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
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Attached please find our comments on the proposed revised rules.

Thank you for your attention and assistance.

Respectfully yours,

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Rule Citation	Rule Title	Page Number	Comments
MARIHUANA LICENSES			
R 420.1(1)(o)	Definitions	3	Rule adds definition of "Limited access area" meaning a "building, room, or other contiguous area of a marihuana business where marihuana is grown, cultivated, stored, weighed, packaged, sold or processed for sale and that is under the control of the licensee." This definition will add greater clarity of limited access areas for licensees. However, what if the licensee has multiple licenses operating at the same location and has a limited access area under the licensee's control, but is not contiguous to the marijuana business?
R 420.1(1)(dd)	Definitions	4	Rule adds definition of a "Restricted access area" meaning a designated and secure area at a marihuana business where marihuana products are sold, possessed for sale, and displayed for sale. The definitions do not define "secure area." I assume this definition adheres to the security requirements in R 420.209, but I would like to see more specific language here, e.g., "secured by four walls and a locking door."
R 420.3(3)	Application procedure; requirements	5	Rule states that partial applications to obtain prequalification status may be administratively withdrawn if application was filed and has been pending for more than 1 year. After a partial application has been withdrawn, the applicant may be required to submit a new application and pay a new nonrefundable application fee. If an application has been partially completed and the application fee paid prior to withdrawal, it seems excessive to make the applicant pay another application fee when they resubmit.
R 420.3(4)	Application requirements; financial and criminal background	5	Rule states that "an applicant who has been granted prequalification status may have that status revoked by the agency and a marihuana license denied should the agency determine that the applicant is no longer suitable or no longer qualifies for licensure under the acts and these rules. An applicant who has had its prequalification status revoked may request a hearing pursuant to R 420.703." This rule concerns me. It gives the MRA complete discretion to revoke prequalification status if "the applicant is no longer suitable." That is a very vague definition.
R 420.5(1)(d)(vii)	Application requirements; complete application	8-9	Rule states that the applicant must submit confirmation of municipal compliance, specifically an attestation "that the applicant will report any changes that occur with municipal ordinances or zoning regulations that relate to the proposed marihuana facility . . . ." This is very broad—any changes that occur with related municipal ordinances? What if an amendment is made but it is not publicly posted? Also, many municipal ordinances covering many topics may apply to the marihuana facility. It seems excessive to expect a licensee to monitor their municipality to report any ordinances that *may* apply. The rule should be written more narrowly to only reference "marihuana licensing or zoning specific" ordinances only.
R 420.11a(5)	Prelicensure investigation; proposed marihuana establishment inspection	15-16	Rule requires applicant to submit certificate of occupancy to agency for prelicensure inspection. If this certificate is not available, "the agency may accept alterative documentation from the building authority." Some of our clients live in small townships without a building authority. I would like this definition to factor that scenario. For example, "from the building authority or **other designated municipal official**."

Rule Citation	Rule Title	Page Number	Comments
MARIJUANA LICENSEES			
R 420.105a(8)	Class A marihuana microbusiness license	7	Rule says "A Class A marihuana microbusiness may purchase or accept a mature plant from an individual, registered qualifying patient, or registered caregiver. What is the statutory authority for authorizing an individual, a registered qualifying patient, or a registered primary caregiver to sell mature marijuana plants to a Class A marijuana microbusiness?
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.
MARIHUANA OPERATIONS			
R 420.206a	Standing Operating Procedures	11	Rule adds requirement for licensees to have up-to-date written standard operating procedures on site at all times. Why is this required in addition to a facility or establishment plan?
R 420.207a(4)	Contactless and limited contact transactions	15-16	Rule allows licensees to designate area for contactless delivery. Section (4) requires separate standard operating procedure in addition to R 420.206a. Why can't the standard operating procedures referenced in R 420.206a cover the contactless delivery? Why does it need to be a separate document?
R 420.214b	Adverse reactions	24	Rule requires licensees to notify the MRA within 1 business day "of when licensee should have been aware of any adverse reactions to a marihuana product sold or transferred by any licensee." First, the rule does not specify how the licensee should notify the MRA. Will the MRA provide notification forms? Is an email to enforcement sufficient? Second, the "should have been aware" language concerns me. If a licensee sells a product to a customer and the customer has a bad reaction after consuming the product 3 weeks later, how would the licensee even be aware of that reaction?
MARIJUANA SALE OR TRANSFER			
R 420.303(6)	Batch; identification and testing	4	Rule allows a cultivator to sell/transfer marihuana products without being tested by a lab to produce live resin, with agency approval but limits the sales/transfer to a producer under this rule if the package contains more than 1 harvest batch. The next line reads "This does not prohibit a cultivator from transferring multiple harvest batches for extraction." This reads as internally conflicting and does not make sense, that a cultivator cannot use the testing exemption under the rule if they sell/transfer a package with more than one batch, but still can sell/transfer multiple batches.

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

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

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September 21, 2021
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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

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

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

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

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

2020-117 LR:

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

420.803 Rule 3 sub 3

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

420.805 Rule 5 sub 2

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

Rule 5 sub 10 and 11

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

R420.806 Rule 6 sub f

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

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

R420.808a

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

R2020-118 LR

Rule 420.704 sub a

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

2020-119 LR:
R420.401 Rule 1d

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

Rule 1 o

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

R420.403 Rule 7 sub a

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

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

Same, Rule 10 sub a

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

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

2020-120 LR:

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

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

420.103 Rule 3 sub 3
also
420.104 Rule 4 sub 4

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

R420.105a

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

R420.107 sub c

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

Rule 420.112a

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

2020-121 LR

R420.4 Rule 4 sub 3

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

R420.5 Rule 1 sub e

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

R420.25 sub 6

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

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

R420.27a

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

2020-122 LR

R420.206 sub 13 and 14

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Rick Thompson
CANNABIS MEDIA SPECIALIST
phone: 586 350-8943
Publisher, *Michigan Cannabis Industries Report* mcirmagazine.com
Owner, Michigan Cannabis Business Development Group micbd.com
Editor, TheSocialRevolution.org
Named **Citizen Activist of the Year 2015** by national media source
Crystal Trichome Award winner- **Journalist of the Year** 2016
Radio: Jazz Cabbage Cafe, The Planet Green Trees Radio Show, *more*
Activism: MiNORML and MiLegalize, Board member of both
Print: *High Times*, *Hybrid:Life Magazine*, *Culture Magazine*, *more*
Internet: Editor, The Social Revolution; contributor, The Weed News, *more*
4mrick@gmail.com

GAGE

To: **Michigan Marijuana Regulatory Agency - Legal Section**
VIA Email: Legal@michigan.gov

From: Jennifer L. Domingue, Director of Compliance for Gage Cannabis Company

Date: September 27, 2021

Re: Comments to Proposed Rules

To whom it may concern,

Thank you for the opportunity to provide comment on the proposed rules. Below are some of the proposed rules we have identified as most important to our operations as a vertically-integrated cannabis company, and to the industry at large.

1. MARIHUANA DISCIPLINARY PROCEEDINGS

Rule 420.802(3) Notification and reporting

(3) Licensees shall report to the agency any proposed material changes to the marihuana business before making a material change ~~that may require prior authorization by the agency~~. 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**.** Material changes, include, but are not limited to, the following:

Comment on Proposed Rule:

- The proposed language is overly broad and puts an undue burden on licensees to make the Agency aware of any changes that it is considering even before it has made a decision to proceed with a material change.
- The proposed language is vague.

Rule 420.802(4)(c) Notification and reporting.

(4) 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 of the following:

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

Comment on Proposed Rule:

- This proposed rule is not limited to the health and safety of the public.

- It is very difficult to determine when a licensee should have become aware of a violation. As written, the Agency could levy fines for an extensive length of time based upon its determination of when a licensee should have been aware of the violation.
- When read together with the definition if proposed rule 420.801(e) and (r), every potential breach of commercial contract could be a reportable event, disrupting routine commercial activity and potentially involving the MRA in purely commercial matters that are within the province of the courts or elsewhere.
- The Agency should more clearly define who will determine when the violation should have been known by the licensee, and the process for making that determination.
- Licensees already have a duty to report matters that are within their control (e.g., employee theft, diversion, etc.).
- Licensees should be given time to investigate alleged violations before bringing them to the Agency.
- The Agency should consider requiring notification to the Agency when the licensee is aware of an issue of public health and safety (i.e. – presence of glass shards in finished product, etc.)

Rule 420.802(7) Notification and reporting.

(7) The licensee shall notify the agency within 10 business days of terminating a licensing, management, or other agreement.

