA when a licensee "should have been aware" of a regulatory violation by any other licensee. (Although MCMA certainly hopes that licensees who become aware of regulatory concerns will bring those to MRA's attention.) MCMA also notes again that this rule would have reporting requirements measured in business days, while R 420.14 has the same reporting requirements measured in calendar days. These should be consistent.

- R 420.808a – While beneficial that MRA is adding a rule to implement the statutory requirement of an exclusion list, portions of the proposed rule should be modified. First, including individuals on the list for theft, fraud or dishonesty even when a conviction has not been obtained takes a step too far. Someone who has been acquitted of criminal activity should not be treated as a criminal. Second, exclusion for "conduct that could negatively impact public health, safety, and welfare" is far too subjective and broad. Third, the cross-reference in subrule (3) to R 420.705 should be corrected to cross-reference R 420.704a. Finally, MCMA is concerned that a hearing under R 420.704a must be requested within 21 days, or else an individual stays on the exclusion list. Those excluded should have other opportunities to contest their exclusion. Subrule 5(c)'s proviso that exclusions are permanent if they are for reasons other than conduct (such as having been found ineligible for licensure at one time) eliminates the opportunity for someone who was denied licensure to reapply in the future, when they may have matured or circumstances otherwise have changed. The prospect of rehabilitation should not be foreclosed.

2021-29 LR – Marihuana Declaratory Rulings Rule Set

- R 420.822(1) – MCMA believes that providing for declaratory rulings is a very positive step forward, and recommends that all declaratory rulings be posted on the MRA website. MCMA, however, believes that language should be added to this rule to clarify that MRA will still respond to questions from licensees concerning the application of rules and provide informal review of product packaging, but MRA's answers to such questions will

be non-binding. A simple sentence should be added to the conclusion of R 420.822(1) that states: "Nothing in this rule is intended to limit or restrict the agency's ability to respond to questions or inquiries from licensees or the general public, but any agency response to such questions or inquiries shall not be binding on the agency."

- R 420.822(2)(c), (d) – The proposed language limits the scope of a declaratory ruling to "statutes, rules, or orders" that may apply to the requested declaratory ruling. The MRA should consider broadening the scope of these rules to also include "constitutional provisions," "judicial opinions," and "ordinances." The implications of the Michigan constitution may factor into a declaratory ruling. Similarly, a judicial opinion, particularly one that constitutes binding legal precedent from the Michigan Court of Appeals or Michigan Supreme Court, may be implicated in a declaratory ruling. Lastly, both the MMFLA, MCL 333.27205(1), and MRTMA, MCL 333.27965(2), prohibit local municipalities from adopting ordinances that conflict with the MMFLA, MRTMA, or rules promulgated by the MRA. There may be instances in which it may be appropriate for the MRA to offer a declaratory ruling with respect to whether a local municipal ordinance conflicts with the MMFLA, MRTMA, or the rules.

- R 420.822(12) – The rule should be slightly modified to make clear that any declaratory ruling issued by the agency also contain the effective date of the ruling.

In conclusion, MCMA again thanks MRA for the effort already put into the Draft Rules and looks forward to the number of positive steps proposed. MCMA also appreciates MRA's consideration of the comments provided in this letter, and values the collaborative approach of the agency. If there are any questions with respect to these comments, please contact me.

Regards,

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MICIA COMMENTS ON DRAFT MARIHUANA RULES

(Rule Sets # 2021-29 LR, 2020-117 LR, 2020-118 LR, 2020-119 LR, 2020-120 LR, 2020-121 LR, 2020-122 LR, 2020-123 LR, and 2020-124 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

I. RULE SET 2021-29 LR (DECLARATORY RULINGS, R. 420.821 ET SEQ.)

Proposed Rules 420.821 through 420.823 create a procedure through which the MRA may issue declaratory rulings as to the applicability to an actual state of facts of a statute, rule, final order, or decision administered, promulgated, or issued by the agency. The MICIA supports the MRA's efforts to promulgate rules outlining the declaratory rulings process and offers the following industry feedback on how those proposed rules may be improved.

The MRA's Legal Authority for Declaratory Rulings Derives from the APA

The MRA asserts that its legal authority for this Proposed Rule Set is conferred by "section 5 of the Michigan Medical Marihuana Act, 2008 IL 1, MCL 333.26425, section 206 of the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27206, sections 7 and 8 of the Michigan

Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27957 and 333.27958, and Executive Reorganization Order No. 2019-2, MCL 333.27001)."

None of those statutes expressly confer on the MRA the authority to issue declaratory rulings or issue rules setting the procedure for same. Rather, Section 63 of the Administrative Procedures Act provides the MRA the authority to prescribe the form and procedure for declaratory ruling requests, submissions, consideration, and disposition by administrative rule. MCL 24.263. Specifically, Section 63 states:

> On request of an interested person, an agency may issue a declaratory ruling as to the applicability to an actual state of facts of a statute administered by the agency or of a rule or order of the agency. An agency shall prescribe by rule the form for such a request and procedure for its submission, consideration and disposition. A declaratory ruling is binding on the agency and the person requesting it unless it is altered or set aside by any court. An agency may not retroactively change a declaratory ruling, but nothing in this subsection prevents an agency from prospectively changing a declaratory ruling. A declaratory ruling is subject to judicial review in the same manner as an agency final decision or order in a contested case.

As such, the boilerplate "authority" language at the outset of the Proposed Rule should be amended to reference Section 63 of the APA.

The MRA's Process Timing is Too Long

Proposed Rule 420.822 affords the MRA 60 days to issue notification to a party seeking a declaratory ruling as to whether the MRA will issue a declaratory ruling and, if so, another 90 days to issue the ruling "unless the agency notifies the interested person in writing of the need for additional time, and the reasons for the additional time." Consequently, the Proposed Rule would provide the MRA 150 days to issue a declaratory ruling unless the MRA decides to take longer for whatever written reason.

The 150-day window with the potential to be extended further is outside of the standard time frame for a declaratory ruling and inconsistent with best practices. See, e.g., Mich Admin Code, R 324.81(2)(b) (requiring EGLE declaratory ruling to be issue "[w]ithin 60 days of receipt of the request" unless additional information is required); MCL 169.215(2) (requiring SOS to issue a ruling "within 60 business days after a request . . . is received"); Mich Admin Code, R 400.951 (requiring MDHHS ruling "within 60 working days"); Mich Admin Code, R 436.1973(2)(f) (requiring Liquor Control Commission ruling "within 90 days after the receipt of the initial request."). Therefore, the MICIA requests that the MRA consider shortening these timeframes to 45 days and 60 days, respectively, and, rather than grant itself the discretion of unlimited extension, provide that: "A person requesting a declaratory ruling may waive, in writing, the time limitations provided by this section." Timing is often a critical component of regulatory certainty and a more expedited process similar to those employed by other state agencies would better accomplish that objective.

There is a Lack of Public Transparency and Industry Participation

The declaratory ruling process outlined by the Proposed Rules lacks transparency and precludes industry participation. For example, Proposed Rule 420.822(5) provides, in part, that:

> Before the issuance of the declaratory ruling, the agency, in its discretion, may choose to do 1 or more of the following: (a) Seek consultation, comments, or advice from legal counsel, experts within or outside the agency, local, state, or federal governmental agencies, or any other source. (b) Request information or clarification from other interested parties. (c) Advise the person requesting the ruling that further clarification of the facts must be provided, or that the agency requires additional time to conduct a review.

But the Proposed Rule neither provides for public notification of a declaratory ruling request nor for participation of interested parties in a declaratory ruling request.

Here, as well, the best practice includes the opportunity for interested persons other than the requestor to participate. See, e.g., MCL 169.215(2) (allowing interested members of the public to comment); Mich Admin Code, R 432.1715(2)(b) (considering "information from other interested persons"). Accordingly, the MICIA asks that the MRA consider amending the Proposed Rule to require the MRA to timely make declaratory ruling requests and decisions open to public view and to further allow for interested persons to submit comments regarding declaratory ruling requests. To accomplish that objective, the MRA could amend the Proposed Rule 420.822(5) to provide that:

> A request for a declaratory ruling that is submitted to the agency will be made available on its website for public inspection within 48 hours after its receipt. An interested person may submit written comments regarding the request to the agency within 10 business days after the date the request is made available to the public. The agency's notification to a party seeking a declaratory ruling as to whether the MRA will issue a declaratory ruling will be made available on its website for public inspection at the time it is issued. If the agency's notification provides that the agency will issue a declaratory ruling, an interested person may submit written comments regarding the subject matter of the declaratory ruling request to the agency within 10 business days after the notification is made available to the public.

