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,

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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?
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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requirements	5	Rule states that partial applications to obtain prequalification status may be administratively withdrawn if application was filed and has been pending for more than 1 year. After a partial application has been withdrawn, the applicant may be required to submit a new application and pay a new nonrefundable application fee.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 420.112a	Licensing, management, or other agreements	13-14	For clarity, this rule 112a should indicate that the phrase "licensing, management, or other agreement" is as defined in R420.101(1)(m). It would appear that the purpose of this rule 112a is to identify agreements between a license holder and another person which are intended to convey the benefits of ownership on the non-license holder, when that non-license holder has not been vetted by MRA. If this is the actual purpose, the rule might be clearer if that were simply stated rather than covered by many words which seem to beat around the bush.
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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.
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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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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

September 9, 2021

Samantha K. Balk
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To the Marijuana Regulatory Agency:

The following documentation encompasses the comments of myself and some of my coworkers in the marijuana industry regarding necessary clarifications and/or suggestions about the ruleset. I have it broken down by each rule.

As the compliance manager at 42 Degrees Processing, LLC, a medical and adult use processing facility in Kalkaska, MI, my first priority is to protect our licenses by making sure that our facility is compliant with all requirements set forth by the MRA. Primarily, that goal is accomplished by a clearly defined set of rules to which can be adhered. What follows are observations based on the challenges I have faced as a compliance officer, as well as comments heard in the public. Any criticism and/or request is my own, but proposed as a means toward the end of clear rules that we can follow without further requirement for clarification. If any further clarification on my comments is required, I would be happy to take a phone call.

My greatest concern is with the areas of potential loopholes. I may also mention cost, though this is frequently due to the cost of operations, which I must also be mindful of.

Thank you very much for the time put into clarifying the ruleset and frequently providing guidance, most especially to me. And thanks to everyone at the MRA for providing and supporting this industry that I thoroughly enjoy, as it presents constant challenges that have given me a rewarding and important job here at 42 Degrees.

MARIHUANA DECLARATORY RULINGS

- Definitions
    - Define what is a “declaratory ruling”
    - When would this be used instead of requesting a clarification on the interpretation of a rule?

EMPLOYEES

- R 420.602 Rule 2 (1) “A licensee shall conduct a criminal history background check…”
    - Does this mean a state background check, federal background check, or both?
    - Do subsequent background checks need to be performed after an employee has been hired? At what interval?

SAMPLING AND TESTING

- Definitions:
    - The definition for a “production batch” needs to be clearer, especially considering edibles. If you would, please include this clear definition everywhere a rule discusses production batches.
        - What defines similar conditions? Same operator, same pot, same tools, same formulation, etc. all should be considered.
        - Is there a batch size limit?
        - The current methodology across the industry as I understand it, from talking to testing laboratories, is that there are multiple pots of gummies being formulated in a linear fashion. First pot, then second pot, then third pot, etc, up until an indefinite number of pots, ie, 30-40 pots, defining a single production batch. However, from the standpoint of recipe and formulation, each pot could vary by a variety of small factors. One pot may get more color than another. One pot may get more THC distillate. Even if it is a small amount, it’s still not exactly the same. Although homogeneity testing is intended to account for this variation, it is only performed every 6 months after initial formulation and will not be able to capture if one pot of 30, 60, 100 (what even is the limit?) is out of sorts. Essentially, this is the same as considering 30-40 (or more) tiny single batches of gummies as one uniform batch. This presents potential safety concerns regarding dosing.
    - The definition for a “production batch” needs to be more clearly defined for concentrates as well. If you would, please include this clear definition everywhere a rule discusses production batches.
        - If two different production runs of extracted concentrate are mixed together, is that acceptable? It seems that it would be unlikely to mix two batches of concentrate together into a homogeneous mixture, which could yield a product of an inconsistent potency. For example, if you produce a concentrate that is 60% potency and mix it with a concentrate that is 80% potency, then the resulting product could be inconsistently mixed with a potency that varies between 60-80%. This would be a more pronounced inconsistency if two different product consistencies were mixed, such as a “sugar” and a “sauce” together.
            - If this is acceptable, are any parameters needed?

    - The definition for “final form” versus “in packaging” needs to be crystal clear.
        - In some bulletins and rules, final form further clarifies that it means “not necessarily in its packaging for sale,” but in the laboratory testing handbook entitled Sampling and Testing Technical Guidance for Marijuana Products, it very clearly states “A sample of marijuana edible product must be in final form for a laboratory to accept this material for compliance testing. *Laboratories are not permitted to sample product in bulk without packaging* [italics mine] for compliance testing. Units should be easily distinguishable.”
            - We ended up changing around our entire standard operating procedure to accommodate having to test gummies in their sale packaging, only to then be corrected by a customer, who had an email from the MRA, stating that it was acceptable to test gummies prior to packaging.
- R 420.306. Guidelines for retesting should be clearer. There were times in the past when the rule was not clear enough, as it stated that when a product failed a retest it *must be destroyed*. However, we found out after we destroyed it that remediation was allowed. The following clarifications are needed:
    - Which failed tests can be retested. Please state these specifically (ie, heavy metals, certain pesticides, etc).
    - How many times a retest can be performed. As written, it is currently allowable to retest as many times as needed until a passing result is achieved, which is an irresponsible practice.
    - If retesting is permitted at a different lab than the one that delivered the failing result, and how that should be submitted if so.
    - Is there a time limit on performing a retest, given that there’s now a 90 day deadline for destruction?
    - Which failed tests can be remediated. Please state these specifically (ie, heavy metals, certain pesticides, etc).
- R 420.305, 9(h): states that potency should be reported in milligrams. It should read milligrams per ____.
- R 420.307, Rule 7, 3: states that R&D testing is prohibited after compliance testing has been completed. This needs further clarification to cover the following:
    - Continued quality studies, such as how a product might degrade or change over time.

    - Reserving a subset of a finished product to perform additional small tests upon it not related to safety, such as terpene composition.
    - It sounds as if the intent of the rule is to not perform R&D testing on the same production batch number, which historically created a problem in METRC by reverting Test Passed product into a Testing in Progress state. But if you pull an amount of and give it its own production batch number so as not to affect test results, would it be acceptable to perform R&D testing on this product?
- Requiring safety compliance tests on small batches of new formulations makes formulating new products prohibitively expensive as the recipe or methodology might be tweaked several times prior to being finalized. We would be grateful if alternative rulings could be explored that allows for more creativity and flexibility as new products are developed.

