Arkansas Department of Health

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Governor Asa Hutchinson
Renee Mallory, RN, BSN, Interim Secretary of Health
Jennifer Dillaha, MD, Director

PUBLIC COMMENT REPORT
Proposed Rules Governing Medical Marijuana Registration, Labeling, and Testing

Public comment period expired April 20, 2022 at 9:00 a.m.
Public hearing held on April 20, 2022 from 9:00 a.m. to 10:00 a.m.

PUBLIC COMMENTS:

Storm Nolen
River Valley Relief
Received three written comments on March 21, 2022, March 23, 2022, and April 20, 2022

March 21, 2022: As a licensed cultivator, I wanted to point out that three of these proposed rules would have a substantial financial impact although the Financial Impact form was marked as though they did not[.] These changes would add more than $100,000 per year in increased costs to each of the licensed cultivators. 1) Testing for terpenes can add $100 to the cost of each sample test. Moreover, there are many cannabis-containing products where terpenes are not expected nor valued like in distillate or edibles derived from distillate. 2) Requiring that edibles be limited to 10mg of THC per package would result in a tremendous amount of unnecessary packaging given that the average current edibles package contains 100mg+ of THC. This would result in at least 10X more packaging needed for current edibles on the market. 3) Requiring that all concentrates and extracts add 'nutritional information' to the label is unnecessary and not helpful since those products are intended to be vaporized, with no nutritional value[.] Requiring this additional information on the extracts and concentrate labels will require larger labels and therefore larger packaging in order to comply with this proposed rule - this would also result in an unnecessary an significant financial impact to licensees and patients. The nutritional information requirement should be limited to edibles only.

March 22, 2022: In rule VII.D.a, it looks like there was a mistake in language used[.] It looks like it should read 'serving' instead of 'package' as most all edible packages sold in Arkansas contain 100mg of THC. Limiting edibles to 10mg per package would be untenable for patients and the industry.

April 20, 2022: I write on behalf of River Valley Relief Cultivation, one of the eight licenses medical marijuana cultivators in the State of Arkansas. We are glad to see improvements and updates to the rules, however, there are several proposed changes that concern us, changes we think will have a detrimental impact on the industry and ultimately on the patients of Arkansas. Here are a list of our comments: (1) Section IV(A)(3): Our recommendation: Strike a, b, and c. [of Section IV(A)(3)] Reasoning: These are unnecessary and burdensome requirements on patients that add to the cost and become a hurdle for patients who wish to access their medical cannabis. (2) Section IV(E)(1). Our recommendation: For patients with chronic conditions allow for the

issuance of cards with no expiration date. Reasoning: This will save patients the often onerous and always expensive chore of booking an appointment with their doctor every year and re-applying for their card on an annual basis. Especially for the low-income and elderly with chronic conditions, this would save them a lot of money and make their medicine much more affordable. (3) Section V(B)(1)(f). Our recommendation: (f) Change to 'customary or metric' units. Reasoning: Only one measurement is needed and only one measurement is common based on the product type. Changing this requirement will lead to less confusion when patients are reading product labels. (4) Section V(B)(1)(g). Our recommendation: Change to 'THC or CBD, if the product contains either of each. Reasoning: Many product types, like edibles, do not contain CBD. Requiring that CBD be listed takes up unnecessary space on the label and can appear to patients like the product is deficient. (5) Section VII(A)(e). Our recommendation: Eliminate the proposed requirement for terpene testing. Reasoning: Many edibles contain no terpenes, and this is an unnecessary expense that would most likely have to be passed on to patients. Each terpene test can cost upwards of $125 each. For many cultivators in the state, that expense could be in excess of $125,000 annually. (6) Section VII(D)(a) and (b). Our recommendation: Correct language to 'serving' instead of package. Reasoning: Most edibles currently on the market contain 100mg of THC per package. Changing this limit to 10mg per package would be almost unworkable. This would result in a terrible amount of over-packaging and increased expense to both patients and cultivators.

AGENCY RESPONSE:

The Arkansas Department of Health ("ADH") completed the Financial Impact form with the information available at the time. In response to public comments, ADH will review potential financial impact from updated testing and labeling requirements. ADH stressed the importance of consumer awareness of any additives or other ingredients in making these proposed changes.

The labeling requirements for terpenes are added to provide for greater consumer awareness of ingredients and additives. ADH determined that the consumer should be made aware of additional ingredients to the usable marijuana and edibles in the most informative manner possible. All added ingredients must be tested for and disclosed to the consumer. After receiving public comments, ADH has revised the labeling requirements to include those ingredients that are added to the product during the cultivation or processing phases.

In response to public comments, ADH has revised Section VII(D)(a) as follows: "Produced and sold with a standardized concentration of cannabinoids not to exceed ten (10) milligrams tetrahydrocannabinol (THC) per portion with an allowable variance of ±10% when testing." (emphasis added)

ADH proposed the label requirement to include "Nutritional information and all ingredients used to make the product including terpene." to provide greater consumer awareness and provide the consumer with the nutritional information in the most informative manner possible. ADH has revised the requirement as follows: "(l) All ingredients used to make edible products including terpenes;". ADH will continue to review the labeling requirements to avoid becoming overly burdensome to the cultivators and processors without infringing on the priority of consumer awareness.

ADH is not proposing any changes to Section IV(A)(3). All requirements for the physician issued written certifications under this Section of the Rules are outlined by Amendment 98 to the Arkansas Constitution and follow Arkansas law.

ADH is not proposing any changes to Section IV(E) regarding the expiration of the registry identification cards. Required expiration periods for the registry identification cards are outlined by Amendment 98 to the Arkansas Constitution and the Rules follow Arkansas law.

ADH is not proposing any changes to Section V(B) "Usable Marijuana Labeling Requirements". All established labeling requirements serve to properly inform the public of necessary information and promote greater consumer awareness, specifically utilizing multiple measurements and the most reasonably informative methods for ingredients and concentrations of active ingredients. Furthermore, if a product does not contain either THC or CBD, omission of any statement is less informative than explicitly stating that the product does not contain one or the other.

Dr. Brandon Thornton, Co-Owner and CEO
Steep Hill Arkansas
Received March 30, 2022.

1. Table 2. List of solvents and their action levels: We suggest leaving Ethanol on this list but exempting non-inhaled products from Ethanol testing. From a patient safety perspective, we should be testing inhaled products for Ethanol. However, Ethanol is safe for patients in cannabis products that come in a topicals, liquid, or edible matrix. 2. SECTION VII (A)(f): The draft regulations include a requirement that concentrates, infused products, and edibles must be tested for "Any additional ingredients used to make a final product". While the other requirements in this section are quality tests performed on cannabis products, "Any additional ingredients used to make a final product" doesn't describe a specific test. It is unclear if the request to test the sample for "any additional ingredients" or to make sure that all additional ingredients are tested for our quality requirements. The ADH has provided a list of specific analytes for Pesticides, Heavy Metals, Cannabinoids, and Solvents. If the intent here is to require that additional ingredients are subjected to quality tests, we would suggest including this language in (A); (A) A cultivation facility or dispensary must test every process lot of cannabinoid concentrate, extract or edible including any additional ingredients used to make a final product for use by a qualified patient prior to selling or transferring the cannabinoid concentrate, extract or edible including any additional ingredients used to make a final product for the following." 3. SECTION VII (D)(a): Amendment 98 and the Alcoholic Beverage Control Cannabis regulations limit food or drink to 10mg active THC per portion. The proposed ADH rules limit packages to 10mg active THC. We recommend remaining consistent and keeping the 10mg per portion limit in place. 4. SECTION V (C)(1)(I): Considering the limited space and font requirements on packaging, we are concerned that licensees will be unable to satisfy labeling requirements with the addition of a nutritional panel. Cannabis products are consumed in very small quantities with chocolate squares (40 calories each) representing the highest calorie product. Allowing an allergy warning instead of a nutritional label, allowing a reduction in font size, or allowing some information to be accessible by QR code could be a solution here.