The MICIA further asks that the agency amend the Proposed Rule to provide that "The agency will make available to the public an annual summary of the declaratory rulings issued under this rule." This added transparency and participation will aid the MRA in its mission and lead to more well-informed decision-making. An assessible compendium of declaratory rulings will also facilitate the compliance of licensees with applicable laws.

The Substantive Scope of Review is Too Limited

Proposed Rule 420.822(9) provides that "[r]equests regarding enforcement issues are not a proper subject for a declaratory ruling." The MICIA asks that the MRA consider deleting or

altering this Proposed Rule for reason that it unnecessarily narrows the scope of subjects on which the agency may provide clarity. By its very nature, as a regulatory agency charged with enforcing the law, a wide swath of the issues that come before the MRA could properly be characterized as "enforcement issues." The intent of an agency declaratory ruling, like a declaratory judgment action within the judiciary, is to provide clarity to affected persons "in order to guide or direct future conduct . . . ." Cf. *UAW v Central Michigan University Trustees*, 295 Mich App 486, 495; 815 NW2d 132 (2012). Nowhere is such guidance more crucial than with respect to controversial matters, where enforcement may become an issue. Further, by limiting the scope of matters that may be addressed by declaratory ruling in this manner, the Proposed rule is far narrower than the controlling statute. MCL 24.263. As an alternative, MRA may consider rewriting Proposed Rule 420.822(9) to clarify only that a matter that has already been referred for enforcement cannot be submitted by that licensee for a declaratory ruling.

There is Judicial Review of Declaratory Rulings

Proposed Rule 420.822(8) provides that "[a] denial or adverse decision of a declaratory ruling does not entitle a person to a contested case hearing." This statement may have the inadvertent effect of chilling a licensee's exercise of the right to appeal MRA's decision on a declaratory ruling. For purposes of clarity, the MRA should consider adding additional language acknowledging that, under Section 63 of the Administrative Procedures Act, "[a] declaratory ruling is subject to judicial review in the same manner as an agency final decision or order in a contested case." The MRA should further provide that its decision not to issue a declaratory ruling is subject to judicial review. See *Human Rights Party v. Michigan Corrections Commission*, 76 Mich App 204; 256 NW2d 439 (1977) ("[W]e find that a refusal to issue a declaratory ruling under M.C.L.A. s 24.263 is subject to judicial review as an agency final decision or order in a contested case").

II. RULE SET 2020-117 LR (DISCIPLINARY PROCEEDINGS, R. 420.801 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.801 through Rule 420.808 to clarify and/or strengthen the MRA's disciplinary processes and notification/reporting requirements. The Proposed Rule Set also seeks to add a new Rule 420.808a which sets forth the grounds on which, and processes by which, the MRA may exclude a person from employment or participation in a marihuana business. The MICIA supports the MRA's efforts to clarify and/or strengthen its disciplinary processes and further agrees with the MRA that clear and transparent disciplinary rules facilitate regulatory compliance and the protection of the public health and safety. The MICIA does, however, highlight that these proposed changes will increase licensee costs and liability but a detailed cost-benefit analysis has not been provided as required by MCL 24.245(3)(h), (3)(k), (3)(l), (3)(n), (3)(p), (3)(q)–(3)(t), & (3)(bb). The MICIA further offers industry feedback on how those Proposed Rules may be improved.

Grounds for Exclusion of Employment or Participation in a Marihuana Business

Proposed Rule 420.808a(1)(a)–(1)(f) sets for the grounds on which the MRA may, in its discretion and pursuant to a contested case hearing if requested, exclude a person from employment at, or participation in, a marihuana business. The MICIA generally supports the stated grounds for exclusion with the exception that a previous finding of ineligibility for licensure, as

stated in Rule 420.808a(1)(c), alone is not a proper basis for exclusion of employment where the standard for holding a license is and should be higher than the standard for general employment.

Contents of Notice of Exclusion

Proposed Rule 420.808a(2) sets forth the contents of a notice of exclusion filed by the agency including "(a) The identity of the subject. (b) The nature and scope of the circumstances or reasons that the person should be placed on the exclusion list. (c) A recommendation as to whether the exclusion or ejection is permanent." The MICIA supports these general contents for a notice of exclusion but submits that the MRA should also provide to the charged person "a detailed factual statement of the alleged grounds for exclusion accompanied by any supporting documentation or witness statements."

Proposed Rule 420.808a(3) states that "[t]he notice shall also inform the person of the availability of a hearing in compliance with R 420.705." In light of Proposed Rule Set 2020-118 LR, the MICIA queries whether the proper citation here is R. 420.704a which will address the hearing process for notices of exclusion.

Service of Notice of Exclusion

Proposed Rule 420.808a(2) provides that the MRA "shall file a notice of exclusion." It is unclear what the term "file" in this context means, and the MICIA submits that the notice of exclusion should be personally served on both the person being excluded and, if applicable, the licensee employing that person.

Proposed Rule 420.808a(6) provides that "[t]he exclusion list must be a public record made available to licensees by the agency and must include information deemed necessary by the agency to facilitate identification of the person placed on the exclusion list." The MICIA submits that the phrase "made available to licensees" lacks detail and that, in light of the resulting disciplinary proceedings that result from employing a person on the exclusion list, the exclusion list should be periodically mailed to licensees, included into the statewide monitoring system, and/or posted on the agency's website. Making this requested change would additionally add clarity to the phrase "knows or reasonably should know is on the exclusion list" in Proposed Rules 420.808a(8),(9).

Due-Process Concerns Regarding Exclusion List

Proposed Rule 420.808a(4) states that "[i]f a hearing is not requested, then the subject's name or excluded person's name must remain on the exclusion list." Proposed Rule 420.808a(7) further clarifies the MRA's intention and provides that "[a] person who is placed on the exclusion list or served with a notice of exclusion is prohibited from being employed by or participating in a marihuana business until a determination by the agency or a court to the contrary."

The MICIA acknowledges that there may, at times, exist unique circumstances where a person's continued involvement in a marihuana business presents an immediate threat to the public health and safety and, in those circumstances, immediate placement on the exclusion list may be warranted. However, aside from an immediate threat to public health and safety, the MRA should

provide basic a higher level of due process to the charged person and that person's placement on the exclusion list should occur until after that person has been afforded a hearing pursuant to R. 420.704a.

Notification and Reporting – Material Changes

Proposed Rule 420.802(3) requires reporting of proposed material changes to a marihuana business and delineates several examples of what constitute a proposed material change. In an apparent effort to further clarify what constitutes a "proposed material change," the agency now provides that "[a] proposed material change is any action that would result in alterations or changes being made to the marihuana business to effectuate the desired outcome of a material change." The MICIA submits that this clarifying language is unnecessary and overbroad and requests that it be removed or narrowed.

Notification and Reporting – Third-Party Violations

Proposed Rule 420.802(4)(c) requires reporting, within 1 business day, of any "[a]ction by another party in actual or alleged violation of the acts or these rules." Proposed Rule 420.801(e) defines "[a]nother party" or "other party" as "an individual or company with which a licensee contracts to use the individual or company's intellectual property or to utilize management or other services provided by the individual or company." The Proposed Rule, which is accompanied by disciplinary action for failure to report, places licensees in an quasi-enforcement role that is unreasonably impracticable and could potentially subject licensees to substantial costs and liability including, but not limited to, third-party litigation for defamation and other claims. The MICIA requests that this aspect of the Proposed Rule be removed or narrowed.

Notification and Reporting – Licensing and Management Agreements

Proposed Rule 420.802(7) provides that "[t]he licensee shall notify the agency within 10 business days of terminating a licensing, management, or other agreement." Proposed Rule 420.801(i) defines "[l]icensing agreement" as "any understanding or contract concerning the licensing of intellectual property between a licensee and another party." And, Proposed Rule 420.801(j) defines "[m]anagement or other agreement" as "any understanding or contract between a licensee and another party for the provision of management or other services that would allow the other party to exercise control over or participate in the management of the licensee or to receive more than 10% of the gross or net profit from the licensee during any full or partial calendar or fiscal year."