Comment on Proposed Rule:

- A licensee should not have to notify the Agency every time it cancels a month-to-month contract with a service provider in the ordinary course of business.
- This proposed rule goes far beyond matters that affect health and safety or ownership and control, and should be amended to only apply to management agreements that cause a material change to the marihuana business.

Rule 420.808a(1)(d) Exclusion.

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

> *... (d) The person has engaged in conduct that could negatively impact public health, safety, and welfare.*

Comment on Proposed Rule:

- 808a(1)(d) is too vague because it relies on arbitrary judgment of MRA hearing officer as to relevance of time and nature of potentially offending conduct.

- The rule lacks sufficient definiteness to allow an ordinary person to understand what conduct it prohibits.

2. MARIHUANA-INFUSED PRODUCTS AND EDIBLE MARIHUANA PRODUCT

Rule 420.403(7)(a); 420.402(8)(d) Requirements and restrictions on marihuana-infused products; edible marihuana product.

(7) A producer shall label all marihuana-infused product with all of the following:

(a) The name of the marihuana-infuse product. The name of the product must be an appropriately descriptive phrase that accurately describes the basic nature of the product.

Comment on Proposed Rule:

- The Agency should provide clarification on what it means by the "basic nature of the product." (e.g., Does that mean that the product should include the words edible, gummy, mint, etc.?)
- The fourth point of this proposed rule is vague in that the phrase "in charge" is not defined. A "managing employee" is already defined and prequalified as a licensee; however, this appears to expand who must be considered a manager.

Rule 420.403(9) A producer of edible marihuana product shall comply with the following:

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

(c) Not produce edible marihuana products that can be easily confused with a commercially available food product. The use of the word candy or candies on the packaging or labeling is prohibited.

(d) Not produce edible marihuana products in the distinct shape of a human, animal, or fruit, or a shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings. Edible marihuana products that are geometric shapes and fruit flavored are permissible.

(e) Not package an edible marihuana product in a package that bears the image, likeness, or contains the characteristics of commercially available food products.

Comment on Proposed Rule:

- This rule will have significant impact on some current market participants. Clients should assess costs that may be imposed related to package or product redesign that may be required to comply with this new rule.
- The final prohibited element "Not [produce a] package that […] contains the characteristics of commercially available food products" is ambiguous and subject to misunderstanding by licensees and other stakeholders. MRA should specify which characteristics are

objectionable. Peanut butter is commonly sold in glass or plastic jars with screw-on plastic or metal lids; does the MRA intend to prohibit sales of marihuana products packaged in glass jars with screw-on lids because such packaging is a "characteristic" shared with a commercially available food product?

- In order to minimize economic impact to stakeholders, MRA should allow a "grandfather" or "sell-through" period or delay implementation of this proposed rule by a reasonable time period following adoption (e.g. six months) during which time licensees would be permitted to sell through existing product inventory before new packaging rules take effect.

3. MARIHUANA LICENSEES

R 420.101 (c, d, k, l, m, x); 420.112a(1-6) Definitions.

(c) "Another party" or "other party" means an individual or company with which a licensee contracts to use the individual's or company's intellectual property or to utilize management or other services provided by the individual or company.

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

(k) "Intellectual property" means 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.

(l) "Licensing agreement" means any understanding or contract concerning the licensing of intellectual property between a licensee and another party.

(m) "Management or other agreement" means 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.

(x) "Parties" means a licensee and another party pursuant to a licensing or management or other agreement.

R 420.112a Licensing, management, or other agreements.

(1) A licensee may contract with another party to use the other party's intellectual property or for the other party to provide management or other services necessary for the operation of the licensee pursuant to a licensing, management, or other agreement approved by the agency.

(2) A licensee shall submit a complete, unredacted, signed copy of the licensing, management, or other agreement to the agency for review and approval prior to performance under the agreement.

Approval by the agency indicates an agency determination that it does not appear based upon the information provided that the other party meets the definition of applicant.

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

(i) All payment terms between the parties. Licensing agreements must also include a requirement that all payments made to the other party pursuant to the licensing agreement must be made by the license and not by any other licensee purchasing the marihuana product.

(ii) Terms specifically naming and clearly defining any service to be performed pursuant to the agreement.

(iii) Terms specifically requiring all business operations related to the production, sales, invoicing, and payment for marihuana products sold pursuant to a licensing agreement must be performed by the licensee.

(iv) A statement indicating that the agreement contains the entire agreement of the parties

(4) Terms that may indicate the other party meets the definition of applicant and is thereby subject to application requirements, including, but not limited to, the following:

(i) Any term or condition that would allow the other party to exercise control over or participate in the management of the licensee. This does not include control or terms specific to a licensing agreement such as production method or packaging requirements.

(ii) Any 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.

(iii) Any term or condition that would result in the other party obtaining an ownership interest in the marihuana business or taking possession or ownership of marihuana product owned by the marihuana business.

(iv) Any 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.

(5) Any term or condition that would allow the licensee to use an assumed name or doing business as in the operation of the licensee is not operative unless the licensee has complied with the requirements of 1907 PA 101, MCL 445.1 to 445.5.

(6) The licensee shall provide any other information requested by the agency that is not inconsistent with the acts and these rules.

Comment on Proposed Rule:

- This proposed rule does not affect the health or safety of the public.
- The proposed language is vague in that it does not define what constitutes management authority. We request that the MRA clearly define what services and activities qualify as management services for the purposes of this rule.
- This proposed rule has an adverse impact on business, when applied to proposed rule 420.112a, in that it requires prior approval for non-cannabis commercial activity, increases the costs of each transaction, and would permit the MRA to determine its own, arbitrary commercial standard.
- This proposed rule, when applied to proposed rule 420 112a, sets an arbitrary limit of 10% of profit to determine that a service provider must apply for a license; MRA lacks the statutory authority to set this arbitrary percentage cap.
- This proposed rule should be limited to only considerations of ownership and control of licensees, and the health and safety of patients and workers.
- The enabling statutes – the Medical Marijuana Facilities Licensing Act ("MMFLA"), the Michigan Medical Marihuana Act ("MMMA") and the Michigan Regulation and Taxation of Marihuana Act ("MRTMA") – do not authorize that level of overreach to the MRA;
- This rule, when applied to proposed rule 420.112a, may violate the US Constitution's Contract Clause (art. I, sec. X, Cl. 1) in that it would purport to allow the MRA to effectively terminate or re-write existing and enforceable agreements with licensees.

4. MARIHUANA OPERATIONS

R 420.203(2)(f)(i)(A-I) Marihuana licenses; licensees; operations; general.

(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.

Comment on Proposed Rule:

- There should be timeline set by the Agency dictating how long these records must be kept by a licensee. Five (5) years is a standard retention time.

R 420.206a(5) Standard operating procedures.

(5) If the agency determines that any standard operating procedure contains inaccurate information or does not comply with these rules and safe food management guidelines, as applicable, the licensee may be required to correct and update the standard operating procedures immediately.

Comment on Proposed Rule:

- It is unreasonable to ask a licensee to amend an SOP on the spot during an inspection. We propose that the Agency issue a deficiency notice to the licensee and allow adequate time for the licensee to make the necessary changes.

R 420.214(b) Adverse reactions.

1. *A licensee shall notify the agency within 1 business day of becoming aware of within 1 business day of when the licensee should have been aware of any adverse reactions to a marihuana product sold or transferred by any licensee.*

Comment on Proposed Rule:

- The Agency does not define an "adverse reaction", which leads to an overbroad interpretation, leading to undue burden on licensees.

- At this point, an adverse reaction could be interpreted as any complaint or symptoms reported by consumers regarding any marihuana product, including but not limited to coughing, a "tickle in their throat", headaches, sneezing, or tiredness. We propose the Agency clarify what type of adverse reactions should be reported.

R 420.401(d) Definitions.

(d) "Final package form" means the form a marihuana product is in when its is available for sale by a marihuana sales location. For marihuana products intended for inhalation, final form means the marihuana concentrate in the e-cigarette or vaping device.

Comment on Proposed Rule:

- This proposed rule does not protect the health and safety of the public.

5. MARIHUANA LICENSES

R 420.6(6) State license under the Michigan regulation and taxation of marihuana act; issuance; qualifications; ineligibility.

(6) A marihuana license is a revocable privilege granted by the agency and is not a property right. Granting a marihuana license does not create or vest any right, title, franchise, or other property interest. A licensee or any other person shall not lease, pledge, borrow, or loan money against a marihuana license.