MARIHUANA SALE OR TRANSFER

- Definitions:
    - Need more clarification on *types* of transfers.
        - Define what type of transfer should be used for which purposes. When to use them, which forms are required, where the forms are located, where to send requests, etc.
            - Specifically, we've had some trouble with untested WIP transfers, fresh frozen transfers, infusion transfers.
            - Some forms are simply not listed on the MRA's website, such as the inventory transfer request form. It would be very helpful if all of the forms were listed in one location. Please investigate, and make compliance easier to do.
- Ensure that METRC and AFS are cohesive for financial audits. The rules for processors make tracking monetary value back and forth unnecessarily cumbersome, as it has forced us to assign monetary value to something for which there was no cost (such as for toll processing, where we charge for services).
- 420.508 (Trade Samples), Rule 8, 4, and 420.509 (Internal Samples), Rule 9, 3: The rules need to clarify what needs to be recorded in METRC during sampling. It was clarified to me personally that I should be recording the ID and employee name for Internal sampling, and I have been recording the License and Vendor name for trade samples.
    - Is any other information required for tracking purposes?
    - It is possible that there needs to be a lot more definition regarding trade samples and employee samples in general. This rule has been the one I've been most aggressively questioned on as to what the MRA's language allows versus what the MRA's intent was when writing the rule.
    - Rules are possibly unclear as to whether or not the Processor license is allowed to internally sample flower to its employees.
    - The rules have an issue with loopholes regarding trade and internal samples, as follows:
        - There is a limit on both internal samples and trade samples. However, when asked, and also provided with intent, the MRA clarified that they do not regulate sale prices. It is therefore possible for a processor to sell product to a retailer for a penny, who can then sell it to the processor's own employees for a penny, and thus makes having a rule pertaining to limits pointless.

            - Which means it is also possible to do exactly the same thing for trade samples, and have either a representative of a retailer or a sales representative to purchase products for a penny and offer them for free to anyone.
            - The same could be said of coupons or rebates, or steep discounts of any kind. If there is the ability to legally obtain products for virtually nothing, then why bother with a limit at all?
            - Nothing currently prevents employees from giving all of their samples to someone else outside of work hours, either, which means that it is also possible for employees to band together and pool their samples for a single person, such as sales personnel.
    - I also have concerns about the custody of products after trade sampling, as follows:
        - It is currently stated that up to a certain limit, anyone may transport trade samples to a retailer. I do not think it is wise to allow anyone other than a secure transporter to transport products. There are a lot of strong relationships between retailer management and sales personnel, and I think it may be possible to abuse the trade sample mechanism to funnel products out of the regulated market in this manner. There is currently no control over ensuring that the trade sample actually makes it to the intended recipient in this manner. What is to stop a sales person from requesting samples for a retailer and simply never delivering them?
        - We've heard that frequently, trade samples go only to retailer management and never make it into the hands of budtenders for the purpose of product sampling. I'm not sure that this would be considered an MRA problem, but wanted to bring it to your attention anyway, as trade samples handled in this matter do not bring much value to the processor value stream.
    - Please clarify how a sample intended for an employee should be treated if the employee refuses the sample.
        - Should it be destroyed? Does it now need two adjustments (one to put it back on its tag, and one to destroy it), or can it just go to destruction, since it has already been removed from METRC?

- R 420.504 (Labeling and packaging requirements): Compliance stickers have been unclear for more than a year now. Clarification was promised but never came. Our customers have been told different things by the MRA which has now forced us to operate under two different SOPs. Please make this clearer as to which tags are required on the compliance label.
    - Define that Package ID means the tag that is delivered to a retailer.
        - We maintain that this should not actually be required. A store that receives the package will have the Source tag ID in their METRC should an issue with the customer's product arise, which makes it easy to search. It is the source that would be the issue anyway if an adverse reaction was reported. Being allowed to label all of our products with only the Package's Source ID and Testing ID would significantly improve operational efficiency and greatly reduce the amount of potential for error. If one batch were to be sent to 100 stores, this is the difference between being forced to create 100 different compliance labels instead of only one.
    - Define that Source ID is the parent tag of the Package ID regardless of testing status.
    - Whether or not a Testing ID is required.
        - Define that Testing ID is the tag that was delivered to the testing facility for the purpose of Safety Compliance Test only.
    - Clarify how to treat a retest for potency when stating potency and testing facility information on the compliance label
    - Remove "any" test analysis date, replace with "safety compliance" test analysis date.
    - Release an example scenario or scenarios with an example label to eliminate all potential confusion.
    - Clarify that the universal symbol must be printed in full color (green).
    - Specify whether or not it is acceptable to say either marijuana or marihuana on the universal symbol.
        - Basically, whether or not ANY modifications to the universal symbol are acceptable whatsoever.
    - Specify that the words must be legible/easily read on the compliance label and universal symbol. Is a size requirement needed? Some of them are so tiny they cannot be read.
- R 420.505 Rule 5. (1) Transferring needs two Rs.

OPERATIONS

- R 420.206, Rule 6, 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 creation of the new combined product.
    - What defines a “form” of marihuana product?
    - What if products are combined prior to a safety compliance test? Examples:
        - Mixing a distillate with a high terpene content product, which will fill cartridges and go to safety compliance testing as a cartridge.
        - Mixing together two concentrates, ie batter plus batter.
- R 420.214a (Internal analytical testing):
    - For the internal analytical testing area, what defines a “separate” testing area?
- R 420.214b-c:
    - How does a retailer return defective/undesirable products that are *not* involved in an adverse reaction to a processor if they are not allowed to transfer it back?
        - For example, poor product quality, or if it has been on the shelf too long and they wish to trade it in.

LICENSES

- Definitions:
    - Please include more clarity on separate areas.
        - Food and marijuana areas are supposed to be kept separate.
            - Separation includes walls and a ceiling and a locked door.
            - Define the purpose of hallways, clarify the difference between a hallway and a room.
                - No food or marijuana in hallways?
                - Storage in hallways
                - Carrying marijuana through the hallways to get to the next room
                - Carrying food through the hallways to get to the next room.
    - It was clarified to me that areas of different task types are also supposed to be maintained separately with a locked door between them, such as:
        - Laboratory rooms can be connected, but not to packaging or storage
        - Packaging rooms can be connected, but not to any production or storage
        - Storage has to be kept separate from packaging and production.
        - These are not terribly specific. Items will be stored temporarily in production areas. Does an edibles kitchen need to be separated from its own packaging operation? Where are the lines defined?
        - Is this really necessary?
        - Why is further security needed within the building when entry to the building itself is controlled by secure entry?
    - Provide more specificity regarding the storage of inventory. Access should be restricted, but if it is behind a locked door and all the staff has access to the locked door, is it really restricted? So whom should have access?

LICENSEES

No questions

MARIHUANA-INFUSED PRODUCTS AND EDIBLE MARIHUANA PRODUCTS

- R 420.403, rule 3, 2: The potency variance has been changed to +/- 10%, not 15%. If this is not the case, there are multiple points throughout the rule set and bulletins where this variance is not in agreement.
- 420.403, Rule 3, 10(a): There is currently no control expressed in the guidelines for an expiration date. It's too arbitrary and does not require a product to demonstrate quality up until its expiration date. Documentation is required for shelf stability, but not for an expiration date qualification. This seems like an oversight.
- 420.403, Rule 3, 9(e): Clarification is needed on what is considered a "commercially available food product". This could feasibly eliminate most forms that an edible product might take, such as:
    - Other types of candies:
        - Chocolates
        - Fudge
        - Peanut butter cups
    - Granola bars
    - Rice krispies treats
    - Brownies
    - Cookies
- 420.403, Rule 3, 9(f): Packaging specifications could use more clarity as well. "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."
    - We've ruled out animals and fruit already. But there are other ways to appeal to children or teenagers. What about such things as:
        - Vehicles such as sailboats, cars, trains, bicycles
        - Color schemes, such as pastels, tie-dyes, bright colors, glitter
        - Other icons, such as moon and stars, clouds, rainbows, flowers, gem stones.