The MICIA opposes these notification requirements and submits that the agency appears to lack statutory and/or rulemaking authority for this expansion of the notification and reporting requirements, which strictly construed are unreasonably impracticable. The MRA has not articulated a rational basis on which it may justify its exercise of regulatory authority over "licensing agreements" of intellectual property. Moreover, the term "Management or other agreement" is overbroad and cuts against the agency's proposed definition of "employee" which excludes trade or professional services. At a minimum, if the MRA persists with its notification requirements with respect to management agreements, MICIA asks that the agency consider

revising the definition of "management agreement" to mean "any contract between a licensee and another party for the provision of management services that allows the other party to exercise control over or participate in the management of the licensee." Such a definition would more fairly mirror the statutory term "managerial employee" under MCL 333.27102(c).

Definition of Employee

Proposed Rule 420.801(h) defines "Employee" as "a person performing work or service for compensation" but "does not include a person providing trade or professional services who is not normally engaged in the operation of a marihuana business." The MICIA supports this common-sense clarification.

III. RULE SET 2020-118 LR (HEARINGS, R. 420.701 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.701 through Rule 420.706 to clarify and/or strengthen the MRA's hearing processes and to add a new Rule 420.704a which sets forth a hearing process by which a person may challenge the agency's decision to exclude the person from employment or participation in a marihuana business. The MICIA supports, without exception, the MRA's Proposed Rules for hearings.

IV. RULE SET 2021-10 LR (EMPLOYEES, R. 420.601 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.601 through Rule 420.602 to strengthen the MRA's requirements for, inter alia, employee training manuals and operational plans. The Proposed Rule Set also seeks to add a new Rule 420.602a that, *inter alia*, restricts employees of a cultivator, producer, marihuana sales location, or microbusiness from also being employed by a laboratory or transporter. The MICIA generally supports this Proposed Rules Set and agrees that the changes will facilitate consistency in the hiring and employment practices of marihuana businesses. The MICIA, however, disagrees with the agency's assertion that these changes will not increase compliance costs and submits that the agency's cost-benefit analysis is deficient. See MCL 24.245(3)(h), (3)(k), (3)(l), (3)(n), (3)(p), (3)(q)–(3)(t), & (3)(bb). In particular, MCL 24.245(3)(bb) requires that the MRA identify "the sources the agency relied on in compiling the regulatory impact statement, including the methodology used in determining the existence and extent of the impact of a proposed rule and a cost-benefit analysis of the proposed rule." This has not been done.

V. RULE SET 2020-119 LR (MARIHUANA-INFUSED PRODUCTS AND EDIBLE MARIHUANA PRODUCTS, R. 420.401 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.401 through Rule 420.403 to continue to refine and make consistent requirements for infused and edible marihuana product to ensure safe handling, production, and labeling. The Rule Set also seeks to update standards referenced for the handling and production of these products. The MICIA's supporting and opposing comments are below.

Product Labeling Requirements

Proposed Rule 420.403(2) provides that "[m]arihuana-infused products processed under these rules must be homogenous" and that "[t]he allowable variation for weight and THC and CBD concentrations between the actual results and the intended serving is to be + or – 15%." The MICIA submits that the labeling, homogeneity, and testing variance percentages should be consistent.

Proposed Rule 420.403(7)(a) requires that producers label all marihuana-infused products with not only the name of the product but also that "[t]he name of the product must be an appropriately descriptive phrase that accurately describes the basic nature of the product." The MICIA supports the agency's labeling requirements but takes issue with the language "appropriately descriptive" for reason that it is vague. The MICIA recommends that the sentence read: "[t]he name of the product must accurately describe the basic nature of the product."

Proposed Rule 420.403(7)(b) requires that producers label all marihuana-infused products with not only the ingredients of the product but also the "component ingredients." MICIA highlights that the term "component ingredients" is undefined and finds the term to be somewhat vague in application. The MICIA suggests that the agency consider striking the term and replacing it with the term "excipients."

Proposed Rule 420.403(7)(e) requires that producers label all marihuana-infused products with "[t]he date of the marihuana product was produced." The MICIA supports this common-sense requirement.

Proposed Rule 420.403(9)(b)-(e) clarifies product and labelling requirements to ensure that edible marihuana products are not confused with commercially available food products or attractive to children. The MICIA supports these clarifications but requests that the agency develop additional guidance and/or establish a process for issuing timely labelling approvals.

Proposed Rule 420.403(10)(a) clarifies how producers are to set expiration dates for edible marihuana products and further provides that on the label that the product must be destroyed after the expiration date. The MICIA supports these changes but submits that the term "marihuana product" in this section should read "edible marihuana product."

Inflexible Product Storage Temperature Mandate

Proposed Rule 420.403(8)(a) requires that producers of edible marihuana products comply with "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food, 21 CFR part 117" but that "[a]ny potentially hazardous ingredients used to process shelf-stable edible marihuana products must be stored at 40 degrees Fahrenheit, 4.4 degrees Celsius, or below."

The MICIA supports application of the federal reference but asserts that the agency's specific storage temperature requirement for hazardous ingredients should be stricken because it is not appropriate in all contexts and not necessarily consistent with the federal reference. See 21 CFR § 117.80(5). Specifically, the specific storage temperature requirement in R. 420.403(8)(a)

requires what is defined in 21 CFR § 117.135 as a "Preventive Control," without offering a licensee the opportunity to conduct a proper Hazard Analysis according to 21 CFR § 117.130 to see if a Preventive Control is warranted. Further, the specific storage temperature requirement in R. 420.403(8)(a) applies this Preventive Control to an undefined sub-category of ingredients ("potentially hazardous ingredients used to process shelf-stable edible marijuana products") without identifying the critical product attribute that is affected by storage temperature.

Recordkeeping

Proposed Rule 420.403(8)(b) requires that producers of edible marihuana products keep formulation records which, *inter alia*, include "test results for all ingredients used." The MICIA suggests that because testing is not required for non-active/excipient ingredients, the Proposed Rule is overbroad and should be appropriately narrowed.

VI. RULE SET 2020-120 LR (LICENSING, R. 420.101 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.101 through Rule 420.11 to prohibit and authorize the purchase of caregiver product depending on licensee type; prohibit certain intra-license product transfers; authorize the provision of marihuana testing for non-licensee adults; and maintain laboratory accreditation exceptions. The Proposed Rule Set also adds a new Rule 420.105a which regulates Class A marihuana microbusiness licenses and a new Rule 420.112a which regulates licensing and management agreements. The MICIA's comments are below.

Caregiver Product Transfers

Proposed Rule 420.102(12) provides that "[a] marihuana grower [licensed under MRTMA] may not purchase or accept the transfer of a mature plant from an individual, registered qualifying patient, or registered primary caregiver." Proposed Rule 420.105(8) contains the same prohibition with respect to microbusinesses licensed under MRTMA. Proposed Rule 420.108(10) contains the same prohibition with respect to growers licensed under the MMFLA.

The MICIA does not take a position on whether grower licensees should be permitted to purchase or accept mature plants from registered qualifying patients or caregivers but submits that the various grower license types should be treated uniformly.

Intra-license Transfers

Proposed Rules 420.103(3) and 420.104(4), delete language authorizing marihuana processors and retailers, respectively, with two or more licenses at different establishments from transferring inventory between licensed establishments owned by the licensee.

The MICIA opposes this change for reason that such transfers between licensed locations promote flexibility and help prevent product waste. Moreover, these proposed changes will increase licensee costs and a detailed cost benefit analysis has not been provided.

Class A Microbusinesses

Proposed Rule 420.105a generally sets forth the rights and obligations of a Class A marihuana microbusiness license including, inter alia, the cultivation of not more than 300 mature plants, packaging of marihuana, purchasing of marihuana concentrate and infused products, sale of marihuana and marihuana products, and the purchase of seeds, tissue cultures, clones or marijuana plants from licensed growers.

The MICIA supports these aspects of the Proposed Rules. However, Proposed Rule 420.105a(8) specifically authorizes such license holders to "purchase or accept a mature plant from an individual, registered qualifying patient, or registered primary caregiver." The MICIA does not take a position on whether grower licensees should be permitted to purchase or accept mature plants from registered qualifying patients or caregivers but submits that the various grower license types should be treated uniformly.