Comment on Proposed Rule:

- With respect to adult-use licenses, this proposed rule seems at odds with the holding in *Brown v. Yousif 445 Mich. 222 (1994)* where the court found Michigan liquor licenses to be a "general intangible" and "personal property" despite an MLCC rule to the contrary—similar to what MRA is proposing here -- because the MLCC did not have statutory authority to overrule article 9 of the Michigan UCC. Does MRA have authority where MLCC did not? *See generally* https://law.justia.com/cases/michigan/supreme-court/1994/96311-6.html

- This proposed rule has the effect of limiting investment and reducing access to capital for Michigan cannabis licensees. Rather than prohibiting a pledge of the license, MRA should require disclosure from lenders who take a license as security (similar to the MLCC's process for parties that lend to liquor license operators). If a lender who is not an applicant seeks to foreclose or assume the license, MRA should support an escrow process for such foreclosed licenses, or facilitate a transfer to a new licensee operator.

R 420.401 Definitions.

(d) "Final ~~package~~ ***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 the e-cigarette or vaping device.***

Comment on Proposed Rule:

- This proposed rule does not protect the health and safety of the public.

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

Summary of Changes:

1) The Agency seeks to amend the current rule that prohibits producers from producing packaging or labels that would appeal to minors to include the shape of the edible product.

2) The MRA proposes to expand the prohibition on producing edibles that can be easily confused with commercially sold candy to include all commercially available food products.

Comment on Proposed Rule:

DW does not have any objection to these proposed rules, but if you, as an operator, believe that any of these rules are unreasonable and should be challenged, please identify those rules.

DICKINSON WRIGHT PLLC

M E M O R A N D U M

To: Michigan Marijuana Regulatory Agency
VIA Email: Legal@michigan.gov

From: Jim Boland and Lloyd Pierre Louis

Date: September 27, 2021

Re: Comments on Proposed Rules

Our law firm represents a number of clients licensed by and participating within Michigan's Medical and Recreational Marijuana Program. The purpose of this letter is to provide comments to the MRA in opposition to the proposed rules below.

Rule at issue: 420.802(3) Notification and reporting

(3) Licensees shall report to the agency any proposed material changes to the marihuana business before making a material change that may require prior authorization by the agency. 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. Material changes, include, but are not limited to, the following:

Comment on Proposed Rule:

- The proposed language is overly broad and puts an undue burden on licensees to make the Agency aware of any changes that it is considering even before deciding to proceed with a material change.

- The proposed language is vague.

Rule at issue: 420.802(4)(c) Notification and reporting.

(4) 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 of the following:

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

Comment on Proposed Rule:

- This proposed rule is not limited to the health and safety of the public.

- It is difficult to determine when a licensee should have become aware of a violation. As written, the Agency could levy fines for an extensive length of time based upon its determination of when a licensee should have been aware of the violation.

- When read together with the definition if proposed rule 420.801(e) and (r), every potential breach of commercial contract could be a reportable event, disrupting routine commercial activity and potentially involving the MRA in purely commercial matters that are within the province of the courts or elsewhere.

- The Agency should more clearly define who will determine when the licensee should have known the violation and the process for making that determination.

- Licensees already have a duty to report matters that are within their control (e.g., employee theft, diversion, etc.).

- Licensees should be given time to investigate alleged violations before bringing them to the Agency.

Rule at issue: 420.802(7) Notification and reporting.

(7) The licensee shall notify the agency within 10 business days of terminating a licensing, management, or other agreement.

Comment on Proposed Rule:

- A licensee should not have to notify the Agency every time it cancels a month-to-month contract with a service provider in the ordinary course of business.

- This proposed rule goes far beyond matters that affect health and safety or ownership and control and should be amended to only apply to management agreements that cause a material change to the marihuana business.

Rule at Issue: 420.808a(1)(d) Exclusion.

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

… (d) The person has engaged in conduct that could negatively impact public health, safety, and welfare.

Comment on Proposed Rule:

- 808a(1)(d) is too vague because it relies on the arbitrary judgment of the MRA hearing officer regarding the relevance of time and nature of potentially offending conduct.

- The rule lacks sufficient definiteness to allow an ordinary person to understand what conduct it prohibits.

Rules at issue: 420.403(7)(a); 420.402(8)(d) Requirements and restrictions on marihuana-infused products; edible marihuana product.

(7) A producer shall label all marihuana-infused product with all of the following:

(a) The name of the marihuana-infused product. The name of the product must be an appropriately descriptive phrase that accurately describes the basic nature of the product.

Comment on Proposed Rule:

- The Agency should provide clarification on what it means by the "basic nature of the product." (e.g., does that mean that the product should include the words edible, gummy, mint, etc.?)

- The fourth point of this proposed rule is vague in that the phrase "in charge" is not defined. A "managing employee" is already defined and prequalified as a licensee; however, this appears to expand who must be considered a manager.

Rule 420.403(9) A producer of edible marihuana product shall comply with the following:

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

(c) Not produce edible marihuana products that can be easily confused with a commercially available food product. The use of the word candy or candies on the packaging or labeling is prohibited.

(d) Not produce edible marihuana products in the distinct shape of a human, animal, or fruit, or a shape that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings. Edible marihuana products that are geometric shapes and fruit flavored are permissible.

(e) Not package an edible marihuana product in a package that bears the image, likeness, or contains the characteristics of commercially available food products.

Comment on Proposed Rule:

- The final prohibited element, "Not [produce a] package that […] contains the characteristics of commercially available food products" is ambiguous and subject to misunderstanding by licensees and other stakeholders. MRA should specify which characteristics are objectionable. For example, peanut butter is commonly sold in glass or plastic jars with screw-on plastic or metal lids; does the MRA intend to prohibit sales of marihuana products packaged in glass jars with screw-on lids because such packaging is a "characteristic" shared with a commercially available food product?

- In order to minimize economic impact to stakeholders, MRA should allow a "grandfather" or "sell-through" period or delay implementation of this proposed rule by a reasonable time period following adoption (e.g., six months), during which time licensees would be permitted to sell through existing product inventory before new packaging rules take effect.

Rules at issue: 420.101 (c, d, k, l, m, x); 420.112a (1-6)

420.101 Definitions

(c) "Another party" or "other party" means an individual or company with which a licensee contracts to use the individual's or company's intellectual property or to utilize management or other services provided by the individual or company.

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

(k) "Intellectual property" means 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.

(l) "Licensing agreement" means any understanding or contract concerning the licensing of intellectual property between a licensee and another party.

(m) "Management or other agreement" means 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.

(x) "Parties" means a licensee and another party pursuant to a licensing or management or other agreement.

R 420.112a Licensing, management, or other agreements.

(1) A licensee may contract with another party to use the other party's intellectual property or for the other party to provide management or other services necessary for the operation of the licensee pursuant to a licensing, management, or other agreement approved by the agency.

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

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

(i) All payment terms between the parties. Licensing agreements must also include a requirement that all payments made to the other party pursuant to the licensing agreement must be made by the license and not by any other licensee purchasing the marihuana product.

(ii) Terms specifically naming and clearly defining any service to be performed pursuant to the agreement.

(iii) Terms specifically requiring all business operations related to the production, sales, invoicing, and payment for marihuana products sold pursuant to a licensing agreement must be performed by the licensee.

(iv) A statement indicating that the agreement contains the entire agreement of the parties

(4) Terms that may indicate the other party meets the definition of applicant and is thereby subject to application requirements, including, but not limited to, the following:

(i) Any term or condition that would allow the other party to exercise control over or participate in the management of the licensee. This does not include control or terms specific to a licensing agreement such as production method or packaging requirements.

(ii) Any 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.

(iii) Any term or condition that would result in the other party obtaining an ownership interest in the marihuana business or taking possession or ownership of marihuana product owned by the marihuana business.

(iv) Any 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.

(5) Any term or condition that would allow the licensee to use an assumed name or doing business as in the operation of the licensee is not operative unless the licensee has complied with the requirements of 1907 PA 101, MCL 445.1 to 445.5.

(6) The licensee shall provide any other information requested by the agency that is not inconsistent with the acts and these rules.