MARIHUANA HEARINGS

No questions

MARIHUANA DISCIPLINARY PROCEEDINGS

- R 420.805, rule 5, 10-11: The list of excluded individuals is kept by the MRA and we do not currently have access to it. How are we going to be able to know that an individual has been excluded from employment or participation in a marihuana business? Would that come up in the background check?
    - Also, we'd like to be able to see this list to protect ourselves and the integrity of the industry.

OTHER QUESTIONS

- With the limitations on names, shapes, and packaging that appeal to children, will there be further restrictions on the names of strains for concentrates and/or vapes?

In conclusion,

Thank you very much for your time and consideration in hearing comments from the public. I fully support clear rules, and greatly appreciate the time and effort that goes into refining this rule set.

Sincerely,

Samantha K. Balk
Compliance Manager
42 Degrees Processing, LLC
Phone: 918-779-8192
samantha@42-deg.com

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

MARIJUANA REGULATORY AGENCY

MARIHUANA SALE OR TRANSFER

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 mari~~h~~**j**uana 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 420.501, R 420.502, R 420.503, R 420.504, R 420.505, R 420.506, R 420.507, R 420.508, R 420.509, and R 420.510 of the Michigan Administrative Code are amended, and R 420.503a is added, as follows:

R 420.501 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) "Administrative hold" means a status given to marihuana product by the agency during an investigation into alleged violations of the acts and these rules. This status includes no sale or transfer of the marihuana product until the hold is lifted.

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

~~(d) "Batch" means all marihuana product of the same variety that has been processed together and exposed to substantially similar conditions throughout processing.~~

(~~e~~**d**) "Cultivator" means a grower under the medical marihuana facilities licensing act or a marihuana grower under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct, or both.

(~~f~~**e**) "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.

(~~g~~**f**) "Employee" means 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 business.

(g) "Final form" means 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.

(h)"Immature plant" means a nonflowering marihuana plant that is no taller than 8 inches from the growing or cultivating medium and no wider than 8 inches produced from a cutting, clipping,

tissue culture, or seedling that is in a growing or cultivating medium or in a growing or cultivating container.

(i) "Internal product sample" means a sample of **marijuana** products ~~possessed by~~ **that** a cultivator, producer, or marihuana sales location ~~that is provided~~ **transfers** directly to an employee for the purpose of ensuring product quality and making determinations about whether to sell **or transfer** the marihuana product.

(j) "Laboratory" refers to a safety compliance facility under the medical marihuana facilities licensing act or a marihuana safety compliance facility under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct, or both.

(k) "Marihuana business" refers to 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.

(l) "Marihuana customer" refers to a registered qualifying patient or 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 both.

(m) "Marihuana equivalent" means usable marihuana equivalent as that term is defined in section 3(o) of the Michigan ~~m~~**M**edical ~~m~~**M**arihuana ~~a~~**A**ct, MCL 333.26424**3**.

(n) "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, 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 act.

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

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

(~~p~~**pq**) "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.

(~~q~~**r**) "Marihuana sales location" refers to 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.

(~~r~~**s**) "Marihuana tracking act" means the marihuana tracking act, 2016 PA 282, MCL 333.27901 to 333.27904.

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

(~~t~~**u**) "Michigan ~~m~~**M**edical ~~m~~**M**arihuana ~~a~~**A**ct" means the Michigan Medical Marihuana Act, 2008 IL 1, MCL 333.26421 to 333.26430.

(~~u~~**v**) "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.

(~~v~~**w**) "Package tag" means an RFID tag supplied through the statewide monitoring system for the purpose of identifying a package containing a marihuana product.

(~~w~~**x**) "Plant" means that term as defined in section 102 of the MMFLA, MCL 333.27102, unless otherwise defined in these rules.

(~~x~~**y**) "Producer" means a processor under the medical marihuana facilities licensing act or a marihuana processor under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct, or both.

(~~y~~**z**) "These rules" means the administrative rules promulgated by the 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.

(~~z~~**aa**) "Tag" or "RFID tag" means the unique identification number or Radio Frequency Identification (RFID) issued to a licensee by the ~~agency~~ **statewide monitoring system** for tracking, identifying, and verifying marihuana plants, marihuana products, and packages of marihuana products in the statewide monitoring system.

(~~aa~~**bb**) "Trade sample" means a sample of marihuana products ~~provided to licensees by~~ **that** a cultivator or producer **provides to licensees** for the purpose of **the licensee** determining whether to purchase the marihuana product.

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

R 420.502 Tracking identification; labeling requirements; general.

Rule 2. (1) ~~All~~ **Each** marihuana product~~s~~ sold or transferred ~~between marihuana businesses~~ must **be clearly labeled with** ~~have~~ the tracking identification numbers ~~that are~~ assigned by the statewide monitoring system affixed, tagged, or labeled and recorded, and any other information required by the agency, the acts, and these rules.

(2) ~~To ensure access to safe sources of marihuana products, the agency, if alerted in the statewide monitoring system,~~ **The agency** may place an administrative hold on marihuana products, recall marihuana products, issue safety warnings, and require a marihuana business to provide **material** information ~~material~~ or notifications to a marihuana customer at the point of sale.

(3) A marihuana business shall not sell or transfer **a** marihuana product that has been placed on administrative hold, recalled, or ordered **or otherwise required** to be destroyed.

(~~4~~4) A marihuana business shall not sell or a transfer marihuana product after the printed expiration date on the package. An expired marihuana product must be destroyed.

(~~4~~**5**) **Prior to selling or transferring a marihuana product, a** ~~A~~ marihuana business must verify in the statewide monitoring system~~, prior to any sale or transfer~~, that the marihuana product has not been placed on an administrative hold, recalled, or ordered to be destroyed.

(6) 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.

R 420.503 Marihuana plant; tracking requirements**.**

Rule 3. Before a marihuana plant is sold or transferred, a package tag must be affixed to the plant or plant container and enclosed ~~with~~ **in** a tamper proof seal that includes all of the following information:

(a) Business or trade name, licensee number, and the RFID package tag assigned by the statewide monitoring system that is visible.

(b) Name of the strain.
(c) Date of harvest~~, if applicable~~.
(d) Seed strain~~, if applicable~~.
(e) Universal symbol~~, if applicable~~.

R 420.503a Sale or transfer of immature plant batches from a cultivator to a marihuana sales location.

Rule 3a. (1) A cultivator approved by the agency to sell or transfer immature plant batches to a marihuana sales location is not required to transfer the immature plant batches using a marihuana transporter.

(2) Immature plant batches transferred from a cultivator to a marihuana sales location are not required to undergo the testing required by R 420.304 and R 420.305.

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

Rule 4. (1) Before a marihuana product is sold or transferred to or by a marihuana sales location, the container, bag, or product holding the marihuana product must be sealed and labeled with all of the following information:

(a) The name and the state license number of the producer, including business or trade name, and tag and source number as assigned by the statewide monitoring system.

(b)The name and the marihuana license number of the licensee that packaged the product, including business or trade name, if different from the producer of the marihuana product.