AGENCY RESPONSE:

In the drafting and promulgation of the original proposed Rules Governing Medical Marijuana Registration, Testing and Labeling in Arkansas, ADH consulted with and incorporated similar rules under the State of Oregon. Oregon has since updated its solvent list and the proposed changes to Table 2 incorporate those changes.

ADH proposed the testing requirement to include "Any additional ingredients used to make a final product." to provide greater consumer awareness and the consumer with the ingredient information in the most informative manner possible. All additional ingredients to each product must be tested for and disclosed to the consumer.

In response to public comments, ADH has revised Section VII(D)(a) as follows: "Produced and sold with a standardized concentration of cannabinoids not to exceed ten (10) milligrams tetrahydrocannabinol (THC) per portion with an allowable variance of ±10% when testing." (emphasis added)

ADH will continue to review the labeling requirements to avoid becoming overly burdensome to the cultivators, dispensaries, and processors without infringing on the priority of consumer awareness. No changes to label requirements for font, size, and/or space are proposed at this time. While cultivators, processors, and dispensaries may and have utilized QR codes to provide additional information to consumers, not all consumers are able to or understand how to utilize a QR code, and therefore it is not an acceptable method to convey necessary information to the consumers, specifically cannot be used to replace the required information that must be included on labels to ensure consumer awareness of necessary and relevant information. Reducing the product and ingredient information down to an allergy warning is not sufficiently informative to the consumer. ADH has revised Section V (C) (1) to including "(n) Allergy warning for edible products." in addition to the ingredient requirement mentioned above.

Corey McBain
Individual, Pediatric Pallative Care Nurse
Received January 19, 2022

I am a Pediatric Palliative Care nurse here in Arkansas, and our team routinely sees the sickest and most medically complex children in all of Arkansas. I am writing on behalf of our patients and their families, who have encountered difficulties and barriers within the current legal framework by which Medical Marijuana ID cards are issued. We are hopeful that this issue can be addressed and changed in order to provide greater access to those in need. The primary issue we have identified is the requirement for minor children to obtain an Arkansas State ID. This necessitates a trip to the OMV for most of our kids, and this is creating a barrier to care for many of our patients. The most common reasons for this are: 1. The child is very ill- in some cases terminally- and is simply not well enough to leave their bed or place of comfort. They may have severe pain, nausea, vomiting, weakness or any number of other debilitating symptoms which prevent a trip to the OMV. 2. The child is immune compromised, and they are being kept isolated away from others in

an effort to prevent infection. An acquired infection for such a person can lead to death, and entering a public place like the OMV greatly increases this risk. 3. The child is medically complex, and may have many pieces of equipment such as a wheelchair, ventilator, IV etc. Often times these patients may only leave their home for essential medical visits, and the required trip to the OMV may be a hardship on the family. It is wonderful that we have access to Medical Marijuana in our State, but it remains important to identify and address existing barriers to care for patients who may benefit. Just within the last month we have cared for two patients who were affected by this issue; one is quite ill and has been unable to get to the OMV, and the other passed away prior to getting access because they were too sick to make this trip. It is wonderful that we have access to Medical Marijuana in our State, but it remains important to identify and address existing barriers to care for patients who may benefit. Just within the last month we have cared for two patients who were affected by this issue; one is quite ill and has been unable to get to the OMV, and the other passed away prior to getting access because they were too sick to make this trip. 1. In all cases where the Designated Caregiver is the parent of a minor child, use methods alternative to an Arkansas Photo ID to establish residency. 2. Add a section/ box to check on the Physician Certification form where the Provider can attest that it would be a medical hardship for the patient to obtain Photo ID. In this way, only certain applications would be processed via alternative means to establish residency. Making a change to the Photo ID rule would significantly benefit pediatric patients in the State of Arkansas, and remove an existing barrier to care. I am hopeful that this change can be made during the upcoming review, and look forward to hearing from your team in the future; please keep us apprised of any changes or updates relevant to this request. Thank you for your time and consideration.

AGENCY RESPONSE:

In review of Arkansas Constitution, Amendment 98, §5 (a), ADH is required to issue registry identification cards to qualifying patients and to qualifying caregivers. The requirement is that the applicant (whether it is the qualifying patient, individually, or a qualifying caregiver, such as a parent of a minor child, applying on behalf of a minor or incapacitated patient) provides the driver's license or identification card when applying for the registry identification card, and that a minor is required to obtain an identification card when the applicant is a qualifying caregiver for the patient regardless of age. However, ADH is proposing an additional provision that will allow ADH, on a case-by-case basis, accept alternative forms of identification upon receipt of satisfactory attestation by a medical profession that it is contraindicated to the health of the qualifying patient to obtain a state-issued identification card.

Bill Paschal
Arkansas Cannabis Industry Association
Received April 14, 2022; read into record during public comment hearing.

SECTION V (C)(l)(l): We agree that ingredient information on medical cannabis taken orally is important considering patients with food allergies. Considering the limited space available on packaging, we recommend adding a warning if the product contains ingredients known to cause common allergies in lieu of a complete ingredient list. Like medications available at pharmacies, a warning would provide allergy information for patients. An alternative would be to reduce the

required font size to get more information on the label. 1. SECTION V (C)(l)(l): Since cannabis products are consumed in very small quantities, we do not believe nutritional information would add enough benefit to justify the costs associated with calculating this data. The highest calorie product available in Arkansas are chocolate squares with a 10mg dose of THC. These squares are less than 40 calories. Considering the small amounts consumed, we do not believe requiring this information would be very beneficial. If ADH insists on providing nutritional information, we suggest a QR code on the label that patient may scan and get that information immediately. 2. SECTION VII (A)(f): The draft regulations include a requirement that concentrates, infused products, and edibles must be tested for "Any additional ingredients used to make a final product". While the other requirements in this section are quality tests performed on medical marijuana products, "Any additional ingredients used to make a final product" doesn't describe a specific test. It is unclear if the request to test the sample for "any additional ingredients" or make sure that all additional ingredients are tested for the quality requirements. The ADH has provided a list of specific analytes for Pesticides, Heavy Metals, Cannabinoids, and Solvents. Is the intent to require additional ingredients are subjected to quality tests (pests, metals, micro, etc)? If so, we suggest; (A) A cultivation facility or dispensary must test every process lot of cannabinoid concentrate, extract or edible including any additional ingredients used to make a final product for use by a qualified patient prior to selling or transferring the cannabinoid concentrate, extract or edible including any additional ingredients used to make a final product for the following." The way it is currently written, testing labs would need to confirm a product contains sugar, cocoa, or gelatin for example. Our testing experts do not believe that is possible. Analytical laboratories require standards for each analyte that is tested. A specialized instrument and validated methods are needed for each assay. While a lab would not be able to test for the presence of an individual ingredient, labs could test those ingredients for the quality tests required; pesticides, micro, heavy metals, and solvents. 3. SECTION VII (D)(a): Amendment 98 and the Alcoholic Beverage Control marijuana regulations the limit food or drink to 10mg active THC per portion. The proposed ADH rules limit packages to 10mg active THC. We recommend remaining consistent with ABC rules and Amendment 98 by keeping the 10mg per portion limit in place.

