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

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

MARIJUANA REGULATORY AGENCY

MARIHUANA EMPLOYEES

Filed with the secretary of state on

These rules take effect immediately upon filing with the secretary of state unless adopted under section 33, 44, or 45a~~(6)~~**(9)** of the administrative procedures act of 1969, 1969 PA 306, MCL 24.233, 24.244, or 24.245a. Rules adopted under these sections become effective 7 days after filing with the secretary of state.

(By authority conferred on the executive director of the marijuana regulatory agency by 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)

R 420.601 and R 420.602 of the Michigan Administrative Code are amended, and R 420.602a is added, as follows:

R 420.601 Definitions.

Rule 1. (1) As used in these rules:

(a) "Acts" refers to the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27101 to 333.27801, and the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27951 to 333.27967, when applicable.

(b) "Agency" means the marijuana regulatory agency.

(c) "Cultivator" means both a grower under the medical marihuana facilities licensing act and a marihuana grower under the Michigan Regulation and Taxation of Marihuana Act.

(~~e~~**d**) "Designated consumption establishment" means a commercial space that is licensed by the agency and authorized to permit adults 21 years of age and older to consume marihuana products at the location indicated on the state license.

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

(f) "Laboratory" means both a safety compliance facility under the medical marihuana facilities licensing act and a marihuana safety compliance facility under the Michigan Regulation and Taxation of Marihuana Act.

(~~e~~**g**) "Limited access area" means 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.

(~~f~~**h**) "Marihuana business" ~~refers to~~ **means** a marihuana facility under the medical marihuana facilities licensing act or a marihuana establishment under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct, or both.

(~~g~~**i**) "Marihuana customer" ~~refers to~~ **means** a registered qualifying patient under the medical marihuana facilities licensing act, a registered primary caregiver under the medical marihuana facilities licensing act, or an individual 21 years of age or older under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct, or all 3.

(~~h~~**j**) "Marihuana establishment" means a location at which a licensee is licensed to operate a marihuana grower, marihuana safety compliance facility, marihuana processor, marihuana microbusiness, **class A marihuana microbusiness,** marihuana retailer, marihuana secure transporter, marihuana designated consumption establishment, or any other type of marihuana related business licensed to operate by the agency under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct.

(~~i~~**k**) "Marihuana event organizer" means a person licensed to apply for a temporary marihuana event license under these rules.

(~~j~~**l**) "Marihuana facility" means a location at which a licensee is licensed to operate under the medical marihuana facilities licensing act.

(~~k~~**m**) "Marihuana product" means marihuana or a marihuana-infused product, or both, as those terms are defined in the acts unless otherwise provided for in these rules.

(~~l~~**n**) "Marihuana sales location" ~~refers to~~ **means** a provisioning center under the medical marihuana facilities licensing act or a marihuana retailer**,** ~~or~~ marihuana microbusiness**, or class A marihuana microbusiness** under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct, or both.

(o) "Marihuana tracking act" means the marihuana tracking act, 2016 PA 282, MCL 333.27901 to 333.27904.

(p) "Marihuana transporter" means a secure transporter under the medical marihuana facilities licensing act or a marihuana secure transporter under the Michigan Regulation and Taxation of Marihuana Act, or both.

(~~m~~**q**) "Medical marihuana facilities ~~license~~ **licensing** act" or "MMFLA" means the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27101 to 333.27801.

(~~n~~**r**) "Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct" or "MRTMA" means the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27951 to 333.27967.

(s) "Producer" means both a processor under the medical marihuana facilities licensing act and a marihuana processor under the Michigan Regulation and Taxation of Marihuana Act.

(~~o~~**s**) "These rules" means the administrative rules promulgated by the ~~Marijuana Regulatory Agency~~ **marijuana regulatory agency** under the authority of the medical marihuana facilities licensing act, the marihuana tracking act, the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct, and Executive Reorganization Order No. 2019-2**, MCL 333.27001**.