(c) The unique identification number for the package or the harvest, if applicable.

(d) Date of harvest, if applicable.

(e) Name of strain, if applicable.

(f) Net weight in ~~United States customary and~~ metric units.

(g) Concentration of Tetrahydrocannabinol (THC) and cannabidiol (CBD) as reported by the laboratory after potency testing along with a statement that the actual value m**a**y vary from the reported value by 10%.

(h) Activation time expressed in words or through a pictogram.

(i) Name of the laboratory that performed ~~any~~ **passing compliance** ~~test~~ **testing on the product in final form** and any test analysis date.

(j) The universal symbol for marihuana product published on the agency's website.

(k) A warning that~~ states~~ **includes** all the following **statements**:

(i) "It is illegal to drive a motor vehicle while under the influence of marihuana."

(ii) "National Poison Control Center 1-800-222-1222."

(iii) For products being sold by a ~~licensee under the medical marihuana facilities licensing act~~ **marihuana facility** that exceed the maximum THC levels allowed for products sold under MRTMA, "For use by registered qualifying patients only. Keep out of reach of children."

(iv) For all other products**,** ~~being sold by a licensee~~ "For use by individuals 21 years of age or older or registered qualifying patients only. Keep out of reach of children."

(v) 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."

(2) An edible marihuana product sold by a marihuana sales location ~~shall~~ **must** comply with R 420.403(7) **to (10)**.

(3) An infused marihuana product sold by a marihuana sales location must comply with R 420.403(7).

~~(~~**(4) 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.**

R 420.505 Sale or transfer; marihuana sales location.

Rule 5. (1) A marihuana sales location **shall verify all of the following prior to** ~~may~~ sell**ing** or transfer**ing** marihuana or a marihuana product to a marihuana customer ~~if all of the following are met:~~

(a) The marihuana product has not been placed on administrative hold, recalled, or ordered **or otherwise required** to be destroyed.

(b) The marihuana product is not past its expiration date.

(~~b~~**c**) The ~~licensee confirms that the~~ marihuana customer presented his or her valid driver's license or government-issued identification card that bears a photographic image of the qualifying patient or primary caregiver, under the ~~medical marihuana facilities licensing act~~**MMFLA**; or bears a photographic image and proof that the individual is 21 years of age or older, under the ~~Michigan regulation and taxation of marihuana act~~**MRTMA**.

(~~c~~**d**) The ~~licensee determines the~~ completed transfer or sale will not exceed the purchasing limit prescribed in R 420.506.

(~~d~~**e**) ~~Any~~ **The** marihuana product ~~that is sold or transferred under this rule~~ has been tested in accordance with R 420.305**.**

(f) The marihuana product ~~and~~ is labeled and packaged for sale or transfer in accordance with R 420.504.

(~~e~~**g**) ~~A licensee selling marihuana product pursuant to the medical marihuana facilities licensing act verifies with the statewide monitoring system that the~~ **The** registered qualifying patient or registered primary caregiver holds a valid, current, unexpired, and unrevoked registry identification card.

(2) A marihuana sales location shall enter all transactions, current inventory, and other information required by these rules in the statewide monitoring system ~~in compliance with the acts and these rules~~. The marihuana sales location shall maintain appropriate records of all sales or transfers under the acts and these rules and make them available to the agency upon request.

(3) A provisioning center licensed under the ~~medical marihuana facilities licensing act~~ **MMFLA shall verify all of the following prior to** ~~may~~ sell**ing** or transfer**ing** a marihuana product to a visiting qualifying patient ~~if all of the following are met~~:

(a) The ~~licensee verifies that the~~ visiting qualifying patient has a valid unexpired medical marihuana registry card, or its equivalent issued in another state, district, territory, commonwealth, or insular possession of the United States that allows the medical use of marihuana.

(b) The ~~licensee confirms that the~~ visiting qualifying patient presented his or her valid driver license or government-issued identification card that bears a photographic image of the visiting qualifying patient.

(c) The ~~licensee determines, if completed, that any~~ transfer or sale**, if completed,** will not exceed the purchasing limit prescribed in R 420.506.

(d) ~~Any~~ **The** marihuana product that is sold or transferred under this rule has been tested in accordance with R 420.305.

(e) The marihuana product is labeled and packaged for sale or transfer in accordance with R 420.504.

(~~e~~**f**) As used in this subrule, "visiting qualifying patient" means that term as defined in section 3 of the Michigan ~~m~~**M**edical ~~m~~**M**arihuana ~~a~~**A**ct, MCL 333.26423.

(4) A marihuana retailer**,** ~~or~~ **marihuana** microbusiness**, or class A marihuana microbusiness** licensed under the ~~Michigan regulation and taxation of marihuana ac~~t **MRTMA** is not required to retain information from customers other than the following:

(a) Payment method.

(b) Amount of payment.

(c) Time of sale.

(d) Product quantity.

(e) Other product descriptors.

R 420.506 Purchasing limits; transactions; marihuana sales location**.**

Rule 6. (1) Before the sale or transfer of marihuana product to a registered qualifying patient or registered primary caregiver, under the ~~medical marihuana facilities licensing act~~**MMFLA**, the licensee shall verify in the statewide monitoring system that the sale or transfer does not exceed either of the daily purchasing limits as follows:

(a) For a registered qualifying patient, an amount of marihuana product that does not, in total, exceed 2.5 ounces of marihuana or marihuana equivalent per day.

(b) For a registered primary caregiver, an amount of marihuana product that does not, in total, exceed 2.5 ounces of marihuana or marihuana equivalent per day for each registered qualifying patient with whom he or she is connected through the agency's registration process.

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

(3) A marihuana retailer, under the ~~Michigan regulation and taxation of marihuana act~~**MRTMA**, is prohibited from making a sale or transferring marihuana to an adult 21 years of age or older in a single transaction that exceeds 2.5 ounces**.**~~, except that n~~**N**ot more than 15 grams of marihuana may be in the form of marihuana concentrate.

(4) A marihuana sales location may sell no more than 3 immature plants to a marihuana customer per transaction.

R 420.507 Marketing and advertising restrictions.

Rule 7. (1) A marihuana product may only be advertised or marketed in ~~a way that complies~~ **compliance** with all **applicable** municipal ordinances, state law, and these rules that regulate signs and advertising.

(2) **A licensee may not advertise a marihuana** ~~Marihuana~~ product ~~must not be advertised~~ in a way that is deceptive, false, or misleading**, or**~~. A person shall not~~ make any deceptive, false, or misleading assertions or statements on any marihuana product, sign, or document provided.

(3) Marihuana product marketing, advertising, packaging, and labeling must not contain any claim related to health or health benefits, unless a qualified health claim has received and complies with a Letter of Enforcement Discretion issued by the United States Food and Drug Administration (FDA), or the health claim has been approved under the significant scientific agreement standard by the FDA.

(4) **A marihuana** product must not be advertised or marketed to members of the public unless the person advertising the product has reliable evidence that no more than 30**%** ~~percent~~ of the audience or readership for the television program, radio program, internet website, or print publication, is reasonably expected to be under the age listed in subrules (7) and (8) of this rule. Any marihuana product advertised or marketed ~~under this rule~~ must include the warnings listed in R 420.504(1)(k).