AGENCY RESPONSE:

ADH proposed the label requirement to include “Nutritional information and all ingredients used to make the product including terpene.” to provide greater consumer awareness and the consumer with the nutritional information in the most informative manner possible. ADH has revised the requirement as follows: “(l) All ingredients used to make edible products including terpenes;”. ADH will continue to review the labeling requirements to avoid becoming overly burdensome to the cultivators and processors without infringing on the priority of consumer awareness. Reducing the product and ingredient information down to an allergy warning is not sufficiently informative to the consumer. ADH has revised Section V (C) (1) to including “(n) Allergy warning for edible products.” in addition to the ingredient requirement mentioned above.

ADH will continue to review the labeling requirements to avoid becoming overly burdensome to the cultivators, dispensaries, and processors without infringing on the priority of consumer awareness. While cultivators, processors, and dispensaries may and have utilized QR codes to provide additional information to consumers, not all consumers are able to or understand how to

utilize a QR code, and therefore it is not an acceptable method to convey necessary information to the consumers, specifically cannot be used to replace the required information that must be included on labels to ensure consumer awareness of necessary and relevant information.

In response to public comments, ADH has revised Section VII(D)(a) as follows: "Produced and sold with a standardized concentration of cannabinoids not to exceed ten (10) milligrams tetrahydrocannabinol (THC) per portion with an allowable variance of ±10% when testing." (emphasis added)

Kyle Mayton, Senior Vice President for Compliance
Natural State Medicinals
Received April 19, 2022; read into record during public comment hearing.

When regulators clearly communicate their expectations and licensees clearly understand the rules and how they are interpreted, this program will function more efficiently. To that end, this letter expresses our understanding of the proposed rules, how they potentially impact our business and the industry, and the costs and effects of implementing them. Please consider this information for the public comment on the recently proposed Department of Health Rules. Several changes were made to the rules governing the labeling of usable marijuana. A subsection was added to the requirements for cannabinoid concentrates labels directing the inclusion of "[n]utritional information and all ingredients used to make product including terpenes." Section V.(C)(l)(l). First of all, adding this affects Section V.(D)(2)(c)(i) ("Statements required by subsections (C)(l)(l)(ii) and (iv) must be in at least 18 point."). Should the proposed Rules be approved as submitted, this subsection would not make sense. It would need to be changed to: "Statements required by subsections (C)(l)(m)(ii) and (iv) must be in at least 18 point." With that said, our paramount concern is the space needed to include this information given the container size of certain products. The information currently required is extensive and already difficult, from a logistical perspective, to include on these labels. Requiring licensees to include nutritional information and all ingredients used would be all but impossible to fit on these labels. There is a subsection that addresses the issue of container size. It states that licensees must include the information required on a principal display panel, the business or trade name, the license number, Unique Identification Number (UIN), concentration of THC and CBD, and the four required warning statements on the container that contains usable marijuana, but they may include all other label information on an outer container or package or a leaflet. Section V.(D)(4). The packaging we use is selected with great care and expense. It is not intended to be packaged in an outer container or package. As such, we would have to either print labels that the dispensary would be required to place on the outside of a child proof container or bag, or we would have to print leaflets that must accompany the product. Each unit of product. The printing of hundreds of thousands of these leaflets or labels every year would cost our business well over one hundred thousand dollars ($100,000) in labor and equipment alone. And this would be the least costly option. Another option is purchasing new packaging, which would surely be prohibitive. Additionally, due to the current state of the supply chain if we were to order new packaging it would not arrive by July 1. Along with significantly increased prices, fulfillment time for our consumable goods has ranged from six to fifteen months. Also, we feel that the language in this subsection is vague, unclear, and unnecessary. We are unsure what the department expects here. Will we be required to use the FDA Nutrition Facts label that we see

on food products? Will the approved, licensed labs that test usable marijuana for pesticides, solvents, water content, etc. be required to determine these levels? As you know, we cannot send these products to an entity that is not licensed, so determining levels of nutritional content by an accredited lab may not be feasible. But if we could, the increased costs associated with testing the levels of nutritional content of products would be much more than one-hundred thousand dollars ($100,000). See ESHA Ebook at https://esha.com/wpcontent/uploads/20 I 4/ 12/ESHA-Obtaining-Nutritional-Analysis-eBook.pdf (lab analysis averages about $800 - $1,000 per sample). We transferred over 2,000 samples of cannabinoid concentrates, extracts, and edibles to labs for testing in 2021. Using these figures, this would increase costs by $1.6 to $2 million. Additionally, considering the serving sizes and the miniscule amount ingested by a patient, there is no need to include this information because it has a negligible effect on a patient's daily dietary intake. As previously stated, the labor and equipment necessary for generating and printing these labels or leaflets would likely exceed this figure alone. Considering the expense for testing specific levels of nutritional content within our final products, if the Department required this level of specificity, further demonstrates that compliance with this rule will exceed the threshold cost requiring a Financial Impact Statement. Because of the increased expense and the vague language, we respectfully request that this subsection be removed and revised. The other change within Section V. pertaining to labels was the addition of language to proscribe the use of a QR code in lieu of the information required. It reads, "A label may not: Be replaced by a QR code." Section V.(D)(7)(C). While we understand the reason behind including this (some people do not have smartphones, although that is a small percentage), we believe that it may discourage licensees from using QR codes on their labels. This would be detrimental to patients and the program. These provide the patients a portal to potentially obtain a great deal more information than could ever fit on a label. For example, our QR codes direct patients to the Steep Hill Certificate of Analysis, which provides more details about test results. Moreover, allowing licensees to use QR codes would alleviate costs for the inclusion of certain information, like terpene profiles, that is difficult to include within a label. We will continue to use QR codes to augment our labels and hope that others in the industry do so as well. Other proposed changes affect the testing of usable marijuana. Two subsections were added to mandate the testing of terpenes and "Any additional ingredients used to make a final product[.]" Section VII.(A)(e) & (f). The latter raises several questions. As previously discussed, will the approved, licensed labs be required to test for these ingredients? Are these labs able to detect and identify all compounds that may be considered an ingredient? We want patients to know what they are ingesting so they can avoid allergic reactions and ensure their health and wellbeing is not at risk. Rather than this broad language that is impracticable, we recommend requiring language that alerts patients to specific ingredients that may cause such reactions or adversely affect their diet. Just as the testing that may be required to list the nutritional content on our labels, this subsection could result in added costs that exceed the threshold amount requiring a Financial Impact Statement. Due to the vague, broad language and potential expense, we respectfully request that this subsection be removed and revised to clarify its intended meaning. NSM tests all of its flower and a good deal of marijuana infused products for terpenes; however, this rule would require testing for terps on all products, which would greatly increase costs. Moreover, there are other operators that do not test for terpenes in the same manner. This requirement would likely result in increased costs of over one-hundred thousand dollars ($100,000) for those licensees in the form of testing fees. We recommend requiring terpene tests for only products that are inhalable. A subsection was added that addresses additional requirements