Comment on Proposed Rules:

- This proposed rule does not affect the health or safety of the public.
- The proposed language is vague in that it does not define what constitutes management authority. Therefore, we request that the MRA clearly define what services and activities qualify as management services for the purposes of this rule.
- This proposed rule has an adverse impact on business when applied to proposed rule 420.112a, in that it requires prior approval for non-cannabis commercial activity, increases the costs of each transaction, and would permit the MRA to determine its own arbitrary commercial standard.
- This proposed rule, when applied to proposed rule 420 112a, sets an arbitrary limit of 10% of profit to determine that a service provider must apply for a license; MRA lacks the statutory authority to set this arbitrary percentage cap.
- This proposed rule should be limited to only considerations of ownership and control of licensees and the health and safety of patients and workers.
- The enabling statutes – the Medical Marijuana Facilities Licensing Act ("MMFLA"), the Michigan Medical Marihuana Act ("MMMA") and the

Michigan Regulation and Taxation of Marihuana Act ("MRTMA") – do not authorize that level of overreach to the MRA;

- When applied to proposed rule 420.112a, this rule may violate the US Constitution's Contract Clause (art. I, sec. X, Cl. 1) in that it would purport to allow the MRA to effectively terminate or terminate re-write existing and enforceable agreements with licensees.

Rule at issue: 420.203(2)(f)(i)(A-I) Marihuana licenses; licensees; operations; general.

(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.

Comment on Proposed Rule:

- There should be a timeline set by the Agency dictating how long a licensee must keep these records. For example, five (5) years is a standard retention time.

Rule at issue: 420.206a(5) Standard operating procedures.

(5) If the agency determines that any standard operating procedure contains inaccurate information or does not comply with these rules and safe food management guidelines, as applicable, the licensee may be required to correct and update the standard operating procedures immediately.

Comment on Proposed Rule:

- It is unreasonable to ask a licensee to amend an SOP on the spot during an inspection. Therefore, we propose that the Agency issue a deficiency notice to the licensee and provide adequate time for the licensee to make the necessary changes.

Rule at issue: R 420.401(d) Definitions.

(d) "Final package 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 the e-cigarette or vaping device.

Comment on Proposed Rule:

- This proposed rule does not protect the health and safety of the public.

Rule at issue: 420.207a Contactless and limited contact transactions.

(1) A marihuana sales location may designate an area for contactless or limited contact transactions unless prohibited by an ordinance adopted by the municipality where the marihuana sales location is located.
(2) A marihuana sales location may accept online orders for marihuana product and payment for the order that will be picked up at the marihuana sales location.
(3) The designated area for contactless or limited contact transactions must be identified in the marihuana business location plan.
(4) A marihuana sales location operating a contactless or limited contact transaction must have a written standard operating procedure in place and be made available to the agency upon request.
(5) Contactless or limited contact transactions must be completed during normal business hours.
(6) A marihuana sales location using a designated area for contactless or limited contact transactions must have in place an anti-theft policy, procedure, or automatic capability.
(7) The designated area for contactless or limited contact transactions must comply with R 420.209.
(8) The contactless and limited contact transaction must comply with R 420.505 and R 420.506.
(9) Marihuana being transferred during a contactless or limited contact transaction must be in an opaque bag and the contents must not be visible to the general public upon pick up.

Comment on Proposed Rule:

- If this rule is intended to provide explicit authority for licensees to operate drive-through service at the licensed premises or delivery services based from the licensed premises using registered employees of the licensee, it would be beneficial to licensees and other stakeholders if MRA would spell those intentions out explicitly in the rule. As proposed, the rule could be construed to permit other types of contactless transactions (e.g., vending machines), which may not be in the MRA's intended scope of authorization.

Rule at Issue: 420.6(6)

> ***(6) A marihuana license is a revocable privilege granted by the agency and is not a property right. Granting a marihuana license does not create or vest any right, title, franchise, or other property interest. A licensee or any other person shall not lease, pledge, borrow, or loan money against a marihuana license.***

Comment on Proposed Rule:

- With respect to adult-use licenses, this proposed rule seems at odds with the holding in *Brown v. Yousif 445 Mich. 222 (1994)*, where the court found Michigan liquor licenses to be a "general intangible" and "personal property" despite an MLCC rule to the contrary—similar to what MRA is proposing here -- because the MLCC did not have statutory authority to overrule article 9 of the Michigan UCC. Does MRA have authority where MLCC did not? See generally https://law.justia.com/cases/michigan/supreme-court/1994/96311-6.html

- This proposed rule has the effect of limiting investment and reducing access to capital for Michigan cannabis licensees. Rather than prohibiting a pledge of the license, MRA should require disclosure from lenders who take a license as security (similar to the MLCC's process for parties that lend to liquor license operators). If a lender who is not an applicant seeks to foreclose or assume the license, the MRA should support an escrow process for such foreclosed licenses, or facilitate a transfer to a new licensee operator.

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

MARIJUANA REGULATORY AGENCY

MARIHUANA-INFUSED PRODUCTS AND EDIBLE MARIHUANA PRODUCT

Filed with the secretary of state on

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

(By authority conferred on the executive director of the marijuana regulatory agency by section 206 of the medical marihuana facilities licensing act, 2016 PA 281, MCL 333.27206, sections 7 and 8 of the Michigan Regulation and Taxation of Marihuana Act, 2018 IL 1, MCL 333.27957 and 333.27958, and Executive Reorganization Order No. 2019-2, MCL 333.27001)

R 420.401, R 420.402, and R 420.403 of the Michigan Administrative Code are amended, ~~to the Michigan Administrative Code~~ as follows:

R 420.401 Definitions**.**

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

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

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

(c) "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 establishment.

(d) "Final ~~package~~**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 the e-cigarette or vaping device.**

(e) "Inactive ingredients" means binding materials, dyes, preservatives, flavoring agents, and any other ingredient that is not derived from the plant *Cannabis ~~S~~sativa L.*

~~(f) "Marihuana business" refers to a marihuana facility under the medical marihuana facilities licensing act or a marihuana establishment under the Michigan regulation and taxation of marihuana act, or both.~~

~~(g) "Marihuana establishment" means a location at which a licensee is licensed to operate a marihuana grower, marihuana safety compliance facility, marihuana processor, marihuana microbusiness, marihuana retailer, marihuana secure transporter, marihuana designated consumption establishment, or any other type of marihuana-related business licensed to operate by the agency under the Michigan regulation and taxation of marihuana act.~~

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

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

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

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

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

(~~m~~**j**) "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.

(~~n~~**k**) "Producer" refers to both a processor under the medical marihuana facilities licensing act and a marihuana processor under the Michigan ~~r~~**R**egulation and ~~t~~**T**axation of ~~m~~**M**arihuana ~~a~~**A**ct.

~~(o) "Records of formulation" means the documentation that includes at a minimum: the ingredients, recipe, processing in order to be shelf stable, Certificates of Analysis for any ingredient used, and description of the process in which all ingredients are combined to produce a final package.~~

(~~p~~**l**) "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.

(~~q~~**m**) "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 product in the statewide monitoring system.

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

R 420.402 Adoption by reference.

Rule 2. (1) The following codes, standards, or regulations of nationally recognized organizations or associations are adopted by reference in these rules:

(a) National fire protection association (NFPA) standard 1, 20~~18~~**21** edition, entitled "Fire Code**,**" is adopted by reference as part of these rules. Copies of the adopted provisions are available for inspection and distribution from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, Massachusetts, 02169, telephone number 1-800-344-3555, for the price of $~~106.00~~**114.50**.

(b) The International Organization for Standardization (ISO), ISO 22000 / ISO/TS 22002-1:2009**,**~~.~~ ~~f~~**F**ood ~~s~~**S**afety ~~b~~**B**undle, available for purchase at: https://webstore.ansi.org/Standards/ISO/ISO22000TS22002FoodSafety, for the price of $275.00.

(c) International Organization for Standardization (ISO), ISO/IEC 17025:2017, ~~g~~**G**eneral ~~r~~**R**equirements for the ~~c~~**C**ompetence of ~~t~~**T**esting and ~~c~~**C**alibration ~~l~~**L**aboratories**,** available at: https://webstore.ansi.org/RecordDetail.aspx?sku=ISO%2fIEC+17025%3a2017, for the price of $162.00.

(2) The standards adopted in subrule (1)(a) to (c) of this rule are available for inspection and distribution at the agency, located at 2407 North Grand River Avenue, Lansing, **Michigan** ~~MI~~,

Commented [TC1]: This is a pretty significant change.

Most municipalities won't be using these rules for 3-5 years.

Why is the MRA updating to this standard?

Some municipalities are still using the NFPA standard from 2015.

Should there not be a provision for the AHJ?

There is an updated section for Cannabis in this new version – but still the AHJ may be out of date.

48906. Copies of these standards may be obtained from the agency at the cost indicated in subrule (1)(a) to (c) of this rule, plus shipping and handling.

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

Rule 3. (1) A producer shall package and properly label marihuana-infused products before sale or transfer.