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

(6) A marihuana product **marketed or advertised** under the ~~medical marihuana facilities licensing act~~ **MMFLA** must be marketed or advertised as "medical marihuana" for use only by registered qualifying patients or registered primary caregivers~~.~~

(7) A marihuana product **marketed or advertised** under the ~~medical marihuana facilities licensing act~~ **MMFLA** must not be marketed or advertised to minors aged 17 years or younger. Sponsorships targeting individuals aged 17 years or younger are prohibited.

(8) A marihuana product **marketed or advertised** under the ~~Michigan regulation and taxation of marihuana act~~ **MRTMA** must be marketed or advertised as "marihuana" for use only by individuals 21 years of age or older.

(9) A marihuana product **marketed or advertised** under the ~~Michigan regulation and taxation of marihuana act~~ **MRTMA** must not be marketed or advertised to individuals under 21 years of age. Sponsorships targeting individuals under 21 years of age are prohibited.

R 420.508 Trade samples.

Rule 8. (1) The following licensees may provide trade samples:

(a) A cultivator may ~~provide~~ **transfer trade** samples of marihuana products to a producer or a marihuana sales location.

(b) A producer may ~~provide~~ **transfer trade** samples of marihuana products to a producer or marihuana sales location.

(2) The transfer of trade samples does not require the use of a secure transporter under the MMFLA or a marihuana secure transporter under the MRTMA if the amount of trade samples does not exceed **either of the following**:

(a) 15 ounces of marihuana.

(b) 60 grams of marihuana concentrate.

(3) Trade samples must not be sold **or transferred by the receiving producer or marihuana sales location** to ~~another licensee~~ **another producer or marihuana sales location** or **to a** consumer.

(4) Any **trade** sample ~~provided~~ **transferred** to ~~another licensee~~ **a producer or marihuana sales location** or received by a ~~licensee~~ **producer or a marihuana sales location** must be recorded in the statewide monitoring system.

(5) Any trade samples ~~provided~~ **transferred** under this rule must be tested in accordance with these rules prior to being transferred to ~~another licensee~~ **a producer or marihuana sales location**.

(6) A ~~licensee~~ **cultivator and producer** ~~is~~ **are** limited to ~~providing~~ **transferring** the following aggregate amounts of trade samples to ~~another licensee~~ **a producer or a marihuana sales location** in a 30-day period:

(a) 2.5 ounces of marihuana.

(b) 15 grams of marihuana concentrate.

(7) ~~Any~~ **In addition to the information required in R 420.403, a trade** sample ~~given to a licensee~~ must have a label containing the ~~following in a legible font:~~

~~(a) A~~ statement ~~that reads~~: "TRADE SAMPLE NOT FOR RESALE" in bold, capital letters attached to the trade sample.

~~(b) All other information required in R 420.403.~~

(8) A ~~licensee~~ **producer or marihuana sales location that** ~~who~~ receives a trade sample may distribute the trade sample to its employees to determine whether to purchase the marihuana product**. 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.**

R 420.509 Internal product samples.

Rule 9. (1) A cultivator, producer, marihuana sales location, ~~or~~ marihuana microbusiness**, or class A marihuana microbusiness** may ~~provide~~ **transfer** internal product samples directly to its employees for the purpose of ensuring product quality and making determinations about whether to sell the marihuana product.

(2) Internal product samples may not be transferred or sold to another licensee or consumer.

(3) **A licensee shall record the transfer of an** ~~Any~~ internal product sample ~~provided under this rule must be recorded~~ in the statewide monitoring system.

(4) A cultivator is limited to ~~providing~~ **transferring** a total of 1 ounce of internal product samples to each of ~~their~~ **its** employees in a 30-day period.

(5) A producer is limited to ~~providing~~ **transferring** 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 ~~their~~**its** employees in a 30-day period.

(6) 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.

(7) A licensee shall have internal product samples tested pursuant to R 420.304 and R 420.305 before transfer to its employees.

R 420.510 Product development.

Rule 10. (1) A cultivator or producer may engage in product development. No other marihuana business may engage in product development.

(2) A cultivator may designate marihuana plants for product development. Any marihuana plants designated for product development count ~~towards~~ **toward** the authorized total amount of marihuana plants for a cultivator and must be tracked in the statewide monitoring system.

(3) A producer may designate marihuana concentrate for product development. Any marihuana concentrates designated for product development must be tracked in the statewide monitoring system.

(4) A licensee engaged in product development may submit ~~their~~ **his or her** product development inventory to a laboratory for research and development testing in accordance with these rules.

(5) Disciplinary action ~~shall~~ **may** not be taken against a licensee for failed research and development test results on ~~their~~ **his or her** product development inventory.

(6) A ~~licensee authorized under this rule to engage in product development~~ **cultivator or producer** may transfer its product development inventory to its employees for consumption. A licensee shall have product development inventory tested pursuant to R 420.30~~4~~**5** and R 420.30~~5~~**6** before transfer**ring it** to ~~its~~ **an** employee~~s. The licensee shall not transfer or sell product development inventory to a marihuana sales location until after test results in the statewide monitoring system indicate a passed test.~~ Any product development inventory that is not properly transferred to an employee must be destroyed pursuant to these rules. **All product development inventory transferred to an employee counts toward the limitations in R 420.509(4) and R 420.509(5), as applicable.**

(7) A licensee shall record the transfer of product development inventory in the statewide monitoring system.

(~~7~~**8**) ~~The inventory designated for p~~**P**roduct development **inventory** may not be consumed or used on the premises of the licensee.

(~~8~~**9**) A licensee shall not transfer or sell inventory designated for product development to a marihuana sales location, or to a marihuana customer, until after **the inventory is tested pursuant to R 420.304 and R 420.305, and the** test results in the statewide monitoring system indicate a passed **full compliance** test**ing**.

(10) Any product development inventory that is transferred to a marihuana sales location must be labeled in accordance with R 420.504.

(~~9~~**11**) A ~~licensee authorized under this rule to engage in product development~~ **cultivator or producer** may also engage in a research study with a**n** ~~college, university, or hospital approved by the United States Food and Drug Administration and sponsored by a non-profit organization or researcher within an academic institution researching~~ **entity duly authorized by the Drug Enforcement Administration to handle** marihuana. A licensee's participation in a research study must be approved by the agency.

(1~~0~~**2**) A licensee participating in an approved research study shall track all marihuana product involved in the research study in the statewide monitoring system.

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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:

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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.

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,

DYKEMA GOSSETT PLLC

R. Lance Boldrey

cc: MCMA Board

TERRAPIN

5370 Manhattan Cir Suite 104 |
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To: Andrew Brisbo, Executive Director Marijuana Regulatory Agency
From: Nico Pento, VP External Affairs Terrapin
Date: September 27, 2021
Subject: Proposed Cannabis Rule Comments

Director Brisbo,

We respectfully submit this public comment on the MRA's current proposed cannabis rules. We ask that you take these comments into consideration prior to final approval.