for edibles. Therein, it states that they must not exceed ten (10) milligrams of THC per package. Section VII.(D). Enforcing the rule as written would effectively halt sale of all edibles in the state as essentially all packages contain more than ten (10) milligrams of THC. Moreover, this subsection conflicts with the language in Amendment 98 and the Alcoholic Beverage Control Division's Rules. Edibles shall not exceed ten (10) milligrams of THC per portion, not per package. Therefore, we request that this subsection be removed and revised to comport with the language in Amendment 98 and the ABC's Rules. As you are aware, the tests performed by our approved, licensed labs are exhaustive and, for that reason, expensive. Moreover, the tests performed meet and exceed the standards for testing food products to ensure their safety. Thus, including all nutritional content is unnecessary to protect the patients. To reiterate, requiring the inclusion of more information on labels is impracticable due to the size of certain products and their packaging, and mandating that no more than 10mg of THC per package is an impossible standard that conflicts with the Arkansas Constitution. And the language prohibiting the use of QR codes to replace a label is not needed and may discourage the use of QR codes in conjunction with the required information printed on display labels. We request that the subsections pertaining to the inclusion of nutritional information and additional ingredients on the labels be removed; the subsection requiring testing of terpenes and any additional ingredients be removed; and the subsection requiring edible packages not to exceed ten (10) milligrams of THC be removed. Since these amended Rules, as proposed, will cost businesses that operate cultivation facilities or dispensaries at least one hundred thousand dollars ($100,000) per year, a Financial Impact Statement should have been included. Ark. Code Ann. §25-l 5-204(e)(4)(A). The original ADH Rules and Regulations, adopted by the Board on April 27, 2017, included a Financial Impact Statement. It stated that the testing and labeling standards "could cost ... approximately $1,000,000." It also stated that the Department "expects to raise approxiamtely [sic] $1,500,000 from fees paid by registrants." In fact, these standards resulted in costs exceeding that estimate. We spent over $2 million on packaging and over $800,000 on testing. Satisfying the subsection in the APA that requires agencies to address alternatives submitted at public comment, the Department stated that it "will consider larger batches in the future should it be determined to be a [sic] safe and effective." It has been nearly five years since these rules were adopted and reviewed by the Legislative Council. Rather than waiting to review just at ten (10) years out, as required under the APA, we think this should be considered now. Therefore, we petition the Board to amend this overly burdensome and costly, arbitrary, and inefficient rule as soon as possible. We surveyed other medical marijuana programs (currently in thirty-seven states) and discovered that a maximum weight limitation for batches is found only in a minority of jurisdictions (Alaska, Delaware, Missouri, North Dakota, and Ohio). With that in mind, we will briefly examine why it should be amended. Burdensome rules exist, more so in some jurisdictions than others, but that is not a sufficient reason to amend them. If the burden is outweighed by the benefit - safety, security, transparency - then it should stay in place. But if it is overly burdensome and there are less costly methods that produce similar or identical results, amending the rule must be considered. There is no articulable reason or scientific evidence that definitively determines that a ten (10) pound batch is the safest. It is certainly not the most efficient or least costly standard. This unnecessary burden is inadvertently passed on to the medical patients. Obviously, we must balance competing interests. We do not want to sacrifice safety to save costs; we do not want to save time if that sacrifices security or transparency. Looking at this from that perspective, a homogenized batch of a single strain from the same harvest, cut down and cured at the same time using the same methods does

not need to be divided into ten (10) pound batches to ensure the safety of the patients, nor does it promise more accurate test results. Any difference in these batches is extremely minimal. For that reason (as well as saving time, avoiding inefficiencies, and reducing cost to patients), other jurisdictions allow labs to take samples from the total weight of the strain from a particular harvest. We recommend that Arkansas follow suit, while keeping the 0.5% testing requirement and removing the limit on weight of batches. This would require greater amounts being sent to testing, commensurate with that which would go if we kept the ten (10) pound batches. It would then be in the hands of our accredited labs, who are in a better position than any of us, to determine how much they needed to test to get an accurate representation that would best serve the patient and the program as a whole.

AGENCY RESPONSE:

ADH will continue to review the labeling requirements to avoid becoming overly burdensome to the cultivators, dispensaries, and processors without infringing on the priority of consumer awareness. No changes to label requirements for font, size, and/or space are proposed at this time. While cultivators, processors, and dispensaries may and have utilized QR codes to provide additional information to consumers, not all consumers are able to or understand how to utilize a QR code, and therefore it is not an acceptable method to convey necessary information to the consumers, specifically cannot be used to replace the required information that must be included on labels to ensure consumer awareness of necessary and relevant information.

ADH proposed the testing and label requirement to include "Nutritional information and all ingredients used to make the product including terpene." to provide greater consumer awareness and the consumer with the nutritional information in the most informative manner possible. ADH has revised the requirement as follows: "(l) All ingredients used to make edible products including terpenes;". ADH will continue to review the labeling requirements to avoid becoming overly burdensome to the cultivators and processors without infringing on the priority of consumer awareness.

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In response to public comments, ADH has revised Section VII(D)(a) as follows: "Produced and sold with a standardized concentration of cannabinoids not to exceed ten (10) milligrams tetrahydrocannabinol (THC) per portion with an allowable variance of ±10% when testing." (emphasis added)

In response to public comments and review of other similarly situated states' rules, ADH is proposing to amend the limits on batch sizes to 50 pound batches.

Annie Iselin, Senior Director of Operations
BOLD Team, LLC
Received April 19, 2022

Section Y Labeling[:] Most of what has been proposed is vague and difficult to follow. Nutritional Information -As written, it is unclear how this requirement will apply to concentrates and extracts. Although we understand the benefit of supplying nutritional information on ingested products, there is no need or benefit of doing so for concentrates and extracts. Additionally, if enacted, it is unclear as to which ingredients will be required to test and list. We ask that, if we are required to display nutritional and ingredient information for end products, that the rule: a. only apply to edible products that are ingested, and, b. Further clarification be provided as to what exactly needs to be tested and what information must be supplied. The cost our business would incur from the nutritional analysis, alone, would greatly exceed $100,000.00 annually. Additionally, the cost for the physical nutritional label on our products would also be in excess of $100,000.00 annually. The requirement to perform terpene analysis for every product is unnecessary, overburdensome, and unclear. If terpene tests are required, it should only be required on products that are inhaled. Additionally, if terpene tests are required, clarification is required as to which terpenes need to be tested and which ones must be displayed. It's possible for nine to fifteen different terpenes to be present in a single product. However some of them are in near zero amounts. A compromise that would be more effective would be a requirement to list the three terpenes that are found to be most prevalent in the product. Not only is it not necessary to list every single terpene, it's logistically not possible due to the real estate available on child resistant packaging. One simple solution would be to allow for the use of a QR code that would direct patients to the analytical report created by the laboratory, and at current the proposed rules specifically prohibit this. The cost to our business associated with performing the proposed terpene analysis would exceed $100,000.00 For your review, I've attached the Packaging and Labeling Review Facility Worksheet from our neighbors in Missouri. Missouri, similar to Arkansas, has a tightly regulated industry, yet does not require this information to be placed on the packaging. We acknowledge that there have been requests by patients to have access to this information, but it is our opinion that this should be left to operators choice and not mandated by the regulatory body. If these proposed rules are adopted, the industry would require more time to comply than the current July deadline. My organization alone uses over 20 different packaging styles. We currently have in excess of $500K of custom labeled packaging in stock. Due to the current supply chain constraints that are affecting individuals and businesses around the globe, it is unlikely that we would be able to obtain new packaging that would comply with these proposed rules in a timeframe that meets the current requirements. The design, manufacturing, and shipment of packaging that meets the already stringent requirements can take anywhere from six to eighteen months to complete in today's climate. With that being the case, if these rules are adopted as currently written, I don't see how any operation could be in compliance prior to January 2023. Additionally, I find it necessary to point out that the increased size of the packaging would add significant constraints for dispensaries safe and secure storage of the product. Our state already has some of the most stringent requirements for testing in the nation. Although required it is stringent and excessive regarding the standards nationwide, and results in an overburdensome, unnecessary cost to the patients. Requiring terpene tests for concentrates would have a significant financial impact to our organization. Although we don't wish to negatively impact the testing facilities' revenue stream, it is our understanding that terpene testing is a