(~~p~~**t**) "Temporary marihuana event license" means a state license held by a marihuana event organizer under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct, for an event where the onsite sale or consumption of marihuana products, or both, are authorized at the location indicated on the state license.

(2) Terms defined in the acts have the same meanings when used in these rules unless otherwise indicated.

R 420.602 Employees; requirements.

Rule 2. (1) A licensee shall conduct a criminal history background check on any prospective employee before hiring that individual. A licensee shall keep records of the results of the criminal history background checks for the duration of the employee's employment with the licensee. A licensee shall record confirmation of criminal history background checks and make the confirmation available for inspection upon request by the agency.

(2) A licensee shall comply with all of the following:

(a) Have a policy in place that requires employees to report any new or pending criminal charges or convictions. If an employee is charged with or convicted of a controlled substance-related felony or any other felony, the licensee shall immediately report the charge or conviction to the agency. If an employee of a licensee under the ~~Michigan regulation and taxation of marihuana act~~ **MRTMA** is convicted of an offense involving distribution of a controlled substance to a minor, the licensee shall immediately report the conviction to the agency. ~~The agency shall maintain a list of excluded employees.~~

(b) Enter in the statewide monitoring system an employee's information and level of statewide monitoring system access within 7 business days of hiring for the system to assign an employee identification number. The licensee shall update in the statewide monitoring system employee information and changes in status or access within 7 business days.

(c) Remove an employee's access and permissions to the marihuana business and the statewide monitoring system within 7 business days after the employee's employment with the licensee is terminated.

(d) ~~Train employees and have an employee training manual that includes, but is not limited to, employee safety procedures, employee guidelines, security protocol, and educational training, including, but not limited to, marihuana product information, dosage and purchasing limits if applicable, and educational materials. Copies of these items must be maintained and made available to the agency upon request.~~ **Train employees in accordance with an employee training manual. Copies of this manual must be maintained and be made available to the agency upon request. The employee training manual must include, but is not limited to, all of the following:**

(i) Employee safety procedures.

(ii) Employee guidelines.

(iii) Security protocol.

(iv) Educational training, including, but not limited to, marihuana product information; dosage and purchasing limits, if applicable; and educational materials.

(e) ~~A licensee under the Michigan regulation and taxation of marihuana act shall, if applicable, include in the employee training manual a responsible operations plan. A responsible operations plan must include a detailed explanation of how employees will monitor and prevent over-intoxication, underage access to the establishment, the illegal sale or distribution of marihuana or marihuana products within the establishment, and any other potential criminal activity on the premises, as applicable. Copies of these items must be maintained and made available to the agency upon request.~~ **A licensee under the MRTMA shall include in the employee training manual a responsible operations plan. Copies of this plan must be maintained and be available to the agency upon request. A responsible operations plan must include a detailed explanation of how employees will monitor and prevent all of the following:**

(i) Over-intoxication.

(ii) Underage access to the establishment.

(iii) The illegal sale or distribution of marihuana or marihuana products within the establishment.

(iv) Any potential criminal activity on the premises, as applicable.

(f) ~~Establish point of sale or transfer procedures for employees at marihuana sales locations performing any transfers or sales to marihuana customers. The point of sale or transfer procedures must include, but are not limited to, training in dosage, marihuana product information, health or educational materials, point of sale training, purchasing limits, cannabidiol (CBD) and tetrahydrocannabinol (THC) information, serving size, and consumption information, including any warnings. Copies of these items must be maintained and made available to the agency upon request.~~ **Establish point of sale or transfer procedures for employees at marihuana sales locations performing any transfers or sales to marihuana customers. Copies of these procedures must be maintained and be made available to the agency upon request. The point of sale or transfer procedures must include, but are not limited to, all of the following:**

(i) Training in dosage.

(ii) Marihuana product information.

(iii) Health or educational materials.