R 420.808a. Rule 8a. Exclusion
This section needs further explanation. It is unclear to us whether or not the licensee is required to determine employees that should be excluded during the background check or upon discovery that the employee meets criteria for exclusion, or if only the agency has the authority to determine exclusion. If businesses could be penalized for not excluding an employee who meets the criteria defined within the rules, further clarification is necessary to ensure compliance.

R 420.602. Rule 2. Employees; requirements
We agree with including a responsible operations plan in the employee training manual, but much of the information required in this section does not apply to cultivation or processing labs. We request that the rules are clarified to apply only to marijuana sales locations.

R 420.602a. Rule 2a. Prohibitions
We agree that employees of a cultivator, producer or sales location should not be an employee of a testing laboratory. We also agree that owners of processing labs, cultivation facilities or sales locations should not own a testing lab or possess a transporter license. However, we believe it would be beneficial to permit transporter employees to also be employees of a producer, cultivation facility or sales location. At present, certain licensees use contract security that also own a marihuana transporter license. As the rules are currently written, these employees would be non-compliant. To ensure that licensees can still use such contract security without being sentenced to noncompliance, we recommend striking the following:

(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, or 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~~.

R 420.502 Rule 2. Tracking identification; labeling requirements; general
Subrule 4 of this section requires marihuana businesses to destroy expired marihuana products. However, R 420.214c (Product returns) states that "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." To maintain consistency, we suggest referencing this rule in R 420.502 (2)(4).

(4) A marihuana business shall not sell or a transfer marihuana product after the printed expiration date on the package. An expired marihuana product must be destroyed, either by the retailer or by being returned to the marihuana processor for destruction, consistent with the provisions in R420.502(2)(4).

R 420.403. Rule 3. Requirements and restrictions on marihuana-infused products before sale or transfer
To ensure compliance regarding the labeling of marihuana-infused products, we recommend that 7(a) and (b) of this section include specific definitions for "basic nature" and "component ingredients." Or at a minimum additional guidance as to what the department will interpret as "basic nature" and "component ingredients."

R 420.303. Rule 3 (4). Batch; identification and testing
Subrule 4 of this section is extremely concerning, particularly from an inventory and compliance perspective. Requiring the destruction of plant tags immediately after a tagged plant is harvested means that plants from harvest batches, which cannot get a package tag until passing testing, would be without a METRC tag while waiting for test results. If plants are unaccounted for any length of time, this can cause serious issues with inventory and create opportunities for diversion, potentially sentencing cultivators to noncompliance. We respectfully request that the MRA either remove the new proposed rules for R 420.303 (3)(4), or change the language to state that cultivators *may*, but are not required to destroy tags immediately after a tagged plant is harvested. Proposed language is below in red:

(4) After ~~**A cultivator shall immediately destroy the individual plant tag once**~~ a tagged plant is harvested, it ~~**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. A cultivator shall ~~**separate the harvest batch by product type and**~~ quarantine a harvest batch ~~**the harvested batch**~~ from all other plants or batches ~~**marihuana and marihuana products when the marihuana batch has**~~ that have test results pending. A harvest batch must be easily distinguishable from other harvest batches until the batch is broken down into packages. **A cultivator may not combine harvest batches.**

OR

(4) A cultivator ~~shall immediately~~ may, but is not required to, 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.

R 420.303. Rule 3 (6). Batch; identification and testing
Subrule 6 allows cultivators to transfer or sell fresh frozen marihuana to a producer without being tested by a lab, with agency approval. Since the MRA also allows trim to get transferred to a lab without testing, we recommend clarifying current language to state that *any harvest batches* may be transferred to a lab without testing, pending agency approval

(6) A cultivator may transfer or sell any harvest batches ~~**fresh frozen** marihuana~~ to a producer without first being tested by a laboratory in order to produce ~~fresh frozen~~ **live resin**, or if the marihuana product will be ~~refined to a concentrate~~ **extracted,** with agency approval.

R 420.306. Rule 6. Testing marihuana product after failed initial safety testing and remediation.
While we understand that safety testing and remediation for marihuana products is necessary to protect public health and safety, we believe that products that failed testing for Aspergillus, as indicated in subrule 3 of this section, should be eligible for remediation. Certain remediation processes, such as x-ray chamber decontamination and ozone-based decontamination, can effectively destroy contamination while maintaining marihuana's biologically active ingredient. Both of these decontamination processes use scientifically proven technology to destroy the full complement of microbial cells, including aspergillus. This results in a product that has been successfully remediated, can pass state testing and is safe for human consumption.

(3) ~~Products that failed testing for Aspergillus are ineligible for remediation.~~

R 420.306. Rule 6. Testing marihuana product after failed initial safety testing and remediation
While we understand the provisions under subrule 4 and 5, we would like more information on failed testing. Since the threshold for certain medical marihuana products is different from certain adult use marihuana products, we would like more details and clarity on what constitutes failed testing.

R 420.203. Rule 3. Marihuana licenses; licensees; operations, general
We understand the intention of this rule and agree that licensees should maintain accurate and comprehensive financial records. However, many licensees have stacked licenses and operate separate businesses at the same location and as such, their accounting documentation is by entity rather than individual license. Since it is possible for licensees to meet the requirements of this rule by providing documentation per entity, we suggest removing "each license" from the language of this rule.

> (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:

R 420.204. Rule 4. Operation at same location
While we understand and agree with the provisions outlined in R 420.204 and 420.212, we recommend that licensees with any combination of marihuana licenses who are operating separate businesses at the same location be permitted to share an on-site storage area for *all* products in final form. That some marihuana products in final form are flower based and some are concentrate based offers no inherent reason for displacement and separation of storage. Since storage areas must be equipped with security features, requiring separate storage areas not only creates undue burden for marihuana businesses from a financial and operations perspective, but it also creates a burden for businesses that may not have sufficient space for separate storage areas. Allowing all products in final form to share a storage area would address these issues. Our proposed language follows below:

4) Operation of marihuana licenses at the same location may include a combined space for the purposes of complying with R 420.214a.

a. A licensee that has any combination of marihuana licenses and is operating separate marihuana businesses at the same location may share an on-site storage area for all marihuana products in final form if the licenses have a stacked licenses, pursuant to Rule 4, 420.204 and share common ownership, as defined in Rule 1, 420.1f.

R 420.206. Rule 14
We agree with safety compliance testing of marihuana products, but it is unclear whether the test requirements in this section would apply to intermediary steps in the processing lab. We believe that requiring testing during intermediary steps is unnecessary and inefficient, as the results of these tests may not be consistent with the final form of the product. Requiring tests during intermediary steps is also time consuming and increases operating costs for the licensee, which ultimately trickles down to the patient or consumer. Since cannabis products are already required to be tested in their final form, which is closest to what the patient or consumer would receive for consumption, we recommend final form testing throughout the program.

> (14) When combining more than 1 form of marihuana or marihuana product into a single marihuana product, ~~each form of marihuana or marihuana product~~ only the final form of the product must have passing safety compliance test results in the statewide monitoring system prior to the ~~creation~~ sale or distribution of the new combined product.

R 420.212. Rule 12. Storage of marihuana product
Consistent with the above comments regarding R 420.204, we recommend that licensees with any combination of marihuana licenses who are operating separate businesses at the same location be permitted to share an on-site storage area for *all* products in final form.