(2) Marihuana-infused products processed under these rules must be homogenous. The allowable variation for weight and THC and CBD concentrations between the actual results and the intended serving is to be + or – 15%. The agency shall publish guidelines for a producer to follow to verify the marihuana-infused product is homogeneous.

(3) A producer of marihuana-infused products shall list and record the THC concentration and CBD concentration of marihuana-infused products, as provided in R 420.305 and ~~subrule (4)~~ **R 420.404** ~~of this rule~~, in the statewide monitoring system and indicate the THC concentration and CBD concentration on the label along with the tag identification as required under these rules.

(4) Marihuana-infused products that are part of a product recall ~~issued in the statewide monitoring system, or by the agency or other state agency, if applicable,~~ are subject to all of the following requirements:

(a) Must be immediately pulled from production by the producer of the marihuana-infused product.

(b) Must be immediately removed from the sales area of a marihuana sales location.

(c) Must not be sold or transferred.

(5) Marihuana-infused products must be stored and secured as prescribed under these rules.

(6) All non-marihuana inactive ingredients must be clearly listed on the product label. Inactive ingredients must be approved by the FDA for the intended use, and the concentration must be less than the maximum concentration listed in the FDA Inactive Ingredient database for the intended use.

(7) A producer shall label all marihuana-infused product with all of the following:

(a) The name of the marihuana-infused product. **The name of the product must be an appropriately descriptive phrase that accurately describes the basic nature of the product.**

(b) The ingredients**, including component ingredients,** of the marihuana-infused product, in descending order of predominance by weight.

(c) The net weight or net volume of the product.

(d) For an edible marihuana product, ~~the marihuana processor shall comply with subdivisions (a) to (c) of this subrule and all of the~~ **both of the** following **must be included**:

(i) Allergen labeling as specified by the Food and Drug Administration (FDA), Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), 21 USC 343.

(ii) If any health or nutritional claim is made, appropriate labeling as specified by the federal regulations regarding Food Labeling, 21 CFR part 101.

(e) The date the marihuana product was produced.

(8) A producer of edible marihuana product shall comply with all the following ~~to ensure safe preparation~~:

(a) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food, 21 CFR part 117.- Any potentially hazardous ingredients used to

Commented [TC2]: The label statement is +/- 10% - but the homogeneity limit is +/- 15?

This is inconsistent.

In addition – since the testing labs are allowed variance in their results of +/- 20% - having a requirement for homogeneity that is lower than that, with a label claim that is even lower than that seems misguided.

Best case scenario – require the labs to tighten their results (which would make many people happy! And has been show by AOAC to be physically possible) and align homogeneity and label claims to the same percentage. +'/- 10% may be appropriate here, but its still quite a lot.

Commented [TC3]: How else might a recall be issued? Are we expecting recalls of materials that are not in METRC?

Why is this section being striked?

Commented [TC4]: There is no definition of component ingredients.

Is this packaging component ingredients?

Cannabis specific ingredients?

Active Ingredients?

Inactive Ingredients?

process shelf-stable edible marihuana products must be stored at 40 degrees Fahrenheit, 4.4 degrees Celsius, or below.

~~(b) Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food, 21 CFR part 110. A marihuana business shall ensure that any handling of marihuana product is compliant.~~

(~~a~~**b**) Keep formulation records for all marihuana products. These records at a minimum must include the recipe, any additional processing **documentation that demonstrates the product** ~~in order~~ to be shelf stable, and test results for ~~any~~ **all** ingredients used.

(~~b~~**c**) Provide annual employee training for all employees on safe food handling and demonstrate an employee's completion of this training by providing proof of food handler certification that includes documentation of employee food handler training, including, but not limited to, allergens and proper sanitation and safe food handling techniques. Any course taken pursuant to this rule must be conducted for not less than 2 hours and cover all of the following subjects:

(i) Causes of foodborne illness, highly susceptible populations, and worker illness.

(ii) Personal hygiene and food handling practices.

(iii) Approved sources of food.

(iv) Potentially hazardous foods and food temperatures.

(v) Sanitization and chemical use.

(vi) Emergency procedures, including, but not limited to, fire, flood, and sewer backup.

(~~c~~**d**) Have an employee **in charge** who is certified as a Food Protection Manager.

(~~d~~**e**) To ensure compliance with the safe preparation standards under this subrule, comply with 1 or more of the following:

(i) ~~The FDA food safety modernization act, 21 USC 2201 to 2252.~~ **Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food, 21 CFR part 117.**

(ii) The International Organization for Standardization (ISO), ISO 22000/ISO/TS 22002-1 adopted by reference pursuant to R 420.402.

(~~e~~**f**) -If requested as provided in this subdivision, provide to the agency documentation to verify certifications and compliance with these rules. The agency may request in writing documentation to verify certifications and compliance with these rules.

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

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

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

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

(d) Not produce edible marihuana products in the distinct shape of a human, animal, or fruit, or a shape that bears the likeness or contains characteristics of a realistic or fictional

Commented [TC5]: This is a huge change.

This is for food handling and GMP requirements.

See my note in Employees draft comments. Are we now being required to follow Part 117 instead of Part 110?

Commented [TC6]: This is a HUGE change.

Going from ~ 11 sections of regulations to 61 sections of regulations!

Commented [TC7]: On the surface this appears to be too broad.

How is it possible to create an edible food product without having it be possible to be confused with any available food products that happen to not be infused?

Labeling I get. Packaging I get. Don't be similar in the label or the package. But the product itself cannot even be made if its similar to other non-infused food products?

human, animal, or fruit, including artistic, caricature, or cartoon renderings. Edible marihuana products that are geometric shapes and fruit flavored are permissible.

(e) Not package an edible marihuana product in a package that bears the image, likeness, or contains the characteristics of commercially available food products.

(**~~ef~~f**) An edible marihuana product must be in opaque, child-resistant packages or containers that meet the effectiveness specifications outlined in 16 CFR 1700.15. An edible marihuana product containing more than ~~one~~ **1** serving must be in a resealable package or container that meets the effectiveness specifications outlined in 16 CFR 1700.15.

(10) A producer shall not produce an edible marihuana product that requires time and temperature control for safety. The agency may publish validation guidance for shelf stable edible marihuana product. The agency may request to review the validation study for a shelf stable edible marihuana product. The end product must be a shelf stable edible marihuana product and state the following information:

(a) A product expiration date, upon which the marihuana product is no longer fit for consumption **and after which it must be destroyed**. Once a label with an expiration date has been affixed to a marihuana product, a licensee shall not alter that expiration date or affix a new label with a later expiration date. **The expiration date must consider all the following:**

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

(ii) The packaging of the edible marihuana product.

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

(b) Any other information requested by the agency that is not inconsistent with the acts and these rules.

(11) As used in this rule, the term "edible marihuana product" means any marihuana-infused product containing marihuana that is intended for human consumption in a manner other than smoke inhalation.

(12) This rule does not affect the application of any applicable local, state, or federal laws or regulations.

Commented [TC8]: What about inanimate objects?

Rocks? Cars? Flowers? Hearts?

Commented [TC9]: Can we get an approval process for this?

Label approval is so inconsistent!

Commented [TC10]: This makes sense – can we get clarification on the new section C – so we can make food products any way but cannot have packaging and labeling that makes them appear to be similar to commercially available food products?

Commented [TC11]: This is normal business practice in other industries.

You asked that I provide some additional guidance about this. The way it is written here appears to be very clear.

Do shelf stability. Label product with end of shelf stability date. Destroy product after that date has been reached.

Commented [TC12]: These would all be part of a normal shelf stability study. Specific to storage conditions, primary packaging container, composition of the product, and expected storage conditions at a vendor (vs how they would be stored while at the producer).

Commented [TC13]: I assume that includes Tinctures, edibles, suppositories.

But does not include rubs, balms, salves, lubes, transdermal patches or lotions aka Topicals.

It would be great to have some additional clarity on that. Especially since – there are no regulations that discuss topicals at all – but the MRA does track them separately.

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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

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

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

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

R420.206 sub 13 and 14

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

R420.207a

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

R420.214a

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

R420.214c

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

2020 R123 LR

R420.503a

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

R420.504 Rule 4 sub 1 sub K sub 5

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

Same, Rule 4 sub 4

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

2020-124 LR

No notes

2021-10 LR

R420.602a

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

2021-29 LR

No notes

--
Rick Thompson
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Named **Citizen Activist of the Year 2015** by national media source
Crystal Trichome Award winner- **Journalist of the Year** 2016
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Activism: MiNORML and MiLegalize, Board member of both
Print: *High Times*, *Hybrid:Life Magazine*, *Culture Magazine*, *more*
Internet: Editor, The Social Revolution; contributor, The Weed News, *more*
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AUGUST 2021, PROPOSED MRA ADMINISTRATIVE RULE COMMENTS FROM THE SPOTT LABORATORY

MARIJUANA DECLARATORY RULINGS

No Comments

MARIJUANA DISCIPLINARY PROCEEDINGS

No Comments

MARIJUANA EMPLOYEES

No Comments.