complicated, expensive analysis with little to no margin for the analytical laboratories that would be performing the tests. We'd like to reiterate that labeling real estate is extremely scarce under the current rules and we have a great deal of concern about how we would be able to facilitate the placement of the additional required information. We certainly want our patients to be informed about the products they are using, however we believe that due to the sheer amount of text that would be present on a label, that the more relevant information would be overlooked. Changes to the batch size Although not referenced in the proposed rule changes, a modification to the batch size limitations is crucial. We are currently restricted to batch sizes of ten pounds. This creates a significant unnecessary financial burden to our organization and in turn to the patients, without any increase of safety or accuracy. The different results produced for these various batches are negligible. In our process, we grow considerably more than ten pounds of a single strain that is planted, grown, harvested, and cured at the same time, in the same manner. For example, if we harvest 821bs of a single strain, we divide it into nine batches with nine different "parent UINs". We then have to take and pay for nine different samples to be tested, that will ultimately yield the same results. This burden increases the cost nearly ten times with no real benefit to the patient. We recommend that the requirement for batch sizes be removed entirely. This would allow for more testing to be affordably performed, such as terpene content.

AGENCY RESPONSE:

ADH proposed the testing and label requirement to include “Nutritional information and all ingredients used to make the product including terpene.” to provide greater consumer awareness and the consumer with the nutritional information in the most informative manner possible. Any additional ingredients should be tested for and disclosed to the consumer. ADH has revised the requirement as follows: “(l) All ingredients used to make edible products including terpenes;”. ADH will continue to review the labeling requirements to avoid becoming overly burdensome to the cultivators and processors without infringing on the priority of consumer awareness.

The labeling requirements for terpenes are added to provide for greater consumer awareness of ingredients and additives. ADH determined that the consumer should be made aware of additional ingredients to the usable marijuana and edibles in the most informative manner possible.

ADH will continue to review the labeling requirements to avoid becoming overly burdensome to the cultivators, dispensaries, and processors without infringing on the priority of consumer awareness. No changes to label requirements for font, size, and/or space are proposed at this time. While cultivators, processors, and dispensaries may and have utilized QR codes to provide additional information to consumers, not all consumers are able to or understand how to utilize a QR code, and therefore it is not an acceptable method to convey necessary information to the consumers, specifically cannot be used to replace the required information that must be included on labels to ensure consumer awareness of necessary and relevant information.

In response to public comments and review of other similarly situated states’ rules, ADH is proposing to amend the limits on batch sizes to 50 pound batches.

Kyle Felling, Ph.D, Owner/Laboratory Director
F.A.S.T. Laboratories
Received April 20, 2022

1. If terpenes become a required test, we need a "minimum" list of terpenes to test for. There are 100s out there, but typically only 10-15 are common in cannabis. I would recommend the 23 terpenes that are considered "medical cannabis" terpenes. 2. There needs to be clarification on page 14 where it states "any additional ingredients ... " . Does that mean sugar if sugar is added? There are a lot of additional ingredients in edibles that are benign and should not have to be tested. However, if melatonin, caffeine, etc ... is added then I do believe those need to be analyzed. 3. On page 14, Section Vil (D}(a), I believe it should state 10mg THC per dose and not per package. However, please consider that some patients require higher dosages and the 10mg limitation requires them to purchase much more product. Please consider raising the minimum per dose to 20-25mg. 4. Please consider removing additional residual solvents. Many of these, no one, short of a chemist, even knows what they are. In addition to the ones already proposed to be removed, I would add ethylene oxide and 2-ethoxyethanol. 5. Please also consider adding yeast/mold to the microbiology requirements. This is the largest problem in cannabis flower, not E. coli. ..

AGENCY RESPONSE:

The labeling requirements for terpenes are added to provide for greater consumer awareness of ingredients and additives. ADH determined that the consumer should be made aware of additional ingredients to the usable marijuana and edibles in the most informative manner possible.

ADH proposed the testing and label requirement to include “Nutritional information and all ingredients used to make the product including terpene.” to provide greater consumer awareness and the consumer with the nutritional information in the most informative manner possible. Any additional ingredients to the products must be tested for and disclosed to the consumer. ADH has revised the requirement as follows: “(l) All ingredients used to make edible products including terpenes;”. ADH will continue to review the labeling requirements to avoid becoming overly burdensome to the cultivators and processors without infringing on the priority of consumer awareness.

In response to public comments, ADH has revised Section VII(D)(a) as follows: “Produced and sold with a standardized concentration of cannabinoids not to exceed ten (10) milligrams tetrahydrocannabinol (THC) per portion with an allowable variance of ±10% when testing.” (emphasis added)

ADH reviewed the guidance for concentration limitations for edibles and the need to provide guidance where none existed in the State previously. With input from the Alcoholic Beverage Commission, ADH determined that 10mg is the appropriate limitation.

ADH has not proposed any changes regarding testing requirements for mold and/or yeast. ADH will review and make recommendations for changes under the subsequent rule promulgation process, if required.

Sean Clarkson, General Counsel
Dark Horse Medicinals
Received April 19, 2022

1. Processing Facilities - Processing facilities are not contemplated by the current or proposed rules. The same rules that apply for cultivation facilities and dispensaries should also be extended to processing facilities. 2. Intermediate Products - There are currently different standards for testing intermediate products depending on the type of facility. This is caused by wording in Section VI that does not allow a grower of marijuana to transfer until all applicable testing is completed. Additional tests that do not add value to the consumer are required in order to send that usable marijuana to a third party for processing/product creation. These same tests are not required if the product creation is done in-house. Regardless, in both cases, testing is required on the batches of end product, which is ultimately what protects the patient. The rules should allow transfer of marijuana that is intended for processing without the same standard of testing as usable marijuana for sale to the patient. 3. Producer/Manufacturer Name and License Number Requirement - For concentrates/extracts/edibles, the manufacturer should be the only name/license required on the label. This is not clear from the current reading of Section V (C)(1)(a). The source of the raw material is irrelevant for the consumer, but it is already tracked through BioTrack. 4. General Labeling Requirements - The labeling requirements are overly burdensome. The amount of information required on a package that should be able to fit in a patient's hand is nearly impossible. The ADH should decide which information is vital for the label and all other information should be available via a QR code or the manufacturer's website. 5. Arranging Tests at Another Facility - Section VI (C)(4) provides a path for cultivation facilities to transport product and arrange for testing at another facility. This should be extended to all facilities. 6. Terpene Testing - Requiring a terpenes test for all products (usable marijuana and edibles/extracts/concentrates) does not provide value for patient health and safety. However, it does increase the costs associated with each batch, thereby raising prices for the patient. A compromise would be to require lab testing for terpenes when the label/manufacturer makes a claim that certain terpenes are included in the product. A standard test is not necessary. 7. Nutritional Information for Edibles - We agree that edibles should include nutritional information on the label. However, a lab test for each batch of edibles for all ingredients is another burdensome requirement that doesn't provide value. As with most all food manufacturing, the ingredients in an edible should be maintained in a company's SOPs and the company should perform routine QA to ensure compliance. A required ingredients test for every batch is overly burdensome and doesn't do anything but add cost to the patient. 8. 10mg per serving - Rule D in Section VII is completely incorrect. The 10mg THC concentration should be implemented per SERVING and not per PACKAGE. 10mg THC per serving would conform to the Amendment, current ABC rules, and standard industry practice in all states. 9. Batch Requirements - Rule (A)3 in Section VIII should be removed. By requiring individual testing for THC/CBD, this nullifies the intent of the exception in (A)2. All batches will be combined for processing and the THC/CBD content is irrelevant. The only relevant THC/CBD percentage is in the extract/concentrate/edible produced from the processing lot. From a practical standpoint, this prevents a grower from transporting any marijuana using the (A)2 testing exception and requires individual batch testing.