1) All marihuana products must be stored at a marihuana business in a secured limited access area or restricted access area and must be identified and tracked consistently in the statewide monitoring system under these rules.

a) A licensee that has any combination of marihuana licenses and is operating separate marihuana businesses at the same location may share an on-site storage area for all marihuana products in final form, if storage is compliant with the provisions of R 420.212 and the following requirements are met:

i) Licensees have a stacked license pursuant to Rule 4, 420.204; and
ii) Licensees have common ownership, pursuant to Rule 1, 420.1f; and
iii) Local jurisdictions permit shared storage.

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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
Michigan Cannabis Industry Association
www.MICannabisIndustryAssociation.org

PLEASANTREES

April 9, 2021

Marijuana Regulatory Agency
Attn: Legal Department
MRA-legal@michigan.gov

RE: Proposed 2021 Rule Amendments

To Whom It May Concern:

RJB Enterprises LLC (d/b/a Pleasantrees Cannabis Company) understands that the rule sets made effective in June of 2020 (the "Dual Rules")[1] are presently under revision. We have been informed that the Marijuana Regulatory Agency ("MRA") is accepting comments from licensees concerning proposed improvements to the Dual Rules and by extension, the orderly function of the regulated industry as a whole.

To that end, Pleasantrees has surveyed staff at each level of its licensed operations and has ordered the resultant comments into a formalized list of suggested changes which are herein provided for the MRA's consideration. We appreciate the opportunity to contribute to this process and look forward to reviewing the MRA's initial draft of what are sure to be universally beneficial revisions to the Dual Rules. If we can answer any questions regarding our suggestions, please do not hesitate to reach out to me or Mr. Buchman directly.

Sincerely,

Randall J. Buchman
Chief Executive Officer
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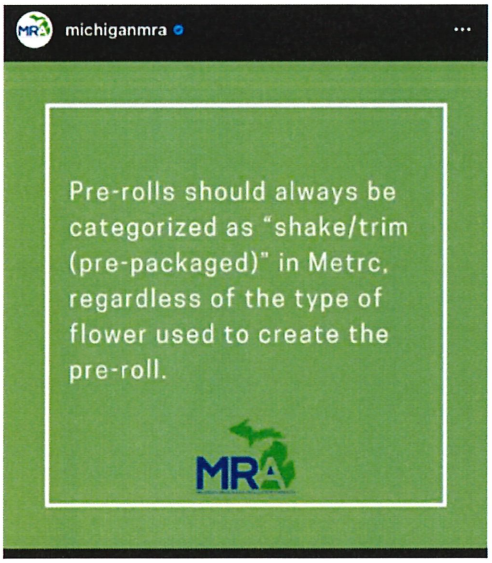
Specific Rule Amendments

[1] The Dual Rules collectively govern licensed cannabis activity under the Michigan Marihuana Facilities Licensing Act, MCL 333.27101, *et seq.*, and the Michigan Regulation and Taxation of Marihuana Act, MCL 333.27951, *et seq.*

- Allow Intra-Company & Third-Party Waste Transfers – Currently, R 420.211(2) requires that plant waste be "rendered into an unusable and unrecognizable form" on site before being disposed of via one of the means set forth in subsection (6) of the rule. For licensees with multiple locations, it would be preferable if inter-company transfers of waste, prior to being rendered unusable, were allowed so that a licensee can focus its resources on the waste destruction infrastructure at a single location, thereby improving efficiency and ecologically responsible disposal practices. For instance, under this approach, companies would be more likely to invest in anaerobic digesters and composters as opposed to relying upon third-party incinerators and landfills. Since subsection (4) requires that waste be recorded in the statewide monitoring system already, it would be easy to facilitate and track the movement of that waste through the use of a secured transporter.

- METRC Categorization of Pre-Rolls – Although not specifically addressed in the Dual Rules, we were recently informed by the MRA, referencing the social media post reproduced below, that all pre-rolls must be categorized as "shake/trim" in all instances.



Upon further inquiry, we were referred to the MRA's recent "Tips for Licensees – Common Issues" bulletin, which addresses testing requirements for various sub-species of pre-rolls but does *not* address the categorization issue in any way. The bulletin does, however, acknowledge that pre-rolls are typically made out of "bud, shake, or trim."

This characterization limitation problematic for licensees because pre-rolls made from ground buds fetch a higher price than those made from shake/trim. Thus, having Metrc tags note "shake/trim" when the product is sold as ground buds is a material inconsistency which can cause customer confusion and the appearance of an unfair trade practice. We raised this issue with the MRA and were told that we should consider naming our products in Metrc with the addition "from BUD" included. This would not necessarily alleviate the risk of consumer confusion, as the tag (which will be presumed "official" by consumers)

will still say "shake/trim." Notably, the Metrc characterization for "Prepackaged Buds" already exists, meaning no additional burden (which we can identify from our vantage) will be imposed upon the MRA or Metrc. For these reasons, we would ask that the MRA reconsider this position and allow licensees to categorize pre-rolls as either "shake/trim" or "prepackaged flower," as appropriate.

- Continuous Camera Recording – Under R. 420.209(9), facilities/establishments must utilize "cameras that record *when motion is detected* at the marihuana business . . . ." (Emphasis added). We suggest that this rule be amended to require that cameras continuously record footage, 24 hours a day, 7 days a week. Given the digital capabilities of sophisticated security equipment, this adjustment should not result in an unreasonable, additional burden being placed upon licensees. On the other hand, as the MRA works to continue combating illicit activity, including the shifting of licensed and unlicensed product within licensed facilities/establishments, we believe it is imperative that bad actors be denied the ability to assert that there is "no footage" so there "must not have been anyone there."

- Clarification of Package Tag Requirements – We have raised this issue with the MRA previously (including in an email sent on February 3, 2021) and are currently developing a formal presentation to more fully illuminate the concerns and confusion caused by the ambiguity of R 420.504(1). Framing the issue, prior Emergency Rule 39 required products sold at the retail level to feature the "tag *or* source number" on their label. R 420.504(1) changed the "*or*" to an "*and*," thereby requiring that both numbers be listed.

  The implications of this rule change are material and there is serious disagreement as between processors/cultivators on the one hand, and sales locations on the other, as to which numbers qualify as the "tag" and "source" in any given setting. This is because every cannabis product necessarily came from the prior parent tag before it (bulk distillate to production batch v. production batch to package transfer ID, etc.). Upstream producers argue that the current version of the rule does not require that the transfer ID number to an individual sales location be affixed to each individual unit sent, and that the sales locations can, and should, be retagging their inventory upon receipt, inspection, and stocking. Sales locations, predicably, argue the contrary as it shifts a great administrative burden onto the upstream wholesalers. This has become a point of commercial negotiation whereby those sales locations with buying power are able to force their interpretation upon wholesalers in spite of the fact that we have seen correspondence from the MRA which supports each position in a conflicting manner.

  For instance, in one case, a sales location was told that "both source id number and metrc Id/transfer number need to be located on the label that is adhere to the package." However, another processor was informed that labels listing the product's current production batch Metrc tag and the source tag of the concentrate used to produce that batch was also compliant. Stated otherwise, the operative question in light of the general production and transport chain is, which package and source tags must be on the labels when products are shipped to sales locations?