Adult Marihuana Testing Services

Proposed Rule 420.107(1)(c) provides that a marihuana safety compliance facility license authorizes the marihuana safety compliance facility to "Receive marihuana from and test marihuana for an individual 21 years of age or older, if the marihuana was produced by the individual and not purchased or obtained from a licensed marihuana business. The marihuana safety compliance facility shall keep documentation for proof of age."

The MICIA asks that the phrase "if the marihuana was produced by the individual and not purchased or obtained from a licensed marihuana business" be stricken. The MICIA's position is that an adult in legal possession of marijuana should not be limited with respect to testing services based upon the legal source of the marijuana. Any adult should have access to product safety testing if they are concerned about the product for any reason, without limitation. When a sample is presented to a lab for testing that was obtained from a licensed business, the chain of custody will be broken on the sample and results cannot be used to represent batch quality. This makes the proposed limiting language unnecessary. Moreover, if a sample is presented to a lab for testing by an adult, the lab has no way of definitively verifying its source, and neither does the MRA. This renders the rule practically unenforceable.

Laboratory Accreditation Exceptions are no Longer Needed

Proposed Rule 420.107(2)(c) and 420.112(2) provide that "[a] safety compliance facility must be accredited by an entity approved by the agency by 1 year after the date the license is issued or have previously provided drug testing services to this state or this state's court system and be a vendor in good standing in regard to those services" that "the agency may grant a variance from this requirement upon a finding that the variance is necessary to protect and preserve the public health, safety, or welfare."

The MICIA submits that these provisions should be amended to read only that "[a] marijuana safety compliance facility must be accredited by an entity approved by the agency prior to issuance of a state operating license." Accreditation protects public health and safety and there

is no longer any need for post-licensure accreditation nor the issuance of variances for accreditation. When the MRA was established in 2018, only four labs were operating in the state, and thus good cause existed for these exceptions to accreditation. Now, almost three years later, with fifteen licensed and operating testing laboratories, there is no need for the lower bar. Accreditation ensures that a laboratory has a functional quality system, complete with validated test methods, to ensure the accuracy of published test results.

Plant Count for MMFLA Grower

Proposed Rule 420.108(2) provides that "[f]or the purposes of this rule, a marihuana plant that meets the definition of a plant in the MMFLA is included in the plant count in subrule (1) of this rule." The MMFLA, however, defines the term "marihuana plant" and "plant" and it is unclear to which term the agency refers in this language. The MICIA submits that the term "marihuana plant" is the correct term.

Regulation of Licensing and Management Agreements

Proposed Rule 420.112a creates a new regulatory regime whereby the MRA seeks to require all "licensing agreements"[1] and "management agreements"[2] of a marihuana licensee to be submitted to the MRA for review and approval prior to performance thereunder and further requires those agreements to specify a litany of detailed contractual terms relating to payment, services, performance, and merger. The Proposed Rule 420.112a(4) further delineates a non-exclusive set of contract terms that would render the non-licensed party subject to the agency's application requirements including: "[a]ny term or condition that would allow the other party to receive more than 10% of the gross or net profit from the licensee during any full or partial calendar or fiscal year" and "[a]ny term or condition that would require the licensee to name the other party as a named insured on any insurance policy required to be maintained as a condition of a marihuana license."

The MICIA opposes these new filing and approval requirements and submits that the agency appears to lack statutory and/or rulemaking authority for this expansion of government regulation, which strictly construed is unreasonably impracticable, and which may retroactively impair contracts. These proposed changes will also increase licensee costs and a detailed cost benefit analysis has not been provided. The MRA has not articulated a rational basis on which it

[1] Proposed Rule 420.101(l) defines "licensing agreement" as "any understanding or contract concerning the licensing of intellectual property between a licensee and another party." Proposed Rule 420.101(k) defines "intellectual property" as "all original data, findings, or other products of the mind or intellect commonly associated with claims, interests, and rights that are protected under trade secret, patent, trademark, copyright, or unfair competition law and includes brands or recipes."

[2] Proposed Rule 420.101(m) defines "management or other agreement" as "any understanding or contract between a licensee and another party for the provision of management or other services that would allow the other party to exercise control over or participate in the management of the licensee or to receive more than 10% of the gross or net profit from the licensee during any full or partial calendar or fiscal year."

may justify its exercise of regulatory authority over "licensing agreements" of intellectual property. Moreover, the term "Management or other agreement" is overbroad and cuts against the agency's proposed definition of "employee" which excludes trade or professional services. At a minimum, if the MRA persists with its filing and approval requirements with respect to management agreements, MICIA asks that the agency consider revising the definition of "management agreement" to mean "any contract between a licensee and another party for the provision of management services that allows the other party to exercise control over or participate in the management of the licensee." Such a definition, albeit broader than the statute, would more fairly mirror the statutory term "managerial employee" under MCL 333.27102(c).

VII. RULE SET 2020-121 LR (LICENSING, R. 420.1 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.1 through Rule 420.27 to, *inter alia*, provide for administrative withdrawals of license applications; expand applicant disclosure requirements; disclaim vested rights in licenses; lower and streamline renewal application fees; and continue to utilize moral character in licensure determination. The Proposed Rule Set also adds a new Rule 420.27a also creates a new class of regulated marihuana educational research licenses. The MICIA's comments are below.

Administrative Application Withdrawal

Proposed Rules 420.3(3) and (6) authorize the MRA to withdraw applications for prequalification and licensure and force applicants to reapply in instances where an application has been pending for over one year. Proposed Rule 420.3(7) further provides that "[t]he agency may administratively withdraw an amendment to any application or marihuana license if the applicant or licensee fails to respond or submit documentation to cure all deficiencies within 30 days after notice of the deficiency."

The MICIA opposes these changes for reason that they are patently unfair. Applicants should not be forced to reapply and/or pay additional licensure fees where, through no fault of their own, the MRA has failed to adjudicate a license application in under one year. Moreover, 60 days would be a more reasonable timeframe in which applicants may cure deficiencies.

Expanded Application Disclosure Requirements

Proposed Rule 420.4(3) deletes language providing that "[e]ach applicant shall disclose all shareholders holding a direct or indirect interest of greater than 5%, officers, and directors in the proposed marihuana establishment" and adds language providing that "[e]ach applicant shall disclose the identity of every person having a 2.5% or greater ownership interest in the applicant with respect to which the license is sought. (a) If the disclosed entity is a trust, the applicant shall disclose the names and addresses of the beneficiaries. (b) If the disclosed entity is a privately held corporation, the names and addresses of all shareholders, officers, and directors. (c) If the disclosed entity is a publicly held corporation, the names and addresses of all shareholders holding a direct or indirect interest of greater than 5%, officers, and directors. (d) If the disclosed entity is a partnership or limited liability partnership, the names and addresses of all partners. (e) If the disclosed entity is a limited partnership or limited liability limited partnership, the names of all

partners, both general and limited. (f) If the disclosed entity is a limited liability company, the names and addresses of all members and managers."

The MICIA opposes this more stringent disclosure requirement for a de minimis ownership interest. It is unnecessary, will jeopardize licensee funding, is unreasonably impracticable, and may retroactively impair contracts. The MICIA further submits that the agency appears to lack statutory and/or rulemaking authority for this expansion of the disclosure requirement beyond the bounds of MCL 333.27102. These proposed changes will also increase licensee costs and a detailed cost benefit analysis has not been provided. The MRA has also failed to articulate a rational basis on which it may justify its increased disclosure requirements.

Vested Rights in Marihuana License

Proposed Rule 420.6(6) asserts that "[a] marihuana license is a revocable privilege granted by the agency and is not a property right" and that "[g]ranting a marihuana license does not create or vest any right, title, franchise, or other property interest."

The MICIA acknowledges that this language tracks and then expands on the language provided that MCL 333.27409. Nonetheless, the MICIA opposes this language for the reason that it may be legally incorrect where a license has been issued, substantial investments made, and state law only authorizes license revocation for cause. Regardless of whether the MRA's assertions are legally accurate, it is patently unfair to deny the existence of a property right where substantial investments are made based on licensure and such licenses may only be revoked for good causes and pursuant to due process.

Application Fees

Proposed Rule 420.7 lowers initial licensure and renewal fees and abandons the process of calculating renewal fees based on gross weight transferred for growers, gross retail sales for retailers and microbusinesses, net weight transported for transporters, and number of tests completed for laboratories. The MICIA supports these common-sense changes.