MARIJUANA HEARINGS

No Comments.

MARIJUANA SALE OR TRANSFER

No Comments

MARIJUANA LICENSES

1. R420.13(1)(a) states:

   "For a licensee seeking renewal under the MMFLA, required information may also be related to the suitability and general fitness of the licensee and include without limitation, 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 required license renewal information listed in this section of the Rule is blatantly discriminatory, based upon subjective attributes of the licensee that are not required for initial licensure and are not enforceable. **This section of the Rule should be omitted in its entirety.**

MARIJUANA-INFUSED PRODUCTS AND EDIBLE MARIJUANA PRODUCT

1. R420.402(2) states:

   Copies of these standards may be obtained by the agency at the cost indicated in subrule (1)(a) to (c) of this rule, plus shipping and handling."

   Copying and resale of copyrighted material is very likely a constitutional and legal violation. Government agencies are not immune to the Fair Use Doctrine found in Article I, section 8 of the Constitution or to the Copyright Act of 1976.

2. R420.403(8)(a) states:

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

   (a) Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food, 21CFR part 117.- Any potentially hazardous ingredients used to process shelf-stable edible marijuana products must be stored at 40 degrees Fahrenheit, 4.4 degrees Celsius, or below."

   It is recommended that "- *Any potentially hazardous ingredients used to process shelf-stable edible marijuana products must be stored at 40 degrees Fahrenheit, 4.4 degrees Celsius, or below"* is removed from the Rule.

   This type of detail is better placed in a clarifying bulletin/ guideline issued subsequent to the Rules where more clarity can be established.

   21CFR Part 117, § 117.80 - Processes and controls, provides the following adequate statement regarding storage of ingredients:

   (5) Raw materials, other ingredients, and rework must be held in bulk, or in containers designed and constructed so as to protect against allergen cross-contact and against contamination and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for rework must be identified as such.

   The quoted language in R420.403(8)(a) attempts to require what is defined in 21CFR Part 117, § 117.135 as a "Preventive Control," without offering a licensee the opportunity to conduct a proper Hazard Analysis according to 21CFR Part 117, § 117.130 - Hazard Analysis to see if a Preventive Control is warranted. Further, the quoted language in R420.403(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.

3. R420.403(8)(b) states:

   "These records at a minimum must include the recipe, any additional processing documentation that demonstrates the product to be shelf stable and ***test results for all ingredients used****."*

   It is recommended that "*and test results for all ingredients used*" is removed from the Rule.

   The quoted language implies that "all ingredients used" must be tested, without defining test requirements for non-active/ excipient ingredients.

4. R420.403(11) provides a definition for "edible marijuana product." This may be better placed in section 420.401, Definitions.

MARIJUANA LICENSEES

1. R420.107(1)(c) allows a testing lab to:

   "Receive marijuana from and test marijuana for an individual 21 years of age or older, if the marijuana was produced by the individual and not purchased or obtained from a licensed marijuana business."

   It is recommended that this be changed to read: "*Receive marijuana from and test marijuana for an individual 21 years of age or older."*

   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.

   - Notably, 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.
   - If a sample is presented to a lab for testing by an adult, the lab has no way of definitively verifying/ proving its source, and neither does the MRA. This renders the rule unenforceable.

2. R420.107(2)(c) and R420.112(2)state:

   "A marijuana safety compliance facility must be accredited by an entity approved by the agency within 1 year after *the date the marijuana safety compliance facility license is issued…."*

   This should be changed to read: "*A marijuana safety compliance facility must be accredited by an entity approved by the agency* ***prior to issuance of a state operating license****."*

   When the MRA was established in 2018, and only four labs were operating in the state, licensure issuance concurrently with accreditation efforts by a new lab made sense. This was a necessary approach to accelerate industry development. Now, almost three years later, with 15+ fully operating state cannabis labs, it is time to tighten accreditation requirements.

   Accreditation ensures that a lab has a functional Quality System, complete with validated test methods, to **ensure the accuracy of published test results**. This protects public health and safety.

   If a lab enters the industry without prior accreditation, the accuracy of test results that they generate cannot be guaranteed. The lab may operate for up to a full year with a sub-standard quality system and release potentially inaccurate results. In effect, this Rule codifies a double standard in which some labs are fully compliant, while newer labs are not. Public perception of the industry suffers and the Rule, as proposed, perpetuates the ongoing national problem of inconsistent cannabis lab results and associated 'lab shopping' within the state of Michigan.

   The very least that the state of Michigan must do is to level the playing field with respect to laboratory accreditation and make it a pre-condition of licensing at this point in the development of the industry.

MARIJUANA OPERATIONS

1. R420.206(2) states:

   Copies of these standards may be obtained by the agency at the cost indicated in subrule (1)(a) and (b) of this rule, plus shipping and handling."

   Copying and resale of copyrighted material is very likely a constitutional and legal violation. Government agencies are not immune to the Fair Use Doctrine found in Article I, section 8 of the Constitution or to the Copyright Act of 1976.

2. R420.202(13) states:

   "All ingredients containing cannabinoids, whether naturally occurring or synthetically derived, that are added to marijuana or marijuana 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."

   This language implies that synthetic cannabinoids are acceptable in Michigan, and that a license is available that allows for synthetic processing.

   Allowance for synthetic cannabinoids in the state of Michigan is not advised. Synthetic cannabinoids exist that are extremely dangerous to public health and safety, as evidenced by the "K2" or "Spice" synthetics that have previously emerged. These are not addressed by the rule as currently written. Even if a cannabinoid is a synthetically derived, but naturally occurring compound, synthetic production involves a substantial risk of product adulteration by toxic reagents and/ or byproducts. These Rules do not adequately regulate synthetic processing to protect public health and safety as currently written. The State of Michigan does not currently provide licensure for cannabinoid synthesis.

   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.

MARIJUANA SAMPLING AND TESTING

3. R420.302(2) states:

   Copies of these standards may be obtained by the agency at the cost indicated in subrule (1)(a) to (c) of this rule, plus shipping and handling."

   Copying and resale of copyrighted material is very likely a constitutional and legal violation. Government agencies are not immune to the Fair Use Doctrine found in Article I, section 8 of the Constitution or to the Copyright Act of 1976.

4. R420.304(2)(a) states:

   "The laboratory shall physically ***collect the sample the*** *marijuana product from another business..."*

   A typographic error exists; the verbiage should read: *"The laboratory shall physically collect the ~~sample the~~ marijuana product sample from another business...."*

5. R420.305(1) states:

   "*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."*

   This should be changed to read: *"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."*

   When the MRA was established in 2018, and only four labs were operating in the state, licensure issuance concurrently with accreditation efforts by a new lab made sense. This was a necessary approach to accelerate industry development. Now, almost three years later, with 15+ fully operating state cannabis labs, it is time to tighten accreditation requirements.

   Accreditation ensures that a lab has a functional Quality System, complete with validated test methods, to **ensure the accuracy of published test results**. This protects public health and safety. If a lab enters the industry without prior accreditation, the accuracy of test results that they generate cannot be guaranteed. The lab may operate for up to a full year with a sub-standard quality system and release potentially inaccurate results. In effect, this Rule codifies a double standard in which some labs are fully compliant, while newer labs are not. Public perception of the industry suffers and the Rule, as proposed, perpetuates the ongoing national problem of inconsistent cannabis lab results and associated 'lab shopping' within the state of Michigan.

   Also note that the statement "*A laboratory shall become fully accredited for all required safety tests in at least 1 required matrix..."* establishes that accreditation involves only one required matrix. This will limit the ability of MRA to require accreditation for additional matrices.

   The very least that the state of Michigan must do is to level the playing field with respect to laboratory accreditation and make it a pre-condition of licensing at this point in the development of the industry.

6. R420.305(2) states:

   "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, per-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."

   This language does not clearly reflect the intent of the Rule nor the way in which the Rule has been enforced to date. Alternate clarified verbiage is:

   "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, per-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."

   (Note: Appendix K is specific to analytical testing and Appendix J is specific to microbial testing.

7. R420.305(3) states:

   "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."