AGENCY RESPONSE:

ADH began a discussion how these Rules affect processors and has been in discussion with processors and other state agencies to determine the best method to amend the Rules to account for processors more efficiently and without unnecessary burdens on the industry. Based on public comments, ADH is proposing changes to accommodate processors and the changes in the industry since the original Rules were promulgated.

ADH will continue to review the labeling requirements to avoid becoming overly burdensome to the cultivators, dispensaries, and processors without infringing on the priority of consumer awareness. No changes to label requirements for font, size, and/or space are proposed at this time.

The labeling requirements for terpenes are added to provide for greater consumer awareness of ingredients and additives. ADH determined that the consumer should be made aware of additional ingredients to the usable marijuana and edibles in the most informative manner possible.

ADH proposed the label requirement to include "Nutritional information and all ingredients used to make the product including terpene." to provide greater consumer awareness and the consumer with the nutritional information in the most informative manner possible. ADH has revised the requirement as follows: "(l) All ingredients used to make edible products including terpenes;". ADH will continue to review the labeling requirements to avoid becoming overly burdensome to the cultivators and processors without infringing on the priority of consumer awareness.

ADH will continue to review the labeling requirements to avoid becoming overly burdensome to the cultivators, dispensaries, and processors without infringing on the priority of consumer awareness. While cultivators, processors, and dispensaries may and have utilized QR codes to provide additional information to consumers, not all consumers are able to or understand how to utilize a QR code, and therefore it is not an acceptable method to convey necessary information to the consumers, specifically cannot be used to replace the required information that must be included on labels to ensure consumer awareness of necessary and relevant information.

In response to public comments, ADH has revised Section VII(D)(a) as follows: "Produced and sold with a standardized concentration of cannabinoids not to exceed ten (10) milligrams tetrahydrocannabinol (THC) per portion with an allowable variance of ±10% when testing." (emphasis added)

In response to public comments and review of other similarly situated states' rules, ADH is proposing to amend the limits on batch sizes to 50 pound batches.

Erika Gee, Attorney with Wright, Lindsey, & Jennings, LLP
on behalf of Good Day Farm Arkansas, LLC and Capitol City Medicinals, LLC
Received April 19, 2022

Section III(38)(3) of the proposed rules revises the previous definition of "written certification." Specifically, the proposed rules remove the prohibition on issuance of a written certification based

on "an assessment performed through telemedicine" and update that to state that that a physician may not issue a written certification based on an "initial assessment performed through telemedicine." However, these proposed revisions continue to conflict with the requirements of Act 1112 of 2021 ("Act 1112") as codified in Ark. Code Ann. § 17-80-401, et seq. Act 1112 became effective on July 28, 2021, but its provisions are still not being followed by ADH, nor are they incorporated into these revised rules. As set out below, this refusal is contrary to Arkansas law and is presently causing harm to our client, as well as thousands of Arkansas residents who rely upon certifications from physicians for their medical use of cannabis. Act 1112 provides for the issuance and renewal of written certifications. Act 1112 expressly defined the term "telemedicine" to provide as follows: "'Telemedicine' does not include the use of audio-only electronic technology by a physician to renew a written certification that was previously issued to the same patient." Thus, it was the General Assembly's clear directive that the renewal of a written certification through audio-only electronic technology is not prohibited by the §2, 19(C) of Amendment 98. Act 1112 of 2021 additionally provides that the initial written certification for issuance of a registry identification card under Amendment 98 may be issued by a physician through a "telehealth certification" as that term is defined. Specifically, Act 1112 defines "telehealth certification" to mean "the electronic assessment of a patient by a practitioner in connection with an application for a registry identification card under §5 of Arkansas Constitution, Amendment 98, also known as the Arkansas Medical Marijuana Amendment of 2016." Despite these clear directives from the General Assembly, these proposed rules continue to fail to fully incorporate the law as set out in Act 1112. Specifically, these proposed rules are contrary to Act 1112 in the following aspects: • The proposed rule does not recognize or incorporate Act 1112's authorization to obtain an initial assessment for a written certification through a telehealth certification. In fact, the proposed rule completely ignores that aspect of the Act. • Act 1112 authorizes the use of audio-only technology for renewal of a writ ten certification. These proposed rules also do not incorporate or acknowledge that method of certification. • The proposed rule instead directs physicians to "comply with Arkansas State Medical Board rules specific to Medical Marijuana physician written certifications." However, as of the date of this comment, no such rules have been written or promulgated by the Arkansas State Medical Board. This portion of the proposed rule therefore has the effect of prohibiting physicians from certifications that are in compliance with Act 1112 by specifically requiring adherence to non-existing rules. In sum, these proposed rules do not incorporate or comply with the provisions of Act 1112 of 2021 and, as such, we object to their promulgation as proposed.

AGENCY RESPONSE:

In response to public comments, Arkansas Department of Health ("ADH") has revised Section III(38)(3) as follows: "A physician shall not issue a written certification to a patient based on an initial assessment performed through telemedicine. Physicians must comply with the Arkansas State Medical Board rules specific to Medical Marijuana physician written certifications." The Board of Health does not regulate the practice of medicine and must, by Arkansas law, defer to the rules and requirements promulgated the by Arkansas State Medical Board regarding telemedicine and physician written certifications for medical marijuana.

Erika Gee, Attorney with Wright, Lindsey, & Jennings, LLP
on behalf of Green Cross Cannabis Dispensary, LLC d/b/a Spring River Dispensary
Received April 19, 2022

1. Labeling and Testing Requirements for Edible Products Should Be Separated from Other Products. The proposed rules add "edibles" for the first time, which is a welcome clarification. However, because edible products are significantly different in both form and function than concentrates and extracts, we submit that the labeling and testing rules for edibles should stand alone. For example, it is nonsensical to require concentrates to include nutritional information. Similarly, it is unduly burdensome and duplicative to require edibles to be tested for pesticides, solvents and heavy metals, as the component parts would have been tested prior to manufacturing of the edible product. Requiring lab tests that do not have any application to that particular product type does nothing to serve the public health and it drives up the costs of production, which ultimately is passed on to the patient. We believe that it is appropriate to separate edibles into standalone rules for labeling and testing that apply to this type of product. 2. The "Nutritional Information" and Terpene Labeling Requirements are Vague. The requirement in Section V(C)(l) to add "nutritional information" to the label for concentrates, extracts and edibles, including all ingredients and terpenes, is vague and unclear. "Nutritional information" is not a term defined in these rules and it is therefore unclear whether this requires just a list of non-cannabis ingredients used or something more. In the event that it intends the label to include more than just a list of ingredients, this requirement is nearly impossible to implement for some types of products in very small containers. Furthermore, it is unclear whether the new requirement to list "terpenes" on the label intends for the label to include added terpenes or all terpenes to be found in the product, which could include hundreds of naturally occurring terpenes. My client supports a requirement to list added terpenes but a requirement to list all terpenes is burdensome and does not contribute to public health and safety. In sum, we request that the rule be revised to clearly state that non-cannabis ingredients and added terpenes must be listed on the label. 3. The new Prohibition on QR Codes is Vague. The new prohibition in Section V(D)(7) against using a QR code to "replace" a label is vague, in that it does not make clear what portion of a label may not use a QR code or whether QR codes are prohibited from use on labels at all for any purpose. While we support a prohibition that would replace important information on the label with a QR code, this rule is drafted so broadly that it may be interpreted to prohibit a QR code that links to testing results, terpene characteristics or other educational information that would benefit the patients. 4. The Revised Testing Rules for Usable Marijuana, Concentrates, Extracts and Edibles are Vague and Overly Inclusive. The requirements in Section VI and Section VII that lab testing must include terpenes is vague and overly inclusive. As mentioned above, any given marijuana product may include hundreds of naturally-occurring terpenes and thus a directive to simply test all "terpenes," without limitation, is very burdensome and expensive. Furthermore, the terpene content is not a potentially dangerous component that must be quantified for public health and safety. Rather, it should be optional information that some producers may wish to include for marketing and branding purposes. We ask that you strike the requirement to test for terpenes and instead allow producers to conduct such testing if they wish to do so. Similarly, the requirement in Section VII(A)(f) that producers of concentrates, extracts and edibles must "test for" "any additional ingredients used to make a final product" is confusing and overly inclusive. Unlike the rest of the rule, this addition does not direct the lab to test for any specific contaminant or for potency. It is