Moral Character

Proposed Rule 420.13(1)(a) retains language for requiring license renewals under the MMFLA to include "information regarding the identification, integrity, moral character, reputation, relevant business experience, ability, probity, financial experience, and responsibility of the licensee and each person required to be qualified for renewal of the license under the MMFLA." The MICIA opposes the inclusion of such subjective attributes of the licensee such as moral character and further notes Senate Bill 619, if enacted, would remove language allowing the MRA to deny a license to any applicant on account of their "moral character" or if they have any previous marijuana-related offenses. License denials based on hyper-subjective criteria create the appearance of arbitrary application.

Marihuana Educational Research License

Proposed Rule 420.21(1)(e) adds marihuana educational research licenses to the list of special licenses which may be issued by the agency. And, Proposed Rule 420.27a sets forth the rights and obligations of a person holding a marihuana educational research license. The MICIA supports these changes.

Excess Grower License Fees

Proposed Rule 420.23(11) provides that "[a]n applicant for an excess grower license is not required to pay the application fee under these rules."

The MICIA highlights that this provision benefits the largest growers and that many of the growers who are not capable of achieving this license type view this fee waiver as inequitable. The MICIA submits that the various grower license types should be treated uniformly.

VIII. RULE SET 2020-123 LR (MARIHUANA SALE OR TRANSFER, R. 420.501 ET SEQ)

This Proposed Rule Set seeks to amend portions of Rule 420.501 through Rule 420.510 to, *inter alia*, address the transfer and/or destruction of expired products; product warning labels and advisory pamphlet distribution; and employee limits for internal and trade samples. The Proposed Rule Set also adds a new Rule 420.503a authorizing the transfer of immature plant batches without utilization of a transporter. The MICIA's comments are below.

Definition of Final Form

Proposed Rule 420.501(g) defines "final form" as "the form a marihuana product is in when it is available for sale by a marihuana sales location. For marihuana products intended for inhalation, final form means the marihuana concentrate in an e-cigarette or a vaping device."

The MICIA requests that the agency clarify that prerolls, deli-style bulk flower packaged by a retailer, and batches of edibles divided into multiple packages, are not required to undergo an additional level of testing. See also Proposed Rule 420.504(1)(i).

Destruction of Expired Products

Proposed Rule 420.502(4) provides that "[a] marihuana business shall not sell or a [SIC] transfer marihuana product after the printed expiration date on the package. An expired marihuana product must be destroyed." Proposed Rule 420.502(6) provides that "[a] marihuana business shall destroy all product required to be destroyed for any reason within 90 calendar days of when the marihuana business became aware of the fact that the product must be destroyed."

The MICIA supports these proposed changes for public safety purposes and requests that the agency clarify that expired product may be transferred from a retailer to a processor for destruction. The MICIA also identifies that this requirement will increase costs and submits that the agency's cost-benefit analysis is deficient.

Transfer of Immature Plant Batches

Proposed Rule 420.503a authorizes approved cultivators to sell or transfer immature plant batches to a marihuana sales location without using a marihuana transporter and without conducting testing. The MICIA supports these common-sense regulations.

Labeling Warnings

Proposed Rule 420.504(1)(v) creates the following labelling requirement: "In clearly legible type and surrounded by a continuous heavy line: "WARNING: USE BY PREGNANT OR BREASTFEEDING WOMEN, OR BY WOMEN PLANNING TO BECOME PREGNANT, MAY RESULT IN FETAL INJURY, PRETERM BIRTH, LOW BIRTH WEIGHT, OR DEVELOPMENTAL PROBLEMS FOR THE CHILD."

The MICIA supports this labelling requirement which is expressly required by MCL 333.27206. The MICIA nevertheless asserts that this requirement will substantially increase labeling costs and submits that the agency's cost-benefit analysis is incorrect in asserting otherwise.

Advisory Pamphlet

Proposed Rule 420.504(4) creates the following requirement: "Before a marihuana product is sold or transferred by a marihuana sales location, the sales location shall make available to each customer a pamphlet measuring at least 3.5 inches by 5 inches, that includes safety information related to marihuana use by minors and the poison control hotline number. The pamphlet must substantially conform to the design published on the agency's website."

The MICIA supports this advisory requirement which is expressly required by MCL 333.27206. The MICIA nevertheless asserts that this requirement will substantially increase labeling costs and submits that the agency's cost-benefit analysis is incorrect in asserting otherwise.

Employee Transfer Limits for Internal and Trade Samples

Proposed Rule 420.508(8) provides that "[a] producer or marihuana sales location is limited to transferring a total of 1 ounce of marihuana, a total of 2 grams of marihuana concentrate, and marihuana infused products with a total THC content of 2000 mgs of internal product samples to each of its employees in a 30-day period." Similarly, Proposed Rules 420.509(6) provides that "[a] marihuana sales location, marihuana microbusiness, and class A marihuana microbusiness are limited to transferring a total of 1 ounce of marihuana, a total of 2 grams of marihuana concentrate, and marihuana infused products with a total THC content of 2000 mgs of internal product samples to each of its employees in a 30-day period."

The MICIA supports these additional clarifications regarding internal and trade sample transfers.

IX. RULE SET 2020-122 LR (OPERATIONS, R. 420.201 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.201 through Rule 420.214 to, *inter alia*, require maintenance of certain financial records and provide for the regulation of natural and synthetic cannabinoid sourcing. The Proposed Rule Set also adds new Rules 420.206a (standard operating plan), 420.207a (contactless tracing), 420.214a (internal analytical testing), 420.214b (adverse reactions), and 420.214c (product returns). The MICIA's comments are below.

Financial Records

Proposed Rule 420.204(2) adds new language stating the following: "(i) A licensee shall maintain accurate and comprehensive financial records for each license that clearly documents the licensee's income and expenses. Applicable supporting source documentation must be maintained, including, but not limited to, all of the following: (A) Cash logs. (B) Sales records. (C) Purchase of inventory. (D) Invoices. (E) Receipts. (F) Deposit slips. (G) Cancelled checks. (H) Employee compensation records. (I) Tax records. (ii) Bulk financial deposits or transactions must be traceable to the individual transactions that comprise the bulk deposit or transaction."

These new more granular financial recordkeeping requirements will increase costs and the MRA has failed to engage in any cost-benefit analysis related to the impact of these requirement on the industry. MCL 24.245(3).

Cannabinoid Sourcing and Synthetically-Derived Cannabinoids

Proposed Rule 420.206(13) adds new language providing that "[a]ll ingredients containing cannabinoids, whether naturally occurring or synthetically derived, that are added to marihuana or marihuana products must be from a source licensed to grow, handle, and produce cannabinoids under a license issued by a governmental authority and entered into the statewide monitoring system."

The MICIA submits that the use of the term "cannabinoids" in the Proposed Rule may be overbroad and may encompass any and all industrial hemp products. MCL 333.7106(2); MCL 286.842(i). The MICIA requests that the MRA add language providing that "a source authorized to grow, handle, and produce cannabinoids pursuant to an Industrial Hemp Pilot Program created by state statute or regulation" is also acceptable. The MICIA further cautions against the blanket authorization of synthetic cannabinoids and synthetic processing where certain synthetic cannabinoids such as "K2" and "Spice" are extremely dangerous to public health and safety and synthetic production involves a substantial risk of product adulteration by toxic reagents and/or byproducts. The MICIA believes that this rule should be revised to explicitly ban all fully or semi-synthetic cannabinoids from the Michigan marijuana industry, except those produced incidentally by otherwise non-synthetic processing steps that have been approved by the agency.

Testing for Product Combination

Proposed Rule 420.206(14) adds new language providing that "[w]hen combining more than 1 form of marihuana or marihuana product into a single marihuana product, each form of

marihuana or marihuana product must have passing safety compliance test results in the statewide monitoring system prior to the creation of the new combined product."

The MICIA flatly opposes this new and non-sensical requirement as both ultra vires and unreasonably impractical. There is no added health or safety benefit gained by testing the same product three different times; only three separate testing fees and three separate samples being destroyed from each batch. These new testing requirements will substantially increase costs and the MRA has failed to engage in any cost-benefit analysis related to the impact of these requirement on the industry. MCL 24.245(3).