   Note that this statement limits safety testing to ***marijuana product that is part of a harvest batch*** which is only plant material by definition. **This excludes testing requirements for marijuana products that are not part of a harvest batch such as concentrates and infused products.**

8. R420.305(3)(f) includes Residual Solvents as a required safety test for marijuana product that is part of a harvest batch. **Residual solvent testing has not been required for plant material to date. This sub-rule should be deleted, as subrule R420.305(7) properly addresses residual solvent testing.**

9. R420.305(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)

   (E) Additional cannabinoids may be tested with approval from the agency."

   The following points are relevant and must be resolved prior to adoption of the Rule:

   a. Reporting of test results is legally required ONLY for the four entities in items (A) through (D) of the subrule as written. **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.

   b. The correct terms for acid forms of cannabinoids are *"Tetrahydrocannbino**ic**"* and *"Cannbidiol**ic**,"* not *"Tetrahydrocannabin**ol**"* or *"Cannabidi**ol**."*

10. R420.305(9) further defines the list of legally required cannabinoids for potency testing.

    It is critical that the following points are resolved prior to adoption of the Rule:

    a. Reporting of test results is legally required ONLY for the four entities in items (a) through (f) of the subrule as written. **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.

    b. R420.305(9)(a) and (c) are redundant. R420.305(9)(a) should be changed to "delta-9 THC Concentration."

    c. R420.305(9)(c) defines mandatory compounds that comprise "Total THC." This definition is extremely problematic such that reporting of Total THC results as defined cannot be met at this time:

    - **Certified analytical reference standards for Delta7-THC** (a fully synthetic and non-psychoactive cannabinoid) **are not commercially available at this time**.
    - Delta 10-THC (a fully synthetic cannabinoid) certified reference standards are available for two separate enantiomers: Delta 10 (6aR, 9S) which is not psychoactive, and Delta 10 (6aR, 9R) which is psychoactive. The Rule needs to clarify which enantiomer must be quantified.
    - "Delta 11" THC is not a recognized term in the current scientific literature. Provided that the term intends to describe THC with a double bond between carbon atoms 9 and 11, the correct nomenclature is "exo-THC." This requires clarification in the Rule as certified reference standards that are available for this compound are named "exo-THC."
    - The calculation provided for determining Total THC includes summing the concentrations of *"Delta 7-11 THCA."*

      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.

    It is recommended that this language be revised to allow 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 Rule set.

11. R420.305(9)(h) does not adequately define reporting units for CBD:

    "*For marijuana infused products, potency must be reported in milligrams of Delta-9 THC and CBD."*

    a. While this definition provides a *magnitude* (milligrams) it does not specify the *quantity* (per what?). Shall the quantity be milliliter of analytical solution, gram of product, serving, etc.? This needs to be clarified in the Rule.

    b. This sub-rule conflicts with R420.305(3)(a)(iii) and R420.305(9) in that it requires reporting individual test results for Delta 9-THC and CBD for infused products, while these analytes are defined as optional in R420.305(3)(a)(iii) and R420.305(9).

12. R420.305(18) states:

    "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 line that reads *"There are no established safety standards for this analysis"* should be omitted, as safety tests for beverages include a requirement to test for phytol.

13. **R420.305(21) is not enforceable as written and should not be included in the Rules.** Licensed laboratories are not equipped to nor otherwise required to identify unknown compounds of any type in product samples. In addition "potentially hazardous" and "potentially injurious to human health" are ambiguous, as any compound fits these terms" under the right conditions. Consider for example, that water is fatal if inhaled, and therefore fits the definition of "potentially hazardous" and potentially injurious to human health."

14. R420.305(22) conflicts with R420.305(12) and R420.305(13) as it requires reporting of STEC and Salmonella *"immediately"* without defining how that term compares with reporting *"within 3 days of test completion."* This sub-rule should be omitted.

15. R420.305a(2) should be revised to read"

    "Laboratories shall use microbial testing methodologies for the required safety tests in subrule R420.305 that are sourced from 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 J 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, per-reviewed, validated cannabis methods, method validation requirements of Appendix J of Official Methods of Analysis must be met in full with guidance from published cannabis standard method performance requirements where available. The agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts. All of the following apply to validated methodologies under this rule:"

    (Note: Appendix K is specific to analytical testing and Appendix J is specific to microbial testing.

16. R420.305b(2)(b) states:

    "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 validation studies."

    Lot-to-lot stability testing is not appropriate as a method validation requirement and should be removed from this sub-rule. For example:

    - Stability testing could be conducted on cannabis products. In this case, the stability testing is not appropriately included as a test method validation requirement; rather it is a product/ process validation item.
    - Stability testing could be conducted on perishable microbial test reagents. This is a reagent manufacturer item, and reagent expiration dates are provided with such reagents, not a method validation requirement.

17. R420.305a(6) states:

    Quality Control acceptance criteria must be published by the agency and be followed. If the method acceptance criteria are more stringent, then the method acceptance criteria ***are (sic)*** *required.****"***

    This should be changed to read: *Quality Control acceptance criteria must be published by the agency and be followed. If method-specific acceptance criteria exist, then the method acceptance criteria* ***are (sic)*** *required."*

    Quality control acceptance criteria currently published by the agency are known to exceed the capabilities of established, industry-accepted test methods, and are more stringent than criteria assigned to those methods by the method authors/ innovators.

    Accordingly, this rule will require licensed laboratories with established test methods to abandon those methods and seek or develop alternate methods that are likely not available. The cost of this may rise to the level that labs will opt to close rather than comply.

September 27, 2021

Shryne Group, Inc
728 E. Commercial St
Los Angeles, California 90012

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

Re: MRA Proposed Rules

To Whom it May Concern:

On August 27, 2021, the Michigan Marijuana Regulatory Agency (MRA) published proposed rules and regulations which provided clarity and consistency to those working in both the medical and adult-use markets. We are responding to the MRA's request for public comments.

Shryne Group Inc. is a Los Angeles-based cannabis holding company with a vertically integrated asset and license portfolio covering the breadth of California, the largest legal cannabis market in the world. We have 18 open retail locations across California with five more locations under construction and plans for 40+ locations open by the end of 2022. We have Cultivation, Manufacturing, and Distribution facilities in Humboldt County, Los Angeles, Oakland, and Lompoc. Shryne is composed of 2,200 employees across business lines. While rooted in California, we also sell products in Arizona, Nevada and Michigan.

Our flagship brand STIIIZY has a passionate following and is inspired by authentic cannabis culture, with the goal of providing the highest quality cannabis products at affordable prices. The STIIIZY product line is the #1 selling vape brand nationally, the #1 overall cannabis brand in California, and the #3 selling cannabis brands overall nationally.

With the foregoing in mind, we respectfully submit the following comments:

R 420.204 Operation at same location.

(3) Operation of a marihuana license at the same location that includes a licensed marihuana sales location ~~shall~~ must have the entrance and exit to the licensed marihuana sales location and entire inventory physically separated from any of the other licensed marihuana businesses so that individuals can clearly identify the sales entrance and exit.

(3)(a) shared entrances are permissible for co-located licenses that exclude a sales facility on the same location.

(4) Operation of marihuana licenses at the same location may include a combined space for the purposes of sharing common use areas, such as a bathroom, breakroom, hallway, shipping/loading bays, IT security storage or building entrances, in addition to complying with R 420.214a.

Rationale for revision:
We recommend that the agency develop and adopt rules to allow shared common areas of the property. Co-located or stacked licenses that occupy the same parcel of land should have the ability to share common use areas, such as bathrooms, breakrooms, hallways, shipping/loading bays, IT security storage, or building entrances. As it is written currently, the regulations have not yet adopted a text that permits this activity.

R 420.214c Product returns.

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

(h) A marihuana retailer may return marihuana flower products that are past its expiration date to a processor for the purposes of extracting the marihuana into marihuana concentrate.

Rationale for revision:
(g) We propose the addition of granting marihuana businesses the ability to return defective products to the originating marihuana producer. If a product is experiencing issues, such as malfunctioning hardware, processors should exchange the item for a non-defective version or grant marihuana businesses an option to exchange the defective product for another item of equal value.

(h) Marihuana sales facilities should have the ability to send expired marihuana flower products to a marihuana processor for extraction. Hydrocarbon extraction is an effective way to retrieve cannabinoids from flower that is dry or otherwise does not meet consumer standards for freshness.

R 420.214a Internal analytical testing.

(d) Internal analytical testing may be performed ~~only~~ on a product grown, harvested, or processed by licensees ~~under common ownership.~~ registered under the Acts.