therefore unclear what the lab should be testing for on these products. Furthermore, in the case of concentrates and extracts the rule already requires testing for solvents which may have been used in the production of the product, making this section duplicative. In the case of edibles, any additional ingredients will by definition be food-grade approved products, rendering the requirement again duplicative. We suggest that this section be deleted. 5. The New Variance Should Be 10mg Per Serving, not Package. Section VII(D) creates a 10% variance on the potency content of edibles but it limits that potency to 10mg of THC per "package," which is not consistent with existing law. We request that the rule be revised to reflect the existing law limiting THC to 10mg per serving.

AGENCY RESPONSE:

ADH proposed the label requirement to include "Nutritional information and all ingredients used to make the product including terpene." to provide greater consumer awareness and the consumer with the nutritional information in the most informative manner possible. ADH has revised the requirement as follows: "(l) All ingredients used to make edible products including terpenes;". ADH will continue to review the labeling requirements to avoid becoming overly burdensome to the cultivators and processors without infringing on the priority of consumer awareness. No changes to label requirements for font, size, and/or space are proposed at this time.

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ADH will continue to review the labeling requirements to avoid becoming overly burdensome to the cultivators and processors without infringing on the priority of consumer awareness.

In response to public comments and review of other similarly situated states' rules, ADH is proposing to amend the limits on batch sizes to 50 pound batches.

Erika Gee, Attorney with Wright, Lindsey, & Jennings, LLP
on behalf of DMCC Acquisition Corp. d/b/a Revolution Cannabis
Received April 19, 2022

1. Labeling and Testing Requirements for Edible Products Should Be Separated from Other Products. The proposed rules add "edibles" for the first time, which is a welcome clarification. However, because edible products are significantly different in both form and function than concentrates and extracts, we submit that the labeling and testing rules for edibles should stand alone. For example, it is nonsensical to require concentrates to include nutritional information. Similarly, it is unduly burdensome and duplicative to require edibles to be tested for pesticides, solvents and heavy metals, as the component parts would have been tested prior to manufacturing of the edible product. Requiring lab tests that do not have any application to that particular product type does nothing to serve the public health and it drives up the costs of production, which ultimately is passed on to the patient. We believe that it is appropriate to separate edibles into standalone rules for labeling and testing that apply to this type of product. 2. The "Nutritional Information" and Terpene Labeling Requirements are Vague. The requirement in Section V(C)(l) to add "nutritional information" to the label for concentrates, extracts and edibles, including all ingredients and terpenes, is vague and unclear. "Nutritional information" is not a term defined in these rules and it is therefore unclear whether this requires just a list of non-cannabis ingredients used or something more. In the event that it intends the label to include more than just a list of ingredients, this requirement is nearly impossible to implement for some types of products in very small containers. Furthermore, it is unclear whether the new requirement to list "terpenes" on the label intends for the label to include added terpenes or all terpenes to be found in the product, which could include hundreds of naturally occurring terpenes. My client supports a requirement to list added terpenes but a requirement to list all terpenes is burdensome and does not contribute to public health and safety. In sum, we request that the rule be revised to clearly state that non-cannabis ingredients and added terpenes must be listed on the label. 3. The new Prohibition on QR Codes is Vague. The new prohibition in Section V(D)(7) against using a QR code to "replace" a label is vague, in that it does not make clear what portion of a label may not use a QR code or whether QR codes are prohibited from use on labels at all for any purpose. While we support a prohibition that would replace important information on the label with a QR code, this rule is drafted so broadly that it may be interpreted to prohibit a QR code that links to testing results, terpene characteristics or other educational information that would benefit the patients. 4. The Revised Testing Rules for Usable Marijuana, Concentrates, Extracts and Edibles are Vague and Overly Inclusive. The requirements in Section VI and Section VII that lab testing must include terpenes is vague and overly inclusive. As mentioned above, any given marijuana product may include hundreds of naturally-occurring terpenes and thus a directive to simply test all "terpenes," without limitation, is very burdensome and expensive. Furthermore, the terpene content is not a potentially dangerous component that must be quantified for public health and safety. Rather, it

should be optional information that some producers may wish to include for marketing and branding purposes. We ask that you strike the requirement to test for terpenes and instead allow producers to conduct such testing if they wish to do so. Similarly, the requirement in Section VII(A)(f) that producers of concentrates, extracts and edibles must "test for" "any additional ingredients used to make a final product" is confusing and overly inclusive. Unlike the rest of the rule, this addition does not direct the lab to test for any specific contaminant or for potency. It is therefore unclear what the lab should be testing for on these products. Furthermore, in the case of concentrates and extracts the rule already requires testing for solvents which may have been used in the production of the product, making this section duplicative. In the case of edibles, any additional ingredients will by definition be food-grade approved products, rendering the requirement again duplicative. We suggest that this section be deleted. 5. The New Rule Should Refer to 10mg Per Serving, not 10mg per Package. Section VII(D) limits the potency content of edibles to 10mg of THC per "package," which is not consistent with existing law. We request that the rule be revised to reflect the existing law limiting THC to 10mg per serving. 6. The New Potency Variance Should Be 15%. Section VII(D) also creates a 10% variance on the potency content of edibles. We request that the rule be revised to reflect a 15% variance, which is consistent with medical marijuana laws in other states. For example: • Florida§ 381.986(8)(e)(8) provides: "Edibles may have a potency variance of no greater than 15 percent." • Illinois 410 ILCS 705/55-21(e) provides: "The acceptable tolerances for the minimum percentage printed on the label for any of subsection (b)(8)(A) shall not be below 85% or above 115% of the labeled amount."

AGENCY RESPONSE:

Please see ADH Response to the same comments from Erika Gee's Letter on behalf of Green Cross Cannabis Dispensary, LLC d/b/a Spring River Dispensary.

In researching and reviewing the changes for concentration for edibles, ADH reviewed and determined that the national average for testing variances is 10%±.