Standard Operating Plan

Proposed Rule 420.206a adds new language providing that "[a] marihuana business must have up-to-date written standard operating procedures on site at all times . . . [which] must detail the marihuana business operations and activities necessary for the marihuana business to comply with the acts and these rules [and] . . . comply with any guidance issued by the agency."

While not opposed to standard operating plans, which are beneficial to licensees, the MICIA opposes government mandates (and associated regulatory enforcement) of such a broad requirement for licensees to have "up-to-date" and "written" procedures that "detail" compliance with every single present or future statutory, regulatory, or even informal guidance requirement of the MRA. That a mandatory SOP detail compliance with informal guidance is plainly at odds with the APA and this Proposed Rule, as written, is unreasonably impractical. Moreover, this new requirement will substantially and continually increase costs and the MRA has failed to engage in any cost-benefit analysis related to the impact of these requirement on the industry. MCL 24.245(3); MCL 243.203(7) (defining a "guideline" as "an agency statement or declaration of policy that the agency intends to follow, that does not have the force or effect of law, and that binds the agency but does not bind any other person").

Contactless and Limited Contact Transactions

Proposed Rule 420.207a adds new language authorizing and regulating the process for contactless and limited contact transactions (including online orders) "unless prohibited by an ordinance adopted by the municipality where the marihuana sales location is located." Such transactions are authorized during normal business hours provided that "the designated area for contactless or limited contact transactions [is] identified in the marihuana business location plan," the "marihuana sales location [has] a written standard operating procedure in place," the "marihuana sales location using a designated area for contactless or limited contact transactions [has] in place an anti-theft policy, procedure, or automatic capability," the "designated area for contactless or limited contact transactions [complies] with R 420.209," the "contactless and limited contact transaction [complies] with R 420.505 and R 420.506," and the "[m]arihuana being transferred during a contactless or limited contact transaction [is] in an opaque bag and the contents [are] not be visible to the general public upon pick up."

The MICIA supports this very necessary Proposed Rule with the exception that any municipal prohibition on contactless transactions should be both direct and specific. As such, the

phrase should read "unless DIRECTLY AND SPECIFICALLY prohibited by an ordinance adopted by the municipality where the marihuana sales location is located."

Storage of Marihuana Product

Proposed Rule 420.212(3) requires all chemicals or solved to be "stored separately from marihuana products and kept with a closed lid in locked storage areas."

The MICIA suggests that the phrase "with a closed lid" be replaced with the phrase "in a closed container" for reason that not all chemicals and solvents are packaged in a container with a lid.

Internal Analytical Testing

Proposed Rule 420.214a adds new language authorizing and regulating the process for internal analytical testing. The MICIA generally supports this Proposed Rule with the following exceptions:

The MICIA asks for clarification and examples of the meaning of the phrase "fully partitioned" as used in Proposed Rule 420.214a(1)(a) (i.e., whether a partition includes walls, dividers, curtains, etc).

The MICIA requests that the MRA strike the requirement in Proposed Rule 420.214a(1)(c) that the product of only one license may be in co-located internal analytical testing spaces at a time. The MICIA fails to see the necessity of this requirement where such products are required to be disposed of, the products cannot return to the licensee, and the results from the testing cannot be used to release the products to the public.

The MICIA seeks clarification regarding the prohibition in Proposed Rule 420.214a(4) that "[n]o marihuana or marihuana product may be stored in the internal analytical testing space." The MICIA submits that the samples of products being internally tested should be permitted to be stored in the space.

The MICIA opposes the requirement in Proposed Rule 420.214a(8) that "[a]ny batch of marihuana or a marihuana product that has undergone internal analytical testing must undergo full safety compliance testing, with failing test results entered into the statewide monitoring system, prior to making a request for remediation." This requirement seems to impose a requirement of outside finished testing prior to remediation and thus limits the ability of licensees to proactively remediate products. Such a requirement would mark a significant departure from current practice.

Adverse Reactions

Proposed Rule 420.214b adds new language requiring that "[a] licensee shall notify the agency within 1 business day of becoming aware or within 1 business day of when the licensee should have been aware of any adverse reactions to a marihuana product sold or transferred by any

licensee" and that "[a] licensee shall enter into the statewide monitoring system within 1 business day of becoming aware of or within 1 business day of when the licensee should have been aware of any adverse reactions to a marihuana product sold or transferred by any licensee."

The MICIA asks that the MRA define what constitutes an "adverse reaction" and clarify whether the phrases "becoming aware" or "should have been aware" encompass only actual adverse reactions or also customer alleged or perceived adverse reactions. The MICIA further requests that the agency issue a form or more detailed guidance as to how to submit such information and identifies that, at present, there is not a method for licensees to upload this information into METRC.

Product Returns

Proposed Rule 420.214c(1) adds new language applicable to marihuana sales locations that authorizes "the return of marihuana product that is reported to have caused an adverse reaction or is determined to be defective." Proposed Rule 420.214c(2) further requires that "[a] marihuana sales location must have a written policy for the return of marihuana product that contains, at a minimum, the following: (a) Product returned to a marihuana sales location must be tracked consistently in the statewide monitoring system as waste in compliance with R 420.211. (b) Product returned to a marihuana sales location must be destroyed in compliance with R 420.211 within 90 calendar days of when the marihuana business became aware of the fact that the product must be destroyed. (c) Product returned to a marihuana sales location cannot be re-sold, re-packaged, or otherwise transferred to a customer or another marihuana business. (d) Product returned to a marihuana sales location shall be returned by the customer who purchased the product. (e) Product returned to a marihuana sales location is prohibited from being returned to the marihuana sales location by way of a delivery driver. (f) A marihuana sales location that does not comply with these rules may be subject to disciplinary proceedings. (g) A marihuana retailer may return a marihuana product that is past its expiration date to the marihuana processor who produced the marihuana product for destruction instead of destroying the marihuana product."

The MICIA requests that the agency issue a form or more detailed guidance as to how to submit such information and identifies that, at present, there is not a method for licensees to upload this information into METRC. The MICIA further submits that the phrase "reported to have caused an adverse reaction or is determined to be defective," is vague and potentially overbroad. The agency has neither defined the terms "adverse reaction" nor "defective" and the phrase "reported to have caused," read literally, could mean "alleged by anyone no matter how far removed." Furthermore, the MICIA asks that the agency reconsider the prohibition in Proposed Rule 420.214c(2)(d) that "[p]roduct returned to a marihuana sales location shall be returned by the customer who purchased the product." This requirement may be extraordinarily difficult to enforce and, as set out in the proposed rule, appears to potentially suggest that a marihuana sales location may be subject to disciplinary proceedings as a result of third-party conduct completely outside the location's control.

X. RULE SET 2020-124 LR (SAMPLING AND TESTING R. 420.301 ET SEQ.)

This Proposed Rule Set seeks to amend portions of Rule 420.301 through Rule 420.307 to, *inter alia*, set maximum batch sizes, revise laboratory accreditation requirements and testing

methodologies, require safety tests on harvest batches, redefine potency analyses, and mandate laboratory policies for potentially hazardous contaminants. The Proposed Rule Set also adds a new Rule 420.303a, establishing producer and sales location packaging and testing requirements, and Rule 420.305a, establishing certain validation requirements. The MICIA's comments are below.

Batch Identification and Testing

Proposed Rule 420.303(4) provides that "[a] cultivator shall immediately destroy the individual plant tag once a tagged plant is harvested and is part of a harvest batch so that a sample of the harvest batch can be tested by a licensed laboratory as provided in R 420.304 and R 420.305."

The MICIA requests that the agency clarify that the individual plant tags (which are used to identify the plants during the drying stage) do not need to be destroyed until after the drying stage is complete.

Proposed Rule 420.303(6) provides that "[a] cultivator may transfer or sell fresh frozen marihuana to a producer without first being tested by a laboratory in order to produce live resin, or if the marihuana product will be extracted, with agency approval."

The MICIA requests that the agency revise the Proposed Rule so that "fresh frozen" includes "any dried biomass" and to replace the term "live resin" with the term "concentrate."