Sales locations' interpretation of R 420.504(1) requires each SKU of product in a given order have the Metrc transfer tag number specific to that delivery. That interpretation forces upstream wholesalers to create a special tag for, and to re-sticker, every single item sold to a specific sales location once an order is placed, resulting in many thousands of new stickers (and related workload) in a given week of business. This is counter intuitive as sales locations are responsible for processing their own inventory and, if a package tag specific to that sales location is what is intended by the "or" to "and" amendment of the rule, it is those facilities/establishments who should be required to do so while processing that inventory. That interpretation is harmonious with the provisions of R 420.303(9), which requires producers to "give [a] marijuana product a new package tag anytime the marijuana product changes form or is incorporated into something else," as well as R 420.303(11), which commands that a marihuana sales location only sell products to a consumer if those products "bear[] the label required for retail sale, under the acts and these rules."

The more arduous interpretation pressed by sales locations leaves upstream wholesalers with two options. As mentioned above, they can re-sticker each product when an order is placed and downstream package tag information becomes available, resulting in hundreds of thousands of units being stored in the licensed premises without any tag information affixed directly to the packaging, creating tracking and traceability concerns. This approach also creates a myriad of operational inefficiencies and requires an increased workforce which will drive up prices, lower speed to market and exacerbate Covid-related personnel issues for operators. By way of example, under this approach, in a given work week, Pleasantrees will have to handle and re-sticker 75,000-100,000 pieces of inventory prior to shipping. Moreover, with this approach, in the event of a large recall, the applicable production batch may have reached 200 sales locations requiring the publication of all 200+ transfer tags as a means to alert the public. Conversely, under the normal course of tracking the production code as the tag number, the publication of only a single number would be required.

Alternatively, the upstream wholesaler could create a production run, and immediately create child packages in various denominations such that the entire tag could theoretically be transferred to sales location when an order is placed. This solution creates two additional problems: (i) voluminous tracking and record keeping within Metrc and physical inventory, and (ii) producers who are trying to remain limber in this newly forming market will be limited to sales in minimum quantities and/or specific quantities and thereby lose flexibility in meeting customer demands and needs.

It is imperative that the MRA consider the implication of R 420.504(1) when amending the rules, clarify the rules language in such a way as to provide a fair and balanced allocation of operational burden as between sales locations and wholesalers, and ultimately provide well-reasoned and much-needed clarity to the industry on this important issue.

- Clarify Recordation of Trade Samples, Internal Samples & R&D Samples – Regarding R 420.508(4), there continues to be confusion and inconsistent advice regarding the appropriate way to "record[] [trade samples] in the statewide monitoring system." Packages can simply be adjusted down, or new packages and related manifests can be created. It may be that both options are acceptable, but providing some additional clarity in the rules, as well as R 20.509 concerning "Internal product samples" and R 420.510 concerning "Product development," would be ideal to ensure consistent practices and standards across the regulated industry.

- Adjust Internal Product Sample Limits – R 420.509(4-5) imposes limits on the amount of Internal Product Samples a licensee can distribute to a given employee in a given month. With regard to the limit on concentrate specifically, it would be ideal if it could be increased "4 grams" per month. That figure is not outside the bounds of general reasonableness and would allow companies greater latitude in providing new concentrate flavors to staff to evaluate flavor formulations.

Suggestions for Additional Rules/Policies

- Centralizing Trim & Enabling Third-Party Processing Services – Under R 420.303(5), before "marihuana product leave the cultivator . . . , a sample of the harvest batch must be tested by a licensed laboratory as provided in R 420.304 and R 420.305." There is an exception to this requirement, as set forth in subsection (6), which allows for the transfer of fresh frozen and thus, third-party toll processing in the industry. As the market condenses and overhead becomes more relevant, it would be ideal if a similar exception could be added to allow recently harvested plants to be transferred – before testing – to other facilities/establishments for drying, trimming and/or packaging. For Pleasantrees, we would seek to centralize all of our drying, trimming and packaging functions in a single facility/establishment, but this exception would also allow for intra-company tolling-curing/trimming/packaging arrangements which will increase efficiencies and ultimately, lower market prices. The MRA could impose a temporal window for these transfers post-harvest to avoid any enforcement concerns related to lost water weight (i.e. transfer must occur within 12 hours of harvest). Of course, testing will be required at the appropriate point in the process once the product was transferred to the curing/trimming/packaging location in the same manner employed in R 420.303(6).

- Mandating Packaged Product at Sales Locations – "Deli-Style" service at sales locations is problematic as it allows a multitude of opportunities for illicit activity relative to unlicensed product. For instance, we are aware that some stores purchase sub-par licensed flower and then switch in higher quality illicit flower under those bulk tags. The only way to establish that this has occurred would be to test the switched product and establish that those test results are meaningfully different from the COA associated with the initial wholesale transfer. For obvious budgetary and manpower reasons, that is not a feasible enforcement approach for the MRA. In concert with the above suggestion re: toll-curing/trimming/packaging, mandating that all product sold to sales locations must be packaged will greatly improve the MRA's enforcement capabilities, neutralize the

opportunity for unfair trade practices, and increase consumer sophistication and the value of the state's cannabis brands. Those facilities/establishments who are unable to package their product independently will be able to rely on a newly developed sub-industry of toll-curing/trimming/packaging firms which will ultimately perfect their processes in the same way processors have presently cornered the toll-processing market.

In addition, this "secret switch" is also common practice with the creation of pre-rolls at a sales location. Specifically, cheap licensed shake/trim is swapped out for caregiver buds and then incorporated into pre-rolls sold at a higher price as "bud-based." For this additional reason, allowing a distinction in Metrc between "shake/trim" and "prepackaged buds" pre-rolls (per the above) will allow the MRA to police this illicit activity. Specifically, any product characterized as "shake/trim" in Metrc but marketed as "bud" will be a key indicator of illicit behavior. In any case, and irrespective of the MRA's response to this suggestion on a universal packaged product limitation, the MRA should immediately prohibit sales locations from creating their own "raw pre-rolls" by amending the "Tips for Licensees – Common Issues" which addresses pre-roll creation and testing.

- Require Products Remediated Before or After Testing to be Labeled as Such – It is our understanding that product which fails testing and has been remediated is noted as such in Metrc, but nothing in the Dual Rules or the July 1, 2020 "Retesting & Remediation Guidance" bulletin requires that the product be labeled as such from a consumer-facing perspective. Moreover, it is common practice for cultivators to remediate product they know will fail testing "in-house" before it is sent to a lab, in which case there is no formal record of the remediation whatsoever. We believe that this should be changed as consumers deserve to know if their products have been blasted with radiation or otherwise remediated in a way that denigrates the quality of the product. Accordingly, we propose a rule amendment requiring cultivators to disclose pre-testing remediation to labs, and that in all cases, product which has been subject to remediation practices be noted as such when sold to sale locations and ultimately, consumers. Enforcing this obligation from a "pre-testing" perspective would not be difficult for the MRA as it could merely review camera footage on fast-forward during the harvest process and until the product leaves the building. Remediation machines are easily recognizable in that regard.