Erika Gee, Attorney with Wright, Lindsey, & Jennings, LLP
on behalf of The Re Leaf Center Dispensary & Farm
Received April 19, 2022

1. Labeling and Testing Requirements for Edible Products Should Be Separated from Other Products. The proposed rules add "edibles" for the first time, which is a welcome clarification. However, because edible products are significantly different in both form and function than concentrates and extracts, we submit that the labeling and testing rules for edibles should stand alone. For example, it is nonsensical to require concentrates to include nutritional information. Similarly, it is unduly burdensome and duplicative to require edibles to be tested for pesticides, solvents and heavy metals, as the component parts would have been tested prior to manufacturing of the edible product. Requiring lab tests that do not have any application to that particular product type does nothing to serve the public health and it drives up the costs of production, which ultimately is passed on to the patient. We believe that it is appropriate to separate edibles into standalone rules for labeling and testing that apply to this type of product. 2. The "Nutritional Information" and Terpene Labeling Requirements are Vague. The requirement in Section V(C)(l)

to add "nutritional information" to the label for concentrates, extracts and edibles, including all ingredients and terpenes, is vague and unclear. "Nutritional information" is not a term defined in these rules and it is therefore unclear whether this requires just a list of non-cannabis ingredients used or something more. In the event that it intends the label to include more than just a list of ingredients, this requirement is nearly impossible to implement for some types of products in very small containers. Furthermore, it is unclear whether the new requirement to list "terpenes" on the label intends for the label to include added terpenes or all terpenes to be found in the product, which could include hundreds of naturally occurring terpenes. My client supports a requirement to list added terpenes but a requirement to list all terpenes is burdensome and does not contribute to public health and safety. In sum, we request that the rule be revised to clearly state that non-cannabis ingredients and added terpenes must be listed on the label. 3. The new Prohibition on QR Codes is Vague. The new prohibition in Section V(D)(7) against using a QR code to "replace" a label is vague, in that it does not make clear what portion of a label may not use a QR code or whether QR codes are prohibited from use on labels at all for any purpose. While we support a prohibition that would replace important information on the label with a QR code, this rule is drafted so broadly that it may be interpreted to prohibit a QR code that links to testing results, terpene characteristics or other educational information that would benefit the patients. 4. The Revised Testing Rules for Usable Marijuana, Concentrates, Extracts and Edibles are Vague and Overly Inclusive. The requirements in Section VI and Section VII that lab testing must include terpenes is vague and overly inclusive. As mentioned above, any given marijuana product may include hundreds of naturally-occurring terpenes and thus a directive to simply test all "terpenes," without limitation, is very burdensome and expensive. Furthermore, the terpene content is not a potentially dangerous component that must be quantified for public health and safety. Rather, it should be optional information that some producers may wish to include for marketing and branding purposes. We ask that you strike the requirement to test for terpenes and instead allow producers to conduct such testing if they wish to do so. Similarly, the requirement in Section VII(A)(f) that producers of concentrates, extracts and edibles must "test for" "any additional ingredients used to make a final product" is confusing and overly inclusive. Unlike the rest of the rule, this addition does not direct the lab to test for any specific contaminant or for potency. It is therefore unclear what the lab should be testing for on these products. Furthermore, in the case of concentrates and extracts the rule already requires testing for solvents which may have been used in the production of the product, making this section duplicative. In the case of edibles, any additional ingredients will by definition be food-grade approved products, rendering the requirement again duplicative. We suggest that this section be deleted. 5. The New Variance Should Be 10% Per Serving, not Package. Section VII(D) creates a 10% variance on the potency content of edibles but it limits that potency to 10mg of THC per "package," which is not consistent with existing law. We request that the rule be revised to reflect the existing law limiting THC to 10mg per serving.

AGENCY RESPONSE:

Please see ADH Response to the same comments from Erika Gee's Letter on behalf of Green Cross Cannabis Dispensary, LLC d/b/a Spring River Dispensary.

Erika Gee, Attorney with Wright, Lindsey, & Jennings, LLP
on behalf of NEA Full Spectrum Medicine, LLC
Received April 19, 2022

1. Labeling and Testing Requirements for Edible Products Should Be Separated from Other Products. The proposed rules add "edibles" for the first time, which is a welcome clarification. However, because edible products are significantly different in both form and function than concentrates and extracts, we submit that the labeling and testing rules for edibles should stand alone. For example, it is nonsensical to require concentrates to include nutritional information. Similarly, it is unduly burdensome and duplicative to require edibles to be tested for pesticides, solvents and heavy metals, as the component parts would have been tested prior to manufacturing of the edible product. Requiring lab tests that do not have any application to that particular product type does nothing to serve the public health and it drives up the costs of production, which ultimately is passed on to the patient. We believe that it is appropriate to separate edibles into standalone rules for labeling and testing that apply to this type of product. 2. The "Nutritional Information" and Terpene Labeling Requirements are Vague. The requirement in Section V(C)(l) to add "nutritional information" to the label for concentrates, extracts and edibles, including all ingredients and terpenes, is vague and unclear. "Nutritional information" is not a term defined in these rules and it is therefore unclear whether this requires just a list of non-cannabis ingredients used or something more. In the event that it intends the label to include more than just a list of ingredients, this requirement is nearly impossible to implement for some types of products in very small containers. Furthermore, it is unclear whether the new requirement to list "terpenes" on the label intends for the label to include added terpenes or all terpenes to be found in the product, which could include hundreds of naturally occurring terpenes. My client supports a requirement to list added terpenes but a requirement to list all terpenes is burdensome and does not contribute to public health and safety. In sum, we request that the rule be revised to clearly state that non-cannabis ingredients and added terpenes must be listed on the label. 3. The new Prohibition on QR Codes is Vague. The new prohibition in Section V(D)(7) against using a QR code to "replace" a label is vague, in that it does not make clear what portion of a label may not use a QR code or whether QR codes are prohibited from use on labels at all for any purpose. While we support a prohibition that would replace important information on the label with a QR code, this rule is drafted so broadly that it may be interpreted to prohibit a QR code that links to testing results, terpene characteristics or other educational information that would benefit the patients. 4. The Revised Testing Rules for Usable Marijuana, Concentrates, Extracts and Edibles are Vague and Overly Inclusive. The requirements in Section VI and Section VII that lab testing must include terpenes is vague and overly inclusive. As mentioned above, any given marijuana product may include hundreds of naturally-occurring terpenes and thus a directive to simply test all "terpenes," without limitation, is very burdensome and expensive. Furthermore, the terpene content is not a potentially dangerous component that must be quantified for public health and safety. Rather, it should be optional information that some producers may wish to include for marketing and branding purposes. We ask that you strike the requirement to test for terpenes and instead allow producers to conduct such testing if they wish to do so. Similarly, the requirement in Section VII(A)(f) that producers of concentrates, extracts and edibles must "test for" "any additional ingredients used to make a final product" is confusing and overly inclusive. Unlike the rest of the rule, this addition does not direct the lab to test for any specific contaminant or for potency. It is

therefore unclear what the lab should be testing for on these products. Furthermore, in the case of concentrates and extracts the rule already requires testing for solvents which may have been used in the production of the product, making this section duplicative. In the case of edibles, any additional ingredients will by definition be food-grade approved products, rendering the requirement again duplicative. We suggest that this section be deleted. 5. The New Variance Should Be 10mg Per Serving, not Package. Section VII(D) creates a 10% variance on the potency content of edibles but it limits that potency to 10mg of THC per "package," which is not consistent with existing law. We request that the rule be revised to reflect the existing law limiting THC to 10mg per serving.

AGENCY RESPONSE:

Please see ADH Response to the same comments from Erika Gee's Letter on behalf of Green Cross Cannabis Dispensary, LLC d/b/a Spring River Dispensary.