Producer and Sales Location Packaging and Testing Requirements

Proposed Rule 420.303a(1) and (2) clarifies that "[a] producer shall give a marihuana product a new package tag anytime the marihuana product changes form or is incorporated into a different product," "[a] producer of a marihuana product in its final form shall have the sample tested pursuant to R 420.304 and R 420.305," "[t]he producer shall quarantine products from all other products when the product has test results pending," "[t]he producer shall not transfer or sell a marihuana product to a marihuana sales location until after test results entered into the statewide monitoring system indicate a passed result for all required safety tests," and that "[n]othing in this subsection prohibits a producer from transferring or selling a package in accordance with the remediation protocol provided by the agency and these rules." Proposed Rule 420.303a(3) further clarifies that "[a] marihuana sales location may sell or transfer a marihuana product only to a marihuana customer under both of the following conditions: (a) The marihuana product has received passing results for all required safety tests in the statewide monitoring system. (b) The marihuana product bears the label required under the acts and these rules for retail sale."

The MICIA supports these proposed clarifications.

Sample Collection

Proposed Rule 420.304(2)(a) provides that "[t]he laboratory shall physically collect the sample the marijuana product from another business to be tested at the laboratory."

MICIA's only comment is that it appears a typographic error exists; the sentence should read: "The laboratory shall physically collect the marijuana product sample from another business to be tested at the laboratory."

Maximum Batch Size

Proposed Rule 420.304(2)(d) further provides that "[t]he laboratory shall develop a statistically valid sampling method and have it approved by the agency to collect a representative sample from each batch of marihuana product. The laboratory shall have access to the entire batch for the purposes of sampling."

The MICIA submits that "statistically valid sampling method" is too vague and that additional guidance should be provided in the proposed rule.

Laboratory Accreditation Requirements

Proposed Rule 420.305(1) provides that "A laboratory shall become fully accredited for all required safety tests in at least 1 required matrix to the International Organization for Standardization (ISO), ISO/IEC 17025:2017, by an International Laboratory Accreditation Corporation (ILAC) recognized accreditation body or by an entity approved by the agency within 1 year after the date the laboratory license is issued and agree to have the inspections, reports, and all scope documents sent directly to the agency from the accreditation body."

The MICIA submits that these provisions should be amended to read only that:

> A laboratory shall become fully accredited for all required safety tests in all required matrices to the International Organization for Standardization (ISO), ISO/IEC 17025:2017, by an International Laboratory Accreditation Corporation (ILAC) recognized accreditation body or by an entity approved by the agency prior to and as a condition of license issuance and agree to have the inspections, reports, and all scope documents sent directly to the agency from the accreditation body.

Accreditation protects public health and safety and there is no longer any need for post-licensure accreditation nor the issuance of variances for accreditation. When the MRA was established in 2018, only four labs were operating in the state, and thus good cause existed for these exceptions to accreditation. Now, almost three years later, with fifteen licensed and operating testing laboratories, there is no need for the lower bar. Accreditation ensures that a laboratory has a functional quality system, complete with validated test methods, to ensure the accuracy of published test results.

Laboratory Testing Methodologies

Proposed Rule 420.305(2) provides, in part, that "[a] laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency. In the absence of published, peer reviewed, validated cannabis methods, Appendix J or K of Official Methods of

Analysis authored by the Association of Official Analytical Collaboration (AOAC) International must be published in full with guidance from published cannabis standard method performance requirements where available."

The MICIA submits that the proposed language does not clearly reflect the intent of the Rule nor the way in which the Rule has been enforced to date. In its place, the MICIA asks the MRA to consider the following language:

> A laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are based upon published peer-reviewed methods, have been validated for cannabis testing by an independent third party, may be monitored on an ongoing basis by the agency, and have been internally verified by the licensed laboratory according to Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Collaboration (AOAC) International, with guidance from published cannabis standard method performance requirements where available. In the absence of published, peer-reviewed, validated cannabis methods, method validation requirements of Appendix K of Official Methods of Analysis must be met in full with guidance from published cannabis standard method performance requirements where available.

Safety Tests on Harvest Batches

Proposed Rule 420.305(3) provides, in part, that "[a] laboratory shall conduct the required safety tests specified in subdivisions (a) through (i) of this subrule on marijuana product that is part of a harvest batch as specified in R420.303, except as provided in subrule (4) of this rule. The agency may publish minimum testing portions to be used in compliance testing."

The MICIA reads this language as limiting safety testing to marijuana product that is part of a harvest batch (which is only plant material by definition) and thus as excluding testing requirements for marijuana products that are not part of a harvest batch such as concentrates and infused products. The agency should clarify its intention in that regard. The MICIA supports the agency publishing minimum testing portions to be used in compliance testing.

Potency Analysis

Proposed Rule 420.305(3)(a)(i) states that "[i]n the preparation of samples intended for potency analysis, the laboratory may not adulterate or attempt to manipulate the total potency of the sample by adding trichomes that were removed during the grinding and homogenization process."

The MICIA opposes this prohibition for reason that it leads to results that are not representative. Simply because a testing lab "damages" or knocks portions off of a licensee's product, does not mean that those portions should not be included in the potency test.

Proposed Rule 420.305(3)(a)(ii) states, in part, that "Kief must not be reintroduced to the flower sample during the homogenization process."

The MICIA opposes this prohibition for reason that it leads to results that are not representative. Kief created during the grinding process is customarily kept and reintroduced by the average consumer.

Proposed Rule 420.305(3)(a)(iii) defines the list of legally required cannabinoids for potency testing as: "(A) Total Tetrahydrocannabinol (THC); (B) Tetrahydrocannabinol Acid (THC-A); (C) Total Cannabidiol (CBD); (D) Cannabidiol Acid (CBDA); [and] (E) Additional cannabinoids may be tested with approval from the agency."

The MICIA reads the rule as only requiring potency test results for the four cannabinoids in items (A) through (D) of the subrule. Consequently, the subrule does not authorize potency testing of d9-THC or Cannabidiol. By default, these two important compounds fall into optional analyte category (E). Omitting mandatory reporting of d9-THC and Cannabidiol test results is not recommended. The MICIA also submits that the correct term for "Tetrahydrocannabinol Acid" is "Tetrahydrocannabinoic Acid" and the correct term for "Cannabidiol Acid" is "Cannabidiolic Acid."

Proposed Rule 420.305(9) further defines the list of legally required cannabinoids for potency testing and provides that "[p]otency shall include the following cannabinoid concentrations listed in subdivisions (a) to (f) of this subrule, subject to subdivisions (g) and (h) of this subrule:

> (a) Total THC concentration;
> (b) THC-A concentration;
> (c) Total THC, which includes Delta 7, Delta 8, Delta 9, Delta 10, and Delta 11 THC and THC-A. The following calculation must be used for calculating Total THC, where M is the mass or mass fraction of delta-9 THC or delta-9 THC-A: Σ Delta 7-11 THC + Σ ((Delta 7-11 THCA) x 0.877)=Total THC;
> (d) Total CBD concentration;
> (e) CBD-A concentration;
> (f) Total CBD. The following calculation must be used for calculating Total CBD, where M is the mass or mass fraction of CBD and CBD-A: M total CBD = M CBD + 0.877 x M CBD-A;
> (g) For marihuana and marihuana concentrates, total THC and total CBD must be reported in percentages; [and]
> (h) For marihuana infused products, potency must be reported as milligrams of Delta-9-THC and CBD."

The MICIA reads the proposed rule as only requiring reporting of test results for items (a) through (f) of the subrule. As such, this list no longer mandates individually reporting of d9-THC or Cannabidiol test results. By default, these important compounds fall into optional analyte category (E). Omitting mandatory reporting of d9-THC and Cannabidiol test results is not recommended. The MICIA also submits that Rules 420.305(9)(a) and (c) are redundant. The

agency should change "Total THC concentration" in Rule 420.305(9)(a) to "delta-9 THC Concentration."

Furthermore, the definition in Rule 420.305(9)(c) of compounds that comprise "Total THC" is problematic such that reporting of Total THC results, as defined, cannot be met at this time where (i) certified analytical reference standards for Delta7-THC (a fully synthetic and non-psychoactive cannabinoid) may not be fully and commercially available at this time; (ii) certified reference standards for Delta 10-THC (a fully synthetic cannabinoid) are available for two separate enantiomers: Delta 10 (6aR, 9S), which is not psychoactive, and Delta 10 (6aR, 9R), which is psychoactive;[3] (iii) although there are various forms of nomenclature, the term "Delta 11 THC" is not a consistently recognized term in current scientific literature;[4] and (iv) the calculation provided for determining Total THC includes summing the concentrations of "Delta 7-11 THCA."[5] Consequently, MICIA recommends that the potency testing requirements be revised to allow the MRA to publish a list of cannabinoids for mandatory testing and reporting and to update the list as needed via bulletins separately from the Rules. It is important to address the emergence of additional THC isomers (like delta-8 THC) without prematurely and unnecessarily complicating the Proposed Rule.