Rationale for revision:

We propose that this provision be struck from the text and allow licensed entities to conduct internal analytical testing regardless of ownership. The cost-feasibility and infrastructure needs pose challenges for all licensees to add this benefitted feature of internal testing into their operations. Furthermore, since regulatory compliance testing is already a mandatory requirement that all marihuana products must pass, internal laboratories should have the ability to perform R&D tests for non-affiliated parties. For this purpose, R 420.112a (1) should apply to this section, allowing licensees to contract with non-affiliated parties to establish agreements for internal testing.

R 420.509 Internal product samples.

(7) A licensee shall ~~have~~ ensure internal product samples are tested pursuant to R 420.304 and R 420.305 before transfer to its employees, if previous testing requirements have not already been met in R 420.508 (5).

Rationale for revision:
The regulation as currently written is ambiguous in its language. One interpretation of the text suggests that an internal sample must be tested twice before being transferred to an employee. Per the regulation definitions, the agency intended that trade samples become internal product samples upon transfer to another marihuana business. By this logic, the receiving marihuana license should have already had its internal product samples tested before it was transferred as a 'trade sample' in the statewide monitoring system. This would imply that all testing requirements have already been met, as listed in R 420.508 (5). We propose that if a product was previously tested in its final form and has already met all requirements listed in R 420.508 (5), then the original test results should suffice requiring no additional testing be made from a receiving licensee. As such, we recommend that R 420.509 (7) be reworded to say that the licensee must 'ensure' the internal product sample has already passed regulatory compliance testing.

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

~~(1)(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."~~

Rationale for revision:
The addition of this warning will significantly challenge producers' ability to adequately house all statements, particularly on smaller packages, such as concentrates in small jars. We agree that this message should be conveyed to the consumer to further public safety but considering its length and the other warning statements that must be applied to all cannabis products, it would be more effective and better housed on the pamphlet described in 420.504 (4) or by granting

licensees the ability to include supplemental labels including hang tags or inserts affixed to the package.

R 420.303 Batch; identification and testing.

(6) A cultivator may transfer or sell fresh frozen or whole-plant harvest 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.

Rationale for revision:
The agency should expand the language in R 420.303 to include whole-plant harvest cannabis biomass. Cultivators may choose to utilize whole-plant harvesting techniques without immediately freezing the crop. The treatment of both fresh-frozen and non-frozen whole-plant harvested crops should be the same.

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

(3) Marihuana-infused products that failed testing for Aspergillus are ineligible for remediation.

Rationale for revision:
Remediation of Aspergillus from marihuana flower should be permitted if the remediation activity is hydrocarbon extraction. Technology exists today to successfully remove Aspergillus if marihuana biomass is extracted into a marihuana concentrate. Remediation using hydrocarbon extraction is an effective method to remove microbial contaminants from marihuana biomass and allows the industry to recover lost costs by converting marihuana into a concentrate.

R 420.303 Batch; identification and testing.

(6) A producer that received a package under this rule that has not been ~~processed~~ extracted may transfer that package to another producer without having the package first tested by a laboratory to produce live resin or concentrate with agency approval.

Rationale for revision:
In the previous sentence, the word 'processed' was struck from the text and amended to use the word "extracted". For consistency purposes, the word "extracted" should be used throughout this subsection.

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

(d) Not produce edible marihuana products in the distinct shape of a human, animal, or fruit, or a shape that bears the likeness or contains characteristics of a realistic or fictional human,

animal, or ~~fruit~~, including artistic, caricature, or cartoon renderings. Edible marihuana products that are geometric shapes and fruit flavored are permissible.

(e) Not package an edible marihuana product in a package that bears the image, likeness, or contains the characteristics of commercially available food products. Edible marihuana packages that depict fruits are permissible.

Rationale for revision:
The prohibition of the depiction of fruit on an edible product's packaging is inconsistent with a producer's ability to create simple fruit-flavored products. Fruit is not inherently attractive to minors and including it on an edible product's packaging only serves to better inform the consumer and strengthen public confidence. The safeguards in place listed in R 420.504 & R 420.403 are robust and restricting the depiction of fruit does not further the deterrence of use by minors. Based on FDA product standards, it is our assertion that edible cannabis products are not considered food and are more akin to dietary supplements, which permit the depiction of food/fruit. Furthermore, the Marijuana-Infused Edibles: Enforcement Guidance advisory bulletin from August 2, 2021, specifically uses an example of edible packaging that depicts alcohol as an acceptable package, which is unequivocally more attractive to teenage minors than strawberries or blueberries. Considering current market conditions and the vast number of edible products available that depict fruit on their packaging, we respectfully question how this regulation is effectively enforced and why fruit is specifically listed, leaving producers to interpret regulations to mean the depiction of other food is permissible.

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

(7)(a) The name of the marihuana-infused product~~. The name of the product must be an appropriately descriptive phrase that accurately describes the basic nature of the product.~~ that includes a product modifier such as "marijuana product", "THC product", or "cannabis product" using the same or larger font.

Rationale for revision:
In relation to Advisory Bulletin 'Marihuana-Infused Edibles: Enforcement Guide" published on August 2, 2021, the agency needs to adopt similar language to state that a name modifier (i.e. THC, Marihuana, or Cannabis) of equal or greater text size is a mandatory requirement for all marihuana-infused edible packaging. Adding this addition to the regulations will provide licensees the necessary information to ensure they are in compliance. Furthermore, it will reduce the percentage of non-compliant marihuana-infused edible marihuana products that exist in the market today. Adding this revision will benefit marihuana licensees from having to repackage, sticker, or destroy non-compliance products as deemed by the agency.

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

(2) Marihuana-infused products processed under these rules must be homogenous. The allowable variation for weight and THC and CBD concentrations between the actual results and the intended serving is to be + or – 15%.

Rationale for revision:
The Allowable Potency Variance in Packaging of Marijuana-Infused Products technical bulletin from June 22, 2020, is inconsistent with R 420.403 (2). For consistency and clarification purposes, the bulletin should be revised to align with the allowable 15% variance. This will reduce the opportunity for confusion amongst procedures, retailers, and the consumer. In addition, R 420.404 referenced in the bulletin needs to also match the 15% variance, as listed in R 420.403(2).

R 420.602a Prohibitions.

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

Rationale for revision:
Employees who are not exercising direction or control of a license should be authorized to work for multiple license types. Owners and shareholders are disclosed to the Department and are correctly scrutinized to ensure they do not have a mutually beneficial relationship in conflicting license types. Hourly employees are not exercising direction or control of the license and have zero motivation to perform any illegal actions that would jeopardize the license or their own employment. The licensee is required to implement strict procedures and controls to prevent diversion or illicit activity. As such, non-owner employees should be authorized to work for multiple license types since there is no competing interest.

R 420.4 Application requirements; financial and criminal background.

(3) ~~Each applicant shall disclose all shareholders holding a direct or indirect interest of greater than 5%, officers, and directors in the proposed marihuana establishment.~~ Each applicant shall disclose the identity of every person having a ~~2.5~~ 5% or greater ownership interest in the applicant with respect to which the license is sought.

Rationale for revision:
The proposed 2.5% in ownership interest is a low threshold and should remain at 5%. Furthermore, subsection (3)(c) lists 5% for publicly held corporations. The percentage should be consistent throughout the regulation.

MRA Bulletins Comment

MRA Bulletins found on the agency's website are sometimes inconsistent with the regulations. We acknowledge that advisory and technical bulletins disseminated to the public are important to further elaborate on informing further detail and clarification regarding the rules. But when bulletins are used to create new rules, this can easily contradict regulations as written and does a disservice to all licensees. Significant information can be easily missed if not found, for example, the bulletin on name modifier requirements for marihuana-infused edible packaging. The agency's regulations must clearly be stated to address these requirements, if not this presents a bigger issue for licensees to remain in compliance. Moreover, it is critical that bulletins remain consistent with regulations on the rules the agency is enforcing. One example to note is the maximum THC concentration limits established by the agency which contradict with the rules set in R 420.403 (2), where the allowable variation for THC concentration is + or -15%. We ask that the agency work to align all advisory and technical bulletins with the current and proposed regulations so that licensees are aware of all requirements that need to be met.

Sources:

Public Hearing on Proposed Rules
Marihuana Operations
Marihuana Sale or Transfer
Marihuana Sample and Testing
Marihuana-Infused Products and Edible Marihuana Product
Marihuana Employees
Marihuana Licenses

Shryne Group appreciates the opportunity to comment publicly on the above and encourages the MRA to consider the above recommendations. If the MRA has any questions or requires additional information, please contact Andrew Hopkins (email: andrew@shrynegroup.com, phone: 480.747.3428).

Sincerely,

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