(iv) Point of sale training.

(v) Purchasing limits.

(vi) Cannabidiol (CBD) and tetrahydrocannabinol (THC) information.

(vii) Serving size.

(viii) Consumption information, including any warnings.

(g) Screen prospective employees against a list of excluded employees ~~based on a report or investigation~~ maintained by the agency in accordance with **R 420.808a(6)**~~subdivision (a) of this subrule~~.

(h) Ensure that employees handle marihuana product in compliance with ~~c~~**C**urrent ~~g~~**G**ood ~~m~~**M**anufacturing ~~p~~**P**ractice**, Hazard Analysis, and Risk Based Preventative Controls for** ~~in manufacturing, packing, or holding~~ ~~h~~**H**uman ~~f~~**F**ood, 21 CFR part 11~~0~~**7**, as specified in these rules.

(i) When a registered primary caregiver is hired as an employee of a grower, processor, or secure transporter licensed under the ~~medical marihuana facilities licensing act~~**MMFLA**, ~~withdraw, or~~ ensure the individual withdraws~~,~~ the individual's registration as a registered primary caregiver in a manner established by the agency.

(j) ~~If a~~ **A** licensee under the ~~Michigan regulation and taxation of marihuana act~~**MRMTA**~~,~~ **shall** not allow a person under 21 years of age to volunteer or work for the marihuana establishment pursuant to section 11 of the MRTMA, MCL 333.27961.

(k) ~~If a~~ **A** licensee under the ~~Michigan regulation and taxation of marihuana act~~**MRTMA**~~,~~ **shall** not employ any individual who has been convicted of an offense involving distribution of a controlled substance to a minor.

(3) If an individual is present at a marihuana business or in a marihuana transporter vehicle who is not identified as a licensee or an employee of the licensee in the statewide monitoring system or is in violation of the acts or these rules, the agency may take any action permitted under the acts and these rules. This subrule does not apply to authorized escorted visitors at a marihuana business.

(4) Employee records are subject to inspection or examination by the agency to determine compliance with the acts and these rules.

(5) Consumption of food and beverages by employees or visitors is prohibited where marihuana product is stored, processed, or packaged or where hazardous materials are used, handled, or stored. The marihuana business may have a designated area for the consumption of food and beverages that includes, but is not limited to, a room with floor to ceiling walls and a door that separates the room from any marihuana product storage, processing, or packaging.

(6) As used in this rule, "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. Trade or professional service~~s~~ **providers** ~~provided by individuals~~ not normally engaged in the operation of a marihuana business, except for those individuals required to have employee credentials under this rule, must be reasonably monitored, logged in as a visitor**,** and escorted through any limited access areas.

(7) Nothing in this rule prohibits a licensee from allowing visitors into the marihuana business**.**~~,~~ **A licensee shall ensure that** ~~if the~~ visitors are reasonably monitored, logged in as a visitor, and escorted through any limited access areas. Visitors that are not employees or individuals providing trade or professional services are prohibited where hazardous materials are used, handled, or stored in the marihuana business.

R 420.602a Prohibitions.

Rule 2a. (1) An employee of a cultivator may not also be employed by a marihuana transporter or a laboratory.

(2) An employee of a producer may not also be employed by a marihuana transporter or a laboratory.

(3) An employee of a marihuana sales location may not also be employed by a marihuana transporter or a laboratory.

(4) An employee of a marihuana transporter may not also be employed by a cultivator, producer, marihuana sales location, or laboratory.

(5) An employee of a laboratory may not also be employed by a cultivator, producer, marihuana sales location, or marihuana transporter.

(6) An employee of a marihuana microbusiness or a class A marihuana microbusiness may not also be employed by a laboratory or a marihuana transporter.

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September 27, 2021

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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:

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- 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.

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- 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.

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- 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,

DYKEMA GOSSETT PLLC

R. Lance Boldrey

cc: MCMA Board