Residual Solvent Testing as Part of Harvest Batch

Proposed Rule 420.305(3)(f) includes "Residual Solvents" as a required safety test for a marijuana product that is part of a harvest batch. Because residual solvent testing has not been required for plant material to date, the MICIA suggests that this subrule be deleted, especially where subrule 420.305(7) properly addresses residual solvent testing.

Reporting Units for CBD

Proposed Rule 420.305(9)(h) states that "[f]or marijuana infused products, potency must be reported in milligrams of Delta-9 THC and CBD."

The MICIA suggests that this language does not adequately define reporting units for CBD. While the definition provides a magnitude (milligrams), it does not specify the quantity. That is, the language does not specify whether the quantity be a milliliter of analytical solution, gram of product, serving, etc. By requiring reporting of individual test results for Delta 9-THC and CBD for infused products, the subrule also seems to conflict with Proposed Rules 420.305(3)(a)(iii) and 420.305(9) which provide that these analytes are defined as optional.

[3] The Proposed Rule should clarify whether both enantiomers or, if only one, which enantiomer must be quantified.

[4] Provided that the term "Delta 11 THC" intends to describe THC with a double bond between carbon atoms 9 and 11, the MICIA would prefer the nomenclature "exo-THC," as certified reference standards are available for "exo-THC."

[5] This requires a laboratory to individually quantify delta 7, delta 8, delta 10, and delta 11 THC acids. Certified reference standards for these cannabinoic acids do not currently exist in the literature, and the delta-9 THC acid isomers themselves may not be known compounds at all at this time.

Terpene Analysis

Proposed Rule 420.305(18) states that "[a] laboratory may perform terpene analysis on a marijuana product by a method approved by the agency, and the method must be accredited on the same frequency as all required safety tests. There are no established safety standards for this analysis."

The MICIA recommends that the phrase "[t]here are no established safety standards for this analysis" be omitted, because safety tests for beverages include a requirement to test for phytol.

Laboratory Policy for Potentially Hazardous Contaminants

Proposed Rule 420.305(21) states that "[a] laboratory shall have a policy or procedure in place for handling and reporting any potentially hazardous contaminants that may be encountered during routine testing. A laboratory shall notify the agency if a test batch is found to contain levels of a contaminant that could be injurious to human health."

The MICIA suggests that this requirement is vague and overbroad and should not be included in the Proposed Rules without further clarification. Licensed laboratories are not equipped or otherwise required to identify unknown compounds of any type in product samples. In addition, under the right conditions and without further clarification, just about any compound fits the terms "potentially hazardous" and "potentially injurious to human health."

STEC Reporting Deadline

Proposed Rule 420.305(22) states that "[m]arihuana-infused products found to contain Salmonella spp. or Shiga toxin producing E. coli (STEC) must be reported to the agency immediately."

The MICIA submits that it is unclear how immediate reporting for STEC required under this Proposed Rule fits with Rules 420.305(12) and (13) which requires reporting within three business days. The MRA should consider omitting or clarifying this Proposed Rule. If the MRA chooses to clarify this Proposed Rule, the MICIA suggests that the term "immediately" should be replaced with the phrase "within one business day."

Validation Protocols

Proposed Rule 420.305a sets forth a litany of new validation protocols and requirements. The MICIA submits that these new requirements will increase laboratory costs and that the MRA has failed to engage in any cost-benefit analysis related to the impact of these requirement on the industry. MCL 24.245(3).

Proposed Rule 420.305a(2)(b) provides that "[v]alidation protocols should perform inoculation of marihuana matrices with live organisms where feasible to ensure that both extraction and detection for the assay are tested. To further test the accuracy of the assay, probability of

detection (POD) analyses, inclusivity, exclusivity, lot-to-lot stability, and robustness studies must be included in the validation studies."

The MICIA submits that "lot-to-lot stability" testing is not appropriate as a test method validation requirement and should be removed from this sub-rule. "Lot-to-lot stability" is a process validation, typically included in validation of a manufacturing process, and is not appropriately employed as an element of analytical method validation.

Quality Assurance and Control

Proposed Rule 420.305b creates a quality assurance and quality control monitoring regime and requires that laboratories adopt and follow detailed written quality assurance measures and standard operating procedures approved by the agency.

The MICIA is concerned that the quality control acceptance criteria currently published by the agency exceed the capabilities of established, industry-accepted test methods, and are more stringent than criteria assigned to those methods by the method authors / innovators. MICIA submits that while published MRA guidance is essential and appropriate, where available, method author / innovator quality control acceptance criteria should prevail. The MICIA further submits that these new requirements are likely to substantially increase laboratory costs and that the MRA has failed to engage in any cost-benefit analysis related to the impact of these requirement on the industry. MCL 24.245(3). Abandoning existing, approved and accredited methods simply to meet tightened MRA specifications without regard to actual existing method capabilities may include major financial impact, including purchasing expensive new equipment and discarding perfectly adequate existing equipment.

The MICIA additionally identifies that the phrase "method acceptance criteria **is** required" in Rule 420.305b(6) should be revised to "method acceptance criteria **are** required."

Aspergillus Remediation

Proposed Rule 420.306(3) provides that "[p]roducts that failed testing for Aspergillus are ineligible for remediation."

The MICIA suggests that products which fail testing for Aspergillus should be further tested and, if applicable, remediated for Mycotoxins. Testing for mycotoxins identifies the presence of aspergillus which, itself, is ubiquitous. This proposed process is similar to the process followed by the USDA https://www.ams.usda.gov/publications/content/fgis%E2%80%99s-role-aflatoxin-testing

Retest Costs

Proposed Rule 420.306(5) provides that "[t]he marihuana business that provided the sample is responsible for all costs involved in a retest."

The MICIA highlights that the various license types have different perspectives on this provision. The MICIA submits that the MRA should not inflexibly dictate commercial terms but should instead leave it to the individual businesses to contract amongst themselves for apportioning such costs.

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, 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
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www.MICannabisIndustryAssociation.org

From: Rick Thompson
To: MRA-Legal
Subject: Part 2 - Comments on the proposed topic-based rules- Administrative Rules hearing Sept 27
Date: Sunday, September 26, 2021 11:18:10 PM

This is the continuation of the earlier email. Thank you for combining the two into one single entry on my behalf.

Rick Thompson
Executive Director, NORML of Michigan
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2020-122 LR

R420.206 sub 13 and 14

This may disallow the inclusion of certain cannabinoids which are beneficial to consumers. The sourcing of the cannabinoids is not necessary to establish, because each component must pass testing and if it passes, its origin is irrelevant. We stand neutral on this change; greater reporting is good for consumers but overregulation is bad for everyone.

R420.207a

We support the diversity in cannabis retail experience this ruleset provides. Although born during the pandemic, this program has value even in non-crisis times. We support these changes.

R420.214a

We heartily endorse product testing prior to release to the public. The establishment of these areas is a welcome addition to the ruleset. We support these changes.

R420.214c

The ability to return product which is poor or unsatisfactory is important to consumer confidence in the regulated market. We support these changes.

2020 R123 LR

R420.503a

We support this but wonder why this privilege is not extended to caregivers and patients who have immature plants available to supply retailers. We support these changes.

R420.504 Rule 4 sub 1 sub K sub 5

This label is mandated by an act of the legislature but there is insufficient and contradictory evidence to make this claim, and we oppose the inclusion of these labels. We stand opposed to these changes.

Same, Rule 4 sub 4

The incidence of minor use is so slight that the mandated presence of pamphlets is an overreaction to an underwhelming and extremely rare occurrence. These pamphlets do not serve a real purpose but are public relations tools. We stand opposed to this change.

2020-124 LR

No notes

2021-10 LR

R420.602a

We find this unnecessary, as diversion of product is defeated by the METRC system, and working more than one job is almost a necessity in 2021 America. Ownership of different license types should be restricted, but employment should not. We stand opposed to this change.

2021-29 LR

No